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An Exploration of Scottish Community Pharmacists' Adoption of Innovative Services and Products relating to Minor Ailment Management

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[B.Pharmacy, MSc (Clinical Pharmacology), PGCert (Research Methods)]

A thesis submitted in partial fulfilment of the requirements of Robert Gordon University

for the degree of Doctor of Philosophy

'I keep six honest serving men; (They taught me all I knew); Their names are What and Where and When And How and Why and Who'

Rudyard Kipling (1902)

Abstract

This research utilised mixed methodology to gain insight into community pharmacists' adoption of medicines and services related to two key innovative policy interventions aimed at enhanced minor ailment management; namely the ongoing legal status reclassification of medicines; and the introduction of the Scottish Minor Ailment Service.

Prompted by the lack of qualitative and large scale quantitative evaluation from the pharmacists' perspective, the aim was to investigate pharmacists' adoption of these innovations. Data were generated to evaluate the process related aspects of innovation adoption from community pharmacists' perspectives; and to identify and quantify key factors associated with the adoption of these innovations, thereby considering the wider relevance to new community pharmacy services.

A range of methods was used including: formal systematic review of peer reviewed published literature on factors associated with innovation adoption following methods recommended by the Centre for Reviews and Dissemination at the University of York; extensive review of policy documents of all the devolved UK Governments; qualitative focus groups and interviews with 20 community pharmacists from four Scottish Health Boards; and lastly a cross sectional survey of the pharmacists responsible for non-prescription medicines from all Scottish community pharmacies (N=1138). The theoretical framework of diffusion of innovations was adopted to design the quantitative research instrument and interpret the data. Rigour was enhanced by consideration of aspects of validity and reliability at all stages. The highest standards of research governance and ethics were applied throughout the study.

Qualitative interviews provided insight into the process related aspects of innovation adoption. Where current changes were embraced reluctantly by many who deemed the pace as fast and furious, others were keen to contribute to developments taking place within pharmacy and were eager to play a more proactive role in leading and introducing change to the public. Regardless of practice setting and ownership model, the merits of each innovation appeared to be considered at the individual practitioner level. Hence an organisational level decision to implement an innovation did not necessarily translate to adoption at the individual practitioner level. Using descriptive, bivariate and multivariate quantitative models informed by the results of the qualitative interviews and systematic

review of the literature, the quantitative study showed pharmacists' perceived attributes of innovations (such as benefits to their professional role development and patients); and patient demand and use of services had the highest association with whether or how far innovations were adopted. Issues such as differences in availability of resources were less able to explain differing level of innovation adoption by the pharmacist respondents. These findings suggest that as innovations around minor ailment management have not yet required reorientation of existing services, the issue of how pharmacists' perceive the characteristics of the innovations such as: potential for financial benefits to pharmacy, professional role development and patients; is key to predicting whether future innovations of a similar nature will be successfully adopted by pharmacists.

Keywords: Community pharmacy, pharmacists, reclassified medicines, e-MAS (electronic Minor Ailment Service), Scotland, acceptance, adoption, innovation.

Acknowledgements

This research would never have been possible without the generous support of many individuals. My deepest gratitude goes to my principal supervisor Dr. Derek Stewart, Reader of Pharmacy Practice at the Robert Gordon University, who has been an inspirational source of guidance, motivation and knowledge during these three years. His commitment to my development as a researcher has been overwhelming. I am immensely thankful for the opportunities I was given to develop my skills as a researcher both within and outside the school.

Many thanks to my other supervisors, Dr Denise Hansford and Dr Scott Cunningham who have been valuable source of advice and enduring support from the beginning of this PhD through regular feedback on the directions and progress of the work. Also to Professor Dennis Tourish, from Aberdeen Business School who was involved for a short but crucial time of the research, mainly around the social science aspects of the research.

Out with the supervisory team, I am also indebted to members of the community pharmacy expert panel namely: Mrs Trudi McIntosh, Mrs Ruth Edwards, Mr Brian Addison, Mrs Gwen Gray and Ms Noelle O Driscoll, who provided me with valuable advice for designing the materials used to collect data in various phases of the research. Many thanks to Dr Lorna McHattie and Dr Lesley Diack from the School of Pharmacy for support during the conduct of focus groups and interviews; and Mrs Katie MacLure for assisting with questionnaire layout. Mrs Alyson Brown and Mrs Frances Notman did a great job in identification of the community pharmacies within different Health Boards for observations of minor ailments activities. Many thanks to Mrs Linda Adams for ensuring that facilities were always there when needed; to Mrs Toni Simpson for training for work with long documents and Mr Brian De Jonckheere for making all the software for data analysis available.

This research would not be possible without the support and cooperation of the stakeholders within and out with the NHS who were involved in the initial phase of this research. I also acknowledge Community Pharmacy Scotland (CPS) and NHS National Services Scotland (NHS NSS) for partly funding this study. Ms Sharon Hems and Prof Marion Bennie from the NSS were great collaborators. Many thanks also to all the participants who participated in this study for being generous to commit their busy time for this research.

I would also like to convey my thanks to Mr Alex Wilson, consultant statistician RGU; Dr Gordon Prescott, Senior Lecturer in Medical Statistics, University of Aberdeen; and Cat Graham at Wellcome Trust Clinical Research Facility, Edinburgh for the advising on important matters regarding statistical analysis.

Apart from the individuals involved in the research, I sincerely owe thanks to my family and friends, many of whom despite being far away were always with me during both exciting and difficult times. Thanks to Ben, Maxwell, Erere and Chidinma in PD1 for bringing welcome distractions. I can't thank my parents enough for the hard work and courage they have shown throughout to take me to this stage. They chose to sacrifice the joy and happiness in us being together, by supporting me to come this far to undertake a PhD for the sake of my future. Thanks to Bandhu, Bindu and Bhinaju for being there when needed; my little niece Arya for amusing me during stressful moments. Sorry I couldn't take you to the park every time you wanted, but you were always generous in accepting my apologies.

I owe a lot to my wife Pawana, who has been working enormously hard supporting and inspiring me throughout my study. We both have kept our lives on hold during these years. Without your dedication, undertaking this PhD, by no means, would be possible.

To my parents Ghanashyam and Saraswati

External outputs

Results of research described within this thesis have been disseminated through following outputs.

Full reports

- Paudyal V, Hansford D, Cunningham ITS, Stewart D. Cross-sectional survey of community pharmacists' views of the electronic Minor Ailment Service in Scotland. *International Journal of Pharmacy Practice*. 2010; 18(4):194-201. (Accepted for fast track publication)
- 2. Paudyal, V, Hansford, D, Cunningham, S, Stewart, D. Community pharmacists' views on feedback data from the electronic Minor Ailment Service (e-MAS) in Scotland. Project report submitted to NHS NSS. December 2008.

Abstracts of conferences

- Paudyal V, Hansford D, Cunningham ITS and Stewart D. Over-the-counter simvastatin: Community pharmacists' adoption practices and attitudes five years post reclassification. *International Journal of Pharmacy Practice*. 2010; (Oral presentation at Royal Pharmaceutical Society Conference: 5-6 September, 2010; London)
- Paudyal V, Hansford D, Cunningham ITS and Stewart D. An investigation into factors affecting the adoption of new non-prescription medicines by community pharmacists. *Pharmacy Practice*. 2010; 8(suppl 1): 51-52.
 (Oral presentation at International Social Pharmacy Workshop: 23-26 August, 2010; Lisbon)
- Paudyal V, Hansford D, Cunningham ITS and Stewart D. Scottish community pharmacists' views and attitudes towards 'pharmacy-only' naproxen for management of primary dysmenorrhoea. *Pharmacy Practice*. 2010; 8(suppl 1): 93. (Poster presentation at International Social Pharmacy Workshop: 23-26 August, 2010; Lisbon)

- 6. Paudyal V, Hansford D, Cunningham S, Stewart D. Feedback on pharmacy practice performance: Exploring opportunities with the electronic minor ailment service in Scotland.
 - (Oral presentation at Health Service Research and Pharmacy Practice Conference, Manchester 2010)
- 7. Paudyal V, Hansford D, Cunningham S, Stewart D. Cross-sectional survey of community pharmacists' views of the electronic minor ailment service in Scotland. Celtic Pharmacy Festival, March 6-7 2010; Edinburgh. (Poster presentation)
- 8. Paudyal V, Hansford D, I.T.S Cunningham, Stewart D. Exploring innovations in Scottish community pharmacy practice: change theory and new non-prescription medicine services. *International Journal of Pharmacy Practice*. 2009; Suppl 2:B72. (Poster presentation at British Pharmaceutical Society Conference: 6-9 September, 2009)

A number of publications are in draft format aimed at peer reviewed journals.

Awards

Apart from the grant from Community Pharmacy Scotland to undertake this research, I have received support from NHS NSS of £2000 after the commencement of the PhD. In addition, I have been privileged to have won the following highly competitive grants and awards and hence acknowledge all those who sponsored the prizes.

- Prestigious Overseas Research Student Assistant Scheme (ORSAS) 2008 to cover the differential tuition fees (between home and international students) from Scottish Funding Council. Amount: £15,000
- Scholarship to cover the attendance at the International Social Pharmacy Workshop:
 23-26 August, 2010. Exemption of € 380
- 3. First prize, Best posters award: Celtic Pharmacy Festival, March 6-7, 2010. £300

Foreword from the Author

This thesis describes my work over the past three years or so, in which I have sought to gain understanding of how community pharmacists in Scotland inform their decision making in relation to adopting changes around enhanced minor ailment management. This experience has developed my research abilities, as well as aims to make an original contribution to knowledge in this emerging research area.

My longing to pursue 'a' PhD was mainly passed to me from my dad, who also had this desire, but pressures of academia and politics prevented this. Hence I started the journey from Nepal by coming to Aberdeen to pursue an MSc Degree in Clinical Pharmacology at the University of Aberdeen. Prior to this, I had completed my B Pharmacy from Pakistan, again, far from home and supported by a regional scholarship. During my MSc, I researched anticancer activities of some novel chemotherapeutic agents in human leukaemic cells. Here I realised that I had less interest in laboratory based research Nevertheless, I completed the course with a distinction and being first in the class. I had decided to seek an exciting opportunity to undertake a PhD in pharmacy practice.

Apart from undertaking my doctoral research, I gained valuable experience as a demonstrator in medical statistics to MSc and PhD students at the University of Aberdeen; and to undergraduate pharmacy students at the Robert Gordon University School of Pharmacy & Life Sciences. I have recently taken up a position as Research Assistant at the Robert Gordon University investigating pharmacovigilance activities of non-medical prescribers, funded by the Medicines and Healthcare Regulatory Agency (MHRA). Time with RGU SPORT was also memorable, representing my University at the Scottish Inter-University Table Tennis Championship in 2008.

Throughout this thesis, I have provided details of background to the research, my aims, objectives, methodology, methods, results, discussions and conclusions. I have been privileged to have received formal trainings to undertake the research in the best possible way from a number of internationally recognised method experts and training organisations. These appear in Appendix X (General). These lists are apart from my extensive reading of books and online materials during these three years and my learning through doing.

The first Chapter introduces the area of minor ailments followed by an extensive, in-depth review of policy documents from England, Scotland, Wales and Northern Ireland demonstrating how policies and services within the area of minor ailment management had evolved during the past 25 years. This is followed by a review of UK peer reviewed literature to identify research gaps. I also have reviewed and critiqued the available theoretical models to debate why Rogers' diffusion of innovations provides an appropriate foundation to undertake this research.

Chapter 2 details debates of different methodologies and methods; and draws conclusions about the suitability of the mixed methodology approach. I have argued that paradigm debates should be left aside and the choice of methodology and method need to be mainly guided by the research aims and objectives. The difficulty of undertaking a systematic review with literature using diverse methodologies is also discussed along with defence of the approach to synthesise the findings.

Chapter 3 to 6 relate to investigation of the ongoing legal status reclassification of medicines. In Chapter 3, I have presented results from the initial exploratory qualitative investigation around pharmacists' perspectives of ongoing changes in practice in general; and around minor ailments management in particular. Key facilitators/barriers to adoption of newly reclassified medicines are presented.

In Chapter 4, I provide a systematic review of literature, specifically to review the peer reviewed literature around pharmacists' perspectives of the adoption of newly reclassified medicines into practice. This further informed the design and content of the research instrument to undertake large scale quantitative evaluation in the next phase of the research.

In Chapter 5, I have detailed development of the content and design of the survey questionnaire using findings of the systematic review, qualitative work and theoretical model of diffusion of innovations.

Chapter 6 presents findings of the quantitative survey. Factors associated with innovation adoption were extracted from these analyses.

Chapter 7 presents results of qualitative work specific to the pharmacists' adoption of e-MAS. Key facilitators/barriers to the service adoption were identified.

Chapter 8 presents results relating to pharmacists' adoption of e-MAS and key factors associated with innovation adoption from quantitative evaluation.

From Chapters 4-9, I have discussed key findings and how these compare to the literature. Discussion of research strengths and limitations of most of the research phases are given in Chapter 9, prior to discussing relevance and importance of all findings. Potential future research questions are presented before a summary of study conclusions.

KEY ABBREVIATIONS

AAPOR American Association of Public Opinion Research

APA American Psychological Association

BNF British National Formulary

CMS Chronic Medication Service

CPD Continuing Professional Development

CPS Community Pharmacy Scotland

DoH Department of Health

DRP Drug Related Problems

EHC Emergency Hormonal Contraception

E-MAS Electronic Minor Ailment Service

GP General Practitioner

GPhC General Pharmaceutical Council

GSL General Sales List (Medicines)

ISD Information Service Division

MHRA Medicines and Healthcare Regulatory Agency

NHS National Health Service

NES NHS Education Scotland

NMUU National Medicines Utilisation Unit

NoSREC North of Scotland Research Ethics Committee

NSS National Services Scotland

P Pharmacy (Medicines)

PCT Primary Care Trust

PGD Patient Group Direction

PIL Patient Information Leaflet

POM Prescription Only Medicines

RPS Royal Pharmaceutical Society

RPSGB Royal Pharmaceutical Society of Great Britain

SIMD Scottish Index of Multiple Deprivations

SOP Standard Operating Procedure

SPA Scottish Prescribing Analysis

WHO World Health Organisation

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CHAPTER 1: INTRODUCTION

1.1 INTRODUCTION TO THE CHAPTER

This Chapter introduces the area of self care and minor ailments followed by an extensive, in-depth review of policy documents from England, Scotland, Wales and Northern Ireland demonstrating how policies and services within the area of minor ailment management had evolved over the past two and half decades. This is followed by review of UK peer reviewed literature around enhanced minor ailment management from community pharmacy to identify research gaps enabling the formulation of aims and objectives for this PhD. Review and critique of relevant theoretical models for their appropriateness to undertake this research are also presented.

1.2 SELF CARE

Self care, as defined by the World Health Organisation (WHO), is what people do for themselves to establish and maintain health, prevent and deal with illness [1]. In historical terms, self care signifies the importance of patient 'autonomy' and 'independence' which relate to people initiating actions by themselves as well as making their own decisions about care [2]. Lately, however, the definition encompasses shared models of care [3] which stress the balance between patient autonomy in decision making as well as dependence on health professionals where necessary [2].

The principles of self care which can be applied to prevention and management of illnesses are known to have arisen from a number of theoretical models such as the theory of self regulation. Self regulation models emphasise the importance of self- efficacy [4], which relates to an individual's belief in their ability to learn and perform specific behaviours; and self-management [5] which relates to adoption into practice of such behaviours.

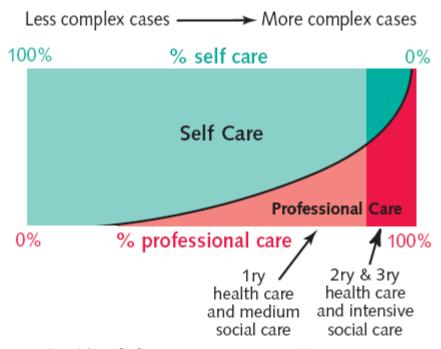
Emphasis on greater patient participation in managing their own health has been stressed in recent health service policies across the UK and beyond. Terminologies like 'expert patient' [3] and patient 'empowerment' [6] have been used to underline this emphasis.

1.3 SELF CARE OF MINOR AILMENTS

Minor ailments are self limiting conditions requiring little or no medical intervention [7,8]. Colds, coughs and indigestion are some of ailments defined as 'minor' both in the published literature [9] and community pharmacists' practice guidelines [10]. The concept

of self care also applies to the management of minor ailments as it does to the prevention and management of long term and complex ailments. The level of professional support however, is known to increase with increasing complexity of illness. Much self care can involve no professional at all (figure 1.1).

Figure 1.1: Spectrum of care showing that most care is shared care and can involve a small or large component of self care.



Reproduced from [11]. 1ry: Primary; 2ry: Secondary; 3ry: Tertiary

Self care of minor ailments may require access to non-prescription medicines. The following section describes the regulatory requirements around patient access to non-prescription medicines in the UK.

1.4 MEDICINES CLASSIFICATIONS: REGULATORY PERSPECTIVES

The 'Medicines Act 1968' [12], which regulates the supply of medicines in the UK, categorises medicines into three classes, described overleaf. In addition to the retail pharmacy supply, these regulations also apply to any other forms of supply such as via the internet and mail order.

1.4.1 Prescription Only Medicines (POM)

Prescription Only Medicines can be obtained from a registered (registered as per the requirements of Section 72 of the Medicines Act 1968) [12] pharmacy premises by patients under a prescription issued by an appropriate practitioner (a doctor, dentist, nurse independent prescriber, pharmacist independent prescriber or supplementary prescriber) [13].

The term 'non-prescription medicines' or 'over-the-counter medicines (OTC)' refers to medicines other than prescription only medicines, and are described as 'pharmacy medicines' and 'general sales list medicines'. The term non-prescription medicines will be used throughout this thesis.

1.4.2 Pharmacy Medicines (P)

Members of the public can obtain these medicines without a prescription but only from a registered pharmacy, supplied by a pharmacist or pharmacy support staff under the supervision of a pharmacist [12].

1.4.3 General Sale List Medicines (GSL)

These medicines can be obtained by members of public from any retail premises with a locked facility including pharmacies. Medicines must, however, be supplied in the original manufacturer's packaging [13].

In addition to the regulations of the Medicines Act, the sale of medicines from pharmacies including internet based pharmacy supplies is regulated by the Royal Pharmaceutical Society of Great Britain's (RPSGB) 'Code of Ethics for Pharmacists and Pharmacy Technicians' and 'Professional Standards and Guidance for the Sale and Supply of Medicines' [14]. These documents set out seven principles of 'ethical' practice (figure 1.2) and ten standards of the supply of non-prescription medicines, with emphasis on self care (figure 1.3). In addition, standards of supply of non-prescription medicines through internet services also are provided [14].^a

Chapter 1: Introduction

^a At the time of preparing this thesis, the demerger of RPSGB was taking place with the subsequent introduction of the Royal Pharmaceutical Society (RPS) and the General Pharmaceutical Council (GPhC), which will have an impact on regulatory and practice standards

Figure 1.2: RPSGB's seven principles of ethical practice for pharmacists and pharmacy technicians.

- ♣ Exercise your professional judgement in the interests of patients and the public
- ♣ Show respect for others
- Encourage patients to participate in decisions about their care
- Develop your professional knowledge and competence
- ♣ Be honest and trustworthy
- Take responsibility for your working practices

Reproduced from [14]

Figure 1.3: Key excerpts from RPSGB's standards of supply of non-prescription medicines.

- Pharmacists or Technicians to intervene and professional advice be given wherever possible
- ♣ P medicines should not be made accessible to the public by self selection
- Sufficient information is obtained from the patient to either advice self-care or to recommend a suitable product
- ♣ If sale is not considered suitable, reason is explained to patient and referred to other healthcare professionals where appropriate
- ♣ All staff involved in supply be adequately trained and consideration given to the medicines that may require personal intervention of a pharmacist e.g. those that have become recently available without prescription or subject to misuse, abuse
- Be able to refuse where there are reasonable grounds for suspecting misuse
- Particular care exercised when supplying to vulnerable groups like children
- ♣ Patient right to confidentiality and privacy are respected
- Information about the medicines provided to patients are up to date, accurate and reliable
- Pharmacy staff to keep up to date with new policies governing supplies and to national and local health promotional initiatives

Reproduced from [14]

From an international perspective, the category of non-prescription medicines requiring pharmacists' supervision or involvement in sales also exists in countries such as Switzerland [15], Australia, New Zealand [16] and Germany [17]. In contrast, in the United States, only one category of non-prescription medicines, the 'over-the counter', category exists and does not require sales to be restricted to pharmacy premises [18]. Although such regulations could be debated to be enabling greater patient access to all non-prescription

medicines through availability in both pharmacy and non-pharmacy premises, wider patient safety implications also take prominence in such debates.

Data from non-peer reviewed sources indicate that over 930 million packs of non-prescription medicines were purchased from UK pharmacies in 2006 [19]. Research also reflects the increasing market share of these medicines over time. For example in the US alone, non-peer reviewed data suggest that sales of non-prescription medicines were reported to have increased nearly ten times since 1971 which equated to \$17 billion accounting for the treatment of 57% of all the health problems [20].

1.5 CASE FOR PHARMACIST^b SUPPORTED SELF CARE OF MINOR AILMENTS

The burden on the NHS resulting from the costs of 'unnecessary' patient visits to general practitioners (GPs) is a much talked about issue in the public and professional press [21,22]. Data from non-peer reviewed literature suggest that currently minor ailments in the UK account for an estimated £1.5 billion a year in lost GP hours alone [9]. The top ten minor ailments that account for three quarter of all GP consultations are reported to be back pain, dermatitis, heartburn/indigestion, nasal congestion, constipation, cough, sprains/strains, migraine, acne and headache [9]. Freeing up GPs' time from minor ailment management has been argued to enable focusing more towards complex and more serious illnesses, reducing patient waiting times [23,24], apart from the potential financial savings to the NHS.

The professional expertise of pharmacist in minor ailment management is another reason why they are considered appropriate to manage these ailments. Despite being considered relatively safe, many non-prescription medicines are also known to contain potent pharmacological agents with potential for adverse drug reactions and drug interactions. Hence their use demands an equal degree of care to the prescription medicines [25]. In order to ensure that widespread consumption of non-prescription medicines incurs minimal harm, their use along with professional advice has been deemed a 'rational' approach to self care [26].

^b Pharmacist/s will refer to community pharmacist /s throughout the thesis except explained otherwise Chapter 1: Introduction 5

The issues of free access to professional advice without requiring any appointment is another factor associated with greater emphasis on pharmacist supported management of minor ailments. This has received support from the pharmacists' professional body, which states that the provision of self care support around minor ailments is a positive contribution to the pharmacist's professional role and image in the society [8].

1.6 REVIEW OF LITERATURE -I

The literature review has been divided into two parts. The first part reviews the Health Policy documents of each of the devolved Government dating from 1995 in order to fully understand their perspective and emphasis on pharmacy management of minor ailments. This is followed by the peer reviewed UK literature around enhanced minor ailment management from community pharmacy. Identified gaps and limitations in the research will inform the questions for this doctoral research.

1.6.1 Enhanced management of minor ailments from community pharmacy: a chronological review of major health policy documents in the United Kingdom

This section is derived from health policy and related documents dating back from 1986 till date published by the UK Government and devolved Governments of Scotland, Wales and Northern Ireland after devolution. Those sections of the policy documents with relevance to the enhanced management of minor ailments from community pharmacy were reviewed. Documents were identified from the websites of Health Departments of each of the devolved Governments [27-30]. Other key events not listed in the documents but relevant to the discussion here are also presented.

The foundation for modern UK community pharmacy minor ailment services could arguably be claimed to have been laid in 1986 with the publication of the report of the Nuffield inquiry [31]. The following statement summed up the position of community pharmacy during those years:

"It (pharmacy practice) is in the area of health services...that the greatest weaknesses are to be found. There is too little information available, relatively weak structures and very little funding" [32] page 415

The report encouraged community pharmacists to move away from routine dispensing work and to be involved in advice giving to patients, among many other roles [31]. It highlighted the importance of further training before pharmacists could undertake the advice giving role. These recommendations around pharmacists' developing roles were endorsed by the British Medical Association (BMA) and Royal College of General Practitioners (RCGP) [31].

In September 1995, the RPSGB launched a consultation *Pharmacy in a New Age* [33]. It highlighted that pharmacists' expertise could be utilised to a greater extent, citing enhanced management of minor ailments as one of four key areas where they could make the greatest contribution to patient care. This consultation was hailed by some as the 'most successful' RPSGB initiative with more than 5,000 pharmacists contributing to the professional body's vision [34].

In 1997, advice giving by pharmacists in relation to minor ailment management was also endorsed in a proposal put forward by the newly elected UK Labour Government, covering a ten year plan to reform NHS [35]. Pharmacists were to be given the opportunity to provide a 'distinct' contribution to community development and health improvement in their local areas.

In 1998, two documents were published by NHS Wales, namely *Putting Patients First* [36] and *Better Health, Better Wales* [37], which set out initiatives encouraging pharmacists to contribute to reducing health inequalities in society. Pharmacists would be encouraged to 'collaborate' with other health professionals rather than 'compete' for the greater benefit of patients. Pharmacists would be supported and encouraged to provide advice on life style matters for disease prevention through introduction of modern technologies and development of staff capacity [37].

Devolution of power to three of the four UK nations: Scotland, Wales and Northern Ireland took place in 1999. Health was among matters which each of these nations would have power and responsibilities over setting policies, legislating [38] and dealing with any health challenges they faced [39]. These nations, despite devolution, still work in close cooperation around devolved as well as UK Governments' reserved matters and therefore regulatory frameworks for pharmacies are also similar across UK nations [40]. Although subtle

differences, however, around approaches to the reform of health service have been noted [41], detailed discussions of these are out with the remit of this review.

In 1999, a White^c paper, Saving Lives, Our Healthier Nation, was unveiled by the English Department of Health (DoH), aiming to set out measures to reduce mortality in key disease areas such as cancer, coronary heart diseases, mental health, stroke and accidents [42]. Health professionals would also be encouraged in the future to advise patients about 'appropriate' places of contacts for disease management including minor ailments. One year later, in July, 2000, the English DoH published the NHS Plan, which stressed the need to increase the quality and range of services offered by the NHS [43]. Ten core principles of the NHS were set out which included providing universal services to all regardless of ability to pay and presented Governments' vision that inequality in the health was the greatest injustice. The importance of 'empowering' patients around the self care of minor ailments was highlighted. NHS Direct would encourage people to get advice from pharmacists not limited to minor ailment matters. To facilitate pharmacists taking on new roles, measures to shift pharmacy income away from prescription dispensing were to be introduced, rewarding instead for professional services. This document also promised the Government's vision to reclassify more medicines to be available on a non-prescription basis (section 1.7.1). As per the vision of this document, new legislation to allow pharmacists to supply certain Prescription Only Medicines within strict protocols (Patient Group Directions, PGDs) was introduced by the UK Government in August 2000 [43].

Later in September 2000, *Pharmacy in the future: Implementing the NHS Plan* [43] was published by the English DoH, which presented measures to meet the ambitions set out by the *NHS Plan* [44]. A vision for new contractual frameworks for pharmacies was presented. Campaigns such as *Choose the Right Remedy* and *Ask Your Pharmacist* would further be promoted. *Delivering the NHS Plan* [45] published in April 2002 (DoH), laid out specific funding plans to undertake these initiatives. Focus was placed on reducing NHS patient waiting times, tackling health inequalities and improving health outcomes.

In January 2001, the National Assembly for Wales published a ten year plan to reform the health care system to offer people faster access to high quality services [46]. This plan aimed to extend pharmacy services by reinforcing capacity development in pharmacy and

^c White Papers are issued by the Government as statements of policy, and often set out proposals for legislative changes, which may be debated before a Bill is introduced. Green Papers set out for discussion proposals which are still at a formative stage.

modernising the profession. February 2001 saw Scotland introducing its national health plan [47] which aimed to improve health of Scottish people and reduce health inequities. In order to do so, national standards of care were to be set and delivered locally across Scotland. Access to care was to be improved by making patients' 'journey of care' easier by improving standards across NHS services and by strengthening primary care staff, enabling them to work together in an effective way. This document also aimed to support availability of smoking cessation medicine to be available out with prescription. In the same year, two other documents were published by the Scottish Government. Key ambitions were to build a national effort to improve health and secondly to reduce health inequalities [48]. A vision was proposed to establish pilot projects allowing the pharmacy supply of non-prescription medicines to patients exempt from prescription charges [48]. Further investments would be made to endorse provision of advice around self care and healthy living in high street pharmacies [49], as well as in rebuilding and renovating pharmacies [48]. The publication of *The Right Medicine* [50] in February 2002 by the Scottish Government put forward an agenda for pharmacy modernisation for the next four years. This delivered the Scottish Government's promises that pilot projects that were being run in some regions of Scotland to allow free supply of non-prescription medicines to those exempt from prescription charges would be rolled out nationwide. Plans for free provision of Emergency Hormonal Contraceptives (EHCs) and smoking cessation services through pharmacy were also discussed. The Right Medicine emphasised the need for community pharmacies to use the NHS logo in their premises so as to encourage more people to use their services.

In February 2002, an 'independent' Wanless report Securing Our Future Health: Taking A Long-Term View [51] was published which assessed the resource requirement of UK NHS departments for the next 20 years and associated reforms around resource allocation and efficiency. A vision of the NHS in 2022 was proposed, which included more patients seeking advice from pharmacists for wide ranging health issues. An update on the progress on these recommendations made by the Wanless report was published in 2004 [52]. It highlighted that level of patient engagement in self care around and out with minor ailments would proportionally influence health care expenditure by 2022-23. This was postulated to be influenced mainly by the level of improved health status based on the patient level of such involvement (figure 1.4).

March 2002 saw the Northern Ireland Department of Health, Social Services and Public Safety launch an investigation to design a framework to tackle health inequalities [53]. A

shift from treatment to prevention of illness was highlighted. May 2002 saw another important development in the area of pharmacy management of minor ailments. The UK Government endorsed proposals by the Medicine Control Agency (MCA) which would not require amendment of legislation each time the legal status of a medicine was changed (section 1.7.1), thereby significantly shortening the process of medicines reclassification from one legal status to another [54].

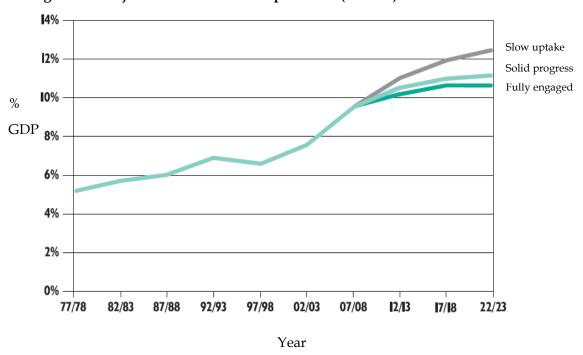


Figure 1.4: Projection of UK Health Expenditure (% GDP).

Reproduced from [51]. The solid lines represent level of patient involvement in self care.

A discussion paper was published in 2002 by the English DoH, *Pharmacy Workforce in the New NHS* [55] and also adopted by the Welsh Assembly Government [56]. This aimed to realise the vision set out by *Pharmacy in the Future* [43] by making necessary changes in the pharmacy workforce. Key aims that were set out included: the continued extension of pharmacists' role in supporting patients to use their medicines; developing 'protocol medicines supply system' whereby trained pharmacy technicians could handle certain duties such as dispensing without pharmacists' supervision; and proposed amendments in the Medicine Act 1968 easing pharmacists' personal involvement in non-prescription sales.

Pharmacies' role in provision of smoking cessation services, offering exercises on prescription, screening patients to identify long term illnesses and services for substance misusers were in a three year action plan to tackle health inequalities published by the Chapter 1: Introduction 10

English DoH in July 2003 [57]. A White paper also by the English DoH published in the same year: *A Vision of Pharmacy in the new NHS* [58], set out further plans of actions in four key areas namely: improving patient access to medicines (such as by further reclassification of medicines); helping people to get best out of their medicines (such as by enabling community pharmacy to deliver medicine management services); redesigning services around patients (such as by introducing local pharmaceutical service schemes aimed at deprived areas; a new contractual framework for pharmacies and pharmacist supplementary prescribing); and enabling high quality pharmacy service provision through competent staff (such as by commissioning training for pharmacists around clinical governance). Yet another document published by the English DoH in 2003 [59] committed continued support to ease restrictions on opening of new pharmacies, expanding ranges of medicines available without prescriptions; and promoting minor ailment schemes for members of public exempt from prescription charges (Section 1.7.1 and 1.7.2).

In 2003, The Welsh Assembly Government announced the abolition of prescription charges to come into effect by 2007 and the Scottish Executive announced the same in 2005 for abolitions to take place by 2011 [60]. These were argued to be addressing the problem of inequality in service access by patients and to reduce NHS emergency admissions relating to minor ailments; though wider implications for stakeholders such as pharmaceutical industries and Government were widely discussed [61].

The decision of the health departments of England, Scotland and Wales to reject the recommendations made by the Office of Fair Trading (OFT) (which is a non-ministerial Government department and is a UK consumer and competition authority) suggesting plans to abolish the *Control of Entry Regulations* (CoE) for community pharmacies in the UK has been hailed as another important event in securing services around enhanced minor ailment management from community pharmacy in 2003 [62,63]. The CoE regulation, which limits the granting of licenses for dispensing NHS prescription (which accounted to as much as 80% of pharmacy turnover) based on the number of new pharmacies already existing in the area, was blamed by OFT to be responsible for the slow increase in the number of new pharmacies per year which accounted average of four pharmacies in a year from 1991-2001[40]. However a review committee of House of Commons reported against such deregulations citing the following concern

"...deregulation concerns the provision of services which may be time-consuming, unprofitable, or have social stigma attached to them ...whether pharmacies in supermarkets would be happy to provide compliance aids and home delivery services or drugs for addicts, emergency contraception and sexual health advice... make certain pharmacies unviable, potentially leaving some of the most vulnerable communities, who have the greatest health needs and are least able to travel long distances, without any local pharmacy provision ..." [63] page 9.

Only a part reform to the provision was however introduced later in August 2004 whereby the Government reviewed entry barriers only in certain areas so that opening a pharmacy would be made 'simpler and faster' [64].

Also in 2004, The Welsh assembly published *Remedies for Success- a Strategy for Pharmacy in Wales* which set out a ten year vision for the pharmacy profession to deliver high quality services [65]. Greater management of minor ailment from pharmacies was among the four key priority areas where expertise of pharmacists would further be supported, with management of long term conditions among others.

The five year *NHS Improvement Plan* published in the same year in June 2004 by the English DoH aimed to enable more medicines to be available without prescription, promote minor ailment schemes (Section 1.7.2), and develop a new community pharmacy contract to allow 'fair' remuneration for the extended service provision through pharmacy [66]. *Modernising NHS Community Pharmacy in Scotland* also published in 2004 delivered similar commitments for fairer remuneration [67]. This set out a vision for the new community pharmacy contract including the introduction of the Minor Ailment Service (Section 1.7.2) nationwide in Scotland. This also set out plans to seek advice from pharmacists about an amended definition of the supervision of non-prescription medicines by pharmacists. The new contractual framework to support service delivery was also highlighted by an English command paper in the same year to enable pharmacists to contribute to a healthy society by maximum use of their skills, providing them with opportunities to offer patients services around self care of minor ailments along with healthy living, smoking and alcohol cessation and sexual health [68].

The Northern Ireland Government published *Making it Better- A Strategy for Pharmacy in the Community* in 2004 [69] which highlighted revised contractual frameworks to support extended service provision in assisting patients with self care of minor ailments.

Detailed proposals for the better use of staff working in pharmacies were set out in the consultation paper *Making the Best Use of the Pharmacy Workforce* [70], published in December 2004 in England (also adopted for consultation by the National Assembly of Wales), February 2005 in Scotland and April 2005 in Northern Ireland [56]. These documents put forward proposals for amendments in the requirement of supervision of POM and P medicines by pharmacists.

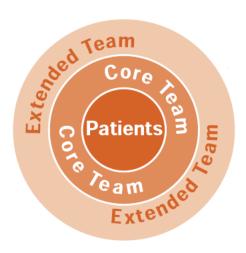
In January 2005, the English DoH published *Self Care- a Real Choice: Self Care Support- a Practical Option* [11]. This emphasised the need to promote pharmacists managing a greater number of minor ailments such as through minor ailment schemes, annual health check schemes and enabling self diagnosis of diseases. It presented the Government's commitment to: extend the expert patient programme and national services framework (NSF) to further disease areas and future initiatives such as enabling self care support networks in local communities. It also committed a self care agenda feature in all future health policy documents. The social care Green paper published in 2005 also by the English DoH called *Independence, Well Being and Choice* emphasized the importance of pharmacists working alongside other health professionals in achieving similar aims [71].

A twenty year vision of health and well being was unveiled in Northern Ireland in 2005 (*A healthier future*). It aimed to enhance community pharmacy involvement in partnership projects to develop services to meet local needs and priorities [72]. Pharmacists were regarded as core professionals delivering services around and out-with minor ailments.

Figure 1.5: Pharmacists within a Multi-Skill Network

Core team

GPs
Community nurses
Health visitors
Social workers
Community
pharmacists
Psychiatric nurses
Receptionist/admin



Extended team

Allied health professionals
Specialist community workers
Public health workers
Health promotion staff
Community dentists
Home helpers
Hospital specialists
Care workers

Reproduced from [72]

In April 2005, *Choosing Health through Pharmacy* [73] was published by the English DoH. This was a ten year programme for promoting public health through pharmacy which delivered Government's greater support for self care, greater working partnership of pharmacists with local authorities, health and social organisations and getting more pharmacists to work as public health practitioners. In the same year, the Welsh Assembly Government also published a ten year vision to reduce health inequalities [74]. Providing a wider range of services and advice around healthy living and disease prevention were the future roles focused for community pharmacy.

Building a Health Service: Fit for the Future was published by the Scottish Government in 2005, highlighting the need to revise 'outdated' models of health service to align with changing demographics and social needs [6]. In the same year in November, Delivering for Health presented a vision for a modernised contractual framework to enable community pharmacists to provide extended services [75]. The Scottish Executive promised through this document to continue to take initiatives to increase pharmacists' professional roles. Delivering Care, Enabling Health [76] also published at the same time set out plans to achieve these ambitions such as by enabling joint working across the disciplines.

The Health Act 2006 [77] allowed UK ministers to redefine the strict requirement of supervision and personal control by pharmacists for the supply and dispensing of prescription and non-prescription medicines as set out by the Medicines Act 1968. This was

intended to allow pharmacists to redeploy their skills in other areas recently introduced [78]. As a result, all the devolved Governments began consultations to redefine the supervision requirements. Also in 2006, an English White paper [79] emphasised extending pharmacists' roles and pharmacists working alongside other primary care service providers as a 'joined-up' system.

In 2007, *Our NHS Our Future: NHS Next Stage Review* published by the English DoH set out a ten year vision to make the NHS 'fairer, more personalised, effective and safe' [80]. Pharmacists were to be directing patients to appropriate care services. In the same year, it also published a White paper *Trust, Assurance and Safety: The Regulation of Health Professionals*, which proposed a key reform in the professional regulation of pharmacists by requiring the development of a new professional representative body for pharmacy [81]. The role of RPSGB being the professional representative body was deemed to be conflicting with its role as regulator of the profession. Based on these recommendations, legislation changes would be sought so as to establish General Pharmaceutical Council (GPhC) that would regulate pharmacists, technicians and pharmacy premises. This ultimately came into force in 2010. The regulation around non-prescription medicines sales and supervision will now be under the control of GPhC as opposed to the RPSGB. This also brought periodic mandatory continuous professional development (CPD) training requirements to be undertaken by the pharmacists so as to ensure public trust in pharmacists' extended service provision [81].

Also in 2007, the Scottish Government put in place systems to electronically transfer prescriptions from GPs to community pharmacy and to ease patient access to any community pharmacy. In the same year two policy documents were unveiled [82,83] which aimed to provide patient walk in access to a wider range of community pharmacy services [82]. An agenda to encourage and facilitate self care through pharmacy by taking patients as partners was proposed.

In 2008, the White paper *Pharmacy in England: Building on Strengths- Delivering the Future*, was published [84]. This White paper aimed to set out a vision for building on the strengths of pharmacies, to enable the UK Government vision of 'safe, effective, fairer and more personalised' care of patients. This also proposed easing current restrictions on dispensing doctors selling non-prescription medicines in rural areas where pharmacies were not unviable allowing easier access for patients to manage minor ailments. In addition to

ensuring further support for pharmacy management of Minor Ailment Services, further programmes to promote and support health literacy including healthy lifestyle advice and support on self care of long terms illnesses including disease risk assessment from pharmacy were proposed. Proposals that in the future, pharmacy services would be registered with Care Quality Commission established by the Health and Social Care Act 2008 in England were presented.

The English DoH published a five year plan for the NHS (2010 to 2015) in 2009 which identified pharmacies as 'crucial local partners' for advice around health and well being of the community [85]. A framework of healthy living pharmacies would be developed to promote health and well-being. Yet another Green paper *Shaping The Future Of Care Together* was also unveiled by the DoH in the same year, aiming to deliver easier access to self care for minor ailments for the vulnerable groups such as the elderly at home.

The newly elected coalition Government in 2010 published a White paper *Equity and Excellence: Liberating the NHS*. Several reforms around the regulation of primary care services were proposed [86]. Power would be given to GP consortia to manage the funds for much of the primary care services but certain pharmacy services were to be exempt from such regulations. It further vowed to enhance pharmacists' roles in enhancing the rationale use of medicines. Pharmacies would be remunerated 'appropriately' for the services they provide and the prospect of performance based incentives for pharmacies was laid out.

1.6.2 Summary of the literature review I

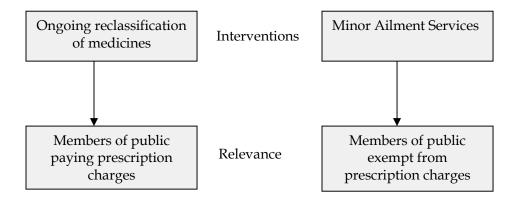
The review of the literature has provided reflection on key developments proposed contained within the health policies proposed by the UK Government and the devolved Governments with particular emphasis on enhanced minor ailment management supported by pharmacy. The Nuffield report had highlighted the need for reform of the nature of community pharmacy services, funding and research in the forthcoming decades. Subsequent key White and Green papers from the UK Health Departments, prior to and post devolution, were reviewed. It appears that all of the devolved Governments are keen to enhance pharmacy's role in minor ailment management and to support patient self care through professional advice and guidance. Extra funding and professional development opportunities for pharmacy were promised and also identified that enhanced minor ailment management from pharmacy would bring: professional role development opportunities; extended use of professional skills; enhance reputation with the society; as

well as contribute to freeing up GPs thus reducing waiting times; and bringing about significant health benefits in the longer term. Greater collaborative working among health professionals was stressed, along with greater patient access and the need to ensure trust amongst members of public in pharmacy services. Two key policy interventions aimed to increase such access to services were identified. These are discussed in detail below.

1.7 DETAILS OF KEY POLICY INTERVENTIONS AROUND ENHANCED MINOR AILMENT MANAGEMENT FROM PHARMACY

The ongoing reclassification of medicine and the introduction of minor ailment services were identified as the key policy interventions aimed at increasing patient access to non-prescription medicines; and hence pharmacy management of minor ailments (figure 1.6). The former has greater relevance to those members of the public who pay prescription charges, whereas the minor ailment services introduced across the UK are relevant to those members of public exempt from prescription charges. In Scotland, this service is known as the electronic Minor Ailment Service (e-MAS).

Figure 1.6: Key policy interventions around enhanced minor ailment management from community pharmacy



1.7.1 Reclassification of medicines

Reclassification from POM to P allows pharmacists to supply medicines without prescription thereby enabling enhanced patient access to these medicines. For any medicine to be reclassified from POM to P, the Medicines and Healthcare products Regulatory Agency (MHRA) requires that it 'no longer should meet' any of the following safety issues in relation to section 58 of Medicines Act [12] and European Commission (EC) Directive on medicinal products for human use (2001/83/EC) [87,88]:

- a direct or indirect danger exists to human health, even when used correctly, if used without medical supervision; or
- there is frequently incorrect usage which could lead to direct or indirect danger to human health; or
- further investigation of activity and/or side-effects is required; or
- they are normally prescribed by a doctor to be administered parenterally.

In ensuring such safety requirements, documents such as Periodic Safety Updates Reports (PSUR), post marketing surveillance studies or published literature as well as clinical trial reports are considered as appropriate sources of evidence [87]. In addition to these documents, the MHRA also needs to be convinced that patients are able to self diagnose the ailment related to the medicine as well as be able to use the medicine without medical supervision [87]. Currently, the regulation allows request of reclassification to be raised by any interested groups such as the company holding the marketing authorisation, RPSGB or MHRA itself. On receipt of applications, the MHRA consults with the Commission on Human Medicines (CHM) regarding the safety profile (figure 1.7). Public consultation

follows via the MHRA, and CSM is finally consulted for any new safety concerns identified during this process before a decision to reclassify is made [89].

Any medicines reclassified to P status then remain under this status for a certain while during which, if no new concerns around safety are raised [12], it could then be considered for reclassification to GSL class [87]. If any new safety concerns are raised during the non-prescription availability, the legal status of medicines could be reverted back to POM status [87].

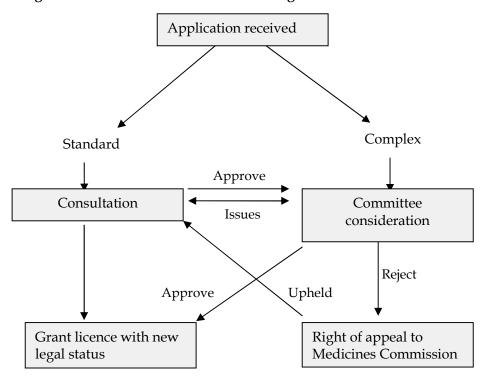


Figure 1.7: Process of reclassification of legal status of medicines

Reproduced from [87].

1.7.1.1 Medicines reclassified from POM to P

Since the first reclassification of loperamide, ibuprofen and terfenadine from POM to P in 1983; to date, there have been more than 80 reclassifications from POM to P status (Table 1.1). Most of the reclassifications relate to acute illnesses. However, lately, medicines for long term use such as simvastatin for the prevention of coronary events and sumatriptan for the treatment of migraine headaches have also been reclassified. Ailments such as irritable bowel syndrome, migraine, chlamydia and arthritis are some of the ailments that pharmacists can now manage with medicines without a prescription. Reclassification

within similar therapeutic areas have taken place in other European nations [90,91] and in the US [25].

Table 1.1: Prescription only medicines reclassified to pharmacy status in the UK (Note: this table extends to two pages)

Medicine	Date	Medicine	Date
Loperamide	1983	Nicotine chewing gum 4mg	1994
Ibuprofen oral	1983	Hydrocortisone pellets	1994
Terfenadine	1983	Triamcinolone dental paste	1994
Hydrocortisone topical 1%	1987	Hydrocortisone rectal	1994
1		ointment and suppositories	
Dextranomer topical	1987	Diclofenac	1994
		diethylammonium (external)	
Ibuprofen s/r oral	1987	Felbinac topical	1994
Ibuprofen topical	1988	Piroxicam topical	1994
Astemizole	1988	Flunisolide nasal spray	1994
Mebendazole	1989	Ranitidine	1994
Dextromethorphan c/r	1989	Minoxidil	1994
Hyoscine Butylbromide	1991	Ibuprofen suspension	1994
Nicotine chewing gum 2mg	1991	Hydroxyzine hydrochloride	1995
Vaginal imidazoles	1992	Pyrantel embonate	1995
-Clotrimazole		5	
-Econazole			
-Isoconazole			
-Miconazole			
Hydrocortisone/crotamiton	1992	Fluconazole	1995
Paracetamol/dihydrocodeine	1992	Ketoconazole shampoo	1995
Nicotine replacement patches	1992	Hydrocortisone rectal	1995
Carbenoxolone granules	1992	Cadexomer iodine	1995
Loratadine	1993	Budesonide nasal	1995
Aciclovir	1993	Azelastine nasal	1996
Ketoprofen topical	1993	Nizatidine	1996
Acrivastine	1993	Hydrocortisone/ Lignocaine	1996
		(Lidocaine) HCl Spray	
Catininia	1002	(Perinal) Mebeverine Hcl	1007
Cetirizine Reclamathecana dipranianata	1993 1994		1997
Beclomethasone dipropionate Cimetidine		Sulconazole Clotrimazole and	1997
Cimename	1994	hydrocortisone cream	1997
Famotidine	1994	Domperidone	1998
Sodium cromoglycate 2% eye	1994	Hydrocortisone and	1998
drops and ointment	1// 1	miconazole topical	1770
Tioconazole 2% vaginal	1994	Levocabastine	1998
Aluminium chloride	1994	Nedocromil sodium	1998

Adapted with revision from [92].

Medicine	Date	Medicine	Date
Ketoconazole Cream 2%	1998	Flixonase (Fluticasone)	2002
		Allergy nasal spray	
Hydrocortisone 0.5% and nystatin 3%	1999	Grisol (griseofulvin)	2003
Aspirin 75mg (packs of 100)	1999	Omeprazole 10mg	2004
Isosorbide mononitrate	1999	Simvastatin	2004
Terbinafine 1% cream/spray	2000	Hyoscine transdermal patch	2004
Nicotine nasal spray	2000	Emla (lidocaine and prilocaine) cream 5 percent	2005
Lodoxamide trometamol eyedrops	2000	Chloramphenicol eye drops	2005
Triamcinolone acetonide nasal spray	2000	Amorolfine nail lacquer	2006
Levonorgestrel (emergency hormonal contraception)	2001	Sumatriptan tablets	2006
Prochlorperazine	2001	Chloramphenicol Ointment	2007
Fenticonazole nitrate	2001	Naproxen	2008
Clobetasone butyrate 0.05%	2001	Domperidone maleate	2009/10*
Flurbiprofen	2001	Diclofenac ethylammonium	2009/10*
Diphenoxylate hydrochloride and atropine sulphate	2002	Tamsulosin hydrochloride	2009/10*

^{*}Accurate date listings could not be retrieved

1.7.2 Minor Ailment Services

Almost 50% of the total population of Scotland is exempt from prescription charges and their prescriptions account for more than 90% of the total number of dispensed items [93]. Despite the reclassification of medicines, many of these members of public are likely to continue using GP services and prescriptions as a means of obtaining the desired medicines due to the cost factor. Hence, mainly to address this issue, minor ailment schemes have been introduced in many regions throughout the UK. These schemes allow these members of the public to register with one community pharmacy of their choice and have their minor ailments treated by the pharmacist free of charge, or where appropriate, to get advice or onward referral to other health professionals [94].

In Scotland, this scheme was initially launched as a pilot project entitled 'Direct Supply of Medicine' in 2001 followed by the 'Direct Care at the Chemist' project at the end of 2003 in two NHS boards: NHS Ayrshire & Arran and NHS Tayside [95]. The scheme was then

officially launched in all community pharmacies of Scotland as a 'core' service under the community pharmacy contract introduced in 2006 with the name 'electronic Minor Ailment Service' (e-MAS) [96]. In England and Wales, such schemes appear as 'enhanced' services and thus PCTs, after assessment of local needs in their area, can decide whether to commission the scheme [97]. In Scotland, pharmacists are reimbursed for the cost of medicines supplied and receive capitation payments based on the number of patients registered [96]. E-MAS is being supported by a national IT network system known as e-pharmacy which enables both identification of existing patient registrations and new registrations using the patient's unique community health index (CHI) number [98]. This service also enables patient consultations and registration details from pharmacies to be verified for reimbursement and remuneration purposes.

Medicine supplies by pharmacists within e-MAS are guided in Scotland by formularies laid out by each NHS Board [10]. A national formulary has also been developed by Community Pharmacy Scotland based on the local formularies [99].

1.8 REVIEW OF LITERATURE II

GREATER PATIENT MANAGEMENT OF MINOR AILMENTS FROM COMMUNITY PHARMACY: A CHRONOLOGICAL REVIEW OF UK LITERATURE 1997- 2010

This section will present UK peer reviewed literature around enhanced minor ailments management from community pharmacy to enable the identification of future research need within this area.

1.8.1 Literature search strategy

Literature from ten years prior to the commencement of this PhD till date was searched (1997- 2010) using databases namely: Ovid MEDLINE (R), International Pharmaceutical Abstracts (IPA), CINAHL, EMBASE and PsychINFO. An example of the search strategy used and those of the databases appear in Appendix I along with rationale for the use of the particular databases. All the search strategies used to retrieve literature in this section and beyond were recorded and maintained in a log book counter signed by the researcher and principal supervisor for ensuring the transparency of the process.

Nurse led management of minor ailments was excluded from review. Only empirical studies (literature other than expert opinions and systematic reviews) that were published in peer reviewed journals were included. Literature around pharmacists' perspectives of health promotion and preventative services including smoking cessation, emergency hormonal contraception, cholesterol management with no specification of minor ailment management were excluded from this review.

1.8.2 Literature overview

A total of 27 studies investigated issues related to greater management of minor ailments from community pharmacy. A summary of methodology, aims/objectives, method, setting and number of research participants and key findings are presented in table 1.2 below.

Table 1.2: Literature around enhanced management of minor ailments from community pharmacy (note: this table extends to five pages)

Author(s) and year	Methodology	Aims/ objectives	Method, setting, and number participating (response rate)*	Key findings
Erwin et al 1997 [100]	Quantitative	Investigate GPs' attitudes to pharmacy supply of H2 receptor antagonists	Cross sectional survey of GPs from eight randomly selected FHSA†s in England 515 (60.5%)	54% agreed to pharmacy availability of H2 receptor antagonists.
Hassell et al 1997 [101]	Qualitative	Understand patient decision making process around visiting pharmacy for minor ailments	Telephone interview of patients receiving advice from nine different pharmacies, participant observations of pharmacy staff and users 44 patients	Pharmacy regarded by patients as an appropriate setting either for minor ailments or onward referral to GP visit.
John and Evans 1997 [102]	Quantitative	Investigate patient attitude to advice giving in pharmacy and non-prescription medicine purchases	Cross sectional survey of Cardiff residents in Wales 810 (37%)	Approximately 83% believed pharmacists were experts in minor ailment management.
Bradley et al 1998 [103]	Quantitative	Investigate patient attitudes to non-prescription medicines and associated professional advice	Cross sectional survey of consecutive patients from six GP practices in West Midlands of England 2765 (91.3%)	Over 54% patients would be willing to buy OTC medicines if recommended by doctors; 83% regarded pharmacists as a good source of advice on minor ailments.
Bleiker and Lewis 1998[104]	Quantitative	Investigate GPs' attitudes to extension of pharmacists' roles in patient care	Cross sectional survey of all GPs of South and West Devon health commission; 299 (81.2%)	Approximately one third respondents were concerned with commercial interests of pharmacy to extend their role in minor ailment management.
Hassell et al 2000 [105]	Qualitative	Explore influences on patient utilisation of community pharmacy for minor ailments	Observational study of 44 pharmacy users from ten pharmacies in North West England and household study involving 549 individuals	Process factors such as lay evaluation of illness and symptoms key in the use of community pharmacies.
Iversen et al 2001 [106]	Quantitative	Investigate of public attitude to extended roles of community pharmacists	Cross sectional survey of random sample of patients from North East of Scotland 173 (55%)	Majority were unsure or disagreed to reclassification of medicines such as antibiotics for minor respiratory infections.

^{*}information presented where available in the literature; †Family Health Service Agency

Author(s) and year	Methodology	Aims/ objectives	Method, setting, and number participating (response rate)	Key findings
Morris et al 2001 [24]	Quantitative	Investigate GPs' attitudes to minor ailment management	Cross sectional survey of one GP from all practices in eight Health Authorities, England 414 (54.5%)	Approximately 78% stated pharmacists should be consulted prior to GPs for minor ailments.
Philips et al 2001 [107]	Quantitative	Investigate cost effectiveness of pharmacy led free head lice treatment scheme to patients; to measure acceptability to stakeholders	32 pharmacies, 5710 patients in Nottingham, analysis of PACT* data and questionnaires to patients (n=336), GPs (n=60) and pharmacists (n=42) in Nottingham, England	Self referral to pharmacy without GP contact rose approximately twice when compared to baseline. Around 70% would use pharmacy in the future. GPs reported marked decrease in consultation rate.
Whittington et al 2001 [108]	Quantitative	Investigate patient transfer from GPs to pharmacies for minor ailment management	Pragmatic study of patients requesting appointment for minor ailment consultation in one general practice in Merseyside 1522 patients	Transfer of a total of one third of GPs' minor ailment work load were achieved with 576 opting to use pharmacy instead of GPs. Only 21 patients required GP referral.
Bednall et al 2003 [109]	Quantitative	Determine frequency of patients attending A & E department for minor ailment management	Retrospective review of 2636 patient records (aged >16) attending A & E department at one hospital in London, England	8% of the cases identified were eligible to be appropriate for management through pharmacy.
Morris et al 2003 [110]	Quantitative	Identify prevalence of minor ailment presentations at GP surgeries from patient and GP perspectives	Cross sectional survey of consecutive patients attending surgery sessions from two GP practices in West Midlands, England 240 (96.4%)	40% of the patients identified themselves as suffering from minor ailments, majority of whom (51%) whereas were identified by GPs as to be more serious ailments.
Walker et al 2003 [111]	Quantitative	Evaluate the use of a "Care at the pharmacy" minor ailment scheme and determine its impact on triaged calls	RCT of 1,888 households allocated to control group of each of the Pharmacy Medicine Access Group (PMAG) group which were provided free medicines and advice if exempt from prescription charges 1,888 households	During 11 weeks of trial, PMAG patients made fewer calls to the triage.

Author(s) and year	Methodology	Aims/ objectives	Method, setting, and number participating (response rate)	Key findings
Baylis and Rutter 2004 [112]	Quantitative	Investigate GPs' attitudes to the ongoing reclassification and pharmacy management of minor ailments	Cross sectional survey of GPs from five randomly selected PCTs in England 135 (31%)	66% agreed that pharmacists had expertise to counsel patients for reclassified medicines usage, 47% agreed that pharmacists could diagnose minor ailments.
Bojke et al 2004 [113]	Quantitative	Evaluate minor ailment scheme for the effect on number of GP consultations and to identify factors affecting patient preferences	Pragmatic study in GP practice in deprived area of Bootle involving 1113 patients who requested GP appointment for minor ailment and were given option to visit pharmacy 1113 patients	Total number of GP consultations unaffected, but decrease in the number for minor ailments by approximately a fifth during intervention; type of minor ailment key to patient choices.
Langley et al 2004 [114]	Quantitative	Evaluate the attitudes of non- users of a 'Pharmacy Direct' minor ailment scheme	Cross sectional survey of patients from Eastern Birmingham PCT who refused to use the scheme 24(80%)	80% agreed they trusted doctors more than pharmacists, a third reflected concern about pharmacists' skills.
Hammond et al 2004 [115]	Quantitative	Investigate patient presentation of minor ailments to GPs	Cross sectional survey of consecutive patients in 13 general practices in West Sussex 3984 (94%)	GPs identified 7% of patients visiting for minor ailment management; 59% of these patients disagreed with GPs' views.
Parmentier et al 2004 [116]	Quantitative	Evaluate schemes offering free minor ailment management service to refugees	Case series analysis of refugees who were offered vouchers for a free minor ailment scheme 184 patients	264 items supplied, with respiratory illness, headache and musculoskeletal pain covering over 50% of ailments that were managed.
Boardman et al 2005 [117]	Quantitative	Quantify reasons for patient visits to community pharmacy	Cross sectional survey of random sample of adults (≥35 yr) in North Staffordshire 6322 (67%)	40% patients visited pharmacy for purchasing non-prescription medicines in the preceding month with cold and flu as the most commonly presented symptoms

Author(s) and year	Methodology	Aims/ objectives	Method, setting, and number participating (response rate)	Key findings
Cantrill et al 2006 [118]	Qualitative	Investigate how patients define minor ailments and explore reasons for seeking a GP consultation about minor ailments	Face to face interviews with purposive sample of patients consulting one GP from two GP practices in the West Midlands, England 19 patients	Patient knowledge and severity of illness were key to how patients define minor ailments; greater perceived severity of the ailments and quicker relief using POM medicines were identified as key reasons to prefer GPs against pharmacy
Dhippayom and Walker 2006 [119]	Quantitative	Investigate if reclassified omeprazole had an impact on prescribing and sales of ulcer healing drugs	Retrospective analysis of three years' data of 22 Local Health Boards in Wales over three years from 2002 to 2005.	The number of prescription items for ulcer healing drugs across Wales was found to have increased in each year of the study.
Porteous et al 2006 [120]	Quantitative	Determine the relative importance of factors that influence patient decision making in the management of minor ailment associated with analgesic use	Cross sectional survey of members of public in Scotland selected from a previous survey 293 (51%)	Self care was the most preferred practice to manage minor ailments and pharmacy was the preferred primary care health service provider for minor ailments. GP waiting time and cost of service were two important factors determining choice
Vohra 2006 [121]	Quantitative	Investigate patients' views of a minor ailment scheme	Cross sectional survey of patients attending the scheme in Chorley and Ribble PCTs in England 123 (40%)	Almost all were positive about the scheme. Approximately 72% indicated they had no objections to seeing pharmacy for minor ailment management in the future.
McCaig et al 2008 [122]	Quantitative	Examine community pharmacists' early experiences of reclassified omeprazole	Cross sectional survey of random sample of GB community pharmacists, 1156 (57.8%)	78% of the participants agreed that omeprazole was a welcome addition to the range of pharmacy medicines; 73.4% expressed confidence in sales and supply.
Pumtong et al 2008 [123]	Qualitative	Investigate community pharmacists' perceptions of a minor ailment scheme	Semi-structured interviews with 26 pharmacists in Nottingham PCT involved in the scheme	Pharmacists were positive about the service, benefits to pharmacy profession and patients identified. Lack of privacy in pharmacy was deemed a barrier.

Author(s) and year	Methodology	Aims/ Objectives	Method, setting, and number participating (response rate)	Key findings
Walker and Hinchliffe 2009 [124]	Quantitative	Investigate impact of chloramphenicol reclassification on prescription volume of the medicine	Retrospective analysis of UK prescription items and sales data from 2003 to 2008	Chloramphenicol reclassification had no significant impact on the number of prescription items dispensed; no savings to Government realised.
Blenkinsopp et al 2009 [125]	Quantitative	Investigate uptake of Pharmacy First minor ailment scheme directed at children; and investigate attitudes of mothers and health professionals.	Pragmatic study, cross sectional survey and focus groups (n=18) of mothers in intervention and control groups. Intervention related to health promotion campaigns and pharmacy minor ailment scheme	A total of 1364 consultations were recorded in the scheme. There was no significant difference between the intervention and control groups in numbers of GP consultations for the minor ailments. Attitudes towards consulting a pharmacist were positive in both groups.

Most of the literature that were identified related to either patient or GP perspectives of enhanced minor ailment management from community pharmacy. Patient perceptions of minor ailments and/or factors affecting their choice of different health professionals for managing the ailments were the focus of ten studies [102,105-107,113,114,118,120,121,125]. Six studies evaluated specific newly reclassified medicines or services aimed at enhanced pharmacy minor ailment management from the patient perspectives [106,107,113,114,121,125]. Patients in general, as reported by most of these studies were in favour of getting minor ailments managed and receiving advice at pharmacies. Patients reported high levels of confidence around the professional competence of community pharmacists [102,103,112]. Perceived severity of illness was often reported as key to patient decision making about the choice of health professionals; with greater the perceived severity, more the tendency to visit GPs [105,113,118]. Costs of non-prescription medicines as well as the issue of access were key to such decision making. Patients were often reported to diagnose minor ailments differently from health professionals [109,110,115]. Studies from patient perspectives would benefit from further in-depth investigation of patient decision making processes using prospective designs. Such research could also aid the identification of appropriate interventions to modify patient behaviour so as to enable them, where possible, to present minor ailments to appropriate health professionals. In addition, further large scale evaluations of different models of care for minor ailments focusing on economic and humanistic outcomes are required to enhance the evidence around pharmacy provision of minor ailment management.

A substantial number of studies also researched GPs' perceptions of managing minor ailments and/or their attitudes towards shifting the role to community pharmacy [24,100,104,112], including the management of peptic disorders [100]. Most of these studies suggested that GPs seem to be in favour of enhanced minor ailment management from community pharmacy. Further research from the GP perspective should focus on areas such as barriers to GPs recommending patients for pharmacy management for minor ailments, an area in which the identified studies lacked information.

Research from the community pharmacists' perspective, despite the policy documents identifying them as major stakeholders of the change (section 1.6), was limited. Only three studies investigated pharmacists' perspectives of enhanced minor ailment management from pharmacy [108,122,123] of which one related to the management of peptic disorders

[122] and two related to attitudes towards minor ailment schemes to those patients exempt from prescription charges [108,123].

Two of the above studies which evaluated pharmacists' views and associated facilitators/barriers to the adoption of services around the policy intervention aimed at those exempt from prescription charges were based in England [108,123]. Both studies used a qualitative methodology. There has been no peer reviewed literature published on pharmacists' perspectives of e-MAS provision in Scotland, neither prior to nor after the nationwide rollout. In the evaluation of Minor Ailment Scheme in Nottingham PCT, benefits of the scheme highlighted by pharmacists were opportunities to: increase professional roles and image in society; provide greater and convenient access to medicines; and reduce GPs' workloads. Barriers highlighted were: paperwork; lack of privacy in pharmacy premises; abuse of the scheme by some customers; issues with protocols; and lack of support from GPs. Whittington et al interviewed community pharmacists from eight pharmacies participating in the Care at the Chemist scheme in Merseyside, England [108]. Pharmacists were found to be supportive of the scheme and highlighted the importance to: the profession in terms of maximizing the utilization of professional skills; and to patients in terms of offering greater accessibility as the service required no appointment and open for longer hours than GP surgeries. Problems highlighted mainly related to the limited scope of the scheme formulary. Within this study, no details on how many pharmacists were interviewed were provided and there were scant details on the nature of the interview topic guide and analytical approach.

Although four other publications evaluated minor ailment schemes to patients exempt from prescription charges [111,113,116,126], pharmacists' attitudes to such extended role were not presented. Within one paper, the perspectives of pharmacists were missing despite listing such exploration of the attitudes as one of the key objective [126].

Despite reclassification of many medicines for the management of minor ailment from community pharmacy (table 1.1), there was a dearth of literature identified which measured pharmacists' perspective of medicines reclassification. As the literature around therapeutic areas such as contraception and cholesterol lowering were excluded, only one study could be included in the review which related to reclassification of omeprazole. This related to reclassification of omeprazole to non-prescription status immediate post reclassification [122]. Pharmacists' support for the reclassified status of medicines was high, as well as the

confidence to supply. Responses to open questions reflected pharmacists' issues around retail price of the reclassified medicine limiting supply decisions and lack of novelty of omeprazole's therapeutic area as compared to existing ranges of medicines.

1.8.3 Summary of literature review II

The current position of research in the area of enhanced minor ailments management from pharmacy in the UK seems to have derived from the notion that: given the patients are ready to opt for pharmacies for minor ailment management and that there is a readiness for GPs to 'shift' responsibility of managing minor ailments to pharmacy; pharmacists' perspective around the changes is minor. It was astonishing to note that few studies investigated pharmacists' perspectives within this key area of change. Indeed, the lack of rigorous studies, both qualitative and quantitative around adoption of innovative medicines and services around enhanced minor ailment management was identified. Roberts et al citing Kanter (1992) explain that 'the point of view of those who think they are creating change as an intentional process will be different from those who are on the receiving end' [127]. Elements of practice within both the ongoing reclassification of medicines and the minor ailment services have demanded a shift of pharmacists' role from routine dispensing towards more personalised and cognitive tasks. It is imperative that future studies have greater focus on how service adoption by community pharmacists can best be facilitated given the centrality of their role in provision of extended services. As adoption into practice of new services in pharmacy is an area of professional practice change, it thus becomes important to understand how research around adoption of new services or innovations [128] is best undertaken.

1.9 INNOVATION

Innovation is defined as the intentional introduction and application of ideas, processes, technologies, medicines, services [129] that are perceived to be 'new' to the relevant unit of adoption [130]. Adoption here is defined as the decision to make use of an innovation by individuals, groups, or organisations [131]. Implementation relates to putting innovations into routine practice [130,132]. When adoption of innovation takes place as a result of responses to external (to individual or organisation) changes, the process of adoption is argued to require on the part of the individual or organisation, changes in behaviours or characteristics [133].

1.9.1 Innovation in health care

Iles and Sutherland distinguish between the following types of changes that take place in health care settings [128]:

1.9.1.1 Planned versus emergent change

These categories relate to whether changes are anticipated by the unit of adoption. Planned changes are usually deliberate and they results due to 'conscious reasoning and actions'. In contrast, emergent changes are those that occur in a 'spontaneous and unplanned way'.

1.9.1.2 Episodic versus continuous change

This categorisation refers to frequency of changes. Episodic refers to infrequent or discontinuous changes; whereas, continuous changes refer to 'ongoing, evolving and cumulative'.

1.9.1.3 Developmental, transitional and transformational change

This categorisation refers to the extent and scope of change. Developmental change relates to changes to improve skills or processes. Transitional changes relate to episodic planned changes and could involve a three stage change process namely 'unfreezing', 'moving' and 'refreezing' [134]. Transformational changes are those requiring significant alterations in individuals' or organisations' culture, structure or ways of working.

1.9.2 Key elements of innovation adoption research

Content, context and process are the three key elements of innovation research [135,136]. Content refers to identifying features of innovations that are likely to be associated with innovation adoption decision by the adopting unit [136]. Internal context relates to organisational conditions 'external' to the individual [136], for example, availability of resources and motivation for change. External context relates to conditions outside the organisation [136,137]. 'Process' relate to phases through which an individual or system adopts the innovation and the key players involved [127,136].

Lack of consideration of processual and contextual dimensions of practice change by healthcare practitioners has been argued to be commonly linked to failure to achieve change [129,138]. Theoretical models are best able to provide the framework to consider these key elements of innovation research.

1.9.3 Use of theoretical models to research innovations

Use of theoretical models in innovation adoption research allows researchers to systematically collect, analyse and or interpret the data [139]. Previous research in community pharmacy practice change has mostly used organisational theory as a basis of research tool development or for the interpretation of data [127,130,139-144]. However, because organisational change starts with and is mediated through new behaviours and decisions on the part of individuals [132,138,145], individual perspective of change deserves no less attention. Greenhalgh argues that individuals within health care organisations should not be regarded as passive adopters of innovations [146] and that the individuals also go through the complex adoption process such as 'seeking innovation as well as experiment, evaluate, develop attitudes about, challenge, complain and gain experience and/or modify it to fit their needs' [146]. Failure to understand conditions under which individuals are likely to undertake new behaviours have been often blamed for resistance to change by potential adopters [145,147-149]. It is essential that key members of organisations are active supporter of change and are ready to adopt it, otherwise, implementation is usually deemed 'impossible' [150].

Theoretical models based on behavioural change theories such as 'the theory of planned behaviour' has also been applied in community pharmacy [151,152] as well as 'the theory of goal directed behaviours' to understand pharmacists' intentions to provide pharmaceutical care [151,153] or to understand the factors associated with differences between intentions of pharmacists to provide pharmaceutical services and actual behaviours [153,154]. Others have used 'human error theory' to understand and change pharmacists' behaviours non-compliant to established norms [155]. However, practice change and more importantly their sustainability have been argued to have been limited [139]. Research into enhanced management of minor ailments from pharmacy also inherits these limitations. Hence there is a need to apply fresh perspectives to research innovation adoption by community pharmacists. Using theoretical models that have been useful in other schools of thoughts such as business, management, economics and law to undertake community pharmacy practice research is argued to be one way forward in addressing these limitations [156,157].

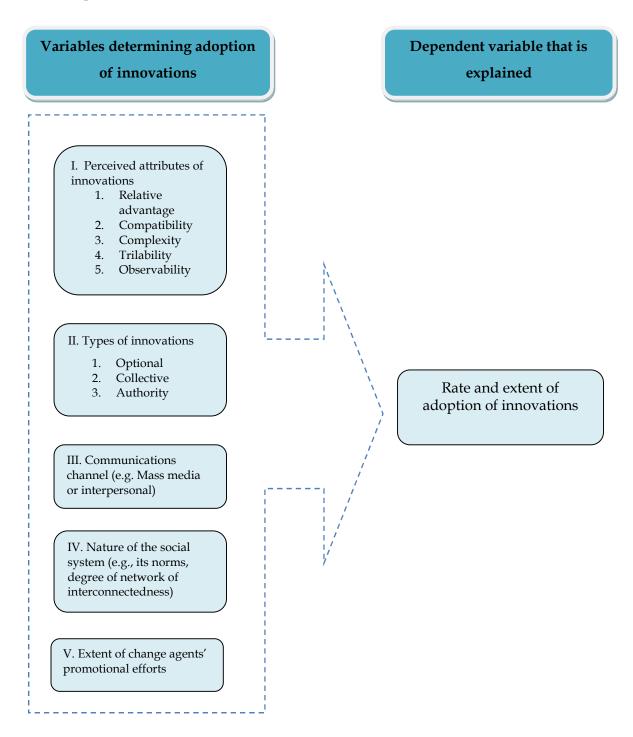
1.9.4 Rogers diffusion of innovations model as a tool to research community pharmacy innovations

Understanding processes of adoption of innovations by health care practitioners and key factors associated with adoption decisions is an area of diffusion research [158]. Such research in healthcare has lately been argued to be likely to benefit from application of the diffusion model [146,159]. Rogers' diffusion model defines 'diffusion' as a 'process through which an innovation is communicated through certain channels over time among the members of social system' [131]. The key elements in the diffusion process are the innovation, its adopter, communication channels, time and the social system and its members [131]. In addition to the characteristics of innovations (content), organisational contextual factors and contexts external to the organisation and factors that are reliant on characteristics of the individual adopters themselves are also argued to be associated with innovation adoption (table 1.3).

Rogers' diffusion model states that individuals assess the innovation from their own perspective such as need and benefit [149]. Individuals also deal with uncertainty about the consequences of adopting innovations into practice [130]. During such processes, individuals go through gaining awareness of the innovation, forming an attitude towards innovation (positive or negative), making a decision whether to adopt it. Individuals may also deal with uncertainty such as fear of loss of control as well as feeling concerned about their own competence in the changed context [128,131] which could lead them to resist or reject innovations [128]. Therefore, the method around how awareness to innovations is raised, as well as how potential adopters are motivated, is key to facilitating innovation adoption [160]. Gathering such sequences of events about how innovations are adopted is referred to in diffusion research as 'process' research [130] and is best known to be undertaken through qualitative methodology (Chapter 2). Rogers exemplifies the use of diffusion model in studying change process as "something like the use of radioactive tracers in studying the process of plant growth: it helps illuminate processes" [131] (p 104).

Understanding the cause of individuals adopting or rejecting innovations by studying interrelationships between the context, content and individual characteristics (figure 1.8) in diffusion research is generally known as 'variance research' [131]. Such research is usually known to employ cross sectional designs, allowing researchers to collect data around innovation adoption by the adopters in one time frame.

Figure 1.8: The theory of diffusion of innovations illustrating the variables determining the adoption of innovations.



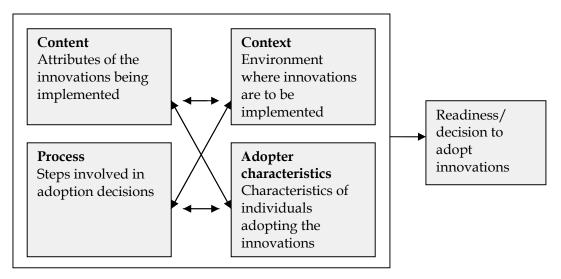
Adapted with modification from [131].

Table 1.3: Factors associated with innovation adoption by individuals.

Factors	Categories	Description of categories
associated with	within the	
innovation adoption	factors	
Attributes of	Relative	Advantage over existing services. Greater perceived relative
innovation	Advantage	advantage by potential adopters enables faster and greater
nino vacion	ria variage	adoption of innovation.
	Complexity	The degree of difficulty involved in learning about and
	1 5	adopting innovation. Greater perceived complexity of
		adoption by potential adopters produces slower adoption or
		rejection of innovation.
	Compatibility	The perceived 'fit' of innovation with existing structures,
		procedures and values. Greater compatibility leads to faster
	m • 1 1 •1••	and greater adoption of innovation.
	Trialability	Degree to which a new service may be experimented on a
		limited basis without major investment of time or resources.
		Opportunity to adopt innovation in a limited basis before full implementation is carried out help adopters to make a
		decision about implementation.
	Observability	Extent to which outcomes of changes are visible. Greater
		observability leads to faster and greater adoption of
		innovation.
	Re-invention	Degree to which an innovation is changed or modified
		during the adoption process.
Adopter	Innovators	Usually venturesome and play key role in launching new
characteristics		ideas in the system by importing innovation from outside of
		the system boundaries. These members are usually willing
	T1	to take risk.
	Early	Individuals usually within the system that adopt innovations relatively quicker than others and usually 'check
	adopters	with' innovations before adopting. Possess opinion
		leadership to help others adopt innovations.
	Early majority	Those adopting new ideas before the average members of
	<i>y</i> , <i>y</i>	the system usually deliberate for some time. Possess opinion
		leadership to help others adopt innovations.
	Late majority	Adopt innovations later than above categories mainly due to
		necessities such as economic or peer pressure and are
		usually cautious. Possess opinion leadership to help others
		adopt innovations.
	Laggards	Usually the last set of individuals to adopt individuals and
		possess no opinion leadership to others, are suspicious of innovations and change agents.
Organisational		Resources, time and support, leadership and management
factors		nesources, time and support, readership and management
External		Change agents
	20 101 171	

Adapted from [128,131,161]

Figure 1.9: Factors and their interrelations claimed to be associated with innovation adoption.



Adapted with modification from [162]. Readiness reflects the extent to which an individual or individuals are cognitively and emotionally inclined to accept, embrace, and adopt an innovation [162].

The utility of diffusion models in understanding innovation adoption by practitioners has have been highly recommended [146,163]. Despite its extensive application in other areas of research within and outside healthcare settings [146], its application in pharmacy practice research has so far been limited and mostly relates to 'variance' research as described above [159,164-166]. Only a dearth of literature has utilised its application in undertaking processual aspects of innovation adoption [167]. Further application of diffusion models in both of these areas is necessary and has been advocated recently by pharmacy practice researchers [168].

1.10 AIM AND OBJECTIVES

This doctoral research focuses on community pharmacists' perspectives of adoption of the two key innovations aimed at enhanced minor ailment management from community pharmacy, namely the ongoing reclassification of medicines and the inception of e-MAS in Scotland. As identified above, despite relevance to different sets of population, both the ongoing reclassification of medicines and the minor ailment schemes aim to: increase patient access to medicines, reduce GP burden of minor ailments, and increase pharmacists' professional roles in patient care. It is hence relevant and appropriate for the context of this research to evaluate both of these initiatives alongside. Considering the directions achieved by the chronological review of literature around UK policy and research, as well as the review on the theoretical model of change, the following research aim was formulated:

1.10.1 Aim

To investigate Scottish community pharmacists' adoption of innovations aimed at enhanced management of minor ailments.

1.10.2 Objectives

Objectives relevant to each of the innovations are presented separately.

1.10.2.1 Objectives relevant to innovation of ongoing reclassification of medicines

Phase I: Qualitative interviews and focus groups (Chapter 3)

- 1. To investigate community pharmacists' views on ongoing changes around enhanced management of minor ailments from pharmacy.
- 2. To evaluate the process related aspects of innovation adoption from community pharmacists' perspectives.
- 3. To explore the key facilitators/barriers^d associated with adoption into practice of reclassified medicines by community pharmacists.

Phase II: Systematic review of literature (Chapter 4)

Phase I led to the focus of the remainder of this PhD on quantification of community pharmacists' facilitators/barriers to innovation adoption of medicines and services around enhanced minor ailment management. A systematic review of literature was required at the outset of such quantitative evaluation with the following objectives:

- 1. To review and critique the methodologies, methods and models to investigate factors associated with community pharmacists' decision making around reclassified medicines described in peer reviewed published literature.
- 2. To list and describe the importance of facilitators/barriers to community pharmacists' decision making around reclassified medicines.

Chapter 1: Introduction

d For most facilitators there is usually an equal and opposite barrier. For example where remuneration is a facilitator, lack of remuneration could be a barrier. Hence the term facilitators/barriers will be used throughout the thesis

Phase III: Pilot survey (Chapter 5)

- 1. To develop survey instrument for phase IV
- 2. To pilot the survey to a small sample of community pharmacists to enhance face and content validity as well as to estimate sample size for phase IV

Phase IV: Main survey (Chapter 6)

- 1. To quantify the level of community pharmacists' support to and adoption of medicines recently reclassified for diverse therapeutic indications.
- 2. To quantify facilitators/barriers associated with pharmacists' adoption of newly reclassified medicines into practice.
- 3. To investigate the utility of Rogers' diffusion model in exploring objectives 1 and 2 above.

1.10.2.2 Objectives relevant to pharmacists' adoption of electronic Minor Ailment Service (e-MAS)

Phase I: Qualitative interviews and focus groups (Chapter 7)

- To identify community pharmacists' views and attitudes to the introduction of e-MAS in Scotland.
- 2. To identify facilitators/barriers to Scottish community pharmacists' adoption of e-MAS.
- To explore community pharmacists' views on future provision and potential usefulness of practice performance feedback from e-MAS as a facilitator of service adoption.

Phase III: Pilot study (Chapter 5)

Same objectives as phase III above.

Phase IV: Main survey (Chapter 8)

- 1. To quantify the adoption of e-MAS into practice by Scottish community pharmacists.
- 2. To quantify facilitators/barriers associated with adoption of e-MAS by Scottish community pharmacists.
- 3. To investigate the utility of Rogers' diffusion model in exploring objectives 1 and 2 above.

Introduction of future services within community pharmacy, focused around and out with the enhanced minor ailment management from community pharmacy may benefit from consideration of the facilitators/barriers; as well as from the identification of pharmacists' issues around processual aspects of innovation adoption, extracted from this study.

CHAPTER 2: METHODOLOGY

2.1 INTRODUCTION TO THE CHAPTER

This Chapter will review the methodology and methods that were applied throughout this research. Approaches to data collection and generation, analysis and interpretation of findings will be summarised along with arguments for the choice of such approaches as well as their drawbacks, where appropriate.

2.2 PHILOSOPHICAL PARADIGMS

Philosophical paradigms are researchers' beliefs that are claimed to guide their actions [169]. These paradigms are also termed researchers' epistemological and ontological stances [170-172]. Ontology refers to researchers' notions about the nature of reality [169] and what is known about it [173]. The ontological position *Realism* assumes that external reality is independent of peoples' thoughts, beliefs and understanding; whereas, *Idealism* assumes that external reality is what we know through the human mind and socially constructed meanings [173]. Epistemology relates to how one can know about the social world [173].

Four distinct philosophical paradigms, each of them relating to different epistemological and ontological positions, are known to exist and are described below.

2.2.1 Positivism

This paradigm assumes that the world is independent of the researcher [173] and facts and values of the social phenomenon can be fully measured using scientific methods [169-171]. Human behaviour under this paradigm is known to be governed by 'law like regularities' and thus is measurable [173]. Understanding 'cause and effect' relationships based on priori theories or hypotheses is the goal of research and is undertaken using an empirical approach [171]. Hypotheses relate to statements of expected research outcomes [174]. Empirical relates to knowledge being derived through experience and direct data collection rather than derived through logic [174].

2.2.2 Constructivism or Interpretivism

Unlike positivism, this paradigm assumes that there are multiple realities [170] and that facts are determined through the perspectives of participants and the subjective understanding of the researcher [173,175]. Researchers acknowledge that their own

personal, cultural and historical values influence the interpretation of findings [169,173]. Facts therefore rely more on the skills of the researcher, who acts as a research instrument, rather than on the research method [176]. Theories are induced from the data [169].

2.2.3 Advocacy/participatory

This advocacy paradigm is reported to have emerged through the criticism that the positivist paradigm is inadequate to address the issue of marginalised individuals, for example, about emancipating them from injustice such as inequality, oppression and domination [175]. Various research communities, with interests in a dedicated research area, have been argued to fall under this paradigm. For example, *feminists* working with the issue of female gender [177] (such as those interested in the issue of feminisation of pharmacy workforce) and, critical theorists who work around issues of race and social class [169,178] (such as understanding of health services utilisation by minority ethnic populations).

2.2.4 Pragmatism

Pragmatists are claimed to be not committed to any one epistemological or ontological position. Truth is considered as that which works at the time and relies on the notion that desired outcomes guide methodological approach [169,179]. Researchers are thus free to choose their methods, techniques and procedures to answer their research questions rather than adhering rigidly to any one approach; including the application of qualitative and quantitative methodology (section 2.4 and 2.5) within one research study [169,180].

2.3 METHODOLOGY AND METHOD

Methodology is the way of studying social reality [172]. Methodology defines practical approaches to quest for knowledge- and thus relates to *methods* which are set of task-oriented procedures and techniques for gathering and analysing data [172,181]. Methodology is argued to be influenced by both ontology and epistemology [176] but this notion has been challenged recently and will be discussed later in section 2.6.

2.4 QUALITATIVE METHODOLOGY

2.4.1 Introduction

Qualitative methodology allows researchers to understand social phenomenon/research problems through the meaning that people bring to them [169,170,182]. This also referred

to as naturalistic inquiry as data are generated in participants' 'natural' settings [169,183]. The term 'qualitative' is known to refer to the quality around the features, characteristics, complexities or hallmarks of the phenomenon under study [184]. Research using qualitative methodological approaches typically provide answers to what, why and how questions [173]. It is the concepts and categories arising from the data that are regarded as important for interpretation of the phenomenon under study as opposed to any incidence and frequency [183]. The written reports of qualitative research usually include the voices of participants, referred to as 'quotes', along with description and interpretation of the problems from the researchers' perspectives [169]. Features of qualitative research are summarised in figure 2.1.

Figure 2.1: Ten key features of qualitative research

- Data collection in natural settings
- **Researcher** acts as key instrument
- **₲** Gather data from **multiple sources**
- ♣ Analysis is **inductive** or uses 'bottom-up' approach
- **♣** Focus on participants' meanings
- Research process is **emergent**, process may change or shift after the researcher enters the field and begin to collect data
- **Theoretical lens** to view the studies, such as the concept of culture
- ♣ Researchers make interpretative inquiry of what they see, hear and understand
- ♣ Taking a holistic account by developing a complex picture of the problem or issue under study.

Adapted from [169].

Qualitative methodology is suited for the exploration of issues that have been under-investigated in the past or are complex or sensitive in nature [173]. Brannen (citing McCracken (1988)) exemplifies the utility of qualitative methodology as –it being not suited to 'survey the terrain' but to 'mine it' [183]. It also enables in-depth understanding of research problems from the perspectives of participants [185]. Application in health services and pharmacy practice research has been increasing in recent years [156,186], with the notion that not all research problems can be explained by hard fact numbers and graphs. For example, although quantitative methods (section 2.5) such as randomised controlled trials are suited to measuring outcomes relating to interventions, qualitative research is best suited to understanding the process by which any intervention may produce a desirable/undesirable outcome [186].

Some critiques of qualitative research have labelled qualitative methodology as being 'unscientific' or 'anecdotal', as findings may be based on subjective accounts [170,187] and that they provide context to what people say as opposed to what they do [187]. However, a number of strategies that are deployed through processes of qualitative research allow the undertaking of research in a transparent way so that findings are valid and reliable. Such measures have been adopted throughout the stages involving qualitative methodology in this research.

2.4.2 Data collection

Data in qualitative research are mainly textual materials obtained either through talking with people or observation [184]. In most instances, researchers act as the instruments of data collection [182,183], though the use of research instruments, traditionally devised to collect quantitative data are being increasingly used to collect qualitative data in health services research [188] (figure 2.2).

Figure 2.2: Use of quantitative tools to collect qualitative data and vice versa

		Type of Mo	ethodology
		Predominantly quantitative	Predominantly qualitative
B	Predominantly quantitative	1. Congruent	2. Incongruent E.g. Quantification of answers to semi- or unstructured interviews or observations in participant observation
Type of Data	Predominantly qualitative	3. Incongruent E.g. answers to openended questions in a structured interview schedule	4. Congruent

Reproduced from [189] page 71

One to one interviews, focus groups, observation and case studies are the most popular methods of data collection in qualitative research [190]. One to one interviews usually use an 'in-depth' approach which allows participants enough time to develop their own accounts of the issues important to them [187]. In semi-structured approaches, the researcher uses a pre-determined agenda, based around the research question, and allows the participant to determine the kind of information produced as per the importance to

them [187]. Other less common approaches used in health services research such as the narrative interview requires participants to adopt a story telling approach for data generation [187]. The use of telephone interviews and focus groups conducted via video conferencing are some of the adaptations to qualitative data collection brought about by technological advances in the research world [191].

2.4.2.1 Use of focus groups in qualitative data collection

The focus group is a method by which data are collected through group interaction led by a researcher [192] 'focused' around a particular topic or set of issues [193]. It allows relatively quicker data collection as opposed to in-depth interviews [193] and thus is also deemed to offer cost effectiveness to researchers as compared to in-depth interviews [182]. Though focus groups have been argued to ideally suit research problems where the study of group norms and processes is desired [194], their applications extend beyond these limits.

Focus groups have also been argued to afford offer greater opportunities to collect more 'natural' data than interviews in that focus groups allow a range of group communication processes taking place amongst participants, such as storytelling, joking and arguing [193]. Group settings are also argued to facilitate personal disclosures rather than inhibiting them, by allowing participants to react to and build on the responses of other group members [182,193]. Focus groups have been noted to be of great importance in generating preliminary data or hypotheses that could be tested or quantified through quantitative methods (section 2.5) [194].

Despite the above advantages, focus groups have been reported to require greater skills on the part of researcher to: control group discussions focusing on the agenda; control any effect of dominant group members; and to persuade 'shy' speakers to express themselves [190,195]. In addition, reduced time for individual participants to speak as compared to one to one approaches mean that 'micro-analysis' of the differences in individual views, as suggested by some authors, is difficult to undertake [182]. Focus group methods have been deemed to be extremely valuable tools in understanding decision-making processes by health professionals [194] and research described in this thesis utilises its application in this area. The exploratory nature of the research presented in Chapter 3 as well as the benefits this method offers over in-depth one to one interviews made it the method of choice. However, problems around recruitment of participants encountered during focus groups led to the consideration of telephone interviews as an alternative data collection measure. A

discussion of the merits and demerits that telephone interviews offers against focus groups appear in Appendix II.

2.4.3 Sampling

Sample sizes in qualitative studies are generally small and mainly determined by the 'diminishing' returns of new information achieved [185]. Resource constraints around data collection and analysis are also known to play a part [185]. The sampling strategy suited to inductive approaches of qualitative data analysis (section 2.4.4.1) involves a purposive sampling technique which allows participants to be chosen from a sampling frame based on participant demographics or other desired characteristics. Less common sampling approaches in qualitative research are *probability* sampling and *convenience* sampling. The former allows random selection of participants from the population where everybody has the equal chance of selection. Convenience sampling also known as *ad hoc* sampling; allows samples to chosen as per ease of access. However, with this approach, the relationship of the data to the wider population is unknown [185]. This is therefore only really justifiable in research with 'invisible' participants such as the investigation of health service utilisation by sex workers or during participatory or democratic consultations where 'anyone' who wants to have a say are given the opportunity to participate [185].

2.4.4 Analysis and reporting of qualitative work

Strauss and Corbin define qualitative data analysis as the interplay between the researcher and the data [172]. Analysis and reporting in qualitative research is usually said to lack rigid guidelines as compared to quantitative research; and hence the concepts arising from the data are likely to be evolving and changing constantly [169]. This can often impose problems in communicating to readers through the process of analysis [169]. Three key techniques of qualitative data analysis exist and are discussed below.

2.4.4.1 Grounded theory

Traditionally, data analysis in qualitative research is usually said to be inductive where ideas are generated from the data as opposed to ideas leading to data [172]. Grounded theory is one of such inductive techniques where theory is allowed to emerge from the data [172]. With this approach, researchers do not begin a project with a pre-conceived theory in mind. The researcher usually conducts data collection so as to identify key concepts arising from the data and then turns to studying one key concept at a time carrying out the sampling process all over again until data are saturated [196] and until another theory is 46

generated [176]. Generalisation of results from qualitative work is usually 'assertional' rather than 'probabilistic' [185]. Representational generalisation relates to within cases and empirical generalisation relates to other similar cases [185]. Application of this technique to health service research is less common. Claims of applications of the grounded theory approach in research reports have also been criticised as often being a means of legitimising findings that are deviated from the original line of query [197].

2.4.4.2 Framework technique of qualitative data analysis

The application of qualitative research in scientific communities has led to the demand that analytical procedures are carried out in a more transparent way which allows researchers' a priori theories or expected concepts to be incorporated in the analytical process [198,199].

The framework technique is one of such approach which allows priori concepts to be incorporated in the analytical process; and was used in the analysis of the qualitative data in Chapter 3. Ritchie and Lewis define the framework method as a "matrix based analytic method which facilitates rigorous and transparent data management such that all the stages involved in the 'analytic hierarchy' can be systematically conducted" [200]. The framework technique thus gets its name from the 'thematic framework' where data are categorized into a matrix system based on emergent themes and categories [200]. The analytical process begins during transcribing by listening/re-listening and reading/re-reading the transcript so that the researcher becomes immersed in the data. A basic step involved in this technique is the 'coding', which is also common to inductive techniques of analysis [172] and involves reducing the data into a smaller number of themes. Key themes describing the data are listed in columns while each participant is assigned a space in each row below. The construction of the initial thematic framework is guided by the research aims and objectives and questions introduced to participants from the topic guides. These are then followed by any new themes emerging during the analysis process. This method, therefore, although being deductive, also offers unique flexibility to allow expression of themes that are emergent during the analysis process [200]. This approach of qualitative data analysis is usually facilitated through Computer Assisted Qualitative Data Analysis Software (CAQDAS) such as QSR NVivo8®.

2.4.4.3 Content analysis

In health services research, the use of so called 'quasi-qualitative technique' or content analysis is also common. This refers to coding of open questionnaire items, thus allowing a

quantitative output from a qualitative data [185]. This technique was used in the data analysis for the analysis of open questionnaire items in Chapter 5.

2.5 QUANTITATIVE METHODOLOGY

2.5.1 Introduction

Quantitative methodology deals with numbers as opposed to the concepts and themes of qualitative research. The focus is mainly on stating hypotheses based around cause and effect relationships and using validated instruments to yield statistical data to accept or reject these hypotheses [175]. Statistics refers to the science of collecting, summarising, presenting and interpreting numerical data [201]. Examining the relationship among and between variables is central to answering questions in quantitative research [175]. Variables are constructs, traits or characteristics that are measured and are likely to vary as per observations [174]. Variables which are used as the basis of analysis in quantitative research may be the outcomes of qualitative research [183]. Other key differences between qualitative and quantitative research are presented in table 2.1

Table 2.1: Some distinctions between qualitative and quantitative methodology

	Quantitative	Qualitative	
Role of research	Preparatory	Exploration of actors' interpretations	
Relationship between researcher and subject	Distant	Close	
Researchers' instance in relation to subject	Outsider	Insider	
Relationship between theory/ concepts and research	Confirmation	Emergent	
Research strategy	Structured	Unstructured	
Scope of findings	Nomothetic	Ideographic	
Image of social reality	Static and external to actor	Processual and socially constructed by actor	
Nature of data	Hard, reliable	Rich, deep	

Reproduced from [185]

2.5.2 Data collection and sampling in quantitative methods

Data in quantitative research are mainly based either on experimental or survey methods. Experimental methods are best suited to test the impact of an intervention through measurement of effects, also known as outcomes [175]. Although experimental methods are

known to be stronger in identifying cause and effect relationships, they are only deemed appropriate in situations where independent variables are capable of manipulation and which random assignment of participants to any one intervention or control group is feasible [196]. Sampling techniques in quantitative research are usually random as described in section 2.4.3. As most surveys utilise probability sampling techniques, they are known to offer greater external validity (Chapter 9) as compared to randomised experiments, although are weak in terms of internal validity (Chapter 9) due to self administered approaches (table 2.2).

Table 2.2: Controlled experiments versus surveys

	Internal validity	External validity
Controlled experiment	+ +	
Surveys		+ +

Reproduced from [202]

2.5.2.1 Mailed questionnaire survey for quantitative data collection

Surveys are a systematic approach to gathering information. A survey is able to provide a quantitative or numeric measurement of views, attitudes, trends or opinions of participants [175]. These measurements are noted to be of great value in health services research as peoples' views and attitudes influence their behaviour [174]. Such values explain why a survey requires as much planning and consideration as experimental methods [174] and also the reason its application was used for data collection in Chapter 4 and 5 of this thesis. Mailed self administered questionnaire techniques offer the opportunity to survey a large number of people in a relatively short period of time [171]. When sent to a cross section of population at a single time point, these are called cross sectional surveys [196].

2.5.2.2 Approach to survey data analysis

The strength of measures such as views and opinions obtained from surveys is usually in the form of numbers [203]. These variables are analysed either descriptively (presentation of data in natural form), normatively (comparisons across groups or to categorise one variable against another, known as univariate analysis [203]) or to establish correlations amongst variables [174]. Correlations amongst variables are most strongly noted and the findings become rigorous when several variables are analysed together [174]. Such methods of analysis, termed multivariate approaches, were thus used in the analysis of selected survey data presented in Chapter 5.

Despite the potential of multivariate analysis adding rigour to the findings, it has been highlighted that to obtain meaningful results from such analyses, there needs to be a strong justification behind the choice of variables that are analysed together [174]; which otherwise can reveal erroneous interpretations [174]. Therefore, qualitative studies and review of the literature, undertaken prior to quantitative phase, as has been used in this research, are best placed to inform such decisions by the analysts.

2.6 MIXED METHODOLOGY

2.6.1 Introduction

Questions are raised by purists (researcher aligned to one particular philosophical paradigm), whether use of qualitative and quantitative methodologies within one research study is considered an acceptable practice. Such opinion has been mainly based on the assumptions that qualitative and quantitative methodologies are aligned to different ontological and epistemological positions. Quantitative research methodology is often labelled as positivist or realist whereas qualitative researchers are claimed to follow social constructivism and idealism [196,198]. Thus, those who view knowledge as hard, objective and tangible should ideally stick to quantitative methodologies; whereas if knowledge is seen as being subjective and softer in nature, then qualitative methodologies are more appropriate [176]. Epistemology is argued to be defined by ontology; methodology is influenced by both ontology and epistemology [176]; and hence qualitative and quantitative methodologies are claimed to be mutually exclusive. Such mixing of methodologies are hence only possible when the researcher 'neglects' the philosophical paradigms; or in other words disconnects methodology from philosophical foundations.

Another argument against using qualitative and quantitative methodologies in one research study is the notion that use of more than one approach may actually 'widen or deepen' the research problem rather than solving it; as each of the methodological approaches are unique in what they are capable of delivering [185]. However, the above assumption has been challenged recently [170,186,196,198] with the argument that philosophical assumptions do neither 'determinate' implications for selecting a particular methodology nor that there is a one-to-one correspondence between a philosophical paradigm and a methodology [196]. The research question itself is deemed more important in informing the choice of methodological approach rather than which philosophical paradigms reflect the researcher's stance [196]. For example, constraints such as the issues of researcher skills, funding and available financial resources often have huge implications around selecting a Chapter 2: Methodology

particular methodology [183]. The excerpts from a few books below provide illustration of this side of argument.

- "...the practice of research is a messy and untidy business which rarely conforms to the models set down in methodology textbooks...it is unusual, for example, for epistemology or theory to be the sole determinant of method. The cart often comes before the horse, with the researcher already committed to a particular method before he or she has taken due time to consider the repertoire of methods suited to exploring the particular research issues." [183] page 3-4
- '...a great many decisions about whether and when to use qualitative methods seem to have little, if, any recourse to broader intellectual issues." [196] page 108
- "...the medical researcher is not supposed to become a social scientist even when during qualitative inquiry." [204] page 486

Researchers from scientific backgrounds also acknowledge that no study, irrespective of the methodology used, can provide findings that are universally transferable [204] and that few findings can be claimed with absolute certainty [186]. Therefore, it has been controversially proposed that the key to ensuring that any methodological approach encompasses scientific quality is to set the philosophical foundations aside and to follow the basic principles of undertaking 'rigorous' research [204].

2.6.2 Benefits of mixing qualitative and quantitative methodologies

Qualitative and quantitative research can be combined within one research study for both complementary (where one phase assists the development of other phase) as well as for the integration of the findings (where findings from two research phases are combined). In each case, a combined approach should be of relevance and appropriateness to the research questions under investigation.

When used for *complementary* purposes, pre-eminence of qualitative over quantitative has been reviewed to be the common practice [183]. In these cases, the quantitative stage offers the opportunity to test hypotheses generated through qualitative stage; or where the

qualitative can aid the identification of variables allowing scale construction, and interpretation of relationships between variables such as for survey design [183]. For example, the use of focus groups findings to aid development of questionnaire scales has been argued as the 'most practical' and most widely used approach of combining qualitative and quantitative methodology [192] as has been used in this study. Amongst the less common *complementary* approaches include qualitative work preceded by a quantitative stage where, for example, the qualitative stage allows clarification or exploration of findings from quantitative data which require further explanations; for example exploring the perspectives of a subgroup identified from a larger quantitative phase. On occasions, because quantitative research is efficient at identifying structure whereas qualitative research is stronger in terms of 'processual' aspects, these strengths are brought together in a single study [189]. For example quantitative outcome studies can reveal a link between intervention and outcome, but are less able to explain the process by which the interventions are translated into the outcome. Qualitative research used alongside quantitative studies, is best able to illuminate these issues [186].

Some authors have argued that for a methodology to be called 'mixed', integration of the either data or joint interpretation at some stage of the research process is essential [205]. Such process of integration is also termed triangulation [206]. The term *triangulation* however also applies to the integration of: results obtained by applying different theories to same data [182,183,186]; interpretation of the same data by different analysts with unique perspectives [182,183]; integration of data collected at different time points with same or different methods [183] or with different populations [199].

Both complementary as well as integrative application of mixed methodology has been increasingly used in pharmacy practice research owing to the above explained benefits [206]. These applications have been extensively applied and explained throughout this thesis.

2.7 EVIDENCE SYNTHESIS THROUGH SYSTEMATIC REVIEW OF LITERATURE

Identifying the existing evidence within a subject area through review of the literature has been suggested to offer a number of benefits to the researcher. Literature reviews when conducted using a pre-defined strategy to literature search and retrieval and to extract and critically appraise the information are referred to as systematic reviews [207]. A systematic

review has been deemed to be scientific 'research in its own right' and uses the studies meeting the pre-defined criteria as 'subjects' [208]. Conducting a systematic review prior to or during the course of an empirical study can offer many advantages. A review, for example conducted prior to an empirical study, can aid: synthesising existing research evidence [208]; identifying, justifying and refining any hypotheses for future work [209]; enabling the researcher to understand and avoid pitfalls of previous work [171,209]; indicating problems that the researcher might come across during the course of research [171]; and warning against 'meandering' in an already explored area of research [209].

Due to the varied applications that systematic reviews can offer during the course of research, there exists no hard and fast rule about where a literature review should be presented in a written report or academic thesis [208]. For example, Creswell highlights that a researcher undertaking an exploratory qualitative study is most likely to offer limited literature at the outset given the lack of research in the subject area [175].

Synthesis of evidence through systematic review requires good critical appraisal skills so that evidence is judged based on the quality and scientific merit of the study [210]. Many critical appraisal tools relate to the quality of evidence merely based on the method/design of the study. For example, findings from multicentre randomised controlled trials are rated as the highest quality of evidence [211]. Some research communities disregard findings from any other type of research other than obtained from randomised controlled trials (RCTs) as a source of 'evidence'. However, lately, this criteria of quality judgement has been relaxed amongst the research community mainly based on the notion that RCTs are not always feasible due to practical or ethical considerations [210] or that RCTs are not a suitable design to generate evidence for every subject area in health services research. This has led to resurgence of systematic reviews comprising diverse methodological applications, including qualitative research, within one review.

2.7.1 Challenges to the inclusion of qualitative and quantitative research within one systematic review

The traditional notion within scientific communities that evidence from quantitative studies, especially RCTs resulted in the best form of evidence led to systematic reviews traditionally focusing only on published studies using RCT designs [212]. Study power and

precision/bias through further statistical analysis of aggregated datasets are often undertaken through the process known as 'meta- analysis' [208,209].

With more health services researchers employing both qualitative and quantitative approaches, the inclusion of qualitative research evidence within the systematic review is receiving more attention. Dixon-Woods et al relate reluctance to integrating diverse methodologies within one systematic review to both methodological 'prejudice' and 'difficulties' [213]. *Prejudice* relates to anticipation and fear that such an approach to evidence synthesis from qualitative studies will be unacceptable by those who are less aware of its methodological foundations. For example, as late until 2001 (no recent figures could be retrieved), only 5% of the citations of the Cochrane methodological database references were for qualitative research [213]. *Difficulties* relate to a lack of precise and robust techniques devised to include qualitative research in systematic reviews [197,213]. Such difficulty and challenges mainly relate to how to make the process of synthesis more transparent and findings more reproducible.

Overcoming challenges to the synthesis of qualitative data within systematic reviews has been dedicatedly researched by a number of collaborations in the UK such as *The Evidence for Policy and Practice Information and Co-ordinating (EPPI) Centre* [214]; *Cochrane Qualitative Research Methods Group* [215] and in Australia by *Joanna Briggs Institute* [216]. One challenge is to deal with the problems brought about by 'distinct' traditions of qualitative and quantitative research. For example formulation of the systematic review questions is often the product/outcome of qualitative research rather than the starting point of the review, whereas, an outcome is tested for proving or disproving an hypothesis in quantitative studies [217]. Thus collating these two approaches within one review requires careful planning and formulation of research questions on the part of the researcher.

2.7.2 Approaches to reviewing qualitative and quantitative research within one systematic review

Syntheses of evidence from both qualitative and quantitative studies have been known to be undertaken using both *aggregative* and *interpretative* approaches.

Narrative synthesis is one approach of aggregative synthesis where qualitative and quantitative findings are 'juxtaposed' side by side [218]. This relies primarily on the use of

words and texts to summarise and explain the findings of the review [219]. Popay et al distinguish traditional narrative literature reviews with narrative synthesis in that the later refers to 'a specific approach to that part of a systematic review process concerned with combining the findings of multiple studies' [219]. Interpretative methods such as the 'Critical Interpretative Synthesis', (another example include the EPPI-centre approach [214]) have been argued to be using a grounded theory approach to synthesis and thus avoids specifying any concepts in advance [218]. Unlike the narrative synthesis, this approach to review yields theory as an output rather than the aggregation of data [213,218,220]. However, some overlap across these two approaches has also been suggested where although the approach to synthesis could be primarily interpretive or integrative; every integrative synthesis is noted to include an element of interpretation, and every interpretive synthesis to include elements of interpretation [218]. However, only a very few worked out empirical examples of such an interpretative approach exist [218]. In addition, grounded theory not being the approach required for the systematic review in Chapter 4, the narrative approach to synthesis of evidence was embraced in Chapter 4 (systematic review of literature).

2.8 SUMMARY OF CHAPTER 2

This Chapter reviewed the meanings and applications of qualitative, quantitative and mixed methodologies; thereby conferring relevance to different phases of this research. Approaches to data collection and analysis within these methodologies were also reviewed. Discussions around why choice of methodologies should mainly be influenced by the research question and not by the philosophical foundation were presented. Mixed methodology was considered appropriate for the purpose of this research through consideration of debate for and against its use. Focus groups due to their exploratory utility will allow questions such as 'how' and 'why' to be asked in the preliminary phase of the research. Focus group data also provide good foundations on which to develop quantitative research instruments for undertaking surveys. The cross sectional survey is an efficient technique to measure and quantity behaviours of large numbers of research participants by gathering views and attitudes through numbers. Opportunities and challenges to synthesising evidence from both qualitative and quantitative research in systematic reviews were also presented. Narrative syntheses of results were shown to be appropriate to synthesise data from primary literature within the systematic review undertaken within this thesis (Chapter 4).

CHAPTER 3: QUALITATIVE RESEARCH

3.1 INTRODUCTION TO THE CHAPTER

This Chapter presents data from the qualitative phase undertaken to study community pharmacists' perspectives of ongoing changes in practice around enhanced minor ailment management. Data relevant to the following objectives are presented in this Chapter.

3.2 OBJECTIVES

- 1. To investigate community pharmacists' attitudes to ongoing changes around enhanced management of minor ailments from pharmacy.
- 2. To evaluate the process related aspects of innovation adoption from community pharmacists' perspectives.
- To explore the key facilitators/barriers associated with adoption into practice of newly reclassified medicines by community pharmacists.

3.3 METHOD

3.3.1 Data collection method

Focus groups were considered the method of choice, primarily to stimulate and encourage discussion between participants. In addition, none of the objectives was considered to potentially generate sensitive information requiring in depth one to one interview methods. Generating and analysing naturally occurring data using methods such as observational studies were considered inappropriate, mainly due to the need for interaction between the researcher and participants.

However, problems were encountered during recruitment of participants for the focus groups with very few pharmacists attending two of the sessions. Hence alternative qualitative methods were considered. Semi-structured telephone interviews were adopted as the method of choice for supplementing focus group data based on merit around recruitment and low resource implications to the researcher [221].

3.3.2 Sample selection and identification of potential participants

Sampling within this phase of the research was informed by e-MAS utilisation data of Scottish Health Boards, a service that was evaluated alongside in the qualitative phase

(results Chapter 7). A two stage sampling approach was undertaken. For the focus groups, four of the fourteen Health Board regions in Scotland were selected, which represented low to high utilisation of e-MAS based on the percentage of GP population registered with the service [222] (figure 3.1). Health Boards in Scotland are responsible for the delivery of health care services at the local level in line with the national health care agenda and represent geographical divisions [223]. NHS Greater Glasgow & Clyde represents the most populous Health Board whereas NHS Highlands covers the biggest geographical area [223].

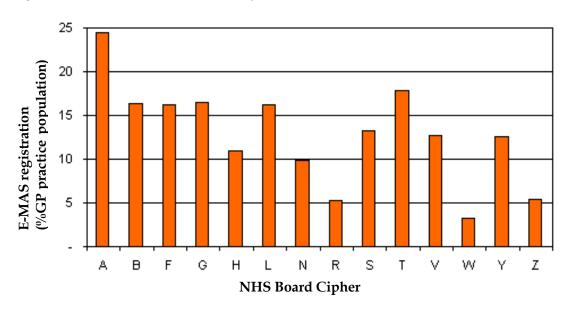


Figure 3.1: E-MAS utilisation data July 2006 to June 2007*

Reproduced from [222]. *NHS Board Cipher A: Ayrshire and Arran; B: Borders F: Fife; G: Greater Glasgow and Clyde; H: Highland; L: Lanarkshire; N: Grampian; R: Orkney; S: Lothian; T: Tayside; V: Forth Valley; W: Western Isles; Y: Dumfries and Galloway; Z: Shetland.

The list of all community pharmacies in Scotland, along with their addresses and telephone numbers, was obtained from NHS Education Scotland (NES). Fifty pharmacies were randomly selected from four Health Boards representing various levels of e-MAS utilisation, based on an anticipated response rate of 20% from previous experiences from within the School of Pharmacy and Life Sciences, Robert Gordon University. The random sample generation was aided by Minitab Version 15 statistical software package. In an attempt to encourage pharmacist participation, initial contact was made by telephone with the 'regular' pharmacist dealing with non-prescription medicines in each of the 50 pharmacies. The researcher briefly introduced the background to the research, the aims, nature of the research and extent of commitment required. Pharmacists were also asked if they would be willing to receive an invitation pack. If in agreement, the researcher requested their names to allow named invitations to be sent. Only one pharmacist from

each pharmacy could participate. Pharmacists refusing to participate were not contacted further.

Recruitment of pharmacists for telephone interviews was conducted in only those two Health Boards (II and III) where there was low focus group recruitment. A further 20 and 15 pharmacies were randomly selected from two Health Boards (II and III) respectively, who were sent with a study invitation pack. These numbers were based on the assumption that response rates to telephone interviews are usually higher than that of the focus groups [221]. No prior contact by telephone was made in this instance.

3.3.3 Invitation

Invitation packs were mailed to pharmacists 25 days in advance of the scheduled date of the focus groups or telephone interviews. The pack contained an invitation letter, participant information sheet, consent/copyright clearance form, reply slip and pre-paid envelope (Appendix II). Pharmacists were asked to send the reply slip along with consent/copyright clearance form in the prepaid envelope or via fax within the given deadline if they were willing to participate.

Focus groups and telephone interviews were planned to last no more than 90 minutes and 20 minutes respectively. The invitation pack for the focus groups also contained a map of the venue and requested information regarding any dietary or mobility needs. The telephone interview reply slip requested the most convenient date and time for interview. All study documents were packed in a sophisticated manner to minimise the risk of papers being left missing inside the envelope when opening [202]. The dates of the focus groups were selected to avoid local holidays or important local events. Other measures to potentially increase participation which were used, together with the evidence for them are listed in table 3.1.

Reminders were sent to non respondents 10 days after the mailing of the first invitation. Those not replying were contacted by telephone to confirm they had received the invitation pack. Reasons for non-participation were not asked as this seemed unethical but were noted if volunteered.

3.3.4 Evidence used to encourage participation

Evidence mainly from the systematic review by Edwards et al was applied where appropriate to encourage participation [224]. Although relevance to maximise the response rate of postal questionnaires was made in this review, those applicable to focus group recruitment were considered.

Table 3.1: Description of evidence used to encourage participation (note: this table extends to two pages)

Item	Strategies	Odds ratio (95% CI) from Edwards et al [224]	Evidence from any other reviews	Strategy used in this research
Incentives	Monetary incentives vs no incentives	2.02 (1.79-0.27)**	[225]	No monetary incentives used due to resource constrains
	Non monetary incentive vs no incentive	1.19 (1.11-1.28)**	-	Light supper and reimbursement of travel expenses
Appearance	Brown envelope vs white	1.52 (0.67 -3.44)**	-	Brown
	Coloured ink vs standard	1.39 (1.16 -1.67)**	-	Coloured ink (blue)
	More personalized vs less personalized	1.16 (1.06 - 1.28)**	[226,227]	Named invitation where appropriate and researcher's signature printed in ink
	Identifying feature on return vs none	1.08 (0.78- 1.51)**	-	Participants asked to reply with their names
Delivery	Recorded delivery vs standard	2.21 (1.51- 3.25)**	-	Standard due to resource constraints
	Stamped return envelope vs business reply or franked	1.26 (1.13 -1.41)**	-	Pre-paid envelope due to financial constrains
	Work address vs home address	1.16 (0.89-1.52)	-	Work address
	First class outward mailing vs other class	1.12 (1.02 -1.23)	-	Other (second) class due to financial constrains
	Pre-paid return envelope vs not pre-paid	1.09 (0.71 -1.68)**	-	Section 3.3.3 above

CI: confidence interval) **Significant at <0.01

Item	Strategies	Odds ratio (95% CI) from Edwards et al [224]	Evidence from other reviews	Strategy used in this research
Origin	University sponsorship	1.31	-	Both University and the NHS
	vs other organization	(1.11 - 1.54)**		
	Sent by more senior or	1.13	-	Names of senior members of the research
	well known person vs	(0.95 - 1.35)		team included but signed by student
	less well known person			researcher
Contact	Pre-contact vs no-	1.54	[225]	Phone contact made to obtain name and
	precontact	(1.24 - 1.92)**		inform participants about the research
	Follow up vs no follow	1.44	-	Reminder and phone follow up for non-
	up	(1.22 - 1.70)**		respondents made
	Mention of follow up	1.04	-	Reminders sent without mention of
	contact vs none	(0.91 - 1.18)		follow up.
	Precontact by	0.90	-	Section 3.3.2 above
	telephone vs post	(0.70 - 1.16)		
Communication	Explanation for not	1.32	[225]	No ethical approval for such requests/
	participating requested vs not requested	(1.05 to 1.66)		noted only if the information were volunteered
	Appeal stresses benefit	1.06	-	Benefit stressed both to the participants
	to participants vs others	(0.92 to 1.22)		and NHS
	Response deadline	1.00	-	Same deadline used in the initial
	given vs no deadline	(0.84 to 1.20)		invitation and the reminder
	Choice to opt out from	0.76	-	Given, due to ethical reasons
	study given vs none	(0.65 to 0.89)		
	Explanation for not	1.32	-	Noted only if volunteered, no contacts for
	participating requested vs not requested	(1.05 to 1.66)		no-show up.

^{**}Significant at <0.01

3.3.5 Development of Topic Guide and Interview Guides

The content of the focus group topic guide was informed by the research objectives. To facilitate development, the researcher spent one day in each of three local community pharmacies in different Health Boards to allow familiarisation with the activities around minor ailment management. The topic guides are given in Appendix III. A 'funnel' approach to questioning was employed, with introductory general questions around 'change' followed by specific and more focused questions about ongoing reclassification of medicines and e-MAS. A tentative duration for discussion was allocated for each question. The topic guide was reviewed for validity of content and clarity of terminology by an 'expert group' of academic staff at RGU, who were also practising community pharmacists, and by the NHS collaborators, as listed below:

- i. Members of the supervisory team
- ii. Mr Brian Addison, practising community pharmacist and lecturer in Pharmacy Practice, RGU
- iii. Mrs Gwen Gray, practising community pharmacist and lecturer in Pharmacy Practice, RGU
- iv. Mrs Ruth Edwards, practising community pharmacist and lecturer in Pharmacy Practice, RGU
- v. Mrs Trudi McIntosh, practising community pharmacist and lecturer in Pharmacy Practice, RGU
- vi. Ms Sharon Hems, Lead Officer, NHS National Medicine Utilisation Unit
- vii. Professor Marion Bennie, Director, NHS National Medicine Utilisation Unit

A practice focus group session of 90 minutes was held with four locum pharmacists who were RGU staff members, who suggested minor changes in the introductory opening questions. The focus group topic guide was modified to form a semi-structured interview guide for telephone interviews and the questions were further condensed to cover those areas requiring additional insight based on the review of focus group transcripts. In developing both the topic guide, particular attention was paid to Morgan's key recommendations to developing topic guides (figure 3.2).

Figure 3.2: Morgan's recommendations for developing topic guide questions for focus groups

- ♣ There are generally five different types of questions: opening, introductory, transition, key and ending
- ♣ Introductory questions should reflect the experiences and connections of participants with the overall topics.
- **♣** Question foster interaction but is not critical to analysis.
- Key questions begin one third to one half way through the discussion
- Ask the first group about the feedback to improve further focus groups
- ♣ Do not ask the question 'why'. But ask in other several dimensions, for example, what prompted you to do this, what features of that particularly interested you? or use what or how questions.
- Simple questions bring dynamic answers and more answers, always ask simple questions.
- Change the questions if the past questions lead you to another level when conducting a series of focus groups.

Adapted with modification from [226]

3.3.6 Recording

A Marantz audio recorder and a digital recorder were used to record the interviews and focus group discussions.

3.3.7 Note taking

Experienced university researchers with expertise in conducting and facilitating focus groups assisted with note taking, primarily as assurance against record failure, but also to note emerging issues from an 'outsider' perspective and to highlight issues such as body language. Immediately following each focus group, the notes were discussed between the researcher and note taker to identify agreement on key issues.

3.3.8 Transcribing

Transcribing was verbatim and was made by the research student. The principal supervisor made a thorough check of all transcripts to ensure reliability of transcribing and to avoid misinterpretation. Transcript of one of the focus groups appears in Appendix III.

3.3.9 Data management and analysis

The analytical process began during transcribing by listening/re-listening and reading/re-reading the transcript to become immersed in the data. Framework approaches of qualitative data analysis were employed and facilitated using QSR NVivo8® qualitative data Chapter 3: Qualitative research 63

management software. The method has been described in detail in Chapter 2. Two analysts independently analysed one transcript. Only the first analyst (VP), however made use of the QSR NVivo8® qualitative data management software. No major disagreements were noted thus avoiding the need for a third analyst. Focus groups and telephone interviews data were analysed together as they aimed to answer common objectives.

3.4 RESEARCH GOVERNANCE

3.4.1 Ethics and NHS R & D approval

This research was conducted in accordance with the RGU framework for research governance. An initial Research Student Project Ethical Review (RSPER) form was submitted along with the Research Degree Registration (RDR) form to the Ethical Review Panel of the School of Pharmacy, Robert Gordon University.

Initial contact regarding the proposed research was made via email (19 Feb 2008) to the North of Scotland Research Ethics Committee (NoSREC). The committee suggested that a more detailed proposal be submitted to allow provision of advice on whether or not a formal, full NHS application would be required. The detailed proposal was submitted on 27 Feb 2008 which also summarised a tentative plan for the mailed questionnaire that would follow the qualitative phase. An e-mailed response from the acting scientific director of the committee was received on the same day. Further clarifications were sought around recruitment, format of the consent form to be used and anonymity of the data. Responses were forwarded to the committee on 29 Feb 2008. NoSREC suggested minor editing of the participant information sheet to include more information about the study. Model consent forms and participant information sheets were provided by the committee and revised participant information sheets and the consent forms were forwarded on 06 March 2008. The acting scientific director, in consultation with the vice chair of the committee, advised that the research, including the mailed survey, would not require a full ethical submission.

NoSREC were also consulted on potential modification to the method resulting from poor focus group recruitment necessitating conduct of telephone interviews. The committee advised that there was no need for a full ethics submission to conduct the telephone interviews.

As community pharmacists in Scotland are contracted by NHS bodies, it was imperative that NHS Research and Development (R & D) committees were also approached for advice on the need for any formal approval. The Multi-centre R & D committee in Scotland was contacted with a copy of the full study correspondence as per NoSREC. No reply was received within thirty days of the initial mailings despite reminders, and it was later identified that the R & D committee was in the process of restructuring itself as Central Access Point (CAP). A response was received from the CAP on 04 Apr 2008, advising that a formal application was not required.

The issues of poor recruitment and attendance of pharmacists at focus groups requiring modification to the data collection approach, multiple communications with the ethics committee and lack of prompt responses from the R & D committee led to a significant delay in the research project.

Copies of all communications with NoSREC and the CAP appear in Appendix III.

3.4.2 Informed consent and copyright clearance

Informed consent and copyright clearance were obtained from all participants as illustrated in Appendix III.

3.4.3 Confidentiality, anonymity and minimizing harm to the participants

All data were anonymised. Hard discs of the recordings along with participant contact details were stored in locked university facilities. The transcripts were stored in a password protected university computer. Access to data was restricted to the researcher and the members of the supervisory team. All data will be kept for a maximum of five years after the publication of last external output from the data after which they will be destroyed as per university regulations. All data analysis was carried out within the university.

Participants were informed that they were free to withdraw from the research at any time without giving a reason. Participants were also permitted to request that the recorder be turned off at any time. In an attempt to minimize any harm, focus group participants were requested that they refrain from disclosing any information which could generate discomfort in the group setting.

3.4.4 Incentives

Focus group participants were provided a light supper in addition to reimbursement of travel expenses at standard rates. No other incentives were offered.

3.5 RESULTS: PARTICIPANT DEMOGRAPHICS

A total of 20 community pharmacists took part in this phase of research, including nine telephone interview participants. Initial listening and reading of the transcripts led to the researcher to realise that saturation of the data in terms of ranges of themes was obtained and hence further recruitment was not undertaken. The recruitment process and demographic characteristics of participants appear in table 3.2 to 3.6.

Table 3.2: Number of pharmacists approached and those participating in focus groups and one to one face-to-face interviews.

Health Board code	Number of pharmacies telephoned to identify potential participants*	Pharmacists unavailable to take call	Refusing to receive invitation pack	Number agreeing to participate after receiving invitation pack ⁺	Number of actual participants
I	50	1	2	6	4
II	50	1	3	5	1
III	50	0	6	6	1
IV	50	0	0	5	5

^{*50} pharmacies contacted in each Health Board †Refers to either verbal agreement or consent form

Table 3.3: Further number of pharmacies approached and those participating in telephone interviews **

Health Board code	Number of pharmacies sent invitations in the Health Boards	Number of pharmacists agreeing to participate [†]	Number of actual participants
II	20	4	4
III	15	5	5

[†]Refers to number of consent forms received; **No prior contact with telephone was undertaken.

Table 3.4: Demographic characteristics of focus group participants

No.	First year in registered as a pharmacist	Qualification	Health Board code	Pharmacy ownership	Employer (a) or Employee (b)	Age	Prescriber Yes(Y)/ No(N)	Sex Male(M)/ Female(F)	Area
1	1984	BSc, Suppl. Prescriber	I	I	a	54	Y	F	Rural
2	2006	M Pharm	I	I	b	27	N	F	Rural
3	1993	BSc (Hons) MSc	Ι	I	a	37	N	M	Rural
4	1978	BSc, Suppl. Prescriber	I	Ι	b	53	Y	F	Rural
5	1976	BSc, Prescriber qualification	IV	L	b	55	Y	M	Urban/Suburban /Rural*
6	1985	BSc	IV	S	b	46	N	F	Suburban
7	1972	BSc	IV	I	a	66	N	M	Rural
8	1975	BSc	IV	L	b	56	N	F	Suburban
9	2003	MPharm	IV	L	b	28	N	M	Urban

^{*}Relief pharmacist and thus related to more than one practice setting; I: Independent (1-4 pharmacies);

Table 3.5: Demographic characteristics of face-to-face interview+ participants

No.	First year in register as a pharmacist	Qualification	Health Board Code	Pharmacy	Employer (a) or Employee (b)	Age	Prescriber Yes(Y)/ No(N)	Sex Male(M)/ Female(F)	Area
10	1991	BSc (Hons)	II	L	a	39	N	M	Suburban
11	2005	MPharm, PG Cert	III	L	b	25	N	F	Urban

⁺ due to low participation of other pharmacists consenting to participate; L: Large chain (>30 pharmacies)

S: Small multiple (5-30 pharmacies); L: Large chain (>30 pharmacies)

Table 3.6: Demographic characteristics of telephone interview participants

No.	First year in register as a pharmacist	Qualification	Health Board Code	Pharmacy	Employer (a) or Employee (b)	Age	Prescriber Yes(Y)/ No(N)	Sex Male(M)/ Female(F)	Area
12	1988	BSc	II	S	b	43	Y	F	Urban
13	1992	BSc/ Diploma	II	S	b	44	Y	F	Suburban
14	2005	MPharm	II	I	b	26	N	F	Suburban
15	2007	MPharm	III	S	b	23	N	F	Rural
16	2003	MPharm	III	L	b	28	N	F	Urban
17	2002	MPharm	II	S	a	29	Y	F	Suburban
18	2005	MPharm	III	I	b	26	Y	F	Urban
19	1983	BSc	II	I	b	47	N	F	Urban
20	1977	BSc	III	I	b	55	N	F	Urban

I: Independent (1-4 pharmacies); S: Small multiple (5-30 pharmacies); L: Large chain (>30 pharmacies)

3.6 RESULTS- PARTICIPANTS' ATTITUDES TO ONGOING CHANGES IN PRACTICE

Key themes emerging from the data relating to participants' views on ongoing changes around enhanced management of minor ailments are presented with illustrative quotes. Where opposing views around a particular subject were identified around the same theme, all are illustrated otherwise the quotes will be representative of others. Three dots within the quotes indicate that some text has been deleted if considered irrelevant to the corresponding theme.

3.6.1 Contribution of new services to professional role development

Participants expressed the view that the pharmacist's role in healthcare has evolved in recent years. Introduction of innovative patient focussed services were deemed to be contributing to such role development. New roles allowing pharmacists to move away from routine dispensing roles were deemed to be relevant to the pharmacist's knowledge and expertise.

"I think it [the role] is changing. Because, historically the perception of pharmacists was the man in the white coat you never saw, possibly someone who is sending medicines through the system. When I started the move, began with the campaign to ask your pharmacist. That has, I think, obviously [changed]. I am talking nearly twenty years later. I'm happy that our role is, if you like taking more responsibilities, getting bigger, 'cause that's what we were trained to do."

Male, 39 Years, Large Multiple

Less surprisingly, the ongoing reclassification of medicines and the introduction of e-MAS, were noted to be key changes around enhanced management of minor ailments from community pharmacy. The opportunity for members of public to access medicines they could not previously access from pharmacy was regarded as reason why these changes were labelled 'significant'.

"The most significant change has been the... start of e-MAS. The Minor Ailment Service, which has been a big change to community pharmacy within Scotland... and also there have been several products which is switched from POM to P as well"

Female, 25 Years, Large Multiple

3.6.2 Adoption of innovation into practice

Several sub-themes were linked to process of innovation adoption by community pharmacists. These reflect the highly individual and diverse experiences of change.

3.6.2.1 'Desire' and 'Need'

Adoption of behaviours around new medicines and services into their day-to-day practice was related by some, notably by the recently trained pharmacists, to both personal 'desire' to change and 'need' to keep pace with developments.

"Personally, I don't have a problem with it [adopting new services]. I [am]... sort of quite forward focussing. Now, I'm much pretty much the beginning in my career. I've only been qualified for three years; this is quite something I'm going to be doing for a long time. And, I feel that, if I don't get a hold of changes quite quickly, I'm just going to be left behind, and people are coming through who already have qualifications or experience of dealing with things like minor ailment service in their degree, will then have more opportunities than I would have. So, I have to keep abreast of changes to make sure that I'm up to date with the things."

Female, 25 Years, Large Multiple

3.6.2.2 'Old dogs new tricks'

On the other hand, a few participants regarded adopting change as being something undertaken reluctantly. Changes were regarded being out with their comfort zone. These participants were relatively senior and more experienced compared to participants who were keenly looking forward for future change.

"I feel very reluctant to take on new things, you know, because... it takes me a while to feel comfortable with something."

Female, 54 Years, Independent

Some participants stressed that younger age was associated with ease of adopting changes into practice. A younger participant also alluded to the benefit of having had training around recently introduced services during their undergraduate education thus adopting such change was perceived to be relatively easier.

I haven't had the problems with dealing with changes as we are so far and again, [I am] kind of young...there is an old thing that you can't teach old dogs new or tricks... if you're young, you take the information much better. You could adopt the change more and much easier."

Female, 25 Years, Large Multiple

3.6.2.3 'Fast and furious' pace

A few participants commented that the pace of recent change was 'too rapid' making it difficult to integrate within the busy working environment of community pharmacy. They suggested that introduction of one new community pharmacy service at a time would be more sustainable, facilitating easier integration into practice. Of note, despite certain participants being in favour of change for the greater good of the profession, they were struggling to manage with all of the recent changes.

"And I'm quite for change, but I do find that there's lot happening, it's quite fast and furious and I think in a busy working day when you're particularly busy, you don't always have time to absorb it... so there's a lot happening..."

Female, 56 Years, Large Multiple

Such discontent was also attributed to the deemed 'unnecessary' workload referred by one participant as 'bureaucracy'.

"I am quite happy to [adopt changes] ... it doesn't upset me too much. Occasionally found [that] especially when there is excess bureaucracy ... to put it in a great deal of work trying to achieve the minimum amount of work required to meet the change."

Male, 28 Years, Large Multiple

Lack of consistency in the process and nature of new services across different Health Boards in Scotland and UK nations were stated to be resulting in difficulties for many pharmacists, especially for those practising as locums. This was noted particularly, but not exclusively by the participants, in relation to PGDs.

"...funds are going out much more localized. So it's been costed [funded] locally...as a pharmacist to travel across borders... I can supply the morning after pills, anywhere in ***** [name of a place] ...but can't in ***** [name of a place] because you have to be, registered. ...I can't possibly be signed to all these different PGD ...the funds [are] available locally for them to decide how to spend it but it does make it quite difficult for us if we got local formularies all over the place and if ***** [name of place] is doing one thing and even within ***** [name

of place] we've got three different CHPs [community health partnerships] doing three totally different things. So, I've concerns about sort of going from [one place to another]. Well, again, even within Britain now, we have the English [pharmacists] doing MURs, Scotland doesn't. We've got minor ailments and urgent supply PGDs, they [English pharmacists] don't, we are charging five pounds they are charging £7.10 or the exemption rates, may be good, may be not... There is now scope from massive differences between as to what we can supply what we can't, how you supply, will we be paid for it?"

Male, 55 Years, Large Multiple

3.6.2.4 'Steady' pace

In contrast to those regarding the current pace of change in community pharmacy as fast and furious, others deemed the pace as steady, expressing the view that change was inevitable and that these new services were being introduced by the Health Boards/ Government steadily and appropriately. In addition, effective organisation of tasks within pharmacy was also deemed key to steady adoption of changes into practice.

"So, they've had so many years... this minor ailment service... before the chronic... before the electronic transmission of prescription comes in... the barcodes on the prescription..., and then they get another time period before the chronic medication service kicks in. I think the fact that [they are] staggered out, means that good for us to get used to it ... and promote one thing at a time and get the public used to the fact that this is how things are changing."

Male, 39 Years, Large Multiple

3.6.2.5 Importance of self learning and staff training

The importance of participants' own continuous professional development needs as well as staff training along with preparation of necessary pharmacy documentation such as standard operating procedures (SOPs) were considered key to the need for spreading the introduction of change as one new service/medicine at a time.

"You need time to be able to tune up yourself and your staff and get all the information together and sort of formulate SOPs and sort of establish what plan is in your shop?"

Female, 44 Years, Small Multiple

3.7 RESULTS: RECLASSIFIED MEDICINES

The following section presents facilitators/barriers relating to pharmacists' decision making around newly reclassified medicines. Decision making here will relate to either adoption into practice or support for the reclassified status of the medicines.

3.7.1 'Content' related facilitators/barriers associated with adoption into practice of newly reclassified medicines

Content here relates to the features of the newly reclassified medicines which participants regarded as enabling or deterring supply decisions.

3.7.1.1 'Extra weapon in the armoury'

Most participants highlighted that, in general, the availability of wider ranges of medicines available for non-prescription supply was a benefit to the pharmacy profession linked to role development exemplified earlier in section 3.6.1.

"I think it's a good thing for a pharmacy... to have a wider range [of medicines]"

Female, 47 years, Small Multiple

One participant voiced that newly reclassified medicines that offer pharmacists an 'extra weapon in the armoury' were more likely to be embraced into practice as opposed to those which were considered 'me too' agents conferring no additional benefits over existing treatments.

"...changing from POMs to Ps is fine if it's [reclassified medicine] given us an extra, a weapon in the armoury"

Male, 55 Years, Large Multiple

Newly reclassified chloramphenicol was noted to be the newly reclassified medicine most highly valued by community pharmacists. One of the reasons was related to high patient demand. Although acyclovir, clotrimazole and loperamide had all been reclassified several years earlier, these were also highlighted as being of particular value, deemed widely adopted by pharmacists and patients.

"I think chloramphenicol has been best POM to P"

Male, 66 Years, Independent

"Most of them Zovirax [acyclovir], Canesten [clotrimazole], nicotine replacement therapy have been welcomed. There's a few [medicines] less welcomed than the others...."

Male, 37 Years, Independent

Sumatriptan and simvastatin were noted as some of the least successful reclassifications with one stating that cardiovascular risk assessment and lifestyle management may be of more value rather than initiating statin therapy for those at moderate risk of coronary events.

"I would say Imigran [sumatriptan] has been a waste of time, Zocor [simvastatin] has been a waste of time as well."

Female, 46 Years, Small Multiple

Although participants expressed reservations over supply of newly reclassified simvastatin, reclassification was deemed by one to be contributing to role development due to the opportunity for advice giving around the associated medical condition. However, supply of was largely deemed outwith the remit of expertise and resources normally available in pharmacy.

"...certainly we can advise the patients on their diet and lifestyle changes and I am more than happy to do that but I think in terms of [supply] ..., [it is] may be good for identifying somebody who has high cholesterol level who we can refer on but ...in terms of treatment I don't think, unless you have the facilities or you've done the supplementary prescriber course or independent prescriber [course], I don't think we really have the time at community pharmacies to go into that sort of details with patients."

Female, 27 Years, Independent

Some explained that they were keenly anticipating reclassification of medicines within certain therapeutic areas. Some of the examples included prochlorperazine for the treatment of nausea and vomiting associated with migraine, trimethoprim for the treatment of uncomplicated urinary tract infections and naproxen for the treatment of dysmenorrhoea. Naproxen was reclassified post conduct of these focus groups and interviews. Introduction of PGDs to allow pharmacy supply of existing POM medicines was also deemed to have enabled enhanced minor ailment management from pharmacy.

"...trimethoprim, I'm really looking forward to [it] a lot."

Furthermore, all participants deemed that in general, pharmacists were competent in the management of minor ailments but that the current lack of medicines within certain therapeutic areas and restricted licenses of reclassified P medicines were viewed to be limiting management of minor ailments. Examples of restrictions around the duration of supply as well the range of indications, as opposed to the supply through prescriptions, were cited.

"...you get folks in who've got skin infections and you know it's infection, you send him to doctor or GP. They either get Fusidin cream [fusidic acid] for impetigo and stuff and ...how far do we want to go with recommending [onto doctors], especially when doctors appointments are getting more and more of a premium. And you know you're here. I know what you need. But, you will need to go and see the doctor."

Male, 37 Years, Independent

However, some reflected that they would be confident to supply P medicines off-label if deemed in the best interest of the patient. Patient care and need had the highest priority.

"In incidents ...say, thrush products... you got all the guidelines there you have...but it's Friday and you know this person not gonna bear. Get an appointment until the following Tuesday. Ok, if you stick hard and fast to the guidelines, you might say, well, no they don't meet that criteria but you send that person away to suffer all weekend, something that are really uncomfortable..."

Female 53 Years, Independent

3.7.1.2 Evidence of medicine efficacy

Evidence of medicine efficacy was deemed by most participants to be important in adopting newly reclassified medicines into practice. Instances were presented where pharmacists perceived lack of evidence of efficacy was found to be militating against supply decisions.

"Patients who want what is quicker to use and I've refused prescribing [supplying] because may be quick to use but the evidence doesn't back up its use. Now, that's I think what we should be doing. But, it can be quite difficult."

Male, 55 Years, Large Multiple

Specific examples, however, were related to non-prescription supply of simvastatin, which was reclassified in 2004.

"Personally, it [simvastatin supply] is not something that I've become very involved in. I'm not great advocate of selling the product OTC. I have reservations for the dose it is. I think it's far better ...for the patient to have a thorough check out [from the doctors] ..."

Female 53 Years, Independent

Lack of belief in an evidence base was also related to a lack of observable outcomes of medicine usage, again exemplified with the case of non-prescription simvastatin.

"...you can't see it [simvastatin] is making you better."

Female, 25 Years, Large Multiple

In contrast, the high value placed on chloramphenical and its subsequent extensive adoption into practice was partly attributed to pharmacists' perceived strength of evidence supporting its efficacy. The importance of keeping up to date with new evidence around reclassified medicines to inform practice was raised by some participants.

"... in relation to products which moved from POM to P...when Beconase [beclometasone] was first launched, it was suitable for over the age of 12. Now its 18 ...you go with the information you have at the time and you'd have to trust the people that are bringing the product to market, have done all the appropriate research ... so we keep up to date with it. It's important that the members of staff kept up to date with that..."

Male, 39 Years, Large Multiple

However, others reflected concern over the lack of updated information around evidence base, highlighting that educational materials were likely to be received only during the initial launch of the medicine under a newly reclassified status.

"I don't think there's a lot of literature really on OTC [over the counter] medications that come in through our doors."

Female, 27 Years, Independent

Of note, one participant expressed that she had to rely on the patient information leaflets contained within the medicines packaging.

"I think the only literature really is what's in the patients information leaflets in the boxes in a lot of cases unless in cases like something that have recently come from POM to P. You get a bit form the reps coming in but there's nothing specific."

Female, 27 Years, Independent

Participants also considered patient feedback to be an informative tool to aid identification of evidence of efficacy. However, such feedback was received only 'occasionally' and was limited to either 'very good' or 'very bad' patient experiences.

"...it would be good to know, 'cause sometimes you find you prescribed [recommended] things, and people buy and its nice to get feedback if they've worked for the patient or if they haven't worked..."

Female, 27 Years, Independent

"The only feedback you get is very good or very bad."

Male, 55 Years, Large Multiple

3.7.1.3 Safety

Participants highlighted that patient safety was a key factor in informing supply decisions in relation to newly reclassified medicines. The wide acceptance of newly reclassified chloramphenical was further attributed to the low potential for risk (in addition to high efficacy). There were also several examples presented where patient requests for newly reclassified medicines were denied by pharmacists based primarily on safety fears.

"Chloramphenicol...this [reclassification] seems to make sense because the likelihood of causing problem [to patients] is small."

Male, 39 Years, Large Multiple

Limiting reclassified medicines to pharmacy sales was deemed important in ensuring that safety measures around the use of medicines were promoted. For the same reason, one participant mentioned that he preferred to recommend P over the GSL licensed medicines to patients where possible, so as to encourage patients coming to pharmacy for repeat supplies.

"Anything that goes GSL, you tend not to recommend to a pharmacy product or ones excluded through pharmacy trying [to stop] folks going into the supermarkets."

Safety concerns surrounding the supply of GSL medicines out with pharmacy were related to uncertainty over stringent supply regulations in general stores.

"There's problem when things go from P to GSL, are they been restricted or controlled enough when they are sold outside pharmacy?"

Male, 55 Years, Large Multiple

3.7.1.4 Medicine retail prices

High retail prices of newly reclassified medicines were often related as barriers to supply decisions. This issue was deemed as contributing to the low uptake of newly reclassified omeprazole and simvastatin, in particular. High cost implication to patients was deemed a bigger issue for those medicines indicated for long term use, such as simvastatin.

"...the company that I worked for was pushing it [simvastatin], because they thought that this is gonna be a really big thing and that they are gonna sell masses of it and it was a great opportunity for them to get into kind of a market which hasn't previously been there. And then, it certainly backfired because those people who came for cholesterol test and they find out how much it was and they will need to take it every month, need to come back every month and buy it and they didn't do it."

Female, 25 Years, Large Multiple

In contrast, greater uptake of newly reclassified chloramphenicol was partly attributed to a more affordable retail price. Some participants regarded the prescription charge as a benchmark for considering the appropriateness of the retail price of newly reclassified medicine.

"That's why I think chloramphenicol has been so successful because so many people come in with eye infections and it is cheaper than prescription."

Female, 25 Years, Large Multiple

For those considering prescription charges as the benchmark, it was not unusual for them to voluntarily refer patients to their GP if treatment with newly reclassified medicines meant higher cost implications.

"...better off on to the doctor and I would advise to do that rather than buying an expensive product."

Female, 27 years, independent

Some regarded patients' abilities to pay as an important factor, further driven by their social status; and hence these decisions were mostly subjective.

"I think it depends as well on what area you are targeting, because if you are in a, an affluent area, probably, ***** [an area], people may be motivated to pay ...but if you're in a poorer area..."

Female, 56 Years, Large Multiple

With the abolition of prescription charges in Scotland by April 2011, pharmacists highlighted that patients would be less inclined to buy the so deemed 'often expensive' newly reclassified medicines.

"...particularly with things like prescription charges [going] down in Scotland as well, ...you just tell them that it would be cheaper on prescription and then they quite happily go to the doctor and get [the medicines] instead..."

Female, 25 Years, Large Multiple

3.7.1.5 Medicines for acute versus long term indications

Participants expressed doubts about whether resources available in community pharmacy, in general, were appropriate for medicines for long term indications to be supplied, largely due to the perceived complex supply procedures. In addition, expertise such as prescribing qualification was thought to be required by some participants as imperative to undertaking the supply.

"...certainly we can advise the patients on their diet and lifestyle changes and I am more than happy to do that but I think in terms of [supply], [reclassification of simvastatin is] may be good for identifying somebody who has high cholesterol level who we can refer on but ...in terms of treatment I don't think, unless you have the facilities or you've done the supplementary prescriber course or independent prescriber, I don't think we really have the time at community pharmacies to go into that sort of details with patients."

Female, 27 Years, Independent

It was interesting to note however, that participants with a prescribing qualification did not support the reclassified status of simvastatin either. General practitioners were considered more appropriate for the management of long term conditions. A few also regarded that patients were comfortable 'anyway' with management of long term conditions from GPs.

"We're really kind first port of call for acute things and...really people are coming... if there's something wrong with them but if it's a long term chronic thing, they come in and we can direct into their GP for the long term chronic thing."

Female, 46 Years, Small Multiple

3.7.2 'Context' related facilitators/barriers associated with adoption into practice of newly reclassified medicines

3.7.2.1 Sources of information/ training

Participants highlighted the importance of and need for timely information and training around newly reclassified medicines to inform their practice. Externally provided training events, such as those provided by RPSGB were attended if they contributed towards pharmacists' mandatory Continuous Professional Development (CPD) requirements.

"You're more likely to read it [information] and do the questions afterwards, if it's gonna count towards your CPD."

Female, 27 Years, Independent

Attending training sessions was thought more useful than solely relying on printed information sources, due to the interactive nature and opportunity to ask questions. Although company representatives were acknowledged to be a source of information, some also noted that personal relationships and friendships could bias information and thus potentially impact on pharmacists' decision making. However, in some situations, it was noted that the representative was really the only source of information, hence explaining why their voice had a greater bearing on pharmacists' decision making.

"I think a lot depends as well, you know the representative coming from company as well, depends on the personal relationship and how far back you go with them and just listen to what they say but the relationship that you tend to have with them... colour your judgement, whether it's right or wrong I don't know."

Female 53 Years, Independent

It's the reps [representatives] doing it [promoting], 'cause it's the only one [source of information] that we get for POM to P for certain conditions.

Female, 46 Years, Small Multiple

A few participants however, considered that manufacturers' information was 'biased' leading to a need for impartial' sources of information. Information in the *Pharmaceutical Journal* was largely considered impartial.

"... [I use] an impartial source, not the manufacturers'. I always get sceptical when I see their data coming through."

Male, 28 Years, Large Multiple

On the contrary, one participant highlighted the importance of using information from multiple sources, including the manufacturers' information for the distinct focus around the information provided by each sources.

"The Society [RPSGB] information is always great for making sure that you're absolutely on the ball regarding the legalities of the situations what you should be and shouldn't be doing regarding the sale of the products. Em..., the manufacturers' information will always give you much more detailed information about potential side effects and things and kind of gives more detailed information about the compositions and make up...'cause you will always have people with weirdest queries em..., with, they got bizarre diet they take into, can't have anything with ...all sorts of weird things in tablets. So you can get that, mostly from manufacturers' information."

Female, 25 Years, Large Multiple

One participant considered personal experience as pivotal to decision-making, and noted this to be superior to knowledge gained through information and training.

"But I'm still sceptical ..., specially on the CPD things... that's lovely, thanks for telling that but I'm still not quite necessarily choose that product over, over something which has been successful for, with other patients or customers before."

Male, 28 Years, Large Multiple

3.7.2.2 Access to patient medical records

A desire for access to patient medical records was strongly voiced. However, this was specific to supply of certain medicines such as simvastatin.

"...whether the patient had a history of or a family history of stroke, whether diabetic..., in isolation, I think it [simvastatin] was pretty much useless exercise."

Male, 55 Years, Large Multiple

Participants were concerned for patient safety implications if supplies were made without being fully aware of the patient's medical history.

"Unless you have access to records... to see what we want..., the only way [to supply simvastatin] is... if we had access to the records, kind of dangerous in a sense if you think about it."

Male, 66 Years, Independent

3.7.2.3 Risk assessment tools

Participants described the importance of risk assessment tools to promote safe supply of newly reclassified medicines. This need was mentioned with reference to specific newly reclassified medicines including simvastatin.

"...as long as they've been through the whole sort of questionnaire, the questionnaire that they give you with the product information is quite good. It's just reassurances it's just so many questions to go through it. It's just impossible to remember everything but it definitely has been great..."

Female, 27 Years, Independent

Others regarded risk assessment as a barrier, particularly in terms of resource implications.

"...time filling out whole Imigran [sumtriptan] [risk assessment form] ... I find that taxing"

Male, 28 Years, Large Multiple

Participants shared common experiences around some patients being reluctant or sometimes unwilling to undertake these risk assessment questionnaires. Many considered that patients often regarded pharmacy as a place to obtain medicines rather than a place for consultations.

"A woman came to buy a pack of Imigran, and I said, have you been interviewed about the suitability to buy this product? No, the other chemist just sold me. So, I have to get the pack out and go through the two page questionnaire with it to determine whether it was suitable

for. And, this was almost ten minutes of her time to get sold the product she already had somewhere else. Had she not been a local customer, I'm sure she would have just walked out. Em..., that obviously, the fact that I was able to sell it her, was... able to explain to her why... the reasons behind the questionnaire without scaring her too much. I suppose, this was just down to the fact that she had the time and was willing to listen to what I had to say."

Male, 39 Years, Large Multiple

One participant cited an example of blood glucose testing in the community pharmacy environment as more appropriate for the 'short' process involved. More complex risk assessment procedures such as cholesterol testing were deemed to be more of a doctor's responsibility and hence a barrier to adoption of certain newly reclassified medicines.

"I think diabetes test one is good. You know, for people that just may be have the symptoms or haven't or have a family history and just want to come in quickly to pharmacy and do, you know a quick blood glucose test, but, there's certain areas that just requires too much detail, that just need to be overseen by a GP and have the patients receive the proper intervention or care... I don't think we would have the time or the facilities anyway in our place to give that level of care ..."

Female, 27 Years, Independent

3.7.2.4 Direct requests for medicines

Participants had overwhelmingly negative attitudes towards the direct requests for newly reclassified medicines. Direct requests were often regarded as 'disrespectful' to pharmacists' professional roles as medicines experts. Presentation of illness was considered a more appropriate practice.

"...they don't come in and [ask] what've you got for period pain? What've you got for fungal nail infection? This is just can I say, can I have the stuff that's advertised on the television? Yes, I can treat your nail infection if you leave it just up to me, let me decide how I going to treat you...You can't walk into a GP practice and say to the doctor, I come on with such and such I saw on telly [television]. The GP won't listen to it. And, I found that quite frustrating."

Female, 46 years, small multiple

Participants highlighted that most of the direct patient requests for newly reclassified medicines were influenced by mass media advertisements and information freely available

on the internet. Nonetheless, verbal recommendations from other health professionals such as the GPs and nurses at NHS24, suggesting to patients the name of the medicines to be 'picked' from pharmacy were also blamed to be contributing to direct requests.

"... hydrocortisone cream for example, its not licensed OTC for the face and you get, they've had the product from the GP to use on the face. The doctor has said to them you can buy it... I wish sometimes that information was made more clear [to the doctors']... that leaves a lot to be desired [by the patients] and sometime makes it difficult for us."

Female 53 Years, Independent

3.7.2.5 Patient behaviour

Participants highlighted the importance of patient willingness to comply with pharmacist and support staff advice so as to promote safe and effective use of newly reclassified medicines. Only a few highlighted that patient behaviour was generally appropriate.

"We don't tend to get a lot of people asking for anything [inappropriate requests], which is good."

Female, 29 Years, Small Multiple

"...when the partner comes in saying oh, 'my wife or my other half is looking for a morning after pill.' 'No I can't sell it to you. I need to sell to the person who needs it and interview her to make sure it's appropriate'. 'How come?' 'Because I need to know if that's appropriate'"

Male, 39 Years, Large Multiple

Patient behaviour was deemed by a few to be 'good' in smaller towns and villages as opposed to larger cities where verbal arguments with patients were often common place. Such arguments were construed as disrespect to professional expertise of pharmacists.

"You spent four years doing your, your degree...the Master's degree...the patients still come in and argue."

Male, 37 Years, Independent

Some patients were noted to move from one pharmacy to another in an attempt to get a denied medicine. Participants accepted that decisions across pharmacies around similar requests were not always consistent, further encouraging patients to 'try' across pharmacies. Some participants were however often resigned to patient requests.

"I think because we are very sort of customer oriented. Your customers can go wherever they want, while with the GP they have to go there all the time. It will be very much sort of bullied. You're not..., giving them [medicines] to keep them happy ..."

Female, 27 Years, Independent

Participants also highlighted that 'disloyal behaviour' from patients could be a barrier to them anticipating future reclassification of medicines such as antibiotics. This was the same participant as above who agreed to being often resigned to such disloyal behaviours from patients. Lack of desire to see antibiotics reclassified was different to the view of most other participants who mentioned trimethoprim as an appropriate candidate of reclassification.

"I don't think I would like to see antibiotics because I think with this, we will be bullied a lot by the customers, you know that insists on that they need antibiotics. I think that the doctors are doing a great job trying to limit them at the minute. So that's one thing I don't think I would like to see coming just and just yet anyway."

Female, 27 Years, Independent

3.7.2.6 Supply guidelines

The importance of clinical guidelines was considered imperative in facilitating adoption of newly reclassified medicines. Participants described ambiguity around labelling certain ailments as 'minor', particularly when repeated requests for the same medicines over time were received. The point at which patients should be referred to their GPs was not considered to be straightforward in current guidelines.

"I think the question is at what point do you stop treating these minor ailments, because we've quite a lot of patients who come in for a lot of lactulose on a regular basis and then you try and explain to them, you know, well if its ongoing, you should maybe go and see your doctor...there's no definite point of what's minor and what do you keep treating. You know and that's where I'm sort of lost."

Female, 27 Years, Independent

"So, is it minor? You know, there's a lot of grey areas about what is minor and what's not. Hay fever have been one of the crackers, as you know by August, it should hopefully have died down. But how often do you go and treat em'? Or when do you tell them to go to the doctor?. Or the one is, oh I got it from the last time from the doctor, can I get from you this time? There's not enough guidance."

Male, 37 Years, Independent

3.7.2.7 Peer support

Peer discussion about innovation issues were considered almost non-existent. Further collaboration among professionals to aid decision making around newly reclassified medicines were considered important by a few participants.

"We don't meet that often to discuss these things. You have to really do it yourself basically, unless you phone somebody and [ask] what do you do in these instances?"

Female, 54 Years, Independent

3.7.2.8 Employer policies

Participants from pharmacies with a multiple ownership structure identified employer policies being the key to stocking decisions around newly reclassified medicines. However such policies did not 'enforce' supply. Decisions to supply were argued by participants to be based on their own judgements, regardless of organisational decisions to implement.

"We've found that although there are more products available...the shelves don't get any bigger and our company dictates what we stock on shelves. So those that might be advertised on telly [television], that isn't necessarily something we are stocking."

Male, 39 Years, Large Multiple

"If somebody demands, we stock as a matter of policy. I didn't agree with it [simvastatin]. I did it when it was contractually required me to... but I've never sold a pack of simvastatin in life. Never had any intention to do it [the supply]"

Male, 55 Years, Large Multiple

3.7.2.9 Relationship and trust with support staff

Good working relationships with support staff were regarded as vital for the adoption of newly reclassified medicines. A lack of trust and relationship with support staff was often regarded as 'barrier' to anticipating reclassification of medicines.

"Fortunately, in the store I am working, I trust my staff members and I know that they go, sort of sell appropriately and always refer to me or the pharmacist in-charge in a responsible manner. Occasionally I have worked in stores where you don't necessarily have that trust in your staff and that's where having these kinds of products [chloramphenicol, omeprazole] available can be more problematic. My staff must know that they must refer to me for the sale of certain products that I might be slightly less comfortable with, just so that I can make sure that the requirement is absolutely definite and that it's the most appropriate product for

the patient and.. Em.., again it depends which stores you're in, whether that's actually happening or not, so it comes down to I think, I don't have a problem with the reclassification of these products."

Female, 25 Years, Large Multiple

3.7.3 Attitudes to current 'processes' leading to reclassification

The following section describes results relating to pharmacists' issues with current regulatory processes of medicine reclassification and notification of such decisions to pharmacists. This section also highlights their views towards their future contributions to the change process.

3.7.3.1 Desire to contribute to MHRA decisions to reclassify

Some participants expressed a desire to contribute to the professional consultation processes of the MHRA that take place prior to reclassification of medicines. However, lack of awareness of this process was highlighted, with a few not being able to recall any past invitations. There was a clear need for further support and direction in this area, particularly as they felt that they were an unheard voice with important views.

"I've never been involved in anything. No, I've never been asked about anything. I'm interested to take part in consultations like that but ..."

Female, 25 Years, Large Multiple

One participant recollected the invitation around the consultation of trimethoprim reclassification but could provide no further details.

"...I think trimethoprim has been a long consultation process out. I think I did do, can't remember where it was."

Male, 37 Years, Independent

3.7.3.2 Awareness of reclassification decisions

Participants felt strongly that there was a lack of timely communication to pharmacists about the MHRA decisions to reclassify. Often no communications around decision to reclassify the medicines was provided to community pharmacists by either regulatory authorities, pharmaceutical industry or their own professional body. Newly reclassified medicines on occasion just appeared 'from nowhere'. Indeed one participant recounted an occasion where he had become aware of a newly reclassified medicine through a television

advertisement which appeared well in advance of any communication to him either via the product manufacturer or the professional body.

"I wasn't even aware that there was an OTC naproxen coming out until it was pointed out on television. To me, I would think I would read in my journal and chemist [Chemist and Druggist] but it's not as early, for cover to cover... then [patients] coming and asking for OTC naproxen which I wasn't even aware...I don't know if I'm alone."

Male, 55 Years, Large Multiple

Participants gave several examples of scenarios highlighting how a lack of timely communication regarding newly reclassified medicines had put pharmacists in professionally uncomfortable and potentially embarrassing situations.

"...before launch it's often in glossy magazines or newspapers whether it is news or whether it is promotional. I have been asked for something that appears on *Daily Mail* or whatever, newspaper that does a new medical drug. Now if I don't read that particularly newspaper, I won't have a clue what they are talking about ...I think..., that doesn't only happen with over the counter drugs, it can also happen with prescription drugs. People asking about new wonder drug for rheumatoid arthritis, which they read about in the Sunday Post, 'Doctor' on Sunday Post."

Male, 55 Years, Large Multiple

Indeed, one participant voiced that pharmacists should be 'leading' messages given to the public about the availability of newly reclassified medicines from pharmacies, as opposed to the current situation where pharmacists were often responding to customer requests, deemed to be stimulated by direct to customer advertising.

"But if it's driven by television advertising ... that people coming and asking for potent medication, I might not be satisfied. I think, it should be, led by us, not led by television. "

Male, 55 Years, Large Multiple

An 'ideal' way to communicate information around reclassification was also suggested.

"They [MHRA] can send us a sort of standardized card with all the information instead of all promotional information, you got to fight the way through to find the information you really want. The card would then allow to sort of pick changes and secondly would give you the standard information."

3.7.3.3 Role of television advertisements

Almost all participants had overwhelmingly negative perceptions about the role of television advertising of medicines and the messages delivered to the public. They were of the opinion that advertisements had the potential to place members of public under undue 'pressure' to medicate themselves, sometimes for what they perceived to be 'inappropriate' reasons.

"You tend to find that these advertisers hold a lot of pressure for the patients, wanting [medicines]..."

Male, 37 Years, Independent

Participants also voiced strong opinions that advertisements could undermine the role of a pharmacist's input in medicine selection and management of minor ailments. Instances where patients had made their mind up after watching the advertisement and before visiting the pharmacy were described. In general participants deemed that patients held a high regard for such advertisements.

"...[reclassified medicine] gets advertised on telly [television], oh... this [medicine] is great, this is great stuff and they come in and, they ask for...They don't come in and [ask] what've you got for period pain? What've you got for fungal nail infection? This is just can I say, can I have the stuff that's advertised on the television? I think, Curanail [amorolfine] must be on the telly just now as well. 'Cause I've had somebody asking for that and that's such an expensive item, something I would not generally recommend first line, but, because it's on the television..."

Female, 46 Years, Small Multiple

Some participants went as far as suggesting banning the direct public advertising of medicines altogether so as to encourage patients that all information around newly reclassified medicines is obtained via pharmacies.

"...it's fine if they don't advertise, 'cause we could control the sales. Since that advertising we're pushed into it [supplying the medicines]... by the patients."

Male, 37 Years, Independent

3.7.3.4 Names and pack sizes of newly reclassified medicines

Participants reported problems attributed to potential confusion created by similarity of brand names of newly reclassified to those of the packs licensed prescription only. One participant recounted a situation where an error in supply occurred as results of such confusion.

"It's quite confusing, when they have fancy [prescription] products like Cansten and they bring out [over the] counter pack which is obviously...[with] the same [name]...its misleading...Things like Canesten [fluconazole], I've given the POM pack you know"

Female, 56 Years, Large Multiple

The issue of similar nomenclature of POM and P packs was also deemed misleading to patients, particularly where similarly named branded medicines actually contained different active ingredients. There were concerns over risk management, patient safety and more complex management of any overdose situation.

"... when you get the name 'extra' 'plus' and it's confusing for the hospitals if there is an overdose because, basically the database will actually show the product as being salicylate product ...I'd have liked to call some other than Feminax Ultra [naproxen] to be honest ..."

Male, 55 Years, Large Multiple

Debate over the pack sizes of newly reclassified medicines took place. Some participants voiced that larger pack sizes of newly reclassified medicines were financially beneficial for pharmacy.

"...and we've also found that the pack sizes of the products we are stocking are getting bigger on the basis that a customer coming into the shop, if we can get them to buy the bigger packet instead of 12 pack if we can get a 24 pack or 32 pack, that's more money in the till."

Male, 39 Years, Large Multiple

Others raised concerns associated with stocking and safety of larger pack sizes.

"Perhaps, the industry could have helped ourselves in some ways of, not produced 30 quantities, 30 packs [of medicines]."

Female 53 Years, Independent

3.8 DISCUSSION OF KEY FINDINGS

The objectives of this qualitative study relevant to the data presented in this Chapter were to: investigate community pharmacists' views on ongoing changes around enhanced management of minor ailments from pharmacy; evaluate the processes aspects of innovation adoption from community pharmacists' perspective; and to explore key facilitators/barriers associated with their adoption into practice of newly reclassified medicines. Although most discussions were focussed around medicines indicated for acute conditions, issues around adoption of newly reclassified medicines indicated for long term indications also emerged during the discussion. This too added rich insight to the understanding of community pharmacists' innovation adoption decision making process. Most participants deemed pharmacies were still suited to manage acute minor ailments.

3.8.1 Attitudes to ongoing changes

Participants' identified that pharmacists' roles are being enhanced by the innovative services around minor ailment management. New services were deemed to be enabling pharmacists to move away from routine dispensing role to enable greater interaction with patients. The ongoing reclassification of medicines and the introduction of e-MAS in Scotland were regarded as the key changes aimed at enhanced minor ailment management from pharmacy.

Despite most participants agreeing the benefits offered by new services, in general, to professional role development; adoption into practice of these innovations, were found to be associated with many facilitators/barriers, perceived to be inherent within the characteristics (or attributes) of medicines as well as related to organisational and external contextual factors; and process related aspects of changes. Data around such facilitators/barriers relevant to the adoption of newly reclassified medicines into practice were presented in this Chapter.

3.8.2 'Content 'related facilitators/barriers to innovation adoption

Opportunities to increase pharmacists' professional roles and image in society were identified as one of the key desirable features that an innovation should possess to facilitate adoption. Many of the newly reclassified medicines were regarded as an opportunity to further enhance their roles by participants in this study. Many participants expressed that Chapter 3: Qualitative research

they were anticipating medicines from diverse therapeutic areas to be reclassified in the future. Of the suggested medicines, naproxen has been recently reclassified into P status [89]. The MHRA has also started consultation around certain POM medicines that participants identified would be useful to further enable enhanced management of minor ailments; such as trimethoprim for the management of urinary tract infection [89]. Opportunities for role development and enhancing professional image have also been reported as key 'motivators' of community pharmacy practice change not limited to minor ailment management in a previous qualitative study [127].

Both benefits and risks to patients were found to be assessed by pharmacists when making decisions to adopt newly reclassified medicines into practice. A recent qualitative study has shown that pharmacists are basically risk averse when making adoption decisions and that lack of evidence of efficacy are less likely to deter pharmacists from supplying them [228]. However, in this study showed that perceived evidence of efficacy of newly reclassified medicines could be of equal importance as the issue of patient safety, while making adoption decisions; exemplified by participants with lack of efficacy being one of the reasons for non-adoption of simvastatin.

The importance of medicine retail prices was often regarded critical to decision making. Many participants cited referring their patients to their GPs where cost of therapy with reclassified medicines would exceed the prescription charges. As noted in this study, the cost of prescription charges as a benchmark to estimate the appropriateness of retail price of medicines by pharmacists sits alongside the findings from previous studies [229]. Patient based studies reflect that the issue of access is an important reason why patients choose to go to pharmacy [105]. However in this study, it was not clear whether pharmacists took account of this factor when making such referrals. The issue of abolition of prescription charges in Scotland by 2011 [230] raises important research questions around how the conflict of issue of access versus the retail price of medicines will affect the sales and supplies of newly reclassified medicines.

This study did not identify the role of profits owing to sales of reclassified medicines to be associated with the tendency to supply. Participants did neither allude to the financial benefits when discussing the merits of ongoing reclassification of medicines. Any preference of P medicines over GSL counterparts was explained in terms of encouraging patients to use pharmacy for minor ailment matters in the future. From the participants'

perspective, patients would benefit from pharmacy only supply. One previous study reported that financial profits owing to sales were associated with pharmacists' tendencies to supply the medicines [231]. However references were mostly made to pharmacists' choice of particular brand from the available ranges [231].

Not limited to the issue of cost implications, those medicines indicated for long term conditions were regarded by the participants as less appropriate for pharmacy supply. Resource requirements around the perceived risk assessment needs and greater expertise were deemed barriers to adoption into practice of such medicines. This was despite the fact that medicines are reclassified once MHRA is assured of the expertise and resources available in pharmacy [87]. Of note, risk assessments such as cholesterol testing were often deemed to be prerequisite for supply despite no mandatory need for such process within the supply guidelines, such as with the case of non-prescription supply of simvastatin [232]. Greater harmony between pharmacists' perceptions around the risk assessment need and clinical guidelines around supply process is important.

The facilitators/barriers around 'content' aspects of newly reclassified medicines relate to the factor attributes of innovations associated with innovation adoption as suggested by Rogers' diffusion model [131] (Chapter 1, table 1.3). Within the attributes of innovations, the importance of relative advantage of having newly reclassified medicines (such as opportunity for role development), perceived *complexity* of the supply process (such as need for risk assessment), compatibility with pharmacists' skills, experiences and expertise, observability of benefits of adoption into practice (such as good feedback about efficacy from patients) and re-invention (comfort to supply the medicines off license) were identified in the data. However, there was no evidence to suggest that pharmacists adopt newly reclassified medicines on a limited trial basis before supply to larger numbers of patients. Hence the factor trialability was not identified. One reason for this might be that many of the newly reclassified medicines discussed had surpassed the stage of trialability. Lack of the importance of trialability has also been reported by other diffusion studies in pharmacy investigating pharmacy based in house immunisation services in the US state of Washington using a multi-stage survey design [233]. It is hence possible that not all pharmacy innovations are predisposed to trialability. On the other hand, it is also possible that late adopters are often known to use feedback from the more innovative adopters and use as a measure of trialability whereas the more innovative ones do not have such precedents available to inform their own practice.

3.8.3 'Contextual' factors

3.8.3.1 Organisational

Training opportunities were identified as facilitators to the adoption into practice of newly reclassified medicines. A few participants complained more about the lack of diverse training opportunities than others. Limited evidence from outside the area of minor ailment management suggests that pharmacists from independent or small multiple ownership experience greater problem with allocation of resources such as around staff capacity development than those practising in large multiple chain ownership structures [234-236].

The issue of insufficient training opportunities for locum pharmacists was also raised. One previous audit around availability of professional and operational information for locums in community pharmacies in Greater Glasgow Health Board in Scotland showed that that locum pharmacists usually encounter lack of information material in community pharmacy [237]. It is imperative that their information and training needs are well researched given that nearly a quarter of pharmacists involved in community, practice as locums [238].

Access to patient medical records was deemed essential for the supply of certain newly reclassified medicines. Such access was again discussed in relation to the supply of medicines indicated for long term conditions. With the increasing number of cognitive services being introduced into pharmacy, not limiting to minor ailments management, ways to enable access to patient medical records need further consideration by wider stakeholders. This issue is discussed further throughout the thesis.

Apart form the issue of resources and training, the importance of trust and relationship with support staff were also identified. Appropriate organisational management and leadership skills could aid pharmacists in establishing healthy working relationships with their support staff. This also has been claimed to be important to enable pharmacists delegate the task of routine dispensing role if further innovative services requiring pharmacists' cognitive roles are to be introduced in the future [127].

3.8.3.2 External

Issues around support from patients, professional bodies, pharmaceutical industries and wider stakeholders were the external facilitators/barriers associated with adoption of newly reclassified medicines.

Aggressive and non compliant patient behaviour was less of an issue for some participants than others in this study. 'Bad' experiences around patient behaviour were often deemed by participants to be deterring them anticipating future reclassifications where perceived risks owing to lack of compliance were higher. Future interventions enhancing the awareness of risks arising from non-compliant behaviour is imperative.

Participants in this study also suggested changes in the currently available information from external sources, such as the RPSGB. The ambiguity relating to the point of patient referral to the doctors was raised. This is interesting in that most RPSGB practice guidelines around the newly reclassified medicines, do indicate the point of referral [232,239].

Nonetheless, some raised issues around lack of adequate external information and training sources. Of note, some participants complained about having to rely on patient information sources such as the PILs. For others, pharmaceutical industry representatives were the only external information sources. External information sources are often labelled *change agents* by the diffusion model who are regarded not only important in facilitating innovation adoption, but also can raise the *compatibility* of innovations to potential adopters by providing them with information around benefits and risks of the innovations [131]. The lack of opportunities for peer networking among pharmacists to discuss issues associated with innovation adoption is also worth noting. The need to facilitate such professional networking among colleagues, who often work in isolation, has previously been emphasised by other pharmacy practice researchers in the context of new pharmacy services not limiting to enhanced minor ailment management [127]. The importance of both vertical (from senior colleagues to junior colleagues) and horizontal (from peer to peer) routes of learning has been highlighted through empirical evidence from studies with other health professionals such as the doctors [240]. It has been known that despite their independent medical practitioner status, doctors are usually known to benefit from discussion of issues around new medical and surgical techniques among professionals of similar hierarchy [240]. There is a scope for stakeholders in pharmacy to enable pharmacists to exercise such opportunities.

The importance of support from and effective communication with health professionals including GPs and nurses was unsurprising given the wealth of evidence around the importance of inter professional relationships [144,241,242]. However concerns were often

noted around the 'inappropriate' referral of patients to pharmacy by the professionals. It is important that pharmacists' desire to ensure autonomy in decision making is respected by other health professionals.

3.8.1 The processual aspect of innovation adoption

As highlighted in Chapter 2, gathering sequences of events about how innovations are adopted is referred to in diffusion research as 'process' research [130]. Such research is most appropriately undertaken using qualitative methodology. A number of key process aspects of innovation adoption were identified from the qualitative data presented in the results.

3.8.1.1 Communication around reclassification decisions

The current provision of information by 'policy makers', specifically the MHRA to pharmacists, around when and how medicines are reclassified was criticised by participants, mainly for the poor timing of such information. Consumer demands, deemed to be generated by early media advertisements, were often blamed to be acting as key drivers for pharmacists to adopt the innovations. Such early advertisements were often putting pharmacists under pressure to adopt newly reclassified medicines at a very early stage before appropriate CPD and training had been received. One qualitative investigation in Australia showed that pharmacists did not identify demand from patients as key drivers of practice change in relation to adoption of innovative services, mainly owing to lack of direct to consumer advertising in Australia [127]. Perspectives of wider stakeholders are necessary to be gathered to see if there is a need for any changes in the regulations around advertisement of newly reclassified medicines.

3.8.1.2 The importance of adopter characteristics

The results highlight that diverse groups of pharmacists exist who embrace and adopt innovations to a different extent and at different paces. It was worth noting that participants who identified themselves as being forward looking also reflected a desire to have a greater involvement in regulatory decision making processes as they apply to pharmacy. The need to identify these pro-active pharmacists who can act as 'movers and shakers' or attain the role of opinion leaders within their organisations and local practices forums [243] has been previously highlighted [159].

Some participants stressed the importance of 'delay' before 'getting used' to the supply of newly reclassified medicines to be adopted into practice. Rogers' diffusion model regards

time as an important variable in the process of diffusion [131]. Those who are known to be on the higher side of the innovative scale are known to adopt innovations quickly as opposed to the ones on the other side of the scale (table 1. 3) [131]. Given the small sample size of this study, it was not fully possible to categorise participants as per their readiness to change to the five categories of innovativeness as suggested by Rogers (table 1.3). It is important for the regulators, professional and organisational leaders to tailor the pace and support around innovative medicines and services to fit the need of these diverse groups of individuals. The deployment of 'contract champions' [244] within Scottish Health Boards from pharmacy proprietary associations such as Community Pharmacy Scotland aiming to enable customised help to community pharmacists/pharmacies in delivering innovative services is an example of how such concepts could be realised in practice. Such support measures via other stakeholders of community pharmacy innovations could facilitate their adoption by practitioners.

3.8.1.3 Personal adoption versus organisational implementation

Some participants, when doubting the benefits of innovations of reclassified medicines to either themselves or to the patients; were often found to be dissociating themselves from the organisational decisions to implement the innovations. Hence, for many, decisions at the organisational level to implement an innovation did not necessarily translate to adoption by individual practitioners. Any discordance around adoption at an individual practitioner level versus implementation at the organisational level is more likely to be relevant for larger organisations where implementation policy are likely to formulated at a central and remote locations, often labelled by participants as 'head office'. Given pharmacists' roles in imparting knowledge and onward training about new services and medicines to support staff to prepare their pharmacy for the implementation, willingness to adopt by pharmacists is important. The facilitators/barriers identified in this exploratory study further enables understanding of how innovation adoption by individual practitioners, around newly reclassified medicines are likely to be facilitated.

3.8.1.4 Naming the newly reclassified medicines

Participants expressed concern towards potential misunderstanding created due to the similarities of P medicines to their POM counterparts. The nomenclature of innovations is often known to be a delicate and important matter, especially for the perception they can bring about in the potential adopters [127]. Although, there are regulatory provisions that POM and P strengths of the same generics are required to have different brand names [89],

errors owing to confusions from similar nomenclature were acknowledged by participants in this study. Hence stringent measures to avoid such errors in the future are imperative.

3.9 SUMMARY OF CHAPTER 3

New services around enhanced minor ailment management were identified by the participants of this study to be contributing to role development and professional image in the society. Ongoing reclassification of medicines and the introduction of e-MAS in Scotland were identified as the key changes in this area. However highly individual and diverse experiences of changes were identified where individuals perceived the need as well as current pace of change differently. The importance of good communications with wider stakeholders including the regulatory decision makers was highlighted.

Facilitators/barriers to adoption of newly reclassified medicines into practice by community pharmacists were also identified and presented in this study. These related to perceived attributes of newly reclassified medicines such as retail prices, benefits and risks of the medicines to pharmacists' professional role and to the patients (such as evidence of efficacy and safety); organisational contextual factors such as sources of information and training; external factors, such as support from wider stakeholders. Many newly reclassified medicines were highlighted by participants to have been highly adopted into practice or were least/not adopted based on these diverse facilitators/barriers.

The strengths and weaknesses of the method adopted as well as relevance to practice of the results will be detailed in Chapter 9 (General discussion).

The next stage of the research will quantify the so identified facilitators/barriers associated for their importance in pharmacists' adoption of newly reclassified medicines into practice. Prior to the quantitative evaluation, a systematic review of literature will be undertaken to facilitate the development of quantitative research instrument.

CHAPTER 4: SYSTEMATIC REVIEW OF LITERATURE

Reporting of this systematic review is based, where appropriate and relevant, on the PRISMA statement 2009 which details the 'Preferred Reporting Items for Systematic Reviews (and Meta-analysis)' [245].

4.1 INTRODUCTION TO THE CHAPTER

The qualitative data aided the identification of key barriers and facilitators associated with pharmacists' decision making around reclassified medicines. Decision making is defined in this research and for the purpose of this Chapter as pharmacists' adoption of reclassified non-prescription medicines into practice; or support for the non-prescription availability of medicines previously available only on prescription. There is a lack of a robust tool to facilitate large scale evaluation of facilitators/barriers to pharmacists' adoption of innovations within this field. Hence there is a need to develop such an instrument for quantitative evaluation. Undertaking a systematic review of literature is essential to inform this development. Such rigorously developed research instrument could potentially serve as a universal tool to undertake research around future reclassification of medicines even out with the scope of this thesis.

4.2 OBJECTIVES

The following were the objectives for the systematic review

- 1. To review and critique the methodologies, methods and models to investigate factors associated with community pharmacists' decision making around reclassified medicines as described in the peer reviewed published literature.
- 2. To list and describe the importance of facilitators/barriers identified from the peer reviewed published literature to community pharmacists' decision making around reclassified medicines.

Achievement of objectives 1 and 2 will aid the design and content development of the quantitative research instrument to be used in Phases III and IV of this research. Results relevant to objective 2 will, in addition, facilitate triangulation of findings from the qualitative interviews and focus groups. Any facilitators/barriers not discussed in the qualitative interviews are also likely to be identified from the literature.

4.3 METHOD

4.3.1 Protocol design

A protocol for the systematic review was prepared and reviewed by an expert panel, including members of the supervisory team and one external advisor, Prof Dennis Tourish, from the Business School at RGU. Standard guidelines and templates recommended by the following institutes were used. Those recommendations explicitly relevant to clinical intervention studies were ignored.

- 1 Centre for Reviews and Dissemination (CRD), University of York, Guidance for Undertaking Reviews in healthcare updated in 2009 [246]*.
- 2 Cochrane Collaboration/Library Guidelines for Undertaking Systematic Reviews published in 2008 [247].

*updated during the review

Any deviation from the systematic review protocol during the review process was recorded following discussion amongst the review team. A copy of the protocol appears in Appendix IV.

4.3.2 Study eligibility criteria

The following inclusion/exclusion criteria were defined

- Any literature providing empirical evidence around factors associated with
 pharmacists' decision making in relation to either: support for reclassified status of
 medicines; pharmacists' perspectives on future reclassification; pharmacists'
 perspectives around temporary provisions allowing them to supply POM medicines
 in over the counter settings other than through reclassification (such as through
 PGDs); factors associated with supply of reclassified medicines.
- Literature around reclassification of medicines around preventative services such as EHC and medicines for long term indications were also included given the lack of literature realised in the general review of literature in Chapter 1 (section 1.8)
- Literature around perspectives of pharmacists based in practice settings other than community, such as those based in hospitals, were excluded. Those studies with participants from diverse settings were only included if the results were distinctly presented for pharmacists from community settings.

- Literature including reviews of literature based only on conceptual models and lacking empirical evidence were excluded.
- Literature explicitly around 'advice giving' was excluded.
- Data collected using patients/ consumers/ members of public as main participants were excluded.
- Language: English only
- Date limit: Initially, the first version of the protocol set 1994 to current as the dates for
 the literature search. However, a scoping search conducted without the date limit
 retrieved relevant literature from the early 1990s. Hence the protocol was amended to
 include literature from 1990 onwards.

4.3.3 Literature sources

The following sources were used to identify relevant literature

4.3.3.1 Databases

Seven databases namely PsychINFO, Ovid MEDLINE (R), CINAHL, EMBASE, International Pharmaceutical Abstracts (IPA), Business Source Premier (BSP) and Cochrane Database of Systematic Review (CDSR) library were searched in addition to the other search tools detailed below. Description of these databases appears in Appendix I and IV.

4.3.3.2 Manual searching of journals

The following core journals related to the pharmacy practice area were searched for relevant titles via the journal websites covering every issue since 1990 (or first date of publication after 1990) up till present date (or date when publication ceased) by browsing individual issues and table of contents.

- International Journal of Pharmacy Practice
- Pharmacy World & Science
- Family Practice
- BMC Family Practice
- Annals of Pharmacotherapy
- Journal of Clinical Pharmacy and Therapeutics
- Journal of Social and Administrative Pharmacy (now published as Research in Social and Administrative pharmacy)
- American Journal of Health Systems Pharmacy
- Journal of Pharmaceutical Marketing and Management (publication ceased 2008)

4.3.3.3 Conference abstracts

Abstracts of the following conferences were searched for relevant titles, either via manual searching of journals or through dedicated conference websites.

- International Social Pharmacy Workshop (Webpage)
- International Pharmaceutical Federation (FIP) congress (Webpage)
- British Pharmaceutical Conference abstracts (as published in IJPP),
- Health Services Research and Pharmacy Practice conference (as published in IJPP)
- European Society of Clinical Pharmacy (Webpage)
- United Kingdom Clinical Pharmacy (as published in PWS).

(IJPP: International Journal of Pharmacy Practice, PWS: Pharmacy World & Science)

4.3.3.4 Other search tools

NHS Scotland 'Community Pharmacy' e-library search fields (now known as NHS Scotland Knowledge Network); and web based databases such as Google and Google Scholar were also used to find relevant literature. Bibliographies of literature used for full text screening were also used to find relevant literature. Grey literature was not searched due to time constraints.

4.3.4 Search strategies

Search strategies applied to the databases are listed in Appendix IV.

User accounts within database hosts were registered with full details of search strategies hence allowing regular updates of new outputs to be notified monthly via email alerts. Web based databases such as Google and Google Scholar as well as the two other databases, the NHS e-library for Scotland Community Pharmacy search field and the CDSR did not offer such sophisticated search strategies and hence the keywords that were used in other databases as detailed in Appendix IV were used in different combinations as exemplified in the systematic review protocol (Appendix IV). 'Full citation details' were imported into 'Refworks' where possible and all cited in this thesis and associated outputs using Write-N-Cite version III software.

Initial screening of titles was carried out to identify potentially relevant papers, followed by screening of abstracts; and by full paper screening against the inclusion/ exclusion criteria. From among the thousands of titles that were retrieved through the search strategy, fifty

titles were independently checked for consistency of inclusion/exclusion by VP and DS to enhance reliability of the process.

4.3.5 Quality assessment of identified studies

Studies were not excluded from the review on the basis of failing any number of items in the quality criteria listed in the quality assessment form. However, such assessment was required to fulfil objective I of the systematic review. Three quality assessment forms were designed, each specific for qualitative; quantitative (including mixed methods); and reviews of literature. These appear in Appendix IV illustrating a completed example. The following sources were used to develop the quality assessment form:

- 1. CRD's Guidance for Undertaking Reviews in Healthcare 2009 [246],
- 2. UK government chief social researcher office publication on frameworks for assessing research evidence [248]; and
- 3. Critical Appraisal Skills Programme (CASP) [249].

Quality assessments were conducted on all included studies independently by two reviewers (VP and DS). The studies were assessed for whether they pass the listed quality criteria and marked either Yes, No, Not applicable; or if unclear, marked so with details. Key items were then converted into an excel matrix detailing the distribution. Any disagreements were discussed and appropriate actions agreed for the next stage of evaluation.

4.3.6 Data extraction

A data extraction form as per the Cochrane guideline [247] was developed with the content developed on the basis of the results of the qualitative interviews and initial scoping of the literature and appears in Appendix IV with an illustrative example.

4.3.7 Strategies to deal with missing data

No strategy to deal with missing data was formulated due to time constraints.

4.3.8 Synthesis of results

From the initial scoping search, outcomes of the research were found to be poorly described in the literature. In addition, the inclusion of both qualitative and quantitative studies in the

systematic review necessitated an approach that would permit the integration of evidence from both these methodologies. Hence narrative syntheses of the results were conducted. As highlighted in Chapter 2, narrative synthesis within a systematic review differs from traditional narrative literature reviews with the former referring to 'a specific approach to that part of a systematic review process concerned with combining the findings of multiple studies' [219]. A dedicated training session of evidence synthesis from diverse methodology was obtained from Cochrane Qualitative Research Methods Group and University of Sheffield (Appendix X, General). Further details of this method are described in Chapter 2.

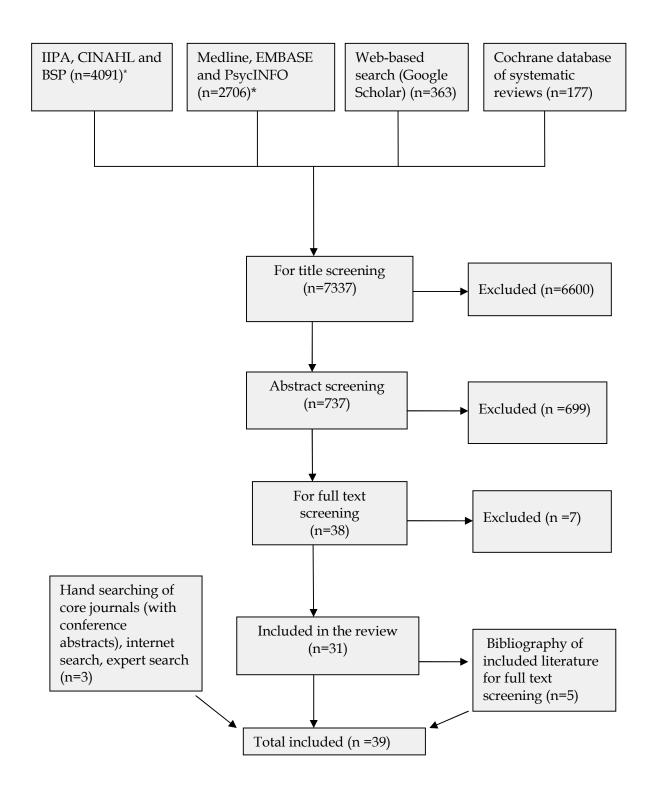
4.4 RESULTS

4.4.1 Study origin

A total of 39 studies were included in the final review. The majority were identified through databases searches with five from the bibliographies of the studies included for full text screening. Manual searching of journal titles, CDSR and NHS e-library Scotland community pharmacy search fields did not produce any additional literature (figure 4.1).

Studies were largely based in the UK (n= 20) followed by USA (n= 8), Australia/ New Zealand (n=9) and one each from Puerto Rico and South Africa (table 4.1). The list of studies which were excluded after full text screening along with justification for exclusion is given in Appendix IV.

Figure 4.1: Flowchart of processes leading to inclusion and exclusion of identified literature for systematic review.



^{*}after removal of duplicates; n= number of titles/literature

4.4.2 Description of included studies

4.4.2.1 Methodology and method

Thirty-seven empirical studies and two literature reviews were included. The majority of the studies employed a quantitative methodology using cross-sectional surveys as data collection tools (n=29). Eight studies used qualitative approaches including semi-structured interviews (n=2), in-depth interviews (n=4), focus groups (n=1) and case studies (n=1) (table 4.5).

4.4.2.2 Study population

Eighteen cross sectional surveys used random samples of community pharmacists (table 4.1). Three studies used the entire population of community pharmacists from the geographical area of interest (table 4.1). Only the most innovative pharmacists were invited to participate in two surveys, for example, those attending education programmes or conferences [250,251]. Unclear descriptions of sampling were given in three studies [252-254]. All but four quantitative studies reported a response rate above 50% whereas response rate could not be estimated in four studies [250,251,253,255]; either due to: lack of information around how many pharmacists were approached or overtly complex recruitment process.

In terms of the qualitative studies, one used purposive samples of community pharmacists, selected based on demographic characteristics [256]. Three invited only those pharmacists participating in non-prescription provision of EHCs [257-259]. Two qualitative studies were part of a larger evaluation around privacy of consultations in community pharmacy [260,261]. One study used a snowballing technique from initial samples that were identified through an advertisement in a pharmacy newsletter [228]. One qualitative study invited only those pharmacists shortlisted from those who applied for training around EHC of which only those with prior health promotion training and reflecting 'enthusiasm' were selected [262].

4.4.2.3 Therapeutic area

Of the 39 studies, all but five [251,263-266] made particular reference to at least one therapeutic area in their study. Of these, 13 had sole focus on pharmacists' perspectives of non-prescription supply of EHC followed by five studies around non-prescription supply of statins (table 4.1).

Table 4.1: Authors, aims and objectives, study method, setting and key findings of included studies arranged in chronological order (Note: this table extends up to eight pages)

A. Quantitative studies

Study	Stated aims/objectives	Study design (delivery*)	Setting(s) †, number of respondents (response rate)†	Key findings
Madhavan and Scondelmeyer 1990 [267]	Assess pharmacists' attitudes towards reclassification of prescription medicines to non-prescription status.	Cross sectional survey (mailed)	Random sample of nationwide US pharmacists 270 pharmacists (35.9%)	Majority of pharmacists were undecided or disagreed with the proposed switch of promethazine, terfenadine and naproxen.
Emmerton and Benrimoj 1991 [264]	Analysis of influences on pharmacists' non-prescription medicines stocking and recommendations.	Cross sectional survey (hand delivered)	Randomly selected Brisbane pharmacists, Australia 57 pharmacists (97.0%)	Successful use of the medicines by patients, feedback from patients were among key influences on recommendations.
Igboko and Thomas 1991 [266]	Determine attributes that community pharmacists consider important when making non-prescription medicines supply decisions.	Cross sectional survey (mailed)	Stratified (based on State) random sample independent community pharmacies selected from eight US states. 634 pharmacists (45.2%)	23 attributes identified as 'determinants' which included factors such as financial benefits, patient acceptance of medicines and safety reputation of manufacturer.
Bond et al 1993 [268]	Community pharmacists' attitudes to their advice-giving role and to the deregulation of medicines.	Cross sectional survey (mailed)	Random sample of community pharmacies from Scotland 204 pharmacists (90%)	Top therapeutic groups for proposed reclassification suggested by pharmacists included eye, skin preparations and infections.
Madhavan 1993 [263]	To identify US pharmacists' preferences around US legal classification of non-prescription medicines and identify factors associated with preferences.	Cross sectional survey (mailed)	Random sample of US pharmacists* 270 pharmacists (34.8%)	Limiting non-prescription medicines sales to pharmacy only was the most preferred for non-prescription medicines sale. Least preferred was general sale.

^{*} of questionnaire where identified; †information presented where identified

Study	Stated aims/objectives	Study design (delivery)	Setting(s), number of respondents (response rate)	Key findings
Emmerton and Benrimoj 1994 [269]	To identify and quantify influences on pharmacists' preferences for non-prescription cough suppressants.	Cross sectional survey (mailed)	Random community pharmacies from across Australia 261 pharmacists (66.8%)	Financial (e.g. profits, deals), social (e.g. influence by colleagues) and clinical (e.g. side effects) appeared to have influences on preference for one medicine over another.
Emmerton et al 1994 [270]	To identify the underlying factors associated with choices around cough and cold medicines supplies by pharmacists.	Cross sectional survey (mailed)	Random sample of community pharmacies from Australia 777 pharmacists (66.0%)	Seven factors were extracted such as non- scientific influences (e.g. preference for newer medicines), social influences (e.g. of colleagues).
Roins et al 1994 [271]	To determine and analyse the factors that influence community pharmacists' choices when recommending non-prescription analgesics for a simple headache.	Cross sectional survey	Random sample of Australian community pharmacies 80 pharmacists (100%)	Four factors were found to influence choices such as advertising influences, medicine characteristics and economic influences.
Erwin et al 1996 [272]	Examine the views of community pharmacists in England towards the non-prescription availability of specific medicines.	Cross sectional survey	Random pharmacies from eight Family Health Services Authorities (FHSAs) in England 272 pharmacists (54.4%)	Majority of the pharmacists agreed to 10 of the 14 drugs listed such as anti-fungal vaginal pessaries to be available without prescription.
McCafferty et al 1996 [273]	To investigate pharmacists' attitudes on the non-prescription supply of H2 receptor antagonists and to examine factors affecting supply (or non-supply) decisions of non-prescription H2-antagnosists.	Cross sectional survey (mailed)	Pharmacists in charge of each of the 189 community pharmacies in Avon, UK 140 pharmacists (74.1%)	Majority agreed with non-prescription availability of H2 receptor antagonists. Medicine efficacy and safety were the most important criteria for decision making.

Study	Stated aims/objectives	Study design (delivery)	Setting(s), number of respondents (response rate)	Key findings
Powis et al 1996 [229]	Determine community pharmacists' views on ongoing reclassification of medicines and recently reclassified medicines	Cross sectional survey	All registered pharmacies of two English counties of Cornwall and Somerset, UK 68 pharmacists (84.0%).	Majority agreed that ongoing reclassification had enabled them to adopt a more clinical role and approved of reclassification of medicines such as acyclovir cream.
Roins et al 1998 [274]	Determine the factors considered by community pharmacists in recommending non-prescription analgesics for three headache scenarios.	Cross sectional survey (mailed)	Stratified (State based) random sample from across Australia. 1025 pharmacists (68.3%)	Clinical factors and financial influences were key to pharmacists' medicine choices.
Roins et al 1999a [275]	Determine the influences on pharmacists' choice of non-prescription analgesics for three types of headache.	Cross sectional survey (mailed)	Stratified (State based) random sample from across Australia. 1025 pharmacists (68.3%)	Pharmacists' brand recommendations were significantly influenced by external factors such as patient choices and demographic characteristics such as pharmacists' qualification and experience
Roins et al 1999b [276]	Understanding pharmacists' decision making processes when recommending non-prescription analgesics for three headache scenarios.	Cross sectional survey (mailed)	Stratified (State based) random sample from across Australia. 1025 pharmacists (68.3%)	Models which assume that- after evaluating a patient, pharmacists choose the non-prescription analgesic brand rather than the active ingredients were more relevant to pharmacists' decision making.
Kennedy and Moody (2000) [277]	Identify influences on pharmacists' choices of non-prescription medicines for a variety of conditions.	Cross sectional survey (mailed)	Stratified random sample of community pharmacists from Great Britain 635 pharmacists (56.7%)	Factors such as evidence base, safety, formulation, price to patient were identified by majority of participants as key influences on recommendations.

Study	Stated aims/objectives	Study design (delivery)	Setting(s), number of respondents (response rate)	Key findings
Hariprasad 2001 [278]	Assess the attitudes and practices of community pharmacists towards non-prescription availability of EHCs.	Cross sectional survey (hand delivered)	All pharmacies from North and Southern Central Durban, South Africa	Majority of respondents indicated that EHCs should be available without a prescription.
Wearn et al 2001 [252]	To identify the attitudes, hopes and concerns of community pharmacists in Great Britain about the proposed deregulation of EHC.	Cross sectional survey (mailed)	112 pharmacists (68.0%) Great Britain community pharmacists sampling 1,205 pharamcists (66.0%)	Majority were in favour of supply of EHC on a non-prescription basis
Kotecki 2002 [279]	Analysis of influences on pharmacists' non-prescription medicine recommendations.	Cross sectional survey (mailed)	Random Indiana pharmacies from US 430 pharmacists (73.1%)	Factors such as ease of self use of medicines by patients and medicine efficacy were key influences on recommendation.
Blenkinsopp et al 2004 [280]	To investigate and appraise the changes required in practice of community pharmacists to enable them to supply simvastatin 10mg over the counter appropriately.	Cross sectional survey	200 randomly selected pharmacists in the Leeds/Bradford area, UK	Majority agreement could not be reached around proposed reclassification of simvastatin. Facilitators such as training, supply protocol, and patient medical records were deemed prerequisite for supply.
McKenney et al 2004 [253]	To determine attitudes and perceptions of pharmacists regarding the impact of non-prescription statins.	Cross sectional survey (online)	Drawn from a database of 2,552 licensed pharmacists 273 pharmacists in the US.	Majority agreed to reclassification of statins to be available over the counter
Inch et al 2005 [281]	To identify Scottish community pharmacists' involvement with, and attitudes to EHC provision.	Cross sectional survey (mailed)	All pharmacists working in community pharmacy in Scotland 914 pharmacists (56.4%)	High adoption of EHCs reported by pharmacists with an average of 132 patients per pharmacy per year.

Study	Stated aims/objectives	Study design (delivery)	Setting(s), number of respondents (response rate)	Key findings
Van Riper and Hellerstedt 2005 [255]	Identify dispensing practices, knowledge and attitudes of South Dakota Pharmacists regarding EHC.	Cross sectional survey (mailed)	All pharmacists from South Dakota, US 293 pharmacists	Majority of respondents opposed to non- prescription status of EHCs.
Howell and Brown 2006* [254]	Report attitudes and experiences of practising community pharmacists about non-prescription simvastatin 10 mg.	Cross sectional survey (mailed)	Portsmouth and Southeast Hampshire, UK 64 pharmacists (20.3%)	Majority did not support the non-prescription availability of simvastatin.
Fuentes and Azize-Vargas 2007 [250]	Identify knowledge, attitudes and practices of a group of pharmacists regarding EHC (after its approval by FDA)	Cross sectional survey (hand delivered)	Pharmacists attending a national convention, Puerto Rico 158 pharmacists	Majority agreed to non-prescription availability of EHCs.
Hansford et al 2007 [282]	Describe community pharmacists' views, attitudes and early experiences of non-prescription simvastatin.	Cross sectional survey (mailed)	Random sample of community pharmacists from Great Britain 1156 pharmacists (57.8%)	Majority respondents agreed that they were entirely confident about selling simvastatin, however low reported supplies by respondents.
Stewart et al 2007 [283]	Describe and compare the personal views of community pharmacists on non-prescription omeprazole and simvastatin.	Cross sectional survey (mailed)	Random sample of community pharmacists from Great Britain 1156 pharmacists (57.8%)	Support for non-prescription availability of simvastatin by respondents lower as compared to omeprazole owing to reasons such as evidence base.
McCaig et al 2008 [122]	Examine early experiences of community pharmacists in relation to sales of omeprazole without prescription.	Cross sectional survey (mailed)	Random sample of community pharmacists from Great Britain 1156 pharmacists (57.8%)	Majority agreed that omeprazole was a welcome addition to the range of pharmacy medicines but had not sold any non-prescription omeprazole in the last 14 days.

^{*}Conference abstract/proceeding

Study	Stated aims/objectives	Study design (delivery)	Setting(s), number of respondents (response rate)	Key findings
Prince and Pharoo 2008 [251]	Assess the attitudes of Alabama pharmacists regarding the creation of a third class of drugs described as "pharmacist- prescribed".	Cross sectional survey (mailed)	Alabama pharmacists attending a continuing education (CE) programmes, US 157 pharmacists	Majority respondents agreed to a need of medicine class equivalent to P class in the UK.
Whitley and Moorman 2008 [284]	Determine pharmacists' opinions about the labelling change of EHC.	Cross sectional survey (online)	Community pharmacists in Alabama, US 47 pharmacists (15.3%)	Majority disagreed with the reclassification of EHC to non-prescription status.

B. Qualitative studies

Study	Stated aims/objectives	Study	Setting(s), number of	Key findings
		design	participants	
Harper and Barrett 1998 [260]	Examine attitudes of community pharmacists towards the possible deregulation of EHCs from pharmacies.	In depth interviews	Pharmacists from three health authorities of South Thames Region	Pharmacist views were 'overwhelmingly negative', largely attributed to moral and religious grounds.
			18 pharmacists, UK	

Study	Stated aims/objectives	Study design	Setting(s), number of participants	Key findings
Barrett and Harper 2000 [261]	Examine the views of community pharmacists towards possible deregulation of EHC.	In-depth interviews	Pharmacists working in three health authorities in the South Thames Region, UK 18 pharmacists	Pharmacists had overwhelmingly negative attitudes to non-prescription availability mainly owing to safety and misuse aspects.
Seston et al 2001 [259]	Explore the views of community towards the reclassification of EHCs from POM to P medicine.	Focus groups	Pharmacists from Health Action Zones in North West of England, UK 14 pharmacists	Concerns owing to patient misuse and litigation issues were expressed by pharmacists around non-prescription supplies of EHCs
Bacon et al 2003 [262]	Evaluate the role of facilitators and barriers to non-prescription supply of EHC from community pharmacists' perspectives.	Case studies	Pharmacies from Lambeth, Southwark and Lewisham Health Action Zone ,UK 22 pharmacists	Pharmacists were worried about potential misuse of non-prescription EHCs. Training around supply was identified as a key facilitator to service provision.
Bissell and Anderson 2003 [257]	Evaluate a scheme to provide free EHC under non-prescription basis via community pharmacies in the North-West of England.	In-depth interviews	Pharmacists participating in the scheme at three Health Action Zone, UK. 24 pharmacists	Almost all of the pharmacists that participated in the interviews expressed positive views about the scheme.
Bissell et al 2006 [258]	Describe pharmacists' views and experiences of supplying EHC via PGDs.	In depth interviews	Those pharmacists that participated in the EHC scheme from Manchester and London UK 46 pharmacists	All but one pharmacist had positive views about non-prescription EHC supply.
Gauld et al 2008* [256]	Investigate pharmacists' experiences of the non-prescription availability of oseltamivir	Semi- structured interviews	Purposive sample (based on demographics) of community pharmacists from New Zealand. 27 pharmacists	Pharmacists expressed positive views towards non-prescription availability of oseltamivir. 14 pharmacists had made the supplies in 2007.

^{*}Conference abstract/proceeding

Study	Stated aims/objectives	Study design	Setting(s), number of participants	Key findings				
Hannah and Hughes 2008* [228]	Explore factors influencing pharmacists' decision making in relation to non-prescription medicines, and whether an evidence base approach are used in such decisions.	Semi- structured interviews	26 pharmacists Northern Ireland, UK	Safety described as the 'over-riding' factor influencing all decisions. Supplies were mostly based on patient request and on a 'do no harm' basis.				
*Conference abstract/proceeding								

C. Reviews of literature

Study	Stated aims/objectives	Study design	Inclusion/exclusion criteria	Key findings
Emmerton and Benrimoj 1994 [265]	Review the methods used in the investigation of medicine choice behaviour by community pharmacists.	Review of peer and non-peer reviewed literature	Studies explaining measured behaviours and attitudes. Literature based on predictive models excluded.	Methods such as case studies, observational studies and surveys were identified to have been used by identified literature. Authors proposed application of the Fishbein behavioural intention model to assess underlying influences on preference for future studies.
Anderson and Blenkinshopp 2005 [285]	To review international peer- reviewed evidence relating to community pharmacy supply of EHC	Systematic review	Peer-reviewed international research from Jan 1990 to Jan 2005 24 studies included	Patient misuse and safety concerns key perceived barriers for pharmacists to supply non-prescription EHCs.

4.4.1 Quality of included studies

4.4.1.1 Quantitative

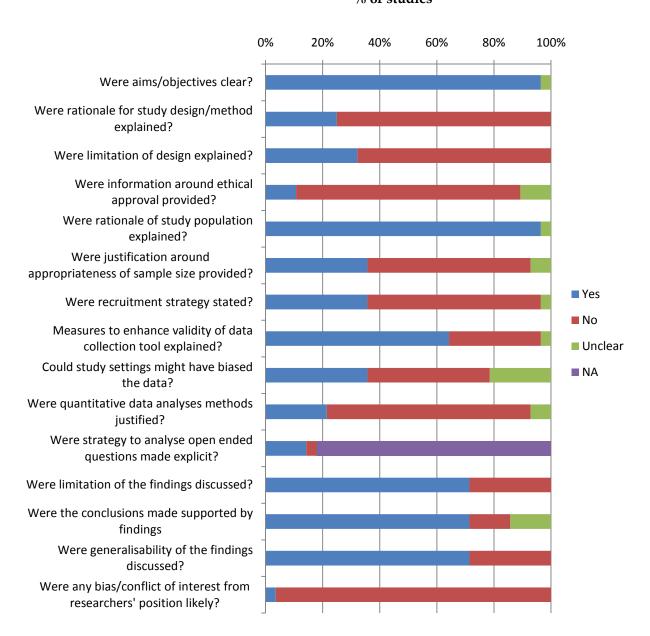
Of the 28 quantitative studies (excluding one conference proceeding/abstracts), all but one presented clear aims or objectives (table 4.2, figure 4.2). Only seven, however, explained the rationale for selecting cross sectional survey approaches (table 4.2). Information about ethical advice was missing from all but three studies which explained that ethical advices were sought from relevant authorities (table 4.2). Three other studies made ambiguous statements about ethical advice, for example, by stating 'the institutional review board at the University approved the study protocol' [255]. Rationale for the inclusion criteria of the study population could be identified from all but one study, however; only around 35% of the quantitative studies provided any sort of justification for the sample size (figure 4.2). Over 60% of the studies failed to provide details of recruitment strategies, for example how potential participants from within a pharmacy were identified or invited to participate [229]. No elements of study validity or the development of the data collection tool such as piloting were presented in one in three studies. Only approximately one in five of the studies justified the use of a particular analytical method. Missing values were often found to be replaced with sample means without justifying the merit of such a technique in terms of likely bias [265,270]. Over 28% of the quantitative studies reported conclusions that were not supported by the reported findings (table 4.2).

Table 4.2: Quality assessment of quantitative studies

Quality assessment criteria	and	Emmerton and Benrimoj 1991	Igboko and Thomas 1991	al 1	Madhavan 1993	Emmerton and Benrimoj 1994	Emmerton et al 1994	19	Erwin et al 1996	McLafferty et al 1996	19	Roins et al 1998	Roins et al 1999a	Roins et al 1999b	Kennedy and Moody 2000	Hariprasad 2001	Wearn et al 2001	2002	p et	, et	et al 2005	er and Hellerstedt	Fuentes and Azize-Vargas 2007	5	; et al 2008	Prince and Pharoo 2008	Whitley and Moorman 2008
Were aims/objectives clear?	Y	Y	Y	U	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Υ	()	Y Y	ΥY	Y	Y	ſΥ	!
Were rationale for study design/method explained?	N	N	Y	N	N	N	Y	N	N	N	N	N	Y	Y	Y	N	N	N	N	N	()	Y	N N	J N	N I	1 N	1
Were limitations of study designs explained?	N	N	Y	N	N	Y	Y	N	N	N	N	N	N	Y	Y	N	N	Y	N	N	(l	N Y	Y N	JN	N Y	ľ	1
Were information around ethical approval provided?	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N I	I I	JĮ	JΥ	Y	Y	JV	J
Were rationale of study population explained?	U	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Υ	()	Y Y	ΥY	Y	Y	ľΥ	(
Were justification around appropriateness of sample size provided?	N	Y	N	N	Y	U	Y	Y	U	N	N	N	N	Y	Y	Y	N	N	N	N	()	Y	N N	JN	N Y	ľ	1
Were participant recruitment strategies stated?	N	N	N	N	N	Y	U	N	Y	Y	Y	N	N	N	N	N	N	N	N	N	()	Y	N Y	Y	Y	V Y	(
Were measures to enhance validity of data collection tool explained?	Y	Y	Y	N	N	Y	Y	N	Y	N	Y	Y	Y	Y	Y	N	U	Y	Y	N	()	Y	N Y	Y	Y	I I	1
Could study settings might have biased the data?	N	Y	N	N	N	U	U	N	N	U	Y	U	U	N	N	Y	U	Y	Y	Y	1	Y Y	Y	JN	N Y	ľΥ	(
Were quantitative data analyses method justified?	N	Y	U	N	Y	N	Y	N	N	N	N	N	Y	Y	N	N	N	N	N	N '	<i>(</i>]	N I	J V	JN	ΝÌ	1 1	1
Were strategy to analyse open ended questions made explicit?	NA	NA	NA	NA	NA	NA	NA	NA	N	NA	NA	NA	NA	NA	NA	NA	Y	NA	N	NA I	JA I	NA N	νА	Y	Y	JA N	JΑ
Were limitations of the findings discussed?	N	N	Y	N	N	Y	Y	Y	Y	Y	N	N	Y	Y	Y	Y	Y	Y	N	N	()	Y Y	ΥY	Y	Y	íΣ	(
Were the conclusions made supported by findings	Y	Y	U	N	Y	Y	Y	N	Y	U	Y	U	N	N	Y	U	Y	N	Y	Y	()	Y ?	ΥY	Y	ΥY	ľΣ	(
Were generalisability of the findings discussed?	Y	N	Y	Y	N	Y	Y	Y	Y	Y	N	N	Y	N	Y	Y	N	Y	N	N '	()	Y Y	ΥY	Y	ΥY	ľΥ	(
Were any bias/conflict of interest from researchers' position likely?	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	Y	N I	I I	N I	N N	J N	N	1 N	1

Y:Yes; N: No; U:Unclear; NA: Not Applicable

Figure 4.2: Stacked bar chart representing quality of quantitative studies % of studies



4.4.1.2 Quality of qualitative studies

Of the six qualitative studies (excluding two abstracts/conference proceedings), all but one were explicit in their aims or objectives. Five of the six did not explain whether ethical approval was sought whereas one made an ambiguous statement (table 4.3, figure 4.3). All studies provided the rationale of the study population but only two provided justification around the number of study participants [258,262]. Only one study was explicit in commenting on the aspects of validity of the data collection tool, such as the use of literature to develop the content [258]. Due to the selection of only those pharmacists that were already involved in the supply of medicine under evaluation, study settings were Chapter 4: Systematic review of literature

expected to have potentially biased respondents and corresponding data in four of the six studies. A majority of the qualitative studies utilised more than one independent coder during data analysis (table 4.3, figure 4.3).

4.4.1.3 Quality of reviews of literature

The quality of one of the reviews was disappointingly poor, achieving the standard for only two of the sixteen quality criteria that were assessed [265]. Despite achieving the majority of quality criteria, the other review lacked information about literature search strategy and data synthesis methods [285] (table 4.4).

4.4.1.4 Quality of abstracts/ conference proceedings

Two of the three abstracts of conference proceedings failed to describe the study population and none tackled issues of sample size and data saturation (table 4.5). Only one detailed study piloting [254].

Table 4.3: Quality assessment of qualitative studies

Quality assesment criteria	Harper and Barrett 1998	Barrett and Harper 2000	Seston et al 2001	Bacon et al 2003	Bissell and Anderson 2003	Bissell et al 2006
Were aims/objectives clear?	Y	Y	Y	Y	N	Y
Were rationale for study design/method explained?	N	N	N	N	Y	Y
Were limitation of design explained?	N	N	N	N	Y	N
Were information around ethical approval provided?	N	N	N	N	U	N
Were rationale of study population justified?	Y	Y	Y	Y	Y	Y
Were justification around appropriateness of sample size/data saturation provided?	N	N	N	Y	N	Y
Were recruitment strategy stated?	N	N	N	Y	N	Y
Were measures to enhance validity of data collection tool explained?	N	N	N	N	N	Y
Could study settings might have biased the data?	U	U	Y	Y	Y	Y
Were independent coder of the data used?	Y	Y	U	Y	Y	Y
Were data analyses methods justified?	Y	N	N	Y	N	N
Were bias arising from analyst position explained?	N	N	N	N	Y	N
Were limitation of findings discussed?	Y	Y	Y	N	Y	Y
Were conclusion/s made relevant to findings?	Y	N	Y	Y	Y	Y
Were theoretical generalisability of the findings discussed?	Y	Y	Y	Y	Y	Y
Were any bias/conflict of interest from researchers' position likely?	N	N	N	N	N	N

Y:Yes; N: No; U:Unclear

Figure 4.3: Stacked bar chart representing quality of qualitative studies % of studies

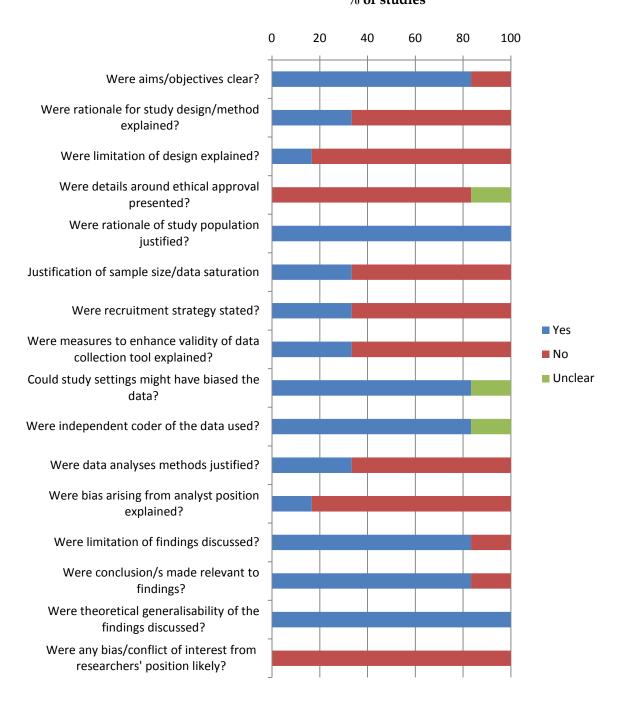


Table 4.4: Quality assessment of reviews of literature

Quality assessment criteria	Emmerton and Benrimoj 1994	Anderson and Blenkinsopp 2005
Were aims/objectives clear?	Y	Y
Were inclusion/exclusion of literature mentioned?	U	Y
Were literature search databases explained?	N	Y
Were literature search strategy detailed?	N	N
Were hand searching of core journals used?	N	Y
Were personal contacts with experts made?	N	N
Were unpublished literature searched?	U	N
Were non-English literature searched?	U	Y
Were quality assesment criteria detailed?	N	Y
Were more than one assesor of the quality of study?	U	Y
Were data synthesis/management method justified?	N	N
Were strenth of the review explained?	N	N
Were limitation of the review explained?	N	N
Were the conclusions made supported by findings	N	Y
Were generalisability of the findings discussed?	N	N
Were any bias/conflict of interest from researchers' position likely?	N	N

Y:Yes; N: No; U:Unclear

Table 4.5: Quality assessment of abstracts/proceedings of conferences

Quality assessment criteria	Howell and Brown 2006	Gauld 2008	Hannah and Hughes 2008
Were aims/objectives stated?	U	Y	Y
Were ethical advice sought?	N	Y	Y
Were study population described?	Y	N	N
Were justification of sample size/data saturation provided?	N	N	N
Were recruitment strategy stated?	N	N	Y
Were measures to enhance validity of data collection tool explained?	Y	N	N
Could study settings might have biased the data?	U	U	U
Were data analysis method clearly presented?	N	Y	Y
Were conclusion/s made relevant to findings?	Y	N	Y
Were generalisability of the findings discussed?	N	N	N
Were any bias/conflict of interest from researchers' position likely?	N	U	N

Y:Yes; N: No; U:Unclear

4.4.2 Review of study framework and models used to investigate pharmacists' decision making around reclassified medicines

This section will review and critique the models and framework used by empirical studies. Greater emphasis will be placed on the review of quantitative models as these are supposed to inform the development of the quantitative research instrument.

4.4.2.1 Descriptive and univariate quantitative models

Five cross sectional surveys investigated pharmacists' support for the non-prescription status of newly reclassified medicines using descriptive and univariate statistics [122,252,273,282,283]. Pharmacists' agreement to reclassification of potential candidate medicines were assessed by two studies in the UK [268,272] and two studies in the US [253,279] also using descriptive statistics based on attitudinal scales. However these four studies did not further explore reasons why certain medicines were more likely to be accepted as reclassified medicines by pharmacists than others. One study in South Africa [278] and three studies in the US [250,255,284] evaluated pharmacists' support for the non-prescription availability of EHC, using similar analytical models.

Two studies in the US investigated pharmacists' attitudes to creating a regulatory class equivalent 'P' medicines in the UK [251,263]. Only one of these studies performed univariate analysis to investigate how demographic variables were associated with support or refutation of such regulatory changes relating to reclassified medicines [263].

Factors associated with recommendations of reclassified medicines were investigated by requesting pharmacists to rate the importance of the listed items and analysed descriptively by four studies [229,273,277,279]. Two used parametric analysis where a non-parametric analytical method could be debated to have been more appropriate in analysing the Likert type scales measuring the importance of the listed items in decision making [277,279].

4.4.2.2 Multivariate quantitative models

Pharmacists' support for the reclassification of medicines to non-prescription status was investigated by using three medicines namely: promethazine, terfenadine and naproxen, which were evaluated using a multivariate design in one study [267]. Items on a scale representing the likely factors associated with support for the proposed reclassification were subjected to principal component analysis. Factor scores indicating acceptable reliability were then subjected to a step-wise discriminant analysis in order to distinguish between respondents with higher approval scores. Interpretation and labelling of the factors retained from the principal component analysis were least convincing as items measuring diverse areas of practice were labelled together as a single factor.

In investigating factors associated with pharmacists' choices of non-prescription analgesics for simple headache in a survey of Australian community pharmacists [271], pharmacists' agreement to the listed items scale statements were measured and the results subjected to principal component analysis. Pharmacists' mean agreement scores of the items, rather than median scores, constituted within each factors were reviewed for association with demographic characteristics, using univariate techniques. Similar analytical limitations were also identified in three other studies using similar multivariate approaches [264,269,274].

The Myert and Alpert determinance model was used to evaluate pharmacists' adoption of particular medicines within a given therapeutic area [266]. 'Determinance scores' were calculated by multiplying respondent score around the agreement on the importance of

each of the listed items for medicine adoption decisions, to how far pharmacists perceived those features to be different across the listed medicines [266]. Again limitations around parametric- non parametric analyses were observed.

The technique of discrete choice modelling was used in one study [275]. Likert type scale items were presented to pharmacists to measure the importance of each in medicines choice decisions and subjected to principal component analysis. Factor scores along with demographic variables were used as explanatory variables in the Logit model where choice was used as the outcome. Similar regression models were also adopted by two other studies around pharmacists' adoption of reclassified EHC [255,281].

In investigating adoption of reclassified medicines into practice, only three studies required pharmacists to rate the number of packs of medicines supplied in a retrospective time frame and hence subject to recall bias [122,254,282]. However, key differences between high and low adopters were not further explored in these studies.

4.4.2.3 Qualitative models

Six studies reported qualitative investigation around pharmacists' agreement to non-prescription provision of EHC [257-262]. Qualitative data obtained from open questions from a quantitative survey in one study were used to compare pharmacists' support for two reclassified medicines [283].

One qualitative study by Hannah and Hughes also investigated via in depth interviews community pharmacists' key influences when making decisions about supplying reclassified cough and cold medicines [228]. Another qualitative study reported issues around supply of reclassified oseltamivir [256]. These papers lacked details around data analytical approaches.

4.4.3 Review and critique of facilitators/barriers to pharmacists' decision making around reclassified medicines

This section of the systematic review will list the facilitators/barriers to pharmacists' decision making around reclassified medicines. These facilitators and barriers will be described individually so that original, additional perspectives could be added to those identified from the qualitative interviews and focus groups (Chapter 3). Shortcomings

around quality issues within the included studies means that the results presented here need to be interpreted with caution.

A total of 28 facilitators/barriers to pharmacists' decision making were identified from the included studies. From all studies, details around each of these facilitators/barriers were brought together to draw narratives. These are listed in table 4.6 and further described in the sections that follow.

Table 4.6: Barriers and facilitators to pharmacists' decision making around reclassified medicines

- Evidence of medicine efficacy [229,266,269-271,273,274,277,279,282,283]
- Medicine safety [122,228,229,252-255,257,259-261,263,266,267,269-274,277,278,283-285]
- Opportunity for pharmacists' role development
 [229,252,254,257,258,268,280,282]
- Pharmacists' confidence/ competence in supply process [122,254-256,259,282]
- Pharmacists' perceived risk assessment need
 [252-254,260,262,267,273,277,282,283]
- Pharmacists' information sources and training [122,229,250,252,255-257,259,260,262,264,266, 269, 270,272,273,277,279,280,282,285]
- Need for access to patient medical records [122,252,253,260,261,280,282-284]
- Support/ communication with medical practitioners [258,260,280]
- Adoption by medical practitioners [266,269-271,274,277,279]
- Financial benefits [266,269-271,274,275,277]
- Retail prices [122,229,252,254,256,257,264,266, 273,279,283]
- Colleagues' opinions [264,269-271,273,274]
- Consumer advertisement [274,275]
- Employer policies/organisational implementation decisions [270]

- Pharmacy resources e.g. space staff [251,252,260,280]
- Patient acceptance/feedback to pharmacists about the medicine [228, 256,260,264,266,271,274,275,277,279,2
 83]
- Confidence in off-licence medicine supply [273,283]
- Delegation of task to support staff [122,282,283]
- Medicine novelty [122,270,274,279]
- Status as 'pharmacy only' [269,270,274,277]
- Manufacturers' reputation [264,266,270,271,274]
- Pharmacists' experiences with the medicines [256,270,271,273,277,279]
- Endorsement by professional/ practice body [266,269,270]
- Medicines for acute indications
 [268,273,283]
- Guidelines/Protocols [122, 260,261,280]
- Moral/ethical issues
 [252,257,258,260,261]
- Pharmacists' beliefs in successful self use of medicine by patients [269,270,272,274,277,279]
- Medicine potential for misuse [252,255,257-262,277,278]

4.4.3.1 Evidence of medicine efficacy

Pharmacists' perceived strength of medicine efficacy was reported to be the 'most important' influence on their recommendations of POM to P switched medicines in nine studies. Results were presented using descriptive statistics [229,273,277,279], multivariate analysis [269-271,274], or through 'determinant' attributes analysis [266]. Concerns were expressed in two studies around the evidence of reclassified simvastatin hence making this a barrier to supply [282,283].

Three studies reported pharmacists regarding there was no place for consideration of evidence base in decision making in two quantitative [253,264] and one qualitative [228] study. One showed that lack of knowledge about evidence base did not deter pharmacists from supply decisions [254]. A substantial number of studies measuring pharmacists' views

on recent or proposed reclassification did not assess the strength of evidence base relating to medicine efficacy. Many studies realized the issues through the analysis of responses to open-ended questions [122,282,283] or were never realised [251,252,256,257,259,260,263,267,272].

Two studies asked for explanations on what community pharmacists considered as evidence base. Pharmacists in one reflected that feedback from patients was an indicator of evidence of efficacy [228]. Reference to 'clinical trials' were made in study by Stewart et al [283].

4.4.3.2 Medicine safety

Concerns around aspects of safety such as the potential for drug interactions and adverse events were also raised around supply of a number of reclassified medicines. This was the case with reclassified H2 antagonists [122,272,273], statins [253,283], EHC [252,255,257,259,261,278,284,285] and generally to be the case against the reclassification of more medicines to non-prescription status [263,267].

Pharmacists' low support for the reclassified status of statins was related to safety concerns in one study [254]. Hannah and Hughes reported safety as the 'over-riding' factor in pharmacists' recommendations of non-prescription cough medicines and this was the only reasons why a sale was as cited as ever being refused [228]. The key importance of safety as an over arching factor was also supported by seven other studies [229,266,269-271,274,277].

Contrary to the above, one study found that the issue of medicine safety had no influence on supply decisions [264]. Six studies identified that safety concerns pharmacists were raising around particular reclassified medicines' supply decisions could not be substantiated through scientific evidence [255,257,259,260,278,285]. Safety concerns were deemed by pharmacists to be minimised through limiting patient choice around service usage to one pharmacy in one quantitative [280] and two qualitative studies [260,261].

4.4.3.3 Opportunity for role development

Reclassification was associated in four studies with pharmacists' perceived opportunities for role development [229,254,268,280]. One study showed that although a few pharmacists disagreed with the non-prescription status of simvastatin, the reclassification was still deemed an opportunity to increase their role through advice giving related to patient life

style matters for cholesterol lowering [282]. Greater clinical responsibility was shown to be reflective of the extension of pharmacists' role in three studies [252,257,258] with specific reference made to risk assessment prior to supply in one study [257].

4.4.3.4 Pharmacists' confidence/ competence in supply matters

Higher confidence of pharmacists was reported to be associated with the sale of reclassified oseltamivir in one study [256]. Higher confidence was further linked to pharmacists' experiences of supply, despite the study being conducted immediately post reclassification [256]. A few studies assessed pharmacists' perceived confidence [122,282] and competence around medicine supply decisions [254,255,259] but did not report whether higher confidence and competence were associated with supply decisions.

4.4.3.5 Risk assessment and counselling need

Patient risk assessment and counselling need prior to supply were often regarded as barriers to reclassified medicines supply, mainly associated with time and resource implications [253,262,277] or to lack of patient willingness to undergo the process [252,260,273]. Higher counselling needs related to less support for reclassification in one study [267]. Pharmacists were found to perceive the need for risk assessment prior to the supply even though such requirements were not stated in the regulatory guidelines [254,283]. Pharmacists in a further two studies expressed confidence in undertaking risk assessments [253,282].

4.4.3.6 Pharmacists' sources of information and training

Key information sources used by pharmacists in informing the supply of reclassified medicines were pharmaceutical industry [122,229,282], journal articles [122,250,255,277,282], pharmaceutical publications [229], pharmacists' professional society guidelines [122,282], CPD meetings [122,282], internet [122,255,282], employer sources [229,282] and pharmaceutical conferences [250]. One study reported demographic variation in the way pharmacists rated the adequacy of sources of information around reclassified medicines [229].

Five studies reported that adequacy of information sources was related to which medicine pharmacists would recommend first line for a given therapeutic condition [264,266,269,270,279].

Training

Training programmes boosting pharmacists' confidence in non-prescription medicines supplywere reported by three studies [256,257,285]. Pharmacists in one UK study identified the Centre for Pharmacy Postgraduate Education, RPSGB and the National Pharmaceutical Association (NPA) as the most preferred training sources [280]. Pharmacists' satisfaction with training around adoption of newly reclassified medicines was reported to be high in three UK studies [122,272,282] and one NZ study [256]; whereas additional training needs were identified in five UK studies [252,259,260,262,280]. Two studies reported that pharmacists within a large multiple chain pharmacy were more likely to have diverse training opportunities than those working under other pharmacy proprietary setting [229,273].

4.4.3.7 Need for access to patient medical records

Lack of access to patient medical records was cited as a barrier to supply of reclassified statins by pharmacists [253,280]. Pharmacists in three studies reflected difficulties arising with verbal recall from patients about their medical history [260,261,283]. Lack of access to patient medical records was also reasoned by some pharmacists to not eagerly anticipating the reclassification of EHC in one study [261].

Access to patient medical records was described by pharmacists as one approach to overcoming the potential misuse of non-prescription medicines [252,260] and to increase the efficiency of repeat supplies [260]. From pharmacists' perspectives patient medical records could both be patient held [280] and pharmacist held [122,280,282,284].

4.4.3.8 Need for communication with medical practitioners

Three studies identified that greater support from medical practitioners was important to ensure appropriateness of supply [258,260,280]. Pharmacists in two UK studies related difficulties of contacting medical practitioners [262,272]

4.4.3.9 Adoption by medical practitioners

Seven studies reported doctors' recommendations of medicines being associated with pharmacists' medicine choice decision for a given indication [266,269-271,274,277,279]. One study identified that doctors' recommendations were associated with decisions to stock

medicines within the pharmacy but that this did not necessarily relate to pharmacist recommendations to patients [264]. No qualitative perspectives could be identified.

4.4.3.10 Financial aspects

Levels of profit from sales were shown in seven studies to be associated with pharmacists' tendencies to supply certain medicines [266,269-271,274,275,277]. Being a proprietor was associated with a higher regard for financial implications in one study [277] but not in another [271]. Desire to have more medicines within the 'P' or equivalent legal classification were related to financial benefits, owing to the exclusive rights for pharmacy sales in two studies [254,263]. Contrary to these findings, pharmacists did not identify the importance of financial advantages in reclassified medicine supply decisions in two studies [264,279].

4.4.3.11 Medicine retail prices

Higher medicine retail price were related by pharmacists in eight studies to potentially deter patients from buying non-prescription medicines [122,229,256,264,266,273,279,283]. Free patient access to non-prescription medicines related to pharmacists noting high acceptance by patients in two studies [257]. On the contrary, pharmacists in another two studies reflected that patients bearing the cost of the medicines could help increase patient adherence and avoid misuse and overuse [252,254]. These studies did not explore what cost pharmacists regarded as 'appropriate'.

4.4.3.12 Colleagues' opinions

Six of the studies which assessed the importance of colleagues' opinions in pharmacists' decision making reported pharmacists highly rating the importance of such opinions [264,269-271,273,274]. Three studies reported little or no influence [266,277,279]. Again, no qualitative perspectives could be identified.

4.4.3.13 Consumer advertisement

A majority of pharmacists reported that decision making was influenced by direct to consumer advertisement in two studies [274,275]; with three other studies reported only a minority of pharmacists considering such advertisements as influential [229,269,273].

4.4.3.14 Employer policy, directions

Pharmacists, through majority agreement in four studies, rated that they had full personal control over medicine supply decisions, with a minority deeming employer directions were

vital to decision making [229,266,273,277]. Only one study found that pharmacist employers' instructions were key to informing adoption decisions [270].

4.4.3.15 Adequacy of pharmacy resources

Pharmacy resources such as availability of consultation areas were related to pharmacists' support for the reclassified status of statins [280] and EHCs [251,252,260].

4.4.3.16 Patient acceptance/feedback

Patient feedback and demand was positively associated in eight studies with pharmacists' desire to supply reclassified medicines [256,264,266,271,274,275,277,279]. Low patient requests were attributed by pharmacists in one study to low supply of reclassified medicine [283]. One study demonstrated that pharmacists placed no importance on the role of patient acceptance/feedback in informing decision making [269].

Pharmacists in four studies related patient requests to be more driven by consumer advertisements [122,272,282,283]. Interestingly, one study reported pharmacists' desires for further advertisement to encourage patient requests [256].

Most of the quantitative studies evaluating the importance of direct patient medicine requests around supply decisions reported that pharmacists were comfortable in declining sales when they considered the requests inappropriate [256-258,261,272,273,282]. Qualitative studies however reflected that such patients requests were 'usually' difficult for the pharmacists to decline [260] or that the supply/non-supply ultimately depended on the patient [228].

4.4.3.17 Off-licence supply

Two studies which covered this aspect of supply reported that, when deemed appropriate, pharmacists were prepared to supply the studied medicines 'off-licence' [273,283].

4.4.3.18 Task delegation to support staff

Pharmacists' perceived need for personal involvement around the supply of reclassified medicines was substantial in all three studies which assessed this aspect of practice [122,282,283]. One study demonstrated that such reservations around task delegation were medicine specific [283].

4.4.3.19 Novelty

'Novel' reclassified medicines were more likely to be recommended than those which pharmacists perceived as providing little therapeutic advantages over the exiting ranges of non-prescription medicines [270,274,279]. One study highlighted concerns about the lack of novelty which were associated with reluctance to supply newly reclassified omeprazole [122].

4.4.3.20 Status as 'pharmacy only'

Three Australian studies [269,270,274] and one UK study [277] reported that medicines available only through pharmacy were likely to be preferred by pharmacists over others more widely available. However, these conclusions were not supported by two other studies, each from Australia [264] and the US [279]. A further two US studies, however, demonstrated that pharmacists were supportive of creating a regulatory class of medicines which is the equivalent of the UK 'P' class [251,263].

4.4.3.21 Manufacturers' reputations

Manufacturers' reputations such as recent history of medicines recalls were shown to be important in five studies in informing pharmacists' medicine supply decisions [264,266,270,271,274]. No qualitative details around the perceived importance could be identified.

4.4.3.22 Pharmacists' experiences

Pharmacists in five studies rated their own experience gained through self use of the medicines to be important in informing supply decisions [270,271,273,277,279]. One study related patient feedback key to experiences [269]. Pharmacists' limited experiences with supply were cited as key reasons for low reported sales of newly reclassified oseltamivir [256].

4.4.3.23 Endorsement by professional/practice body

Two studies by Emmerton et al reflected that endorsement by the Pharmacy Guild of Australia had positive influences on pharmacists' adoption of reclassified medicines [269,270]. A US study also reported that medicines endorsed by State formularies were more likely to be supplied by pharmacists than those not listed in the formulary [266].

4.4.3.24 Medicines for acute conditions

Two UK studies noted that pharmacists mostly cited medicines for acute conditions as appropriate candidates for future reclassification [268,273]. No further details about the reasons(s) for such preference could be identified from these studies. Pharmacists' concerns around reclassified simvastatin were shown to be partially related to the long term indication and need for the medicine [283].

4.4.3.25 Guidelines/ Protocols

Two studies highlighted the need for protocols to be in place to facilitate the supply of reclassified medicines [122,280]. Two qualitative studies around non-prescription supply of EHC also highlighted the advantages of protocols in terms of protecting pharmacists against litigation issues and promoting consistent decision making across pharmacies [260,261].

4.4.3.26 Moral/ethical

Five studies identified that issues associated with pharmacists' moral/ethical standings deterred pharmacists from the supply of EHC [252,257,258,260,261]. Pharmacists' moral issues were mostly related to its perceived abortifacient action.

4.4.3.27 Successful patient self use of medicine

Five studies concluded that those reclassified medicines perceived by pharmacists to be relatively easy for patient use were shown to be associated with their desire to recommend [269,270,274,277,279]. Patient reluctance to accept pharmacists' advice was reported as a barrier to reclassified H2 antagonists supply [272].

4.4.3.28 Medicine potential for misuse

Pharmacists' concerns around misuse were mainly identified in studies evaluating non-prescription availability of EHC [252,255,257-262,278]. However, one study discussed the importance of this issue generically for all therapeutic classes [277].

4.5 DISCUSSION

4.5.1 Discussion of findings

The objectives of this systematic review was to review and critique the methodologies, methods and models to investigate factors associated with community pharmacists'

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decision making around reclassified medicines described in peer reviewed published literature; and to list and describe the importance of facilitators/barriers identified from the peer reviewed published literature to community pharmacists' decision making around reclassified medicines. A limited number of studies covering only a narrow range of therapeutic areas were included despite over 80 medicines reclassified from POM to P status in the UK. Studies included in the systematic review reflected that in those countries where the 'P' or equivalent category of non-prescription medicines exists, pharmacists expressed much support, in general, for ongoing reclassification of medicines. Studies from the US also reflected that the majority of pharmacists studied were in favour of creating an equivalent regulatory class of medicines.

A narrow range of methodologies and methods were adopted by the identified literature. Use of descriptive and univariate models dominated the designs of quantitative studies. Much of the literature evaluated the importance of facilitators and barriers individually. Although perspectives around these individual facilitators/barriers are important, basing pharmacy practice change models which focus on individual facilitators/barriers singly has been cautioned as 'will not to be successful' [241]. This is basically due to practice change being a complex phenomenon, involving interplay of multi dimensional factors, as has been realised in the qualitative study in Chapter 3. This leads to the notion that multivariate models are more appropriate to undertake such research.

The quality limitations of the studies utilising multivariate models, however, need to be carefully considered before these models could be applied or adapted to future evaluation within this doctoral research and beyond. For example, those studies utilizing a factor analytical method did not employ cross researcher reliability in labelling of the factors. Hence the factor labelling was arguable in many studies. The use of parametric statistics to analyse ordinal variables also raises questions over the validity of the results that were presented. Though parametric approaches to analyse such ordinal data are frequently utilized for larger sample sizes, there is no accurate definition of what minimum size is appropriate for such analysis [286].

Content wise, much of the focus of the descriptive, univariate and multivariate quantitative models was on pharmacists' perceptions of the 'content' or 'attributes' of reclassified medicines. However, the lack of focus on wider social and organisational factors, such as pharmacy resources, in decision making process was notable. Consideration of these wider

factors should be included within future evaluations. The lack of a rigorous approach to development of research instrument content could be attributed to a lack of use of theoretical models in the identified studies. The use of theoretical models, as described earlier, has been suggested to benefit gathering and interpretation of data [139]. One literature review included in the study suggested that application of the Fishbein behavioural model was relevant to future research in the area of pharmacists' decision making [265]. However the authors of the review cautioned the need for further empirical testing before application of such a theoretical model could be 'recommended' for pharmacy practice research.

No studies adopted a pragmatic research approach such as measuring actual adoption into practice and relating supplies to the facilitators/barriers associated with decision making. This highlights limitations in study design while at the same time reflects the difficulty of conducting pragmatic studies in this research area. A few studies used a recall approach to rate the frequency of supply to measure adoption into practice. However, the analytical models did not compare participants' ratings themselves across different levels of adoption of the reclassified medicines so as to identify factors associated with decision making.

This is the first systematic review to list and review the importance of facilitators/ barriers to adoption into practice of reclassified medicines which can be used in future evaluations of the pharmacist perspective of medicines reclassification. It is interesting to note how the studies differed in their conclusions around the importance of individual facilitators/barriers in decision making. For example the issue of evidence base was reported in a few studies as one of the most important features in pharmacists' decision making, while others reported no place for the evidence of efficacy in decision making [228]. Such contrasting findings are also noted around the importance of medicine safety, adoption of medicines by medical practitioners, financial benefits owing to sales of medicines, retail prices of medicines, opinions of colleagues, consumer advertisement, employer policy directions and direct requests for medicines. These contrasting findings reflect that facilitators/barriers are often unique to the therapeutic areas, cultural settings, legislative frameworks etc. and hence, the factors associated with decision making.

Such differing conclusions however, are not only limited to the reasons listed above.

Differences in study settings and countries, sampling and bias around participant selection, and more importantly the analytical models and study quality may also explain variations.

For example, although any sample size cannot be regarded as 'small' as long as it justifies the appropriateness for the research questions, justification was missing from most quantitative studies, and similarly data saturation was not addressed in any of the qualitative studies. In addition, there was a general lack of information around participant recruitment and associated bias. Although data for the systematic review were extracted from the results sections of the included studies, conclusions drawn were often not grounded in the data, with little discussion of limitations. Such lack of discussion around limitations itself becomes a limitation of the study, potentially biasing conclusions [241].

Noting these limitations, facilitators/barriers to pharmacists' decision making around reclassified medicines were often similar to those from the qualitative work described in Chapter 3. Results from these two approaches could be triangulated to gain additional insight.

4.5.2 Discussion of systematic review method

The strength of this systematic review is exemplified from the lack of recent and robust published systematic reviews in this field of research.

A wide range of databases was used to search the literature. Manual searching of core journals for relevant titles, searching of bibliography for literature led to disappointing results, hence raises questions around whether such process should be adopted in the future. Experts based outside the university were not consulted for potentially missing literature due to the time constraints of a PhD and similarly neither grey literature including unpublished data nor missing data from published studies were considered due to the same reason. Nevertheless, it is said that even the information retrieval experts are able to retrieve only as much as 50% of the relevant literature [156].

Two researchers working independently in short listing titles retrieved added to the rigour of the literature inclusion/exclusion decisions. In addition, this strengthened the review process in terms of data extraction and quality rating.

Development of quality assessment forms as per standard guidelines [246,248,249] helped to ensure that important elements around study quality were properly scrutinized. Structured data extraction forms ensured that no relevant data were missed. A narrative synthesis of findings allowed results from diverse methodologies and methods to be

presented together and for the same reason meta-analysis of the results was not possible. A clear, externally validated protocol, listing the process around every aspect of systematic review meant that any deviations from the set procedures could also be recorded, increasing transparency.

4.5.3 Future directions for doctoral research

The systematic review has provided a platform to progress with the quantitative evaluation of newly reclassified medicines. Findings of the systematic review will have relevance to the next stage of the research as described below.

4.5.3.1 Design aspect

- Need to define the outcome: Outcome measures were poorly defined in the literature and hence future evaluation should communicate key outcomes that are being measured, with emphasis on validity, reliability and responsiveness
- 2. Multivariate models reviewed are appropriate for adaptation in the next phase of the research. However, future evaluation is needed to address limitations noted.
- 3. While many facilitators/barriers are common to reclassified medicines, some were found to be medicine specific. Hence, research around factors associated with decision making is best undertaken through quantitative evaluation of reclassified medicines from diverse therapeutic areas with the same sample of pharmacists.
- 4. Emphasis should be placed on theoretical frameworks.

4.5.3.2 Content aspects

The facilitators/barriers to pharmacists' adoption of reclassified medicines
identified from the systematic review along with the results of qualitative interviews
will be used to develop the content of the quantitative research instrument.

4.6 SUMMARY OF CHAPTER 4

Methods and models used to study pharmacists' decision making around reclassified medicines were reviewed through a systematic review of literature. Strengths and limitations of these methods and models were described using a systematic approach. Within quantitative models, there was a lack of rigorous multivariate approach to undertaking research to understand pharmacists' perspective of decision making around adoption of reclassified medicines. Lack of theoretical framework to undertaking research was also identified in the included studies. A total of 28 facilitators/barriers to pharmacists' Chapter 4: Systematic review of literature

decision making in relation to support for and adoption into practice of reclassified medicines were also identified. These results are of relevance to the design and content aspects for the development of the quantitative research instrument to be used in the next phase of the research.

CHAPTER 5: DEVELOPMENT AND PILOTING OF SURVEY INSTRUMENT

5.1 INTRODUCTION TO THE CHAPTER

This Chapter details the development and piloting of the questionnaire used to undertake the main survey. Results of the pilot survey (Phase III) and descriptions of any modifications made prior to finalising the questionnaire (phase IV) are also presented.

5.2 OBJECTIVES OF THE MAIN SURVEY

- 1. To quantify pharmacists' support for and adoption into practice of medicines newly reclassified from POM to P status for diverse therapeutic indications.
- To describe and quantify facilitators/barriers associated with pharmacists' decision making around reclassified medicines (support for the reclassified status and adoption into practice).
- 3. To investigate the utility of Rogers' diffusion model in exploring findings related to objectives 1 and 2.

5.3 QUESTIONNAIRE DESIGN

5.3.1 Technicalities of design and administration

Indicators of best practice suggested by the American Association of Public Opinion Research (AAPOR) [287], key messages from Dillman's text on survey design [288]; and a dedicated training session on survey design and administration [202] were followed. These key messages are summarised in figure 5.1.

Figure 5.1: Best practices for survey design and administration

- Take great care in matching question wording to the concepts being measured and population being studied
- ♣ Select samples that will represent the population to be studied
- ♣ Pre-test questionnaires and procedures to identify problems prior to the survey
- Maximise response rates within the limits of ethical treatment of human subjects
- Use statistical analytic and reporting techniques appropriate to the data collected
- Carefully develop and fulfil pledges of confidentiality given to the respondents
- ♣ Disclose all methods of the survey to permit evaluation and replication
- A well designed layout prevents items or answer categories from being missed because of their location on the page
- Formats to consider- A4 paper folded to create an A5 booklet stapled along the spine
- **♣** Consider layout to allow natural eye movements
- For complex questionnaires, shaded background fields are very useful and thus these help identify all answer spaces and therefore reduce non-response
- ♣ Do not split questions or answer categories between pages

Extracted from [202,287,288]

5.3.2 Evidence based strategies to encourage participation

Evidence based strategies known to increase the response rate, as described in Chapter 3 were used. However, strategies used in the survey differed from those used in the qualitative phase as follows:

- 1. No monetary nor non-monetary incentives were used to facilitate participation in the survey.
- 2. Invitations were anonymous.
- 3. No identifying features were supposed to appear on return.
- 4. No prior telephone contact with potential respondents was made.

In addition to the above strategies, the following innovative techniques were also utilised with the aim of maximising the response rate:

1. Three questions in very large and legible font were placed on the front page of the questionnaire booklet to allow potential respondents to quickly check the relevance and interest of the survey to themselves. These three questions were as follows:

Are you a community pharmacist?

Do you deal with non-prescription medicines?

Are you interested in issues about innovations?

- 2. A 'post it note' was attached to the top right corner of the questionnaire cover page containing a statement signed by the researcher in ink inviting pharmacists to participate. This was based on limited previous research suggesting that such a strategy may increase the response rate by up to 70% [289]. This message appears in Appendix V.
- 3. Questionnaire was designed in A5 size (half the A4) to make it look like a small booklet.

5.4 CONTENT SETTING

The draft questionnaire comprised three sections: reclassified medicines; e-MAS (Chapter 8); and respondents' demographic characteristics.

5.4.1 Section A: Reclassified medicines

Newly reclassified medicines from diverse therapeutic areas introduced in the last five years (during the period of this survey design) were evaluated. As identified in the Chapters on the qualitative study and systematic review of the literature, facilitators/barriers to decision making are often unique to each of the newly reclassified medicines. Hence, factors associated with decision making may be best understood by evaluating as many newly reclassified medicines from diverse therapeutic indications as possible. Medicines were selected on the basis of legal reclassification within the preceding six years; and that the indications encompassed acute and chronic indications. The following newly reclassified medicines were evaluated:

1. **Omeprazole**: Reclassified in 2004 [92], a 10 milligrams dose of this medicine is indicated for the relief of heartburn symptoms associated with acid reflux in adults 18 years or above [239].

- 2. **Simvastatin**: Reclassified in 2004 [92], a 10 milligrams dose of this medicine is indicated for prevention of first major coronary events in individual with moderate risks [232].
- 3. Chloramphenicol eye drops: Reclassified in 2005 [92], a 0.5% w/v solution is indicated for the treatment of acute bacterial conjunctivitis in children two years and above and for adults and the elderly [290].
- 4. **Naproxen**: Reclassified in 2008, a 250 mg dose is aimed for the treatment of primary dysmenorrhoea in women aged between 15 and 50 years [291].

5.4.1.1 Outcome measures

Two key outcome measures were used; support for the reclassified P status of the listed four medicines by pharmacists (the acceptance); and level of supply of the reclassified medicines by pharmacists or their support staff (adoption into practice). Acceptance was measured by asking pharmacists "Please indicate how much you appreciate having these reclassified products available for your OTC practice". The responses were measured on a five point semantic differential scale where the extremes indicated "Not-at-all" and "Very highly". Adoption into practice was similarly measured with the question "To what extent do you and/ or your support staff supply these products?" The extreme categories in the responses were "Not-at-all" and "Very frequently".

5.4.1.2 Sources of information on reclassified medicines

Twelve sources of information identified from the qualitative interviews and the systematic review of literature were listed to identify and quantify which listed source (s) pharmacists were utilising.

5.4.1.3 24-item scale

A 24- item scale featuring diverse issues associated within decision making as identified from the qualitative work, the systematic review of the literature and the theoretical framework of Rogers' diffusion model [131] was designed. Of these; 16 items represented pharmacists' perceived characteristics of new medicines, including benefits professionals; benefits and risks to patients; three items on organizational aspects of innovation adoption; five items on external support including those from patients, GPs and the professional body. These scale items as they related to Rogers' description of factors associated with

innovation adoption by potential adopters [131], are also labelled in table 5.1. Descriptions of the terms within Rogers' diffusion model are explained in Chapter 1 (Introduction).

Table 5.1: 24-Scale items of questionnaire (Note: this table extends to four pages)

Scale item	Relevance of the scale to practice	Examples of supporting statement from interviews	Rogers' description	Rogers' broader category
This is/was a good opportunity to extend my role as a health professional	Role development	"changing from POMs to Ps is fine if it's given us an extra, a weapon in the armoury"	Advantage	Attributes of innovations
This product has potential for good financial returns for my pharmacy	Financial aspects	"because the company that I worked for was pushing it, because they thoughtthat they are gonna sale masses of it and it was a great opportunity for them to get into kind of a, a market which hasn't previously been there"	Advantage	Attributes of innovations
I believe that the OTC regimen for this product is likely to be effective	Evidence base	"I have reservations for the dose it [simvastatin] is."	Advantage	Attributes of innovations
I believe this product has potential to engender patient satisfaction	Feedback from patients	"people coming back to me and say, that product wonders, it was great"	Advantage	Attributes of innovations
This product matches with the business/service ambitions of my pharmacy	Financial aspects	"the different areas you're in, there will be different products which would be utilized more or less as well"	Compatibility	Attributes of innovations
I find the processes involved in the supply of this product complex	Complexity of adoption process	"time filling out whole Imigran (sumtriptan) (risk assessment) I find that taxing"	Complexity	Attributes of innovations
I believe that this product is a welcome addition to the range of pharmacy medicines	Pharmacists' expectations	"Trimethoprim, I'm really looking forward to, a lot" "Most recent one was chloramphenicol, wonderful We'd been looking for that"	Compatibility	Attributes of innovations
Introduction of this product may have represented a 'step too far' for OTC products	Change match with expectations	We're really kind of first port of call for acute thingsbut if it's a long term chronic thing, they come in and we can direct into their GP	Compatibility	Attributes of innovations

Scale measure	Relevance of the scale to practice	Supporting statement from interviews	Rogers description of the theme	Rogers' broader category
I am happy to delegate the task of supplying this product to support staff	Complexity of adoption process	"Occasionally I have worked in stores where you don't necessarily have that trust in your staff and that's where having these kinds of products available can be more problematic"	Complexity	Attributes of innovations
I feel confident about my ability to supply this product	Pharmacists' confidence on supply process	"Unless I had some experience already[to supply]I am always more on the safe side you know"	Complexity	Attributes of innovations
The similarity of POM and P packs of this product could create confusion	Complexity of adoption	"you've got POM pack and P pack, identical. I'm not always convinced"	Complexity	Attributes of innovations
I believe there are high risks of adverse events associated with this product	Safety of medicines	"Chloramphenicol is fine because its such an obvious thing. You know and nothing much [side effects] can happen."	(Dis)Advantage	Attributes of innovations
It is likely that customers could misuse this product	Product potential for misuse by patients	"We've had three teenagers tryin' to sign up the smoking cessation scheme. And we reckon what they're needing, we reckon they're using it for other motives"	(Dis)Advantage	Attributes of innovations
Lack of access to patient medical records makes it difficult to adopt this product into practice	Patient medical records	"you have to have some more access to recordsto actually be aware of what you actually treating someone actually, actually, needs treatment"	Complexity	Attributes of innovations
It is easy for me and/or my customers to know if treatment with this product is effective	Observable treatment outcomes	"whether people benefit and if they come back after certain amount of time to see if it [the condition] had improved"	Observability	Attributes of innovations
I am/would be comfortable going off guidelines to supply this product	Flexibility for off label supply	"I also like going off the formulary if I need to."	Re-invention	Attributes of innovations

Scale measure	Relevance of the scale to practice	Supporting statement from interviews	Rogers description of the theme	Rogers' broader category
Insufficient resources (e.g. staff, space etc) within my pharmacy has limited the practice of this product	Staff, space, equipments	"I don't think we really have the time at community pharmacies to go into that sort of details [cholesterol testing] with patients."	Organizational factors	Organizational factors
I have access to sufficient sources of information relating to this product	Access to information sources	"I think the only literature really is what's in the patients information leaflets in the boxes in a lot of cases"	Organizational factors	Organizational factors
It has been my management's decision rather than my own as to if/ how far to adopt into practice	Role in decision making within organization	"our company dictates what we stock on shelves."	Organizational factors	Organizational factors
Customers not accepting my advice around this product makes me less likely to adopt this product	Patient cooperation	"I think because we are very sort of customer oriented. I think with that, that's one thing [antibiotic], I wouldn't like to see coming just and just yet anyway."	External factors	External factors
My customers often complain about the cost of this product (not including e-MAS supply)	Retail price for patients	"those people who came for cholesterol testfind out how much it was and they will need to take it every monthand buy it and they didn't do it."	External factors	External factors
Many customers ask for this product by name	Patient acceptance	"What a demand from the customers [for chloramphenicol]"	External factors	External factors
I get adequate support from my professional body to adopt this product	Support from professional body	"that the trainings before these products come out. It's the reps doing it, 'cause it's the only one that we get for POM to P for certain conditions."	External factors	External factors
Lack of proper way to communicate with the local medical practice is a barrier to adopt this product	Communication with GPs	"You know if they're gonna be on it [simvastatin], then their GP needs to know about it."	External factors	External factors

5.4.2 Section B: About e-MAS

Details of this section will be explained in Chapter 8.

5.4.3 Section C: Demographic characteristics and self innovativeness

Section C of the questionnaire featured items around respondents' demographic characteristics. The categories used were the same as those in the Royal Pharmaceutical Society of Great Britain's census and register analysis reports [292,293] where possible so as to enable estimation of the representativeness of the respondents to the total population. Pharmacists were also asked to rank their perceived innovativeness in relation to new ways of practice based on Rogers' diffusion model which states that greater perceived innovativeness relates to a higher adoption of innovations into practice [131]. The scale was adapted from a previous study measuring pharmacists' adoption of innovations around non-medical prescribing [294].

5.5 REVIEW BY EXPERT PANEL

Development of questionnaire items followed an iterative process. Statements were formulated and reworked to avoid any ambiguity. Apart from three academic supervisors, the following panel of experts and peer evaluators checked for face and content validity of the questionnaire.

- 1. Prof. Dennis Tourish Professor, Aberdeen Business School, RGU
- 2. Mr Brian Addison Lecturer in pharmacy practice, RGU, and practising locum community pharmacist
- 3. Mrs Ruth Edwards Lecturer in pharmacy practice, RGU, and practising locum community pharmacist
- 4. Mrs Trudi McIntosh Lecturer in pharmacy practice, RGU, and practising locum community pharmacist
- 5. Mrs Gwen Gray Lecturer in pharmacy practice, RGU, and practising locum community pharmacist
- 6. Mrs Katie MacLure Research assistant in pharmacist prescribing, RGU.
- 7. Ms Noelle O' Drescoll PhD student, RGU, and locum community pharmacist
- 8. Mr Alex Wilson Consultant statistician for Robert Gordon University
- 9. Cat Graham Wellcome Trust Epidemiology and Statistics Support Group, Clinical Research Facility, Edinburgh.

 Dr Gordon Prescott - Senior Lecturer of Medical Statistics, Department of Population Health, University of Aberdeen

Feedback from the expert panel was received in the form of either verbal, email or hand written notes. Most of the suggestions related to improving the grammar and clarity of the statements. Discussion with expert statisticians related to appropriateness of content setting, scales and analytical approaches.

5.6 PILOT SURVEY

The following were the set objectives for the pilot phase:

- 1. To test the face and content validity of the questionnaire items to inform any modifications to be made to the questionnaire prior to the use in the main survey
- 2. To predict the response rate likely to be achieved in the main survey so as to allow estimation of the study sample size.

5.6.1 Method

5.6.1.1 Identification of potential participants for piloting

A list of all registered pharmacy premises in Scotland were obtained from NHS National Education Scotland. Pharmacies represented in the qualitative work were excluded where identifiable. A random sample of 50 pharmacies was extracted using Minitab version 15. This number was based on the advice of experienced pharmacy practice researchers within the school. The questionnaire was addressed to the pharmacist with the responsibility for non-prescription medicine supply and hence was anonymous. A return pre-paid postage envelope was provided. The questionnaire booklet also contained a detachable participant information page.

5.6.1.2 Consent

No consent form was included in the invitation pack as any questionnaire returned completed would imply respondents' consent to participate.

5.6.1.3 Reminders

No reminders were sent during the pilot phase. A deadline of three weeks was suggested for the participants to return the completed questionnaire.

5.6.1.4 Data input and analysis

Data were entered into SPSS version 15 (SPSS Inc). Analyses of response rate and demographic characteristics were performed. Any missing data were identified.

5.6.2 Results from pilot survey

5.6.2.1 Response rate

Thirteen replies were received giving a response rate of 26%.

5.6.2.2 Demographic characteristics of participants

The demographic characteristics of the pilot questionnaire participants are shown in the table 5.2 below:

Table 5.2: Demographic characteristics and perceived innovativeness of pilot survey respondents

Title	Categories	Data from Pilot samples n (%)*
Gender (N=13)	Male	5 (39%)
	Female	8 (62%)
Age (N=13)	≤29 years	3 (23%)
	30-39	4 (31%)
	40-49	2 (15%)
	50-59	4 (31%)
	60 or above	0 (0%)
Type of pharmacy ownership	Independent (1 store)	2 (15%)
(N=13)	Small multiple (2-4 Stores)	3 (23%)
	Medium sized multiple (5-25 stores)	1 (8%)
	Large multiple (over 25 stores)	7 (54%)
Position within pharmacy (N=13)†	Owner	2 (15%)
	Manager	11 (85%)
	Relief	0 (0%)
	Second	1 (8%)
	Locum	0 (0%)
	Non-store	1 (8%)
Number of years in practice (N=13)	5 years and under	4 (31%)
	6- 10 years	2 (15%)
	11-15 years	1 (8%)
	16-20 years	2 (15%)
	20 and above	4 (31%)
Postgraduate qualification (N=13)	Yes	5 (39%)
	No	8 (62%)
Location of pharmacy (N=13)	Urban	3 (23%)
	Suburban	6 (46%)
	Rural	4 (31%)
Prescriber (N=13)	Yes	3 (23%)
	No	10 (77%)
Perceived innovativeness (N=13)	I am venturesome and willing to	
	take risks with new ways of working	5 (39%)
	I serve as a role model for others in	4 (31%)
	relation to new ways of working	
	I deliberate for some time before	2 (15%)
	adopting new ways of working	2 (4 = 0/)
	I am cautious in relation to new	2 (15%)
	ways of working; tend to change	
	once most peers have done so	0 (00/)
	I resist new ways of working	0 (0%)

^{*%}figure are rounded to whole numbers †multiple selections allowed

5.6.2.3 Missing data

One respondent failed to rank the agreement scores relating to one item in the 24-items scales.

5.6.2.4 Responses to open questions

Two respondents made comments under the open questions.

5.6.3 Discussion of pilot and any modifications for main survey

5.6.3.1 Response rate

The response rate that was achieved without using any reminders (26%) was considered appropriate to proceed to the main survey. This was also consistent with response rates obtained from other pilot research phases within the pharmacy practice area in the university. Based on this figure, it was decided that two reminders would be used in an attempt to maximize the response rate in the main study.

5.6.3.2 Section on reclassified medicines

The responses from pilot survey respondents and feedback from peer evaluators implied that respondents understood the questionnaire items.

A minor alteration was undertaken to one of the 24-items within the scale so as to overcome the difficulty faced in coding of the responses as a result of piloting. It was unclear whether the statement "Level of resources allocated by my pharmacy management has affected supply decisions" was a 'positive' or a 'negative' statement. Therefore, it was rearticulated as "Insufficient resources (e.g. staff, space etc) within my pharmacy have limited the practice of this product" to be used in the main survey.

5.6.3.3 Innovativeness categories

The very high percentage of respondents belonging to the category of innovativeness implying 'venturesome' necessitated the need to reverse the order of categories presented within the questionnaire. For the main survey, the category hence would start from 'resistant' leading to 'venturesome'.

5.6.3.4 Missing data

All data above were considered random and thus no major changes were considered.

5.7 SUMMARY OF THE CHAPTER

The questionnaire was designed based on the qualitative data and systematic review of literature and theoretical framework of diffusion of innovations. This was piloted to a random sample of fifty community pharmacies within Scotland. Analysis of responses from the pilot study and advice from expert panel indicated that the content was valid with no need for major editing of the layout or content needed. The response rate achieved in the pilot will be used to compute the sample size for the main survey.

CHAPTER 6: MAIN SURVEY

6.1 INTRODUCTION TO THE CHAPTER

This Chapter presents the results of the main survey undertaken to achieve the objectives listed in the previous Chapter. Attention will also be given to the discussion of key findings.

6.2 METHOD

Methods relevant to survey design and administration are in Chapter 5. This section details mainly the computation of sample size and approaches to data analysis.

6.2.1 Sample size estimate

Sample size calculation for the main survey was based on the minimum sample size required for the analytical steps to be followed. Principal component factor analysis, bivariate correlation and logistic regression were the key analytical steps which required sample size estimation. A minimum of 300 samples has been suggested to be required for factor analysis [295], whereas, a sample size of 5 to15 is suggested for each explanatory variable to be used for logistic regression analysis. Considering there would be a maximum of 38 variables likely to be used in the regression analysis, a minimum sample size of 380 would be needed. Thirdly, for correlation analysis, it is required that for a standard P value of 0.05 and a recommended power of 80%, 783 participants are needed to detect a small effect size (r=.1), 85 participants to detect a medium effect size (r=.3) and 28 participants to detect a larger effect size (r=.5) [295]. Based on above estimates and the projected response rate of 46% with two reminders (pilot response rate plus 10% with each reminder), it was decided that whole population of community pharmacies in Scotland (N= 1143) needed to be sampled.

6.2.2 Data entry and analyses

SPSS version 15.0 was used to enter and analyse the data.

Diverse methods of analysis were used. Descriptive analysis was used to report response rate, pharmacists' responses to the outcome measures and responses to 24 items scale and demographic characteristics. Non-parametric analyses such as median (interquartile range) were also used to report ordinal and discrete variables. Bivariate correlation analysis was used to understand correlation between two outcomes [295]. Principal component factor Chapter 6: Main survey

analysis and binary logistic regression analysis were used to quantify factors associated with decision making [295]. Cross tabulation analysis of the outcome measures with the explanatory variables (the 24 items and the demographic characteristics) was performed to shortlist the explanatory variables for regression analysis. Only those variables showing significant association with the outcome measures based on Chi-squared statistics ($P \le 0.05$) were used in the regression analysis. Fisher's exact test was used where Chi-squared tests could not be applied due to $\ge 20\%$ of the cells showing an expected count of less than 5 [295]. Where the pattern of responses did not allow binary logistic regression analysis (explained in section 6.6.2.5 and 6.6.2.6), bivariate correlation of the outcome measures with the explanatory variables was used. Responses to open questions were analysed by content analysis as detailed in Chapter 2 (section 2.4.4.3).

6.2.3 Strategies to deal with missing data

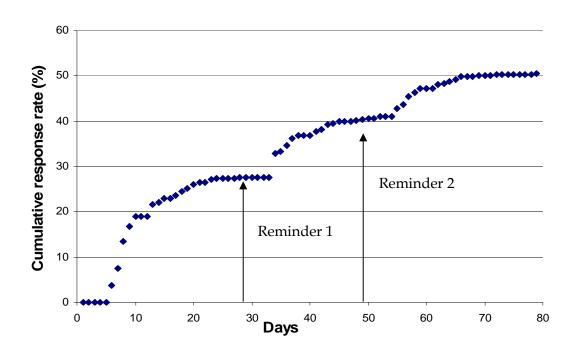
No strategy was used to deal with missing data. This was due to the demerits of using any computational strategies being outweighed by the benefits of using such techniques [296].

6.3 RESULTS: SECTION A

6.3.1 Response rate

A log book was maintained whereby responses received each day were recorded and a graph was plotted featuring cumulative response rate to the number of days from the initial date of questionnaire mailing (figure 6.1). A total of 563 usable responses were received over the course of approximately 80 days giving a usable response rate of 49.5%. Eleven blank replies were also received which were excluded from the analysis. Of the responses obtained, 55.1% were obtained after the first mailing; whereas 25.6% and 19.4% were contributed by the first and second reminders respectively.

Figure 6.1: Cumulative response rate over the data collection period, illustrating the impact of reminders.



6.3.2 Demographic characteristics

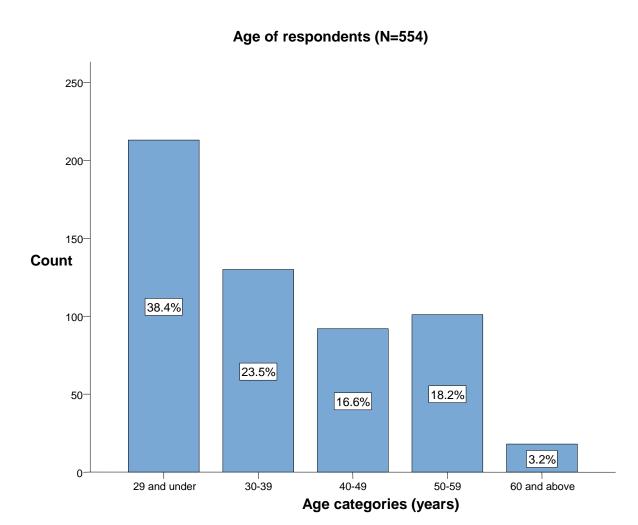
6.3.2.1 Gender (N=553)

The majority of respondents were female (61.1%, n=338).

6.3.2.2 Age (N=554)

Median age of the respondents was 30-39 years (25.3%, n=130) (figure 6.2)

Figure 6.2

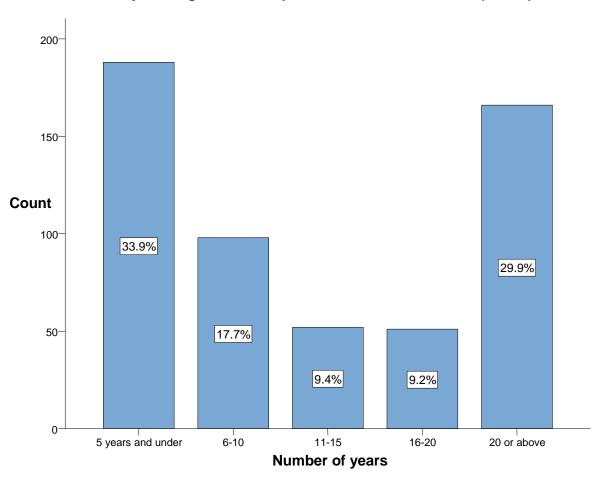


6.3.2.3 Practice experience (N=555)

The median years of RPSGB registration as a pharmacist was 6-10 years (17.7%, n=98) (figure 6.3)

Figure 6.3

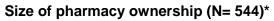


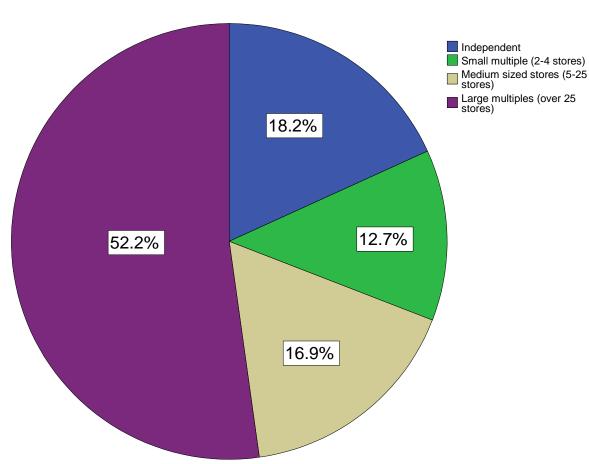


6.3.2.4 Size of pharmacy ownership (N=544)

The majority of respondents were employed by large multiple chains (52.1%, n=284) (figure 6.4).

Figure 6.4





*16 locums excluded from analysis

6.3.2.5 Employment type (N=562)

The majority (72.4%, n= 407) of respondents were pharmacy managers (table 6.1).

Table 6.1: Respondents' employment category

Employment category	n (%)*
Owner (N=562)	97 (17.3)
Manager (N=562)	407 (72.4)
Relief (N=562)	40 (7.1)
'Second' pharmacist (N=562)	21 (3.7)
Locum (N=562)	16 (2.8)
Non-store (N=562)	1 (0.2)

^{*} Numbers add up to >100% as multiple selections were allowed

6.3.2.6 Geographical area (N=503)

Respondents mostly worked in suburban areas (42.9%, n= 216). (Table 6.2)

Table 6.2: Respondents' geographical area

Geographical area (N=503)	n (%)†
Urban	157 (31.2)
Suburban	216 (42.9)
Rural	130 (25.8)

^{†40} reliefs and 16 locums excluded from this analysis

6.3.2.7 Postgraduate qualification (N=557)

A minority of respondents (16.3%, n=91) possessed postgraduate qualifications.

6.3.2.8 Prescribing qualification (N=557)

26.2% (n=146) were registered as prescribers with the RPSGB.

6.3.2.9 Perceived innovativeness (N=552)

Half of respondents (50.5%, n=279) rated themselves deliberating for sometime before adopting new ways of working (table 6.3).

Table 6.3: Respondents' perceived innovativeness

Innovativeness categories (N=552)	n (%)
I resist new ways of working (resistant)	0 (0)
I am cautious in relation to new ways of working; tend to	52 (9.4)
change once most peers have done so (cautious)	
I deliberate for some time before adopting new ways of	279 (50.5)
working (deliberate)	
I serve as a role model for others in relation to new ways of	146 (26.4)
working (role model)	
I am venturesome and willing to take risks with new ways of	75 (13.6)
working (venturesome)	

6.3.3 Respondent sources of information on newly reclassified medicines

6.3.3.1 Responses to listed sources of information (N=559)

Of the twelve different sources of information listed in the questionnaire, almost a third (30.1%, n=168) of respondents cited using at least three different sources (mode=3). The median number of information sources per respondent was 3 with an inter-quartile range (IQR) of 1. More detail is provided in figure 6.5. The source of information utilised most was manufacturers' information sources (70.7%, n=395) followed by journals (61.7%, n=345). (Table 6.5)

Figure 6.5

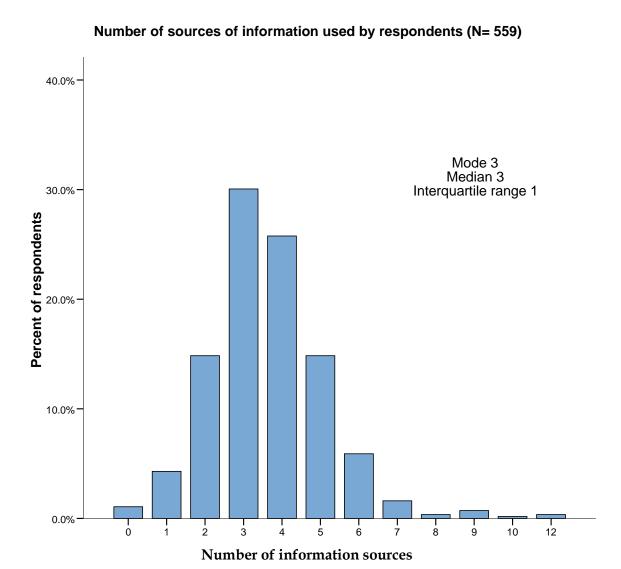


Table 6.4: Respondents' sources of information

Information source as per questionnaire (N=563)	Rank in descending order of n (%)	n* (%)
Drug company training sources	1	395 (70.7)
Journals	2	345 (61.7)
RPSGB guidance	3	323 (57.8)
National/ Local formularies	4	211 (37.7)
Patient information leaflets	5	209 (37.4)
Fellow pharmacists	6	197 (35.2)
My pharmacy management	7	153 (27.4)
Professional leaders	8	49 (8.8)
Television	9	45 (8.1)
Senior colleagues	10	38 (6.8)
Newspapers	11	27 (4.8)
Contract champions	12	23 (4.1)

^{*} Numbers add up to >100% as multiple selections were allowed

Sixteen respondents provided comments to the open question asking to list any other information sources. The following is the summary of responses.

Table 6.5: Responses to open question around sources of information

'Other' sources of information used by respondents (N=16)	n†
Pharmacy management/employer	6
Chemist and Druggist	2
Internet	2
30 minute tutors	1
Drug company training sources	1
Health Board PGDs	1
MHRA	1
NPA	1
Newsletters	1
S*** (Name of a person)	1
Unclear quote	1

[†] More than one comment made by some respondents

6.3.4 Outcome: Respondents support for reclassified status 'Acceptance'

Of the four listed medicines, chloramphenicol was rated most highly with over 99% (n=551) rating their support, 3 or above, in the five point scale. Support for the reclassified status of simvastatin was very low with approximately 75% (n=412) rating their support either 1 or 2 (Table 6.6). Median (IQR) acceptance scores for omeprazole, naproxen, simvastatin and chloramphenicol were 3 (2), 3 (1), 1(2) and 5 (0) respectively. (Table 6.6)

Table 6.6: Pharmacists' support for the reclassified status of medicines

How much do you appreciate having the following reclassified medicines into your OTC practice?

	Scale level				
Medicines (N)	1* n (%)	2 n (%)	3 n (%)	4 n (%)	5† n (%)
Omeprazole (N=555)	91 (16.4)	106 (19.1)	155 (27.9)	134 (24.1)	69 (12.4)
Naproxen (N=552)	35 (6.3)	89 (16.1)	176 (31.9)	193 (35.0)	59 (10.7)
Simvastatin (N=552)	278 (50.4)	134 (24.3)	94 (17.0)	30 (5.4)	16 (2.9)
Chloramphenicol	1	4	9	30	512

⁽N= 556) (0.2) (0.7) (1.6) (5. * Labelled as "not at all" in questionnaire; † labelled as "very highly"

6.3.5 Outcome: Adoption into practice of newly reclassified medicines

Over 98% (n=549) of the respondents ranked their adoption of chloramphenicol 3 or above, on the five point. In contrary to this, less than 5% (n=27) respondents provided the same score for simvastatin. Over a third of the pharmacists (n=201) were not supplying omeprazole. Median (IQR) scores for omeprazole, naproxen, simvastatin and chloramphenicol were 2 (2), 2 (1), 1(0) and 5 (0) respectively. (Table 6.7)

Table 6.7: Pharmacists' adoption of newly reclassified medicines into practice

How much do you or your support staff supply the following reclassified medicines?

Medicines (N)	1**	2	3	4	5¥
	n (%)				
Omeprazole	201	202	100	44	7
(N=554)	(36.3%)	(36.5%)	(18.1%)	(7.9%)	(1.3%)
Naproxen	96	197	168	82	14
(N=557)	(17.2%)	(35.4%)	(30.2%)	(14.7%)	(2.5%)
Simvastatin	459	71	17	5	5
(N=557)	(82.4%)	(12.7%)	(3.1%)	(0.9%)	(0.9%)
Chloramphenicol (N=557)	2	6	11	79	459
	(0.4%)	(1.1%)	(2.0%)	(14.2%)	(82.4%)

^{**}Indicated in questionnaire as 'not at all'; \(\frac{1}{2}\) indicated in questionnaire as "very frequently"

6.3.6 Correlation between acceptance and adoption scores

Bivariate correlation analysis showed that respondents' acceptance and adoption scores were significantly correlated for all four medicines. This implies that the more the support for the reclassified status, the greater was the adoption into practice. Spearman's rank correlation was used for the measurement for omeprazole and naproxen. Due to excess tied ranks on one side of the scale, Kendal's T was the most appropriate statistical test for simvastatin and chloramphenicol [295] (table 6.8). Highest correlation values were obtained for omeprazole, with the lowest for chloramphenicol.

Table 6.8: Bivariate correlation between acceptance and adoption scores

	Spearman's rank		Kendal's T		
	Omeprazole adoption	Naproxen adoption	Simvastatin adoption	Chloramphenicol adoption	
Omeprazole acceptance	.666***	=			
Naproxen acceptance		.561***			
Simvastatin acceptance			.427***		
Chloramphenicol acceptance				.401***	

^{**} Correlation significant at P ≤0.001.

6.3.7 Summary of responses to outcome measures

Support for the reclassified status of medicines and their adoption into practice were rated differently by the respondents. Scores on both the outcomes 'acceptance' and 'adoption' were highly skewed towards the higher side of the scale for chloramphenicol, implying high support for the reclassified status and high adoption into practice. Responses, whereas were skewed towards the lower side of the scale for simvastatin, meaning support for the reclassified status and adoption into practice were rated low for this medicines. Responses to naproxen and omeprazole were less skewed as compared to the above two medicines. Both the outcomes correlated well with each other in bivariate analysis with the case of all four medicines.

6.4 RESULTS: SECTION B

6.4.1 Facilitators/barriers to decision making: Descriptive statistics of 24 items scale

Responses to the 24 item facilitator/barrier scale are presented this section (table 6.9).

6.4.1.1 Opportunity to increase role

The majority reflected agreement that reclassification of omeprazole, naproxen and chloramphenical had offered an opportunity to increase their professional roles. The majority were unsure or disagreed to role development offered by reclassification of simvastatin.

Table 6.9: Descriptive statistics of responses around facilitators/barriers to decision making (note: this table extends up to 13 pages with descriptions in between until section 6.4.1.24)

	This is/was a good opportunity to extend my role as a health professional					
Medicines	Strongly disagree n (%)	Disagree n (%)	Neither agree nor disagree n (%)	Agree n (%)	Strongly agree n (%)	
Omeprazole	23	67	175	201	90	
(N=556)	(4.1)	(12.1)	(31.5)	(36.2)	(16.2)	
Naproxen	11	42	154	268	81	
(N=556)	(2.0)	(7.6)	(27.7)	(48.2)	(14.6)	
Simvastatin	81	122	161	129	63	
(N=556)	(14.6)	(21.9)	(29.0)	(23.2)	(11.3)	
Chloramphenicol	2	5	13	115	423	
(N= 557)	(0.4)	(0.9)	(2.3)	(20.6)	(75.8)	

6.4.1.2 Compatibility to pharmacy service ambitions

The majority agreed/strongly agreed that naproxen and chloramphenicol matched with service ambitions of respondents' pharmacies. The majority expressed being unsure or had disagreement with omeprazole and simvastatin.

Table 6.9

	This product matches with the business/service ambitions of my pharmacy					
Medicines	Strongly disagree n (%)	Disagree n (%)	Neither agree nor disagree n (%)	Agree n (%)	Strongly agree n (%)	
Omeprazole	31	80	220	146	79	
(N=556)	(5.6)	(14.4)	(39.6)	(26.3)	(14.2)	
Naproxen	19	50	201	206	80	
(N = 556)	(3.4)	(9.0)	(36.2)	(37.1)	(14.4)	
Simvastatin	98	111	207	96	44	
(N=556)	(17.6)	(20.0)	(37.2)	(17.3)	(7.9)	
Chloramphenicol	6	8	71	121	351	
(N= 558)	(1.1)	(1.4)	(12.7)	(21.7)	(63.0)	

6.4.1.3 Financial potential of medicines

Only chloramphenicol eye drops received the majority of respondents agreeing or strongly agreeing to 'good' financial potential for pharmacy. At least one in three respondents were unsure of the financial potential of omeprazole and naproxen and almost half disagreed or strongly disagreed that simvastatin had potential for good financial returns.

Table 6.9

	This product has potential for good financial returns for my pharmacy					
Medicines	Strongly disagree n (%)	Disagree n (%)	Neither agree nor disagree n (%)	Agree n (%)	Strongly agree n (%)	
Omeprazole	83	95	185	129	58	
(N=550)	(15.1)	(17.3)	(33.6)	(23.5)	(10.5)	
Naproxen	45	74	205	171	56	
(N=551)	(8.2)	(13.4)	(37.2)	(31.0)	(10.2)	
Simvastatin	144	116	167	84	41	
(N=552)	(26.1)	(21.0)	(30.3)	(15.2)	(7.4)	
Chloramphenicol	17	30	165	144	196	
(N=552)	(3.1)	(5.4)	(29.9)	(26.1)	(35.5)	

6.4.1.4 Retail price of medicines

A high majority of respondents agreed or strongly agreed that they often received complaints about the retail price from patients when supplying omeprazole and simvastatin. This was not the case for chloramphenicol, with a high majority disagreeing or strongly disagreeing to such complaints being common. Over one third were unsure about this issue in relation to naproxen.

Table 6.9

My customers often complain about the cost of this product (not including e-MAS supply) Strongly Disagree Neither Agree Strongly **Medicines** disagree n (%) agree nor n (%) agree n (%) disagree n (%) n (%) Omeprazole 41 73 152 151 138 (N = 555)(7.4)(13.2)(24.9)(27.4)(27.2)47 Naproxen 139 213 95 61 (N = 555)(8.5)(25.0)(17.1)(11.0)(38.4)Simvastatin 45 59 159 118 172 (N = 553)(8.1)(10.7)(28.8)(21.3)(31.1)Chloramphenicol 135 248 116 33 21 (N = 553)(24.4)(44.8)(21.0)(6.0)(3.8)

6.4.1.5 Pharmacy resource implications on supply

The majority of respondents strongly disagreed or disagreed that resource barriers within pharmacy had limited the adoption into practice of any of the listed medicines.

Table 6.9

Insufficient resources (e.g. staff, space etc) within my pharmacy has limited the practice of this product						
Medicines	Strongly disagree n (%)	Disagree n (%)	Neither agree nor disagree n (%)	Agree n (%)	Strongly agree n (%)	
Omeprazole	170	188	125	50	23	
(N= 556)	(30.6)	(33.8)	(22.5)	(9.0)	(4.1)	
Naproxen	176	204 (36.6)	120	38	19	
(N= 557)	(31.6)		(21.5)	(6.8)	(3.4)	
Simvastatin	159	162	122	73	41	
(N= 557)	(28.5)	(29.1)	(21.9)	(13.1)	(7.4)	
Chloramphenicol (N= 558)	234 (41.9)	216 (38.7)	85 (15.2)	9 (1.6)	14 (2.5)	

6.4.1.6 Medicine potential for misuse

The majority of the respondents strongly disagreed or disagreed that customers could misuse any of the four listed medicines.

Table 6.9

It is likely that customers could misuse this product								
Medicines	Strongly disagree n (%)	Disagree n (%)	Neither agree nor disagree n (%)	Agree n (%)	Strongly agree n (%)			
Omeprazole	112	205	105	104	30			
(N = 556)	(20.1)	(36.9)	(18.9)	(18.7)	(5.4)			
Naproxen	85	196	121	132	23			
(N = 557)	(15.3)	(35.2)	(21.7)	(23.7)	(4.1)			
Simvastatin	146	243	99	54	14			
(N = 556)	(26.3)	(43.7)	(17.8)	(9.7)	(2.5)			
Chloramphenicol	129	227	93	87	21			
(N= 557)	(23.2)	(40.8)	(16.7)	(15.6)	(3.8)			

6.4.1.7 Issue of patient compliance

The majority of the respondents disagreed or strongly disagreed that undesirable patient behaviours in general, were a barrier to the adoption of chloramphenicol, with approximately one third being unsure in relation to omeprazole, naproxen and simvastatin.

Table 6.9

	Customers not accepting my advice around this product makes me less likely to adopt this product					
Medicines	Strongly disagree n (%)	Disagree n (%)	Neither agree nor disagree n (%)	Agree n (%)	Strongly agree n (%)	
Omeprazole	85	151	160	124	32	
(N=552)	(15.4)	(27.4)	(29.0)	(22.5)	(5.8)	
Naproxen	83	163	172	108	27	
(N = 553)	(15.0)	(29.5)	(31.1)	(19.5)	(4.9)	
Simvastatin	82	138	159	133	41	
(N=553)	(14.8)	(25.0)	(28.8)	(24.1)	(7.4)	
Chloramphenicol (N= 554)	109 (19.7)	180 (32.5)	149 (26.9)	87 (15.7)	29 (5.2)	

6.4.1.8 Complexity of supply process

A high majority of the respondents disagreed or strongly disagreed that the process involved in the supply of omeprazole, naproxen and chloramphenicol was complex. Over 40% of respondents agreed or strongly agreed that the supply procedure for simvastatin was complex.

Table 6.9

I find the processes involved in the supply of this product complex							
Medicines	Strongly disagree n (%)	Disagree n (%)	Neither agree nor disagree n (%)	Agree n (%)	Strongly agree n (%)		
Omeprazole	101	245	137	52	18		
(N=553)	(18.3)	(44.3)	(24.8)	(9.4)	(3.3)		
Naproxen	99	276	131	37	10		
(N=553)	(17.9)	(49.9)	(23.7)	(6.7)	(1.8)		
Simvastatin	74	137	107	144	92		
(N=554)	(13.4)	(24.7)	(19.3)	(26.0)	(16.6)		
Chloramphenicol	177	275	71	23	8		
(N=554)	(31.9)	(49.6)	(12.8)	(4.2)	(1.4)		

6.4.1.9 Task delegation to support staff

A majority of the respondents disagreed or strongly disagreed that they were comfortable in delegating supply task relating to omeprazole and simvastatin to support staff. However, less than half would delegate the task for the supply of naproxen and simvastatin.

Table 6.9

I am happy to delegate the task of supplying this produ to support staff							
Medicines	Strongly disagree n (%)	Disagree n (%)	Neither agree nor disagree n (%)	Agree n (%)	Strongly agree n (%)		
Omeprazole	78	201	99	146	29		
(N=553)	(14.1)	(36.3)	(17.9)	(26.4)	(5.2)		
Naproxen	62	172	96	194	30		
(N=554)	(11.2)	(31.0)	(17.3)	(35.0)	(5.4)		
Simvastatin	156	241	66	67	24		
(N=554)	(28.2)	(43.5)	(11.9)	(12.1)	(4.3)		
Chloramphenicol	64	153	61	198	79		
$(N=555)^{-}$	(11.5)	(27.6)	(11.0)	(35.7)	(14.2)		

6.4.1.10 Patient requests for medicines

A high majority of the respondents agreed or strongly agreed that direct patient requests were common for reclassified chloramphenical whereas most disagreed or strongly disagreed to such requests being common for omeprazole, naproxen and simvastatin.

Table 6.9

Many customers ask for this product by name								
Medicines	Strongly disagree n (%)	Disagree n (%)	Neither agree nor disagree n (%)	Agree n (%)	Strongly agree n (%)			
Omeprazole	186	228	83	50	7			
(N=554)	(33.6)	(41.2)	(15.0)	(9.0)	(1.3)			
Naproxen	145	216	89	96	7			
(N=553)	(26.2)	(39.1)	(16.1)	(17.4)	(1.3)			
Simvastatin	238	205	74	33	5			
(N=555)	(42.9)	(36.9)	(13.3)	(5.9)	(0.9)			
Chloramphenicol	55	99	73	195	133			
(N= 555)	(9.9)	(17.8)	(13.2)	(35.1)	(24.0)			

6.4.1.11 Confidence in supply process

A high majority expressed confidence in their abilities to supply all the four listed medicines.

Table 6.9

I feel confident about my ability to supply this produ						
Medicines	Strongly disagree n (%)	Disagree n (%)	Neither agree nor disagree n (%)	Agree n (%)	Strongly agree n (%)	
Omeprazole	9	20	43	253	230	
(N=555)	(1.6)	(3.6)	(7.7)	(45.6)	(41.4)	
Naproxen	5	13	38	254	246	
(N = 556)	(0.9)	(2.3)	(6.8)	(45.7)	(44.2)	
Simvastatin	27	79	80	207	163	
(N=556)	(4.9)	(14.2)	(14.4)	(37.2)	(29.3)	
Chloramphenicol	8	2	6	172	368	
(N=556)	(1.4)	(0.4)	(1.1)	(30.9)	(66.2)	

6.4.1.12 Compatibility to pharmacy ranges of medicines

A high majority agreed or strongly agreed that omeprazole, naproxen and chloramphenicol were welcome additions to the range of pharmacy medicines. However, the majority did not agree around reclassified simvastatin.

Table 6.9

I believe that this product is a welcome addition to the range of pharmacy medicines							
Medicines	Strongly disagree n (%)	Disagree n (%)	Neither agree nor disagree n (%)	Agree n (%)	Strongly agree n (%)		
Omeprazole	39	66	119	219	113		
(N=556)	(7.0)	(11.9)	(21.4)	(39.4)	(20.3)		
Naproxen	18	42	107	259	131		
(N=557)	(3.2)	(7.5)	(19.2)	(46.5)	(23.5)		
Simvastatin	132	159	132	83	51		
(N=557)	(23.7)	(28.5)	(23.7)	(14.9)	(9.2)		
Chloramphenicol	4	2	6	101	445		
(N=558)	(0.7)	(0.4)	(1.1)	(18.1)	(79.7)		

6.4.1.13 Adequacy of information sources

The majority of respondents expressed agreement that information sources relating to all four medicines were adequate.

Table 6.9

	I have access to sufficient sources of information relating to this product						
Medicines	Strongly disagree n (%)	Disagree n (%)	Neither agree nor disagree n (%)	Agree n (%)	Strongly agree n (%)		
Omeprazole	9	46	57	260	181		
(N=553)	(1.6)	(8.3)	(10.3)	(47.0)	(32.7)		
Naproxen	5	33	52	277	186		
(N=553)	(0.9)	(6.0)	(9.4)	(50.1)	(33.6)		
Simvastatin	18	65	68	232	171		
(N=554)	(3.2)	(11.7)	(12.3)	(41.9)	(30.9)		
Chloramphenicol	4	9	24	260	257		
(N= 554)	(0.7)	(1.6)	(4.3)	(46.9)	(46.4)		

6.4.1.14 Evidence base

Respondents' beliefs in the evidence of efficacy were high with chloramphenicol, naproxen and omeprazole. Less than one in five, however, agreed in relation to simvastatin, with approximately a quarter being unsure.

Table 6.9

I believe that the OTC regimen for this product is likely be effective							
Medicines	Strongly disagree n (%)	Disagree n (%)	Neither agree nor disagree n (%)	Agree n (%)	Strongly agree n (%)		
Omeprazole	30	99	123	221	82		
(N=555)	(5.4)	(17.8)	(22.2)	(39.8)	(14.8)		
Naproxen	14	51	126	265	98		
(N=554)	(2.5)	(9.2)	(22.7)	(47.8)	(17.7)		
Simvastatin	139	173	140	79	26		
(N=557)	(25.0)	(31.1)	(25.1)	(14.2)	(4.7)		
Chloramphenicol	5	3	17	176	356		
(N= 557)	(0.9)	(0.5)	(3.1)	(31.6)	(63.9)		

6.4.1.15 Naming of newly reclassified medicines

A high majority of the respondents disagreed or strongly disagreed that similarity of POM and P packs could create confusion in practice. Approximately one in five agreed that the similarity in the nomenclature of chloramphenical POM and P packs could create confusion during sales or supplies.

Table 6.9

The similarity of POM and P packs of this product coul create confusion							
Medicines	Strongly disagree n (%)	Disagree n (%)	Neither agree nor disagree n (%)	Agree n (%)	Strongly agree n (%)		
Omeprazole	159	249	100	36	11		
(N=555)	(28.6)	(44.9)	(18.0)	(6.5)	(2.0)		
Naproxen	157	260	93	35	10		
(N=555)	(28.3)	(46.8)	(16.8)	(6.3)	(1.8)		
Simvastatin	153	249	105	36	11		
(N=554)	(27.6)	(44.9)	(19.0)	(6.5)	(2.0)		
Chloramphenicol	136	214	97	75	33		
(N=555)	(24.5)	(38.6)	(17.5)	(13.5)	(5.9)		

6.4.1.16 Observability of efficacy

A majority of respondents agreed or strongly agreed that it was easy for them or the patients to know whether therapy with chloramphenicol, naproxen and omeprazole was

effective. Approximately two thirds disagreed or strongly disagreed to the observable benefits of simvastatin.

Table 6.9

It is easy for me and/or my customers to know if treatment with this product is effective							
Medicines	Strongly disagree n (%)	Disagree n (%)	Neither agree nor disagree n (%)	Agree n (%)	Strongly agree n (%)		
Omeprazole	27	64	161	238	61		
(N=551)	(4.9)	(11.6)	(29.2)	(43.2)	(11.1)		
Naproxen	8	39	145	275	84		
(N=551)	(1.5)	(7.1)	(26.3)	(49.9)	(15.2)		
Simvastatin	175	187	136	44	10		
(N=552)	(31.7)	(33.9)	(24.6)	(8.0)	(1.8)		
Chloramphenicol	6	13	71	207	257		
(N= 554)	(1.1)	(2.3)	(12.8)	(37.4)	(46.4)		

6.4.1.17 Potential for patient satisfaction

Almost half of the respondents were unsure that simvastatin had potential to engender patient satisfaction. The majority agreed or strongly agreed that naproxen and chloramphenical had potential to engender patient satisfaction with over 38% unsure for omeprazole.

Table 6.9

	I believe this product has potential to engender patient satisfaction					
Medicines	Strongly disagree n (%)	Disagree n (%)	Neither agree nor disagree n (%)	Agree n (%)	Strongly agree n (%)	
Omeprazole	26	60	203	185	59	
(N=533)	(4.9)	(11.3)	(38.1)	(34.7)	(11.1)	
Naproxen	20	57	187	209	62	
(N=535)	(3.7)	(10.7)	(35.0)	(39.1)	(11.6)	
Simvastatin	71	148	231	63	20	
(N=533)	(13.3)	(27.8)	(43.3)	(11.8)	(3.8)	
Chloramphenicol	20	37	102	172	205	
(N=536)	(3.7)	(6.9)	(19.0)	(32.1)	(38.2)	

6.4.1.18 Safety of medicines

Just under half of the respondents agreed or strongly agreed to naproxen possessing potential for high risk of adverse events. Almost one third were unsure of the patient safety

implications with simvastatin. A high majority deemed that safety was not an issue for the supply of chloramphenicol.

Table 6.9

	I believe there are high risks of adverse events associated with this product						
Medicines	Strongly disagree n (%)	Disagree n (%)	Neither agree nor disagree n (%)	Agree n (%)	Strongly agree n (%)		
Omeprazole	60	287	159	38	8		
(N=552)	(10.9)	(52.0)	(28.8)	(6.9)	(1.4)		
Naproxen	19	129	167	202	37		
(N=554)	(3.4)	(23.3)	(30.1)	(36.5)	(6.7)		
Simvastatin	34	168	176	140	35		
(N=553)	(6.1)	(30.4)	(31.8)	(25.3)	(6.3)		
Chloramphenicol	100	312	116	24	3		
(N= 555)	(18.0)	(56.2)	(20.9)	(4.3)	(0.5)		

6.4.1.19 'Step too far'

A high majority of respondents disagreed or strongly disagreed that reclassification of omeprazole, naproxen and chloramphenicol was a 'step too far' for pharmacy. Over 40% of the respondents, however, agreed or strongly agreed that reclassification of simvastatin was a 'step too far'.

Table 6.9

	Introduction of this product may have represented a 'step too far' for OTC Medicines							
Medicines	Strongly disagree n (%)	Disagree n (%)	Neither agree nor disagree n (%)	Agree n (%)	Strongly agree n (%)			
Omeprazole	157	252	91	37	16			
(N=553)	(28.4)	(45.6)	(16.5)	(6.7)	(2.9)			
Naproxen	164	255	89	30	16			
(N=554)	(29.6)	(46.0)	(16.1)	(5.4)	(2.9)			
Simvastatin	98	151	81	134	90			
(N=554)	(17.7)	(27.3)	(14.6)	(24.2)	(16.2)			
Chloramphenicol	282	230	30	6	5			
(N= 553)	(51.0)	(41.6)	(5.4)	(1.1)	(0.9)			

6.4.1.20 Role in decision making

A high majority indicated that their professional decisions were more important or relevant than recommendations of management or 'head office' around their adoption of the listed medicines into practice.

Table 6.9

It has been my management's decision rather than my own as to if/ how far to adopt into practice								
Medicines	Strongly disagree n (%)	Disagree n (%)	Neither agree nor disagree n (%)	Agree n (%)	Strongly agree n (%)			
Omeprazole	172	162	102	75	33			
(N=544)	(31.6)	(29.8)	(18.8)	(13.8)	(6.1)			
Naproxen	174	162	102	74	32			
(N=544)	(32.0)	(29.8)	(18.8)	(13.6)	(5.9)			
Simvastatin	172	155	99	79	40			
(N=545)	(31.6)	(28.4)	(18.2)	(14.5)	(7.3)			
Chloramphenicol	184	170	101	62	29			
(N=546)	(33.7)	(31.1)	(18.5)	(11.4)	(5.3)			

6.4.1.21 External support: Professional body

The majority of respondents reflected satisfaction with the support they were receiving from their professional body. Approximately a third, however, were unsure about the adequacy of such support for all four medicines.

Table 6.9

	I get adequa		rom my profe	essional bo	dy to adopt
Medicines	Strongly disagree n (%)	Disagree n (%)	Neither agree nor disagree n (%)	Agree n (%)	Strongly agree n (%)
Omeprazole	20	55	179	228	69
(N=551)	(3.6)	(10.0)	(32.5)	(41.4)	(12.5)
Naproxen	19	55	182	228	66
(N = 550)	(3.5)	(10.0)	(33.1)	(41.5)	(12.0)
Simvastatin	28	63	188	212	61
(N=552)	(5.1)	(11.4)	(34.1)	(38.4)	(11.1)
Chloramphenicol	15	37	147	250	104
(N=546)	(2.7)	(6.7)	(26.6)	(45.2)	(18.8)

6.4.1.22 External support: Local medical practice

The majority of the respondents disagreed or strongly disagreed that lack of local medical practice communication was a barrier to their adopting any of the four listed medicines into practice.

Table 6.9

	Lack of proper way to communicate with the local medical practice is a barrier to adopt this product							
Medicines	Strongly disagree n (%)	Disagree n (%)	Neither agree nor disagree n (%)	Agree n (%)	Strongly agree n (%)			
Omeprazole	101	210	175	50	12			
(N=548)	(18.4)	(38.3)	(31.9)	(9.1)	(2.2)			
Naproxen	99	223	179	36	11			
(N=548)	(18.1)	(40.7)	(32.7)	(6.6)	(2.0)			
Simvastatin	89	185	171	79	25			
(N=549)	(16.2)	(33.7)	(31.1)	(14.4)	(4.6)			
Chloramphenicol	129	229	161	23	8			
(N=550)	(23.5)	(41.6)	(29.3)	(4.2)	(1.5)			

6.4.1.23 Access to patient medical records

Over 53% and 30% of the respondents had agreement that lack of access to patient medical records was a barrier to adopting simvastatin and omeprazole into practice respectively. The majority did not consider that access to patient medical records was important for the adoption of chloramphenicol.

Table 6.9

Lack of access to patient medical records makes it difficult to adopt this product into practice									
Medicines	Strongly Disagree Neither Agree Strong disagree n (%) agree nor n (%) agree n (%) agree n (%) agree n (%)								
Omeprazole (N= 553)	55 (9.9)	185 (33.5)	145 (26.2)	130 (23.5)	38 (6.9)				
Naproxen (N= 553)	60 (10.8)	206 (37.3)	143 (25.9)	116 (21.0)	28 (5.1)				
Simvastatin (N= 554)	(7.6)	113 (20.4)	104 (18.8)	(36.8)	91 (16.4)				
Chloramphenicol (N= 555)	148 (26.7)	263 (47.4)	95 (17.1)	30 (5.4)	19 (3.4)				

Chapter 6: Main survey

6.4.1.24 Supply off guidelines

Although a high majority of respondents disagreed or strongly disagreed that they were comfortable supplying any of the listed medicines off guidelines, approximately one in five indicated they supply chloramphenical off guideline where required.

Table 6.9

	I am/would this produc		ble going off	guidelines	s to supply
Medicines	Strongly disagree n (%)	Disagree n (%)	Neither agree nor disagree n (%)	Agree n (%)	Strongly agree n (%)
Omeprazole	125	253	82	73	17
(N=550)	(22.7)	(46.0)	(14.9)	(13.3)	(3.1)
Naproxen	130	265	79	60	17
(N=551)	(23.6)	(48.1)	(14.3)	(10.9)	(3.1)
Simvastatin	162	269	71	34	15
(N=551)	(29.4)	(48.8)	(12.9)	(6.2)	(2.7)
Chloramphenicol	120	241	73	87	32
(N=553)	(21.7)	(43.6)	(13.2)	(15.7)	(5.8)

6.4.2 Summary of descriptive statistics

Descriptive analysis reflected respondents' key barriers and facilitators to decision making. Support for the reclassified status and adoption into practice were rated very high by the respondents with the case of chloramphenicol, followed by naproxen and omeprazole. Respondents' ratings of simvastatin around both the key outcomes acceptance and adoption were very low. Key differences in respondents' agreement were observed in 12 of the 24 listed items. The differences in proportion lying within categories 'agree' or 'strongly agree' across four medicines were mainly noted around 12 of the 24 items listed below. Within these 12 items, proportion of respondents agreeing or strongly agreeing mostly followed the pattern chloramphenicol > naproxen> omeprazole> simvastatin where items were positive; and the reverse order where the items were negative.

- 1. Opportunity to increase role as a health professional
- 2. Customers complaints about the cost
- 3. Patients requests for the medicines
- 4. Belief that the medicine a welcome addition to the range of pharmacy medicine
- 5. Therapeutic area of reclassified medicine matching with business/service ambition of pharmacy

- 6. Financial potential of the medicine
- 7. Complexity of supply process
- 8. Comfortable in delegating the task of supplying the product to support staff
- 9. Believe in evidence of efficacy of the non-prescription dose of the medicines
- 10. Observability of efficacy
- 11. Medicine potential to engender patient satisfaction
- 12. Perceived need for access to patient medical records for the supply

Differences in such proportion across 'agree' and 'strongly agree' were less notable in items measuring aspects of practice such as adequacy of resources to inform supply; adequacy of information sources and external support.

6.5 ANALYSIS OF RESPONSES TO OPEN QUESTION

Eighty-two respondents provided comments in response to the open questions. These responses were analysed by content analysis method as detailed in Chapter 2 (section 2.4.4.3) and are summarised in table 6.10.

Table 6.10 Responses to open question on factors associated with decision making* (Note: this table extends up to two pages)

Response	Number of	Exemplar quotes (Respondent code)
categories	responses	
Retail price of medicines/	33	"Cost affects my patients esp as I work in a low income/high unemployment area" (R28)
patient cost implications		"Price- pharmacy in quite deprived area. So I don't keep expensive items." (R29)
		"The local market. i.e. patients will not pay for a new brand medicine if they may be able to obtain it free on NHS prescription." (R139)
		"Don't recommend if expensive and there are other effective but less expensive items available." (R302)
Evidence base	9	"Is the dose effective? Many of the products have doses below the apparent therapeutic dose of the prescription product. Loads of questions about their effectiveness." (R332)
Pharmacy resources	9	"Time- both talking to patient/ and or staff training." (R509)
		"No time to go through lengthy advice giving plus questioning sessions." (R528)
Patient demand	6	"Purely cost/ demand. I don't store Zocor (simvastatin) because no one has asked for it." (R173)
Access to patient medical records	5	"With omeprazole + simvastatin need to check PMR (patient medical records) held at GP and blood levels for simvastatin." (R61)
		"The fact that I have been here 6 years, know all my patients well, know my GPs etc. Confidence in their histories etc." (R63)
Perceived risk assessment	5	"Not able to carry out tests to monitor." (R33)
needs (Complexity)		"Complexity of some of the processes you must comply with can be time consuming." (R234)
Safety	4	"Potential side effects and interactions." (R67)
		"As an independent contractor I use my own professional judgement on safety of products to sell as P's." (R490)
Training	4	"Inadequate training material from manufacturers would discourage me from stocking product." (R287)
		"Adequate plus robust training packaging for my staff." (R106)
Acute vs chronic indication	3	"Long term treatment should be from GP!" (R195)

^{*}Some respondents provided more than one comment

Response	Number of	Exemplar cotes (Respondent code)
categories	responses	
Pharmacists' confidence	3	"Lack of confidence initially with new POM to P products." (R432)
		"Gaps in our product knowledge- keeping up to date with POM to P switches due to work demands." (R390)
		"Certain POM to P switch occurred before I qualified, not always easy to find current info on them to be able to recommend." (R205)
Guidelines	2	"Health board PGD's. Health Board communications on their opinion of product in area" R399
Past experience with use	2	"Previous experience in use." (R559)
Novelty/whether a welcome	2	"Similar products already available (R155)
addition to pharmacy		"If the product is a "me too" product I am likely to stick with existing or less expensive products." (R302)
Organisational implementation decision	2	"We have no choice, head office tells us, we are doing it." (R295)
Communication with local medical practice	1	"I would be comfortable as long as there is support and communication with medical practice." (R323)
Expiry date	1	"Expiry date of the product." (R128)
Full time/part time	1	"Whether full-time/ part time may be a factor." (R77)
Patient compliance issues	1	"Patients wanting/ expecting to purchase because wow OTC + not listening to recommendations." (R342)
Perceived innovativeness/at titudes to change	1	"My team and I embrace and welcome change." (R53)
Pharmacy business interests	1	"HC pharmacy. Very few OTC sales." (R143)
Prescribing qualification of respondent	1	"I am an independent prescriber." (R170)
Unclear quotes	4	"Don't think that simvastatin should be OTC- waste of money, time." (R361)
		"Confidentiality issues" (R73)
		"When I don't agree with the drug. e.g. Orlistat." (R79)
		"I don't feel Omeprazole or naproxen are necessary for OTC. Naproxen, chloramphenicol useful particularly over a weekend." (R159)

6.6 BIVARIATE/MULTIVARIATE ANALYSIS

Descriptive analysis as shown above were used to present responses to the outcome measures and to the 24 items scales. So as to further understand factors associated with decision making, it is also important to distinguish why, for example, some respondents rated naproxen very highly, whereas others did not. Such understanding will be enabled via multivariate/bivariate analysis as detailed below.

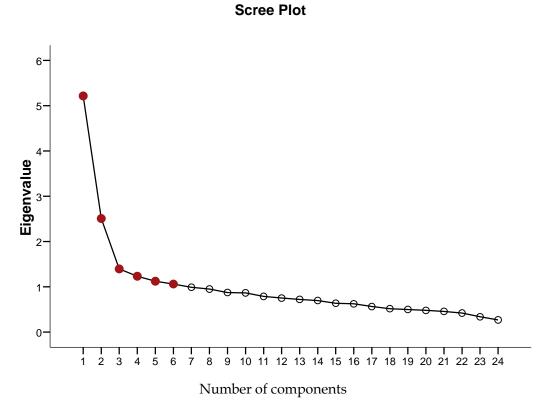
6.6.1 Principal component factor analysis

Factor analysis was performed on the 24 items scale measuring facilitators/barriers to decision making using principal component analysis for each of the listed medicines. This analysis was conducted to potentially reduce the 24 item scale to a smaller number of meaningful factors so that these reduced items. Responses to all negative items were reversed scored for this analysis to ease interpretation. Kaiser-Meyer-Olkin measure of sampling adequacy (KMO) and Barlett's test of sphericity was used to identify whether factor analysis was appropriate for the results. KMO measure represents the squared correlation between the variables to the squared partial correlation (correlation between two variables while adjusting for the third variable) between the variables. KMO value close to 0 indicates that the factor analysis is likely to be inappropriate, whereas value close to 1 indicates that factor analysis should yield distinct and reliable factors [295]. Barlett's test of sphericity tests the strengths of correlations between the variables. A significant correlation means it is apt to proceed for the factor analysis [295]. Cronbach's alpha measure was used to test the reliability of how closely the extracted items within a component relate to each other. Components with Cronbach's alpha ≥0.7 are known to be considered reliable. Whereas, the alpha value for 'if any item is removed from the scale' should not exceed 0.8 [295].

6.6.1.1 Omeprazole

The KMO measure of sampling adequacy was 0.854 and Barlett's test of sphericity was significant (Chi square = 2882.86 p < 0.001) reflecting it was appropriate to continue with factor analysis. Visual inspection of the Scree plot (figure 6.6), the number of factors with an eigenvalue greater than 1 and item loadings on factors well above 0.4 showed that six components could be extracted (table 6.12). These six components accounted for over 52% of the variance in the data (table 6.11).

Figure 6.6: Scree plot for omeprazole principal component factor analysis*



^{*}Method of extraction used: Principal component with varimax rotation and Kaiser normalization.

Table 6.11: Percentage variance of the six components that were extracted from factor analysis of 24 items for omeprazole

		Initial Eigenva	lues	Rot	ation Sums o Loading	
			Cumulative		% of	Cumulative
Component	Total	% Variance	%	Total	Variance	%
1	5.215	21.728	21.728	4.016	16.734	16.734
2	2.507	10.447	32.176	2.452	10.215	26.949
3	1.395	5.813	37.989	1.805	7.522	34.471
4	1.235	5.147	43.136	1.552	6.467	40.938
5	1.123	4.680	47.816	1.533	6.387	47.325
6	1.063	4.429	52.245	1.181	4.920	52.245

However, the rotated component matrix table (table 6.12) showed that items retained within each components were difficult to interpret, with scale items having very different meanings from both theory [131] and practice points of view. These six factors also failed to meet the reliability test based either on Cronbach's alpha ≥0.7 or Cronbach's alpha for 'if items removed from the scale' >0.8 [295].

Table 6.12: Rotated component matrix showing factor analysis of 24 items for omeprazole*

Items	Component					
	1	2	3	4	5	6
This is/was a good opportunity to extend my role as a health professional	.815	.081	032	066	024	088
This product matches with the business/service ambitions of my pharmacy	.810	.061	.040	137	004	042
This product has potential for good financial returns for my pharmacy	.684	164	.009	.056	.172	.151
I believe that this product is a welcome addition to the range of pharmacy medicines	.762	.119	.147	.233	.042	146
I believe that the OTC regimen for this product is likely to be effective	.707	.095	.090	.118	.125	086
It is easy for me and/or my customers to know if treatment with this product is effective	.578	.199	.037	.119	.187	.097
I believe this product has potential to engender patient satisfaction	.508	-2.67E- 005	018	.292	.142	.073
Many customers ask for this product by name	.390	.073	368	.218	040	.222
It is likely that customers could misuse this product [†]	.026	.709	013	110	022	.112
Customers not accepting my advice around this product makes me less likely to adopt this product [†]	.031	.660	.066	.180	.030	.133
Insufficient resources (e.g. staff, space etc) within my pharmacy has limited the practice of this product [†]	.026	.522	.249	.085	.134	093
I believe there are high risks of adverse events associated with this product [†]	.102	.482	.353	126	.055	077
I find the processes involved in the supply of this product complex [†]	.174	.470	.164	.458	.056	126
Lack of access to patient medical records makes it difficult to adopt this product into practice [†]	.188	.407	.423	.043	.258	.273
Introduction of this product may have represented a 'step too far' for OTC Medicines [†]	.422	.310	.565	.097	057	090
The similarity of POM and P packs of this product could create confusion [†]	.023	.010	.653	.201	.166	083
It has been my management's decision rather than my own as to if/ how far to adopt into practice [†]	.017	.188	.554	134	084	.017
I am/would be comfortable going off guidelines to supply this product	.062	121	.073	.738	113	.010
I am happy to delegate the task of supplying this product to support staff	.140	.182	114	.573	.146	.076
I get adequate support from my professional body to adopt this product	.190	038	.027	.000	.761	069
Lack of proper way to communicate with the local medical practice is a barrier to adopt this product [†]	.069	.225	.379	009	.571	.316
I have access to sufficient sources of information relating to this product	.183	.360	113	.095	.525	372
I feel confident about my ability to supply this product	.217	.369	.034	.267	.289	464
My customers often complain about the cost of this product (not including e-MAS supply) [†]	.035	.140	095	.100	.012	.664

^{*}Method of extraction used: Principal component, Rotation used: Varimax with Kaiser normalization. Values equal to or above 0.4 are highlighted; †Items reversed scored

The following tables summarize the overall Cronbach's alpha value and overall alpha value if any item was deleted for each of the retained component (table 6.13).

Table 6.13: Reliability analysis for components 1-5 extracted from factor analysis of 24 item evaluation scale of omeprazole. (Not this table extends up to five pages with descriptions in between)

Component 1

Item	Scale mean if item deleted	Scale variance if item deleted	Corrected item-total correlation	Cronbach's alpha if item deleted
This is/was a good opportunity to extend my role as a health professional	23.91	26.614	.663	.814
This product matches with the business/service ambitions of my pharmacy	24.13	26.353	.657	.814
This product has potential for good financial returns for my pharmacy	24.43	26.616	.530	.831
I believe that this product is a welcome addition to the range of pharmacy medicines	23.88	25.004	.723	.804
I believe that the OTC regimen for this product is likely to be effective	23.99	26.255	.642	.815
It is easy for me and/or my customers to know if treatment with this product is effective	23.96	28.246	.521	.831
I believe this product has potential to engender patient satisfaction	24.05	28.822	.460	.838
Introduction of this product may have represented a 'step too far' for OTC Medicines	23.51	29.219	.416	.843

Overall Cronbach's alpha for the component .843

Component 2

Item	Scale mean if item deleted	Scale variance if item deleted	Corrected item-total correlation	Cronbach's alpha if item deleted
It is likely that customers could misuse this product	17.48	11.162	.386	.650
Customers not accepting my advice around this product makes me less likely to adopt this product	17.72	10.763	.462	.622
Insufficient resources (e.g. staff, space etc) within my pharmacy has limited the practice of this product	17.18	11.249	.407	.641
I believe there are high risks of adverse events associated with this product	17.33	12.621	.374	.654
I find the processes involved in the supply of this product complex	17.31	11.768	.407	.642
Lack of access to patient medical records makes it difficult to adopt this product into practice	17.81	11.046	.438	.630

Overall Cronbach's alpha for the component .843

Component 3

Item	Scale mean if item deleted	Scale variance if item deleted	Corrected item-total correlation	Cronbach's alpha if item deleted
The similarity of POM and P packs of this product could create confusion	10.74	5.612	.270	.517
Introduction of this product may have represented a 'step too far' for OTC Medicines	10.76	4.772	.460	.368
It has been my management's decision rather than my own as to if/ how far to adopt into practice	10.99	4.805	.262	.542
Lack of access to patient medical records makes it difficult to adopt this product into practice	11.50	4.785	.352	.452

Overall Cronbach's alpha for the component .544

Component 4

Item	Scale mean if item deleted	Scale variance if item deleted	Corrected item-total correlation	Cronbach's alpha if item deleted
I find the processes involved in the supply of this product complex	4.99	2.797	.275	.262
I am/would be comfortable going off guidelines to supply this product	6.38	2.867	.199	.395
I am happy to delegate the task of supplying this product to support staff	5.93	2.407	.260	.282

Overall Cronbach's alpha for the component .408

Component 5

Item	Scale mean if item deleted	Scale variance if item deleted	Corrected item-total correlation	Cronbach's alpha if item deleted
I get adequate support from my professional body to adopt this product	7.63	2.174	.347	.321
Lack of proper way to communicate with the local medical practice is a barrier to adopt this product	7.50	2.343	.278	.439
I have access to sufficient sources of information relating to this product	7.11	2.321	.298	.406

Overall Cronbach's alpha for the component .490

Component 6

Cronbach's alpha value for component 6 was found to be negative due to a negative average covariance among items. This violated reliability model assumptions and thus results are not presented.

6.6.1.2 Naproxen, chloramphenicol and simvastatin

Factor analysis of the 24-items scale relating to napoxen, chloramphencial and simvastatin also displayed similar issues in terms of items with dissimilar meanings aggregating together as one factor, as well as failing the reliability tests. Table 6.14 summarises the analysis. Details of factor analysis of these three medicines appear in Appendix VI.

Table 6.14: Summary of principal component factor analysis

Reclassified medicines	Total number of components extracted	Number of reliable components extracted	% variance explained by the reliable component(s)
Omeprazole	6	0	0%
Naproxen	7	1	14%
Simvastatin	6	1	15%
Chloramphenicol	8	0	0%

6.6.1.3 Summary of factor analysis

Factors associated with decision making could not be extracted from principal component factor analysis as described above. These results reflect that although items within the scale align to theoretical constructs as shown in Chapter 5, each item within the 24-item scales is more likely to represent unique issues to practice. Hence, each of the 24 individual items within the scale were used in further analyses, attempting to differentiate respondents' ratings of acceptance and adoption

6.6.2 Binary logistic regression analysis

Binary logistic regression analysis was performed to differentiate respondents scoring the outcome measures of support and adoption differently. Factors associated with decision making could further be understood by exploring from the regression analysis, for example, why some respondents rated omeprazole very highly than others. For the purpose of this analysis, the following variables were defined:

Outcome measures

Binary logistic regression analysis requires binary outcomes. Outcome measure scales (and some explanatory variables discussed below) were redefined as per the approach of

systematic review studies [250,255,272,281] for each of the four medicines, separately as follows:

- A. Respondent scores on 'Acceptance' scale. Those scoring 3 or above in the scale (termed high acceptors) versus others (termed low acceptors)
- B. Respondent scores on 'Adoption' scale: Those scoring 3 or above in the scale (termed high adopters) versus others (termed low adopters)

Explanatory (dependent) variables

Respondent agreement with each of the items of the 24 items scale and the demographic characteristics were used as explanatory variables. All responses on the 24-items scale and four of 13 demographic characteristics were also modified to binary variables along with perceived innovativeness.

- A. **Agreement:** Agree and strongly agree as 'high agreement'; and the remainder of the responses as 'low agreement'
- B. Innovativeness: Resistant, cautious or deliberate; and role model or venturesome
- C. **Age**: 39 years or under; and 40 years or over
- D. **Number of years registered with RPSGB:** 10 years and under; and 11 years or over
- E. **Size of pharmacy ownership:** Independent or small multiple; and medium or large size multiple

Short listing of explanatory variables for regression analysis

Cross tabulation analysis of all the explanatory variables with both outcome measures for each medicine were conducted using Chi-squared tests or Fisher's exact test. Responses to all negative items were reversed scored to ease interpretation of the output. Only those explanatory variables that had significant association with the outcome measures, based on P value ≤ 0.05 , were entered into the regression analysis. Both the univariate and multivariate statistics are reported for one of the analyses relating to the outcome 'omeprazole acceptance'. Only the multivariate outputs are shown for other outcomes, with univariate cross tabulation analysis appearing in Appendix VI. The items reported within the multivariate analyses in the following sections has been based on the standards set out by the American Psychological Association (APA) as detailed by Field (2005) [295].

Regression method

Stepwise regression method, called Forward LR method was used. This is a method of binary logistic regression, whereby the SPSS begins with developing a model starting with only the regression constant and adds one explanatory variable at a time based on such variables making significant prediction of the outcome measure. The analytical process is proceeded until none of the remaining predictors make any further contribution to the model. At each step, the SPSS also is known to examine if any of the explanatory variable can be removed. Though other methods to conduct binary logistic regression are also known to exist, Forward LR method is said to be suitable to conduct regression on research where no previous similar models are known to exist [295].

6.6.2.1 Omeprazole acceptance

Eighteen explanatory variables showed significant association with the outcome in univariate analyses. The cross tabulation analysis showed that: 81.4% of the respondents that had high agreement that omeprazole has a good financial potential for pharmacy were likely to have scored 3 or more in the five point 'acceptance' scale as compared to only 55.8% of those disagreeing or were unsure about the financial potential of the medicine. In other words, the more the respondents saw the financial potential of the medicine, the more they were likely to support the reclassified status of the medicine. The rest of the statements should to be interpreted accordingly. Only significant associations are displayed in the table below. Non-significant associations appear in Appendix VI.

Table 6.15: Univariate cross tabulation statistics of explanatory variables and significant association with the outcome 'omeprazole acceptance' (note: this table extends up to two

pages)

Scale items	Categories [¥]	Low acceptance n (%)*	High acceptance n (%)*	P value
This product has potential for	Low agreement	159	201	< 0.001
good financial returns for my		(44.2)	(55.8)	
pharmacy (N= 543)	High agreement	34	149	
		(18.6)	(81.4)	2 221
This is a good opportunity to	Low agreement	157	107	< 0.001
extend my role as a health		(59.5)	(40.5)	
professional (N= 549)	High agreement	38 (13.3)	247 (86.7)	
This product matches with the	Low agreement	168	161	<0.001
business/service ambitions of	Low agreement	(51.1)	(48.9)	10.001
my pharmacy (N= 549)	High agreement	27	193	
	0 0 0	(12.3)	(87.7)	
Customers not accepting my	Low agreement	122	194	0.039
advice around this product	O	(38.6)	(61.4)	
makes me less likely to adopt	High agreement	68	161	
this product† (N= 545)		(29.7)	(70.3)	
I find the processes involved in	Low agreement	89	118	0.004
the supply of this product		(43.0)	(57.0)	
complex † (N= 546)	High agreement	103	236	
	<u> </u>	(30.4)	(69.6)	2.22
am happy to delegate the task	Low agreement	145	228	0.007
of supplying this product to	III: ala a anno anno anno	(38.9)	(61.1)	
support staff (N= 546)	High agreement	46 (26.6)	127 (73.4)	
Many customers ask for this	Low agreement	181	311	0.020
product by name (N= 547)	Low agreement	(36.8)	(63.2)	0.020
product by marie (i.e. o ii.)	High agreement	11	44	
	0 0 0	(20.0)	(80.0)	
I feel confident about my ability	Low agreement	50	22	< 0.001
to supply this product (N= 548)	Ü	(69.4)	(30.6)	
	High agreement	143	333	
		(30.0)	(70.0)	
I believe that this product is a	Low agreement	142	79	< 0.001
welcome addition to the range		(64.3)	(35.7)	
of pharmacy medicines (N= 550)	High agreement	52	277	
Lhave again to sufficient	Lowers	(15.8)	(84.2)	~ 0.001
I have access to sufficient	Low agreement	58 (51.8)	54 (48.2)	<0.001
sources of information relating to this product (N= 547)	High agreement	(51.8) 135	(48.2) 300	
to this product (IN- 047)	High agreement	(31.0)	(69.0)	
I believe that the OTC regimen	Low agreement	140	110	<0.001
for this product is likely to be	2011 ugiccincin	(56.0)	(44.0)	-0.001
effective (N= 549)	High agreement	53	246	
, ,	THE HUBICCHICH	(17.7)	(82.3)	

^{*}High agreement refers to agree or strongly agree. Low agreement refers to either disagree, strongly disagree or unsure* % represents proportion of respondents within row categories; Low acceptance relate to respondents score 1 or 2 in the five point scale. High acceptance relate to score 3 or above.† Items reversed scored

Scale items/variables	Categories	Low	High	P
•	C	acceptance	acceptance	value
		n (%)	n (%)	
It is easy for me and/or my	Low agreement	122	127	< 0.001
customers to know if treatment		(49.0)	(51.0)	
with this product is effective	High agreement	68	228	
(N=545)		(23.0)	(77.0)	
I believe this product has	Low agreement	130	157	< 0.001
potential to engender patient		(45.3)	(54.7)	
satisfaction (N= 527)	High agreement	54	186	
		(22.5)	(77.5)	
Introduction of this product	Low agreement	78	66	< 0.001
may have represented a 'step		(54.2)	(45.8)	
too far' for OTC Medicines†	High agreement	114	289	
(N=547)		(28.3)	(71.7)	
Lack of access to patient medical	Low agreement	121	190	0.040
records makes it difficult to		(38.9)	(61.1)	
adopt this product into practice [†]	High agreement	71	165	
(N= 547)		(30.1)	(69.9)	
Experience (N= 547)	10 years and	116	168	0.011
	under	(40.8)	(59.2)	
	11 years or over	79	184	
		(30.0)	(70.0)	
Owner (N= 554)	Yes	18	79	< 0.001
		(18.6)	(81.4)	
	No	178	279	
) () () () () ()	3/	(38.9)	(61.1)	10.001
Manager (N= 554)	Yes	160	239	< 0.001
		(40.1)	(59.9)	
	No	36	119	
		(23.2)	(76.8)	

[†]items reversed scored

The eighteen variables found to have significant association with the outcome were entered into regression analysis using the Forward LR stepwise method. Six variables were retained in the final binary logistic model. The strongest association was observed with the item measuring whether omeprazole was a welcome addition to pharmacy ranges of medicines. Those agreeing with this statement were approximately three times more likely to have rated their support for the reclassified status of medicines 3 or more in the five point scale than those having less agreement. Ownership status was also strongly related with owners indicating more support for the reclassified status than employees. The significant Wald statistic suggests that the B-coefficient is significantly different from zero, indicating that each of the six variables was making a significant contribution to the model. The 'model if item removed' statistic also indicates that each item has an important contribution to make



Table 6.16: Binary logistic regression model of the outcome 'omeprazole acceptance' with the explanatory variables

			Exp(B)	95.0% C.I.	for EXP(B)	Mod	el if item remov	red
Items retained in the model	Wald	P value	(odds ratio)*	Lower	Upper	Model Log Likelihood	Change in -2 Log Likelihood	P value of the Change
This is a good opportunity to extend my role as a health professional	11.543	0.001	2.582	1.494	4.463	-231.818	11.712	0.001
This product matches with the business/service ambitions of my pharmacy	6.153	0.013	2.217	1.182	4.158	-229.101	6.279	0.012
I feel confident about my ability to supply this product	5.763	0.016	2.291	1.164	4.508	-228.967	6.011	0.014
I believe that this product is a welcome addition to the range of pharmacy medicines	21.883	0.000	3.374	2.027	5.616	-237.040	22.157	<0.001
I believe that the OTC regimen for this product is likely to be effective	10.344	0.001	2.247	1.372	3.679	-231.096	10.267	0.001
(Not an) Owner	7.539	0.006	.385	.195	.761	-230.070	8.217	0.004
Regression constant	4.593	.032	.394					

^{*} for score 3 or above

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The highly significant model Chi-square value (p<0.001) in the table suggested that the model significantly improved with the explanatory variables that were retained in the model, than when only the regression constant was included. Both the Cox and Snell R square and Nagelkerke R square values suggest that the explanatory variables were useful predictors of the outcome (a value close to 0 suggests that explanatory variables are useless and close to 1 indicates the outcome is predicted perfectly [295]). The Hosmer and Lemeshow test goodness of fit statistics was not significant suggesting that observed data were not significantly different from the values predicted by the model (table 6.17).

Table 6.17: Regression model statistics relating to outcome 'omeprazole acceptance' (Note: this table is divided into three parts within this page)

Omnibus Tests of Model Coefficients

	Chi- square	Df	P value
Step	5.982	1	0.014
Block	198.098	6	< 0.001
Model	198.098	6	<0.001

Df: degree of freedom

Model summary with -2 Log likelihood ratio and R² values.

-2 Log	Cox & Snell R	Nagelkerke R
likelihood	Square	Square
451.924(b)	.326	.449

Hosmer and Lemeshow Test statistics

Chi-square	P value
5.1193.471	0.645

6.6.2.2 Omeprazole adoption

Twenty-two explanatory variables showed significant associations with this outcome in univariate analysis (Appendix VI). Of these, seven were retained in the regression model. The strongest odds ratio was obtained with the item measuring confidence in supply where those reflecting greater confidence in supply matters were approximately five times more likely to have rated their adoption 3 or more in the five point 'adoption' scale as compared to those who stated low confidence in supply matters. The rest of the variables should be interpreted accordingly (table 6.18). None of the 14 demographic characteristics were

retained in the multivariate model alth	ough three of then	n showed as	ssociation i	n the
univariate analyses (Appendix VI).				

Table 6.18: Binary logistic regression model of the outcome 'omeprazole adoption' with explanatory variables

			Exp(B)	95.0% C.I.	for EXP(B)	Model if item removed		
Items retained in the model	Wald	P value	(odds ratio)*	Lower	Upper	Model Log Likelihood	Change in -2 Log Likelihood	P value of the Change
This is a good opportunity to extend my role as a health professional	4.681	0.031	1.955	1.065	3.588	-222.274	4.720	0.030
This product matches with the business/service ambitions of my pharmacy	7.798	0.005	2.201	1.265	3.830	-223.882	7.936	0.005
I am happy to delegate the task of supplying this product to support staff	8.207	0.004	2.024	1.249	3.278	-224.037	8.246	0.004
Many customers ask for this product by name	11.966	0.001	3.478	1.716	7.048	-226.045	12.263	<0.001
I feel confident about my ability to supply this product	4.505	0.034	5.050	1.132	22.529	-223.218	6.609	0.010
I believe that this product is a welcome addition to the range of pharmacy medicines	3.929	0.047	2.004	1.008	3.984	-221.944	4.060	0.044
I believe that the OTC regimen for this product is likely to be effective	9.345	0.002	2.460	1.381	4.381	-224.770	9.712	0.002
Constant	38.227	<0.001	.008					

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^{*} for score 3 or above

The model Chi-square value was highly significant (P <0.001). Both the Cox and Snell R square and Nagelkerke R square values suggested the explanatory variables were making important contribution. Hosmer and Lemeshow test goodness of fit statistics was not significant suggesting that observed data were not significantly different from the values predicted by the model (table 6.19).

Table 6.19: Regression model statistics relating to outcome 'omeprazole adoption' (note: this table is divided into three parts with descriptions in between)

Omnibus Tests of Model Coefficients

	Chi- square	Df	P value
Step	4.720	1	0.030
Block	142.217	7	< 0.000
Model	142.217	7	< 0.000

Df: degree of freedom

Model summary

-2 Log	Cox & Snell R	Nagelkerke R
likelihood	Square	Square
439.828(b)	.250	.361

Hosmer and Lemeshow Test statistics

Chi-square	P value
3.471	.838

6.6.2.3 Naproxen acceptance

Seventeen variables showed significant association with the outcome 'naproxen acceptance'. Five were retained in the regression model. The highest odds ratio was observed with the item 'opportunity to extend professional role' (table 6.20).

Table 6.20: Binary logistic regression model of the outcome 'naproxen acceptance' with the explanatory variables

		_	Exp(B)	95.0% C.I. for EXP(B)		Model if item removed		
Items retained in the model	Wald	P value	(odds ratio)*	Lower	Upper	Model Log Likelihood	Change in -2 Log Likelihood	P value of the Change
This is a good opportunity to extend my role as a health professional	19.140	0.000	3.735	2.070	6.741	-188.584	19.558	0.000
This product matches with the business/service ambitions of my pharmacy	9.824	0.002	2.823	1.475	5.400	-183.919	10.229	0.001
I believe that this product is a welcome addition to the range of pharmacy medicines	10.819	0.001	2.623	1.476	4.658	-184.152	10.694	0.001
I believe that the OTC regimen for this product is likely to be effective	9.234	0.002	2.348	1.354	4.070	-183.367	9.123	0.003
Size of pharmacy ownership (Medium or large multiples)	3.962	0.047	1.735	1.008	2.984	-180.769	3.928	0.047
Constant	18.705	<0.001	.313					

^{*} for score 3 or above

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The model Chi-square value was highly significant (P <0.001). Both the Cox and Snell R square and Nagelkerke R square values suggested the explanatory variables retained were making important contributions. Hosmer and Lemeshow test goodness of fit statistics was not significant suggesting that observed data are not significantly different from the values predicted by the model (table 6.21).

Table 6.21: Regression model statistics relating to outcome 'naproxen acceptance' (note: this table is divided into three parts with descriptions in between)

Omnibus Tests of Model Coefficients

	Chi-		
	square	Df	P value
Step	3.928	1	.047
Block	157.203	5	< 0.001
Model	157.203	5	< 0.001

Df: degree of freedom

Model summary

-2 Log	Cox & Snell R	Nagelkerke R	
likelihood	Square	Square	
357.610(a)	.279	.424	

Hosmer and Lemeshow Test statistics

Chi-square	P value	
5.987	0.541	

6.6.2.4 Naproxen adoption

The 26 variables that were significant in univariate analysis were entered into the regression analysis. Using 'Forward LR' as the stepwise method, seven were retained in the final model. The strongest association was observed with the item measuring respondent agreement about whether naproxen was a welcome addition to pharmacy ranges of medicines (table 6.22).

Table 6.22: Binary logistic regression model of the outcome 'naproxen adoption' with the explanatory variables

				95.0% C.I. for EXP(B)		Model if item removed		
Items retained in the model	Wald	P value	Exp(B) (Odds ratio)*	Lower	Upper	Model Log Likelihoo d	Change in -2 Log Likelihood	P value of the Change
This is a good opportunity to extend my role as a health professional	8.044	0.005	2.160	1.269	3.678	-242.275	8.027	0.005
This product matches with the business/service ambitions of my pharmacy	15.657	<0.001	2.624	1.627	4.231	-246.084	15.646	<0.001
My customers often complain about the cost of this product (not including e-MAS supply)†	5.487	0.019	1.759	1.097	2.822	-241.034	5.545	0.019
Many customers ask for this product by name	7.199	0.007	2.172	1.233	3.829	-241.988	7.453	0.006
I believe that this product is a welcome addition to the range of pharmacy medicines	21.127	<0.001	3.890	2.180	6.941	-249.520	22.518	<0.001
Innovativeness (Role model or venturesome)	10.502	0.001	2.128	1.348	3.359	-243.633	10.743	0.001
Size of pharmacy ownership (Medium or Large multiples)	16.192	<0.001	2.742	1.678	4.483	-246.673	16.823	<0.001
Constant	89.572	<0.001	.031					

[†] Item reversed scored; * for score 3 or above

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The model Chi-square value was highly significant (P <0.001). Both the Cox and Snell R square and Nagelkerke R square values suggested the explanatory variables retained were making important contribution. Hosmer and Lemeshow test goodness of fit statistics was not significant suggesting that observed data are not significantly different from the values predicted by the model (table 6.23).

Table 6.23: Regression model statistics relating to outcome 'naproxen adoption' (note: this table is divided into three parts with descriptions in between)

Omnibus Tests of Model Coefficients

	Chi- square	Df	P value
Step	5.545	1	0.019
Block	171.032	7	< 0.001
Model	171.032	7	< 0.001

Df: degree of freedom

Model summary

-2 Log likelihood	Cox & Snell R Square	Nagelkerke R Square	
476.523	.306	.409	

Hosmer and Lemeshow Test statistics

Chi-square	P value	
14.565	0.068	

6.6.2.5 Simvastatin

With only a small minority of respondents rating their support for and adoption into practice of simvastatin on the higher side of the five-point scale, it was not possible to undertake logistic regression analysis with either of the outcome measures. This analysis, as previously mentioned requires at least 5-10 respondents per explanatory variable on each side of the binary outcomes that are to be entered into the regression analysis [295]. Hence only the bivariate analysis was undertaken with the both the outcome measures to each of the 24-items scale, demographic characteristics and self innovativeness without merging any response categories using Kendal's T measures. Correlation was deemed adequate for Kendal's T values ≥.2 and showing significant P values and are presented in table 6.24 below. Values in the order of .1 have been suggested as weak correlation [295].

Out of the 38 variables subjected to such correlation analysis, ten and eight items showed correlation value of ≥.2 with the outcome simvastatin 'acceptance' and 'adoption'

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respectively. The item 'I believe that the product is a welcome addition to pharmacy medicines' showed the strongest correlation with both the outcomes having Kendal's T correlation values of .3 or above (table 6.24). The opportunity to extend professional role, therapeutic area matching with pharmacy service ambitions, belief in evidence of efficacy also showed strong correlations with both the outcomes (table 6.24). None of the thirteen demographic characteristics or the perceived innovativeness demonstrated Kendal's T value of ≥.2 (Appendix VI). All bivariate correlation Kendal's T values of <.2 appear in Appendix VI.

Table 6.24: Bivariate analysis showing significant correlations with values ≥.2 of the outcome 'simvastatin acceptance' and 'simvastatin adoption' with the 24 items scale

Statements	Kendal's T values with outcome 'simvastatin acceptance'	Kendal's T values with outcome 'simvastatin adoption'
This is/was a good opportunity to extend my role as a health professional	.454***	.290***
This product matches with the business/service ambitions of my pharmacy	.432***	.278***
This product has potential for good financial returns for my pharmacy	.273***	.202***
I am happy to delegate the task of supplying this product to support staff	.228***	¥
Many customers ask for this product by name	.217***	.204***
Introduction of this product may have represented a 'step too far' for OTC products [†]	.298***	¥
I believe that this product is a welcome addition to the range of pharmacy medicines	.490***	.311***
I believe that the OTC regimen for this product is likely to be effective	.321***	.246***
It is easy for me and/or my customers to know if treatment with this product is effective	.257***	.223***
I believe this product has potential to engender patient satisfaction	.253***	.220***

^{***}P≤0.001 † items reversed scored; ¥ correlation values <.2 and hence appears in Appendix VI.

6.6.2.6 Chloramphenicol

Similar bivariate analysis was undertaken with chloramphenicol using Kendal's T measures as differentiation between high and low acceptors and adopters of the reclassified medicine could not be made through regression analysis, with too few respondents on the lower side of the outcome measures.

Six and eight items respectively showed correlation values ≥.2 respectively. The strongest correlation for both outcomes was noted with items such as those measuring opportunity

for role development, financial compatibility, confidence in supply matter, belief that medicine was a welcome addition to pharmacy ranges of medicines and evidence base (table 6.25). Again, no demographic characteristics or self innovativeness showed a correlation value of \geq .2 with the outcomes (table 6.25). These appear in Appendix VI.

Table 6.25: Bivariate analysis showing significant correlations with values ≥.2 of the outcome 'chloramphenicol acceptance' and 'chloramphenicol adoption' with the 24 items scale

Statements	Kendal's T correlation values with outcome 'chloramphenicol acceptance'	Kendal's T correlation values with outcome 'chloramphenicol adoption'
This is/was a good opportunity to extend my role as a health professional	.383***	.280***
This product matches with the business/service ambitions of my pharmacy	.259***	.211***
This product has potential for good financial returns for my pharmacy	¥	.252***
I find the processes involved in the supply of this product complex [†]	¥	.228***
I feel confident about my ability to supply this product	.265***	.241***
I believe that this product is a welcome addition to the range of pharmacy medicines	.426***	.312***
I believe that the OTC regimen for this product is likely to be effective	.246***	.226***
Introduction of this product may have represented a 'step too far' for OTC products [†]	.221***	.204***

^{***}P≤0.001 † items reversed scored; ¥ correlation values <.2 and hence appears in Appendix VI.

6.6.2.7 Summary of binary logistic regression/bivariate analysis

The binary logistic regression and the bivariate analysis allowed quantitative explanation of the factors key to pharmacists' innovation decision making. Greater agreement around: perceived opportunity for role development offered by the reclassified medicines; financial potential of the medicines; compatibility of therapeutic area to: existing ranges of pharmacy medicines, to pharmacy business interests and pharmacists' expectations; whether the medicine was a welcome addition to pharmacy ranges of medicines; benefits to patients (evidence base); confidence in the supply process; and patient acceptance and affordability of the medicines were related to higher adoption of the reclassified medicines into practice and greater support for the reclassified status.

Some unique factors specific to the medicines evaluated were also identified. For example, respondents' belonging to the larger size of pharmacy ownership were found to be important with high acceptance and adoption of naproxen. Similarly the issue of task delegation was retained to be important with the cases of omeprazole and simvastatin decision making. Least useful in distinguishing respondents' rating of 'adoption' and 'acceptance' differently related to their responses around items such as those measuring perceived adequacy of pharmacy resources, availability of information sources, extent of organisational influence in decision making and level of external support. Apart from pharmacists' status as a owner and the size of the ownership, none of the other 13 demographic characteristics showed association with decision making in either bivariate and multivariate analysis.

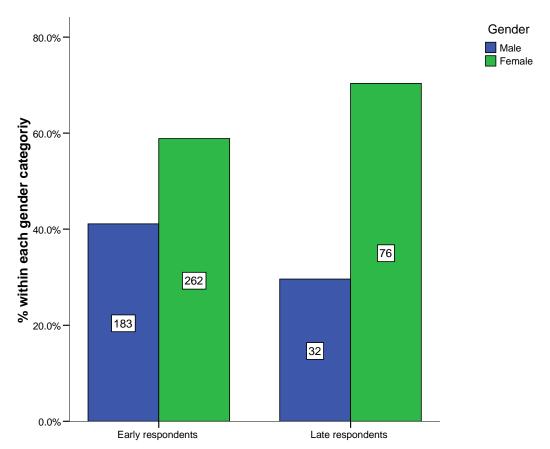
6.7 NON-RESPONDENT ANALYSIS

Non-respondent analysis was performed to check the external validity of the findings. It has been suggested that the demographic characteristics of late respondents are similar to those of non-respondents [297]. Therefore, a non-respondent analysis was performed by comparing the demographic characteristics of those respondents who replied after second reminders (late respondents) to the rest. Cross tabulation analysis showed that only the proportion of respondents in demographic characteristics 'gender' and 'innovativeness' were found to be significantly different amongst early respondents and late respondents (figure 6.7). No other demographic categories were found significantly different across the two response categories. Data for non-significant relationships for this analysis appears in Appendix VI.

Approximately 70% of the respondents in the late respondent category were female compared to approximately 59% in early respondent category (P= 0.037).

Figure 6.7



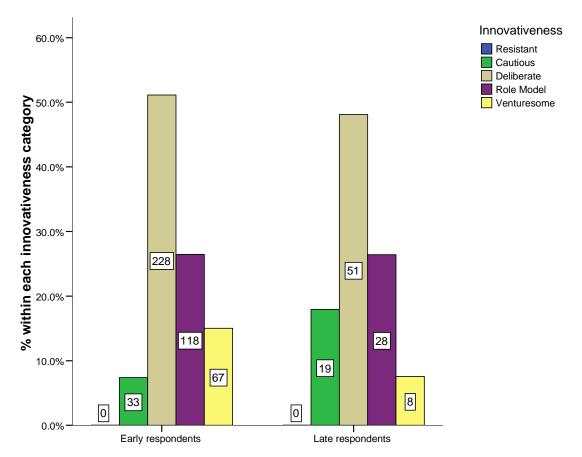


Respondent categories (numbers within bars represent n)

Approximately 18% of the respondents in the late respondent category were "cautious" in relation to new ways of working compared to 7% in early respondent category. In addition, late respondents had noticeably half the proportion of respondents in the venturesome category compared to early respondents (7.5% vs 15%) (overall Pearson Chi-square P= 0.003) (figure 6.8).

Figure 6.8

Perceived innovativeness as per response time (N=552)



Respondent categories (numbers within bars represent n)

6.7.1.1 Summary of non-respondent analysis

The non-respondent analysis hence reflected that the sample of this survey was representative of the rest of the population in most of the demographic characteristics.

6.8 DISCUSSION OF KEY FINDINGS

6.8.1 Sources of information on newly reclassified medicines

Respondents reported the use of diverse information sources to inform adoption decisions. This might reflect the perceived need to reduce any bias as highlighted by some interview participants. The proportion of respondents citing journals, manufacturers' information sources, RPSGB information sources and formularies were comparable to a similar previous study in this field [282]. The extent of pharmacists consulting their peers is surprising in the light of findings from the qualitative study where respondents described a lack of support at organisational and external levels for peer networking. The high proportion of

respondents using PILs and public media could be explained by the lack of timely information from organisational or external sources and requires urgent attention

6.8.2 Pharmacists' attitudes towards and adoption into practice of newly reclassified medicines

Results specific to each of the four evaluated medicines will be discussed in this section, along with comparison to any available literature with similar objectives undertaken in the therapeutic area. Factors associated with decision making will discussed by comparing the responses to 24 items scale across the medicines in this section and the section that will follow (section 6.8.3).

6.8.2.1 Omeprazole

Respondents were fairly supportive of the non-prescription availability of omeprazole. Compared with the study conducted with a random sample of 2000 community pharmacies from GB, immediate post reclassification, where over 70% of the respondents were yet to adopt the omperazole into practice [122], it could be postulated that, over time, more pharmacists have adopted the reclassified medicines into practice.

Although medicines for peptic disorders such as cimetidine, ranitidine and famotidine had been available on a non-prescription basis for over a decade when this survey was undertaken [92], a majority of respondents still considered omeprazole a welcome addition to the range of pharmacy medicines. The majority expressed confidence in supply matters. However, a majority also rated low confidence in their support staff undertaking the supply. Such low confidence around task delegation is most likely to be due to the cognitive element associated with the supply process, and hence the issue is likely to be medicine specific. This is supported by the finding that a high proportion of respondents in this study showed willingness to delegate the task of supplying reclassified naproxen and chloramphenicol. Comparisons of results with those of the McCaig et al study reflect that pharmacists' confidence in delegating tasks to support staff has not changed sharply in the five years following reclassification despite likely accumulated experience [122].

Patient cost implications of non-prescription therapy were found to be one of the key barriers to supply, perhaps influenced by the duration of indication, which is likely to last for up to two weeks [239]. Such high cost might exceed the current prescription charge in

Scotland. It is worth noting that the availability of generic versions of omeprazole, often cheaper than branded, was delayed due to legal challenges by the patent owner [298].

The proportion of respondents doubting the evidence base of the non-prescription dose was surprising given the licensed indication, allowing pharmacists to supply two 10 mg doses (=20 mg) per day until symptoms of peptic disorders are alleviated [239]. Evidence in support of the efficacy of both 20 mg [299,300] and 10mg [299] omeprazole in relieving heartburn associated with acid reflux exist in the published literature [300], although evidence is stronger in favour of the 20 mg dose [300]. The clinical efficacy of 20 mg omeprazole for over the counter setting has been established in the US [301] where, ironically, the lower strength of 10 mg dose is only available under prescription [302].

It is interesting to note that only a minority of the respondents did not regard the risk of an adverse event as a barrier to supply or that the medicine was susceptible to patient misuse. This was despite the issue of safety, as for example, liver toxicity had led to rejection of the non-prescription status of this medicine in the US [303,304].

6.8.2.2 Naproxen

This survey was conducted less than one year after the reclassification of naproxen to P status in the UK. Despite the short interval between the reclassification and this research, over 80% of respondents had already adopted this medicine into their practice. Many respondents, however, indicated receiving low numbers of patient requests, implying that sales were mostly based around pharmacists' recommendations.

Unlike omeprazole, many respondents considered the non-prescription regimen of this medicine to be effective for its licensed indication. This high level of belief in evidence of efficacy matches findings from clinical studies where naproxen has been shown to consistently demonstrate superior efficacy over other Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) with doses as low as 200 mg for the management of dysmenorrhoea [305]. The high agreement on items referring naproxen as a welcome addition to pharmacy ranges of medicines, and the opportunity to extend professional role could be as a result of the specific novel indication of naproxen for primary dysmenorrhoea, which differs from the other available NSAIDs. Analysis of other statements also reflected that the majority expressed high confidence in the supply process and many were willing to delegate the supply to support staff despite their short experience with pharmacy status of the medicine.

Respondents' concerns around the high risk of adverse events and the potential for medicine misuse matched those of the regulators. MHRA had voiced concerns over gastro-intestinal effects and had tentatively planned Periodic Safety Update Reports (PSUR), against which the RPSGB had objected [306]. The US has a longer experience of non-prescription naproxen, with 200 mg in 1994 [307] and reports from the spontaneous Adverse Events Monitoring System (AERS) reflected similar concerns [308]. In April 2009, naproxen was among the list of analgesics that the US Food and Drug Administration (FDA) revised regulations for ensuring that non-prescription naproxen labels were updated to include the risk of GI bleedings and liver damage [309]. Emerging evidence from meta-analysis of safety studies, however, reflects that overall adverse events of naproxen at non-prescription doses are comparable to placebo [310]. Further experience and monitoring of non-prescription naproxen use in the UK should add to the understanding of the safety profile.

6.8.2.3 Simvastatin

Most attitudes towards and questionnaire data around the adoption of simvastatin are comparable with the findings from qualitative interviews. Adoption into practice was very low and responses to attitudinal statements were overwhelmingly skewed towards higher or lower agreements. Despite representing a very new therapeutic area, the perceived opportunity to increase professional role and its compatibility with existing ranges of medicines were poorly rated.

The responses around evidence of efficacy were negative and reflect the debate reported in the literature during the time of and post reclassification [282]. The evidence of efficacy of the 10 mg simvastatin has generated varying views, both in support of its efficacy [311,312] as well as against it [313]. In particular, no evidence of efficacy; nor patient ability to accurately self diagnose the need for the medicine had been demonstrated in the community pharmacy setting at the time of reclassification [313].

Contrary to the concerns around evidence of efficacy, the majority were unsure of either adverse effects or patient misuse as barriers to supply. Some have argued that the likelihood of adverse events with large scale use as well as potentially discouraging patients from the adoption of life style changes would outweigh any epidemiological benefits with

reclassification [314,315]. These concerns even led to requests to reclassify simvastatin and other statins in the US being rejected by FDA on several occasions [311].

Respondents reflected a very low level of patient requests for simvastatin. Anecdotal evidence suggests that the reclassification was aimed at those ineligible for a free NHS prescription [316]. However a recent study with 102 patients recruited from three community pharmacies in Bristol has shown that willingness or lack of willingness to pay did not relate to patients' prescription charge- exemption status or the risk of heart disease [317].

In one survey prior to reclassification, over 40% of the 200 randomly sampled community pharmacists from the Leeds/Bradford area agreed or strongly agreed with the idea that simvastatin should be available without prescription [280]. Though the population sampled were different to this study, the same regulatory framework applies to both the areas. Acceptance scores from this survey show that pharmacists now regard this medicine being of less value to practice. The study by Hansford et al undertaken immediate post reclassification showed that approximately 83% of the respondents had not supplied any simvastatin in the last 14 days [282]. Hence, five years post reclassification, the proportion of respondents not adopting the medicines into practice is very similar when compared to data immediate post reclassification [282]. This reflects that pharmacists' adoption is less likely to change in the future and could be argued that other interventions in this therapeutic area such as lifestyle and dietary advice could be of interest to stakeholders.

Findings from this survey suggest that even those respondents with a non-medical prescribing qualification were no more likely to adopt the medicine into practice than with no additional prescribing training, does not sit alongside the voice of some of the interview respondents where additional skills and expertise were deemed to lead to greater adoption of simvastatin into practice. One of the reasons for this could be due to the reason shown by a recent study suggesting as many as one third of all pharmacists with prescribing qualifications based in community are yet to use their prescribing expertise [318].

Despite such low adoption of simvastatin by respondents, a decline in the volume of GP simvastatin prescriptions post reclassification has been reported recently. Fillion et al using analysis of the General Practice Research Database (GPRD) showed that, post reclassification, the prescription of both 10 mg and 20 mg simvastatin has decreased

markedly [319]. However, as prescription items for other statins had also decreased in the same period [319], such changes could not be attributed to the reclassification alone. A majority of GPs are known to be against pharmacy supply of non-prescription simvastatin, although, less against the issue of pharmacy based risk assessment to identify patients in need of the medicine [320]. Hence it is unlikely that recommendations for pharmacy purchases by GPs have been made.

6.8.2.4 Chloramphenicol eye drops

Respondents' support for the non-prescription status of chloramphenicol and adoption into practice was very high. This medicine has been advocated by pharmacists to be reclassified for many years, until the decision was taken in 2007 [268]. The belief in medicine evidence of efficacy was high. Results from the qualitative interviews and focus groups suggested that positive patient feedback was adding to pharmacists' belief in the evidence base. Recent evidence, however, suggests that acute infective conjunctivitis, including bacterial, are self limiting conditions and hence do not require an antibiotic [321]. However, qualitative studies with patients [322] as well as GPs [323] have revealed that non-clinical forces such as pressure from parents to help children (population where bacterial conjunctivitis is prevalent) early return to school; and perceptions of the 'magical' effects of antibiotics may supersede any clinical need.

Concerns around the issue of chloramphenicol safety, either the risk of adverse events or misuse was very low. During the time of reclassification, there were concerns around the safety of this medicine among the medical professionals and the MHRA [291], mainly owing to the risk of haematological toxicity. There has been debate that emergence of bacterial resistance may be exacerbated by the pharmacy availability of chloramphenicol [324], as its use has been increasing disproportionately since reclassification. Studies have reflected that an increase in overall pharmacy sales and supply of topical chloramphenicol has been unaccounted for by any reduction in number of prescription items [325,326]. This raises the notion that whether the reclassification has led to an overall increase in consumption of this medicine. This also led to the active advocacy by the chief medical officer of England against reclassification to pharmacy status of any further antibiotics [325], despite GPs being in favour of non-prescription chloramphenicol at the time of reclassification [100].

With all four medicines that were evaluated, respondents' responses to the 24-item attitudinal scale also reflected that only a minority were dissatisfied with the adequacy of information sources. In addition, only a few regarded the lack of available resources such as staff mix and space within pharmacy to be a barrier to the adoption of medicines. This suggests that, for the majority of pharmacies, pharmacy resources in Scotland should promote pharmacists' adoption and organisational implementation of future medicines to be reclassified, given that other important criteria identified here are fulfilled for decision making.

Support from the professional body was deemed adequate reflecting satisfaction over guidance materials and associated training. The desire for enhanced access to patient medical records was evident and hence any future enhanced access is likely to enable pharmacists to eagerly anticipate reclassifications where the perceived need for access to inform supply decision is high. The need for greater communication with GPs was less strong, implying that issue of access to patient medical records is more important.

6.8.3 Factors associated with decision making: bivariate/ multivariate analysis

The bivariate/ multivariate analyses of the data further allowed for the quantification of factors associated with support for the non-prescription status (acceptance) of the reclassified medicines and their adoption into professional practice. The use of factor analysis in reducing the 24-items to a fewer numbers of meaningful units did not produce interpretable output. This implied that although the statements within the 24-items scale were conceptually similar in theoretical terms, empirically however, individual items had meanings unique enough to require separate analysis.

The items that were most strongly and commonly retained throughout the bivariate/multivariate analyses to be associated with innovation adoption and acceptance related to: opportunity for role development, financial potential of the medicine, compatibility of therapeutic area to pharmacy service ambitions, confidence around supply process, belief if the medicine was a welcome addition to pharmacy ranges of medicines, benefits to patients and patient acceptance of the medicines. These factors are hence likely to be relevant for other medicines and services not evaluated in this thesis. Factors important in respondents' decision making unique to particular medicine(s) that were Chapter 6: Main survey

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evaluated were also identified. For example, respondents from larger pharmacy ownership were found to have better embraced and adopted naproxen. Similarly, issue of task delegation was found to be important with the case of omeprazole and simvastatin decision making; and low perceived complexity were related to higher adoption of chloramphenicol.

The results reflected that adequacy of pharmacy resources, availability of information sources and extent of organisational influence in decision making were least associated with acceptance and adoption, implying that this issue take less prominence in decision making as compared to how pharmacists perceive the merits of innovations. In order words the 'content' issue took prominence over the 'internal contextual' factors. It is possible that these reclassifications have least necessitated reorientation of existing services in pharmacy and hence, pharmacists in diverse demographical settings might be coping well with the resource requirements generated by these reclassifications. Being an owner and the size of the ownership were the only two among the 13 demographic characteristics that showed association with decision making in either bivariate or multivariate analysis.

From Rogers' theoretical point of view [131], perceived attributes of innovations in this study: the relative advantage was most strongly associated with both outcomes. Relative advantages and their observability have been regarded so important in informing adoption decisions about innovations by potential adopters that, where such advantages are less obvious and visible, such as the case of use of preventative health services by the patients (as against the use of curative services), adoptions are difficult to diffuse [131]. However, although the importance of *relative advantage* was obvious, disadvantages (risks to patients) of innovation were not associated with acceptance and adoption. This is against the findings from the qualitative phase (Chapter 3); and another qualitative study around pharmacists' adoption of non-prescription medicines decision making, where safety has been depicted as of paramount importance to pharmacists in non-prescription medicines supply decisions above any perceived advantages such as the evidence of efficacy [228]. In this survey however, even with the case of naproxen, where many respondents were concerned about adverse events and misuse, respondents' level of concern did not emerge as a factor associated with decision making. Perceived benefits of medicines to patients seemed to have superseded any harm that was likely.

Rogers' diffusion model suggests that among the attributes of innovations, *relative* advantage, observability and compatibility are positively associated with innovation adoption

[131]; whereas, *complexity* of adoption process is negatively associated. This survey hence did not identify any deviations in the direction of association so suggested, although the strength of such association was variable across the medicines evaluated.

The perceived complexity of adoption and low self confidence around supply matters were found to be negatively associated with decision making in this study. Perceived complexity of adoption process is known to be diminished through experience and experimentation [146]. Aspects of *compatibility* measured in this survey only related to whether the therapeutic area of the reclassified medicine represented pharmacy business interests; whether or not the medicine was a welcome addition to the existing range of medicines and whether the reclassification was a step too far (measuring pharmacists' expectations). The importance of *compatibility* with socio-cultural norms and values was not assessed. As reviewed in Chapter 4, these issues have been shown to be important in pharmacists' decisions to supply reclassified medicines such as the EHCs [252,258,260,261].

The abundance of items relating to perceived attributes of innovations in the bivariate/multivariate models fits within the tradition of results reported by diffusion research. The current evidence is that the five of the above explained perceived attributes of innovations (relative advantage, observability, compatibility, complexity and trialability) are known to explain 49-87% variance in the rate and extent of adoption of innovations by potential adopters [131].

The importance of *reinvention* to decision making was hardly observed. A majority of respondents were less keen to supply the listed medicines off guidelines. It has been suggested that not all innovations are regarded as 'fit to re-invent' [146] and that such practices are known to be more suited to innovations that arise spontaneously and through informal, decentralised and horizontal social networks [146]. Despite some respondents in the qualitative interviews suggesting that supplies of medicines off guidelines was the norm where perceived need and confidence allowed such divergence, results of the survey reflected that supplies off guidelines represented only a small proportion of all supplies barely enough to quantitatively differentiate the level of adoption of the medicines that were evaluated.

The relationship of perceived innovativeness with both outcomes was also rarely observed in the multivariate analyses. The literature from which this scale was adapted reported

perceived innovativeness related to actual readiness to change practice in both univariate and multivariate analyses [327]. In this study, however, higher perceived innovativeness was noted to be associated with innovation adoption on only one instance with the outcome- adoption of naproxen. The reason for the lack of consistent association might be attributed to two reasons. Firstly, establishing validity and reliability of the perceived innovative scale may need further work, as the distribution of the percentage of respondents across the innovativeness categories did not match with those known from research within [165] and outside pharmacy [131]. Secondly, as reflected by the studies with other health professionals, there are no universal adopters and innovators when it comes to adopting new medicines [328,329]. This case has been further supported also by a study reporting issues around innovation adoption by pharmacy organisations which mentions that, for example, it is not always possible for a same PCT to be innovative in delivering every potential pharmacy innovations [159]. Regarding all innovations as identical units from the analytical point of view has been regarded as 'dangerously incorrect' [131], especially for the difficulty in isolating the so called 'idiosyncratic' features of one innovation and the true predictive power of the innovation attributes common to diverse innovations [161]. The evaluation of four reclassified medicines from diverse therapeutic areas selected so as to understand the factors associated with innovation adoption are further justified by these notions.

Respondents in this study reflected their autonomy over decisions around whether to and how far to adopt the reclassified medicines into their practice, with only a minority deeming decisions of their management organisations as decisive. Because a majority of respondents in this study were pharmacy managers, personal decision might have been regarded equivalent in meaning to decision making by the pharmacy 'management'. For those respondents who were not the managers, the possibility also exists that the decision making process is a two step process. Within such two stepped processes, often classified as 'contingent' decision making [131], practitioners choose whether to/how far to adopt the innovations into practice after an initial decision by the organisational management. The likelihood of this being relevant to many pharmacies, especially those with multiple ownership structures, is supported by the results of the qualitative interviews. Even with the so known 'contingent' decision making process, literature [131] as well as the results of this survey and qualitative interviews reflect that individual practitioners are the ultimate decision makers about the provision of services to patients. This further justifies the

importance of research on individual practitioners' decision making processes, the focus of all phases of this doctoral research.

This study generated some comparable as well as contrasting results in relation to other studies applying bivariate/multivariate quantitative models to quantify factors influencing similar outcomes. The literature investigating 'adoption' as the outcome identified: financial benefits owing to sales [269,271,275], evidence of efficacy [269,271], patient acceptance of the medicines [275] and younger age or lesser practice experience [267] were amongst the most commonly retained factors. Medicines safety (risks) was only rarely identified as important [269]. Key factors positively associated with 'acceptance' to ongoing reclassification were shown to be perceived benefits to professional roles [267] and patients, compatibility with business interests and negatively associated with high counselling need [267]. In addition to the limitations of these studies, already highlighted in Chapter 4 (systematic review), one of the drawbacks of studies measuring 'acceptance' as the outcome worth noting here is the consideration of all potential reclassifications as one innovation against the norm of diffusion research.

Results from this survey are also comparable to pharmacy innovation adoption studies outside the area of enhanced minor ailment management utilising a diffusion model. Perceived benefits to pharmacy, professional roles and patients were the most important predictors of adoption of pharmacy based immunisation in a two staged survey of 526 community pharmacists from Washington State in the US (response rate: 46.9% and 42.1%). Perceived *complexity* and *compatibility*, although found to be associated with the outcome adoption, were not retained in multivariate analyses [233]. Financial benefits to pharmacy were among the most important factors associated with adoption or rejection of pharmaceutical care models in a study of 153 pharmacists in two US States [166]. Yet another diffusion study of medication information to patients with 156 pharmacists in the US state of Michigan around adoption of written medication information services for patients reported *complexity* as the most important 'deterrent' to decision making; with compatibility with pharmacists' business needs, professional values and past experiences showing the most positive influence on adoption [330]. The importance of observability of benefits, compatibility, complexity of adoption process and trialability of innovation were regarded as the most important desirable features of innovations in a study of 300 Dutch pharmacists (response rate: 49.3%) exploring the implementation of patient oriented education activities, although differences in the availability of resources influenced the

intension to adopt the innovations [165]. Most of the findings reported by the literature together with the results of this survey hence enable the conclusion that perceived attributes of innovations are the most common predictor of successful adoption of innovation by pharmacists. The notion about importance of investing effort in identifying 'innovation' differences (how perceived characteristics of innovation affect their adoption) than 'people' differences (research into importance of adopter characteristics) as highlighted by Rogers [131] are hence justified by these pharmacy literature and this survey.

6.8.4 Response rate and demography of respondents

Surveys within the area of non-prescription medicines have recently been suggested to have inflicted "research fatigue" on pharmacists [331]. However, the response rate obtained in this study suggests that innovative methods used to encourage participation may have been successful with a positive impact on the achievement of an 'adequate' response rates. This response rate is comparable to the 42% rate obtained in a GB study of community pharmacists conducted by RGU researchers at the same time [332]. The response rate obtained should also be interpreted in the context of the questionnaire design which included over 150 variables, arguably higher than that found in most conventional questionnaires. The contribution of two reminders to increasing the response rate was above the average of 20% (10% from each) as suggested by others [202].

The demographic characteristics of respondents compared well with a recent GB community pharmacists' census and register analysis [238,293] except that in this study there was over-representation of pharmacy managers; under-representation of locum pharmacists and those working in independent units; who represented approximately 29%, 36% and 31% respectively in 2008 census [238]. Statistical analysis on the differences of the demographic characteristics of this study to those of the census and register data could not be conducted due to vast differences in sample sizes. In addition, not all census and register data specifically represent pharmacists practising within community [238,293]. Nonetheless, the results from the non-respondent analysis indicated that the responses could be considered representative of the population of community pharmacists in Scotland.

6.9 SUMMARY OF CHAPTER 6

Newly reclassified medicines evaluated in this survey were, to a varying degree, adopted by respondents of this survey. Chloramphenicol eye drops had the most support and adoption into practice, whereas simvastatin was least supported and adopted. Despite being the latest reclassification among the medicines that were evaluated, naproxen was better adopted than simvastatin or omeprazole. Adoption of omeprazole into practice by respondents was however, higher when compared to studies immediately post reclassification. Patients are likely to benefit from easier access of these medicines available from pharmacy, except with the case of simvastatin.

The evaluation of four reclassified medicines enabled quantification of important factors associated with innovation decision making by pharmacists through descriptive, bivariate and multivariate analysis. Such factors were often unique to medicines that were evaluated. Higher agreement in the following issues offered by the newly reclassified medicines were associated with higher regard for the reclassified status and adoption into practice namely:

- 1. Perceived opportunity for role development offered by the reclassified medicines
- 2. Financial potential of the medicines
- 3. Compatibility of therapeutic area to: existing ranges of pharmacy medicines; to pharmacy business interests and pharmacists' expectations
- 4. Belief whether the medicine was a welcome addition to pharmacy ranges of medicines
- 5. Benefits of medicines to patients (evidence base of medicines efficacy), and the observability of such benefits
- 6. Pharmacists' confidence and low perceived complexity around supply process; and
- 7. Patient acceptance and affordability of the medicines

Both the key outcomes, support for the reclassified status of the medicines, and their adoption into practice, were influenced by similar factors. Wide ranging sources of information were used by community pharmacists for decision making, many of which had not been previously realised by the literature. These factors are important in prediction of successful adoption of future pharmacy innovations not limited to reclassified medicines.

CHAPTER 7: PHARMACISTS' ADOPTION OF E-MAS (QUALITATIVE)

7.1 INTRODUCTION TO THE CHAPTER

The minor ailments service in Scotland, known as e-MAS, is another key intervention (service innovation) aimed at enhanced management of minor ailments from community pharmacy. The relevance of ongoing reclassification of medicines, as described in previous Chapters, is more to those members of the public who pay prescription charges. In Scotland, almost 50% of the total population is exempt from prescription charges [93]. E-MAS, introduced nationwide in Scotland in 2006 as a core part of the community pharmacy contract [96], allows those members of the public exempt from prescription charges to register with one community pharmacy of their choice and have their minor ailments treated by the pharmacist free of charge, or where appropriate, to get advice or onward referral to other health professionals [94].

E-MAS is being supported by a national IT network system known as e-pharmacy which enables both identification of existing patient registrations and new registrations using the patient's unique community health index (CHI) number [98]. This service also enables patient consultation and registration details from pharmacies to be verified for reimbursement and remuneration purposes. E-pharmacy is an effective, electronic data capturing system, potentially allowing service activities to be recorded remotely within NHS NSS, and is managed by the National Medicines Utilisation Unit (NMUU) within the Information Service Division (ISD) of NSS. There is potential for these data to be disseminated as a means of allowing pharmacists to reflect on their e-MAS practice.

'The Right Medicine: A strategy for pharmaceutical care in Scotland' published in 2002, identified the need to set up the NMUU to provide NHS bodies with information regarding how medicines are being used in the NHS [50]. The e-pharmacy programme within the NMUU has the capacity to collate the e-MAS activity data from each pharmacy delivering the service as each is now linked with the e-pharmacy system [222]. Hence there is scope for a wealth of data to be utilised as a source of feedback of practice performance to community pharmacists so as to potentially facilitate service adoption. Feedback can be defined as 'summary of health care practice performance over a specified time period' [333]. Feedback of practice performance, similar to other educational strategies such as: printed educational

materials, outreach visits, seminars and workshops, training sessions, medicine information centres; has been shown to be useful in supporting the adoption of new services or behaviours by health care practitioners [334]. Pharmacists have been utilised as a source of feedback to doctors' performances about medicines supply practice [335]. However, the published literature around pharmacists' feedback needs to support innovation adoption sparse. Understanding the needs of potential users has been argued to be essential to enable information providers to accurately plan and disseminate such feedback information [335,336].

This Chapter presents results of data analysis from phase I, specific to the following objectives:

- To identify community pharmacists' views and attitudes to the introduction of e-MAS in Scotland.
- 2. To identify facilitators/barriers to pharmacists' adoption of e-MAS in Scotland
- To explore community pharmacists' views on future provision and potential usefulness of practice performance feedback from e-MAS as a facilitator of service adoption.

7.2 METHOD

Aspects of design, method, research governance and ethics; and participant demographic characteristics appear in Chapter 3. However, use of the illustrative materials specific to objective 3 above has not been discussed previously.

7.2.1 Use of illustrative materials

Examples of e-MAS performance feedback data were generated in collaboration with the ISD and were presented to the focus group participants (using Microsoft Power Point software) to facilitate discussion around objective 3. Two visits to the NHS NSS head office in Edinburgh were made by the researcher for the purpose. Data sets representing aspects of service delivery, such as: type of medicines supplied, and number of patients registered by individual/group of community pharmacies were presented. For telephone interview participants, the same data sets were provided in print versions which were sent through the mail or by fax in advance of the interview date. A copy of all such illustrative materials that were used appears in Appendix VII. An example is presented in figure 7.1.

140 Chapter BNF O1 - GASTRO-INTESTINAL SYSTEM 120 ◆ 03 - RESPIRATORY SYSTEM 100 07 − OBSTETRICS,CYNAE+URINARY TRACT DISORDERS No of Items (Dispensed) 09 - NUTRITION AND BLOOD ★ 10 - MUSCULOSKELETAL & JOINT DISEASES 0 11 - EYE ■ 12 - EAR, NOSE AND OROPHARYNX \Rightarrow ◆ 13 - SKIN 40 ★ 19 - OTHER DRUGS AND PREPARATIONS × 20 - DRESSINGS $\dot{\nabla}$ 21 - APPLIANCES ◆ DU - DUMMY CHAPTER 2007/08 Q2 2007/08 Q3

Figure 7.1: Example of performance feedback data used as illustrative materials*

Financial Year/Quarter

7.3 RESULTS

Key themes are presented and illustrated with quotes which aligned to the main framework of analysis, consisting of three broader categories namely: the attitudes towards the service, facilitators/barriers to service adoption; and pharmacists' views on future provision of feedback of performance data from e-MAS. Themes and sub-themes within these broader categories are also presented with illustrated quotes. Where opposing views around a particular subject were identified around the same theme, all are illustrated. The three dots within a quote indicate that some text has been deleted if considered irrelevant to the corresponding theme.

7.3.1 Attitudes towards the service

Participants identified benefits of e-MAS to diverse groups of stakeholders including the pharmacists and patients as well as the NHS.

^{*} Figure shows number of non-prescription medicine items supplied by a pharmacy in four quarters through 2006 to 2008 through e-MAS. The most number of items supplied by the particular pharmacy in any given quarter related to skin preparations.

7.3.1.1 Benefits to pharmacists' professional practice

Reference to both professionals and patients were made when highlighting the benefits to professional practice. Provision to allow pharmacists to manage minor ailments free of charge to patients in need was a feature of e-MAS highly valued by the participants.

"... I've been quite delighted when I can actually help people [in need] feel all right... that helps me further."

Male, 28 Years, Large Multiple

The perspectives of pharmacists working in socially deprived communities reflected that service implementation was particularly important given the large number of patients likely to benefit. One participant mentioned that sales of non-prescription medicines prior to the service were limited due to patients' inability to afford the retail price of medicines.

"Where we are here, it's not a very well to do area. So we don't tend to sell a lot of [non-prescription] medication. Things like Zanprol [omeprazole], we just wouldn't sell here...are too expensive for people to buy here...that would more come under the minor ailment [service]"

Female, 47 years, Small Multiple

The opportunity to ensure equity of access to service provision was appreciated. The service was also valued for enabling pharmacists to ensure supply of even the so deemed 'pricy' newly reclassified P medicines to patients where needed; otherwise these were deemed to be limited to patients of higher social status.

"The combination of POM to P switches along with the ability to prescribe them on the minor ailments service means that, often, when these products become available to buy over the counter, they are quite pricy. So, by being, enabling you to provide these [medicines] free of charge to people who are exempt from prescription charges means that much more people can get benefit of POMs to P switch as well"

Female, 25 Years, Large Multiple

The provisions to allow pharmacists to supply certain POM medicines under PGDs within e-MAS were also valued highly for similar reasons as above.

"We've got PGDs [of morning after pill] for age 13 to 19. Yes, there's this for 25 pounds and at which point they will go, ok I will not bother then. So, that person hasn't got the treatment that they possibly need because of price. So I think it helps where our professional care is supported by either by the Health Boards or some other initiatives so that the person who needs the medication can get it. Obviously the minor ailment service does that to a degree."

Male, 39 Years, Large Multiple

Participants also alluded to benefits to practice offered by the requirement within e-MAS where patients must register with 'one pharmacy' of their choice. Benefits of such requirements highlighted related to strengthening the relationships between professionals and patients.

"... the pregnant mothers who are coming in and they are having the service explained to them and they come back and you see them right through their pregnancy and then the women comes along. So you then kind of realize that actually you do get to know people over a certain length of time and more and more faces become familiar and then more and more people use the pharmacy for other prescriptions or other things as well. So you definitely do get to know people, patients more efficiently."

Female, 25 Years, Large Multiple

However, for many, this potential merit was yet to be realised, mainly due to the tendency of patients to shift their registration status across pharmacies. This issue will be detailed later in section 7.3.2.4. Nevertheless, participants were keen to see such registration requirements to be extended to other services being delivered through e-pharmacy.

"If you are talking about registration with e-pharmacy, then, just, in general, you go to that pharmacy for everything you do at the doctor's."

Female, 56 Years, Large Multiple

7.3.1.2 Benefits to the NHS

Participants were highly aware of potential NHS savings through greater pharmacy management of minor ailments such as within e-MAS as compared to management through other primary care services.

"... in lot of cases, the average cost of doctor's script is 70 pounds and ours is 3 or 4 pounds. The fact that people can walk in, there is no appointment. E-MAS itself saves the NHS money."

Participants were also keen to know how their contributions to the e-MAS service had brought any real term benefits to the NHS.

"I think it would be interesting to see for even like say, for example the chloramphenicol...has their [GPs] prescription for eye infections dropped? ...[has] their [patient] waiting list [dropped]?"

Female, 27 years, Independent

Some, however, were more sceptical of real term benefits to the NHS, mainly resulting from overuse of the service by some patients. This issue will be discussed in detail later in section 7.3.2.4.

"It'd be interesting to know if it's saving any money. Because, the whole idea was to save doctor's surgery time. Has it actually happened? Has the waiting time decreased, to be seen by doctors, has gone down, for minor ailments?"

Male, 55 Years, Large Multiple

7.3.2 Facilitators/Barriers to adoption of e-MAS

Twelve key facilitators/barriers to adoption of e-MAS were identified from the data. Many were common to those identified around ongoing reclassification of medicines (Chapter 3). Details around these facilitators/barriers also provide important processual insights about how these work in practice.

7.3.2.1 Remuneration and reimbursement

Appropriate remuneration was highlighted as a key motivation to pharmacies. Participants were keen to add to their current roles and the ranges of services offered through their pharmacies but emphasised the need for financial benefits to ensure the sustainability of such initiatives.

"I think it is important that pharmacy in general is remunerated for that [extended service provision]. I just hope that the funding for it [e-MAS] continues and makes [our time] worthwhile"

Male, 39 Years, Large Multiple

Participants' views around current remuneration and reimbursement patterns, however, were largely negative. They complained that payments were 'unfair' given the size of the potential savings the service was likely to bring to the NHS.

"We are saving a lot more time for the others [doctors], who we're helping the best to make my time valuable because we're getting paid c**p for it basically"

Female, 46 Years, Small Multiple

"... [e-MAS] loaded onto us simply to save doctor's [time] and it's unfair, it's working at the moment."

Male, 55 Years, Large Multiple

Participants suggested that potential NHS savings through greater patient management should be top-sliced and added into current pharmacy remuneration being provided for e-MAS.

"...how much you saved on an individual GP's cost by seeing so many of their patients, 'cause they're registered at that practice."

Female, 46 years, Small multiple

Current e-MAS remuneration schemes requiring pharmacists to undertake and record at least one patient consultation per year were criticised. Comparisons to GP remuneration structures were often made to justify the argument that such requirements be abolished.

"... I think it's unfair that... patient lapse after a year. You can register the GP,... they don't go to the GP for years, but the GPs still getting paid for that patient. If they [patients] haven't used it, why should we be penalized for they [patients] being healthy?"

Male, 37 Years, Independent

Participants also complained that existing remuneration structures could potentially endanger the focus around continuity of care with pharmacies resourcing their effort mainly towards increasing patient registration numbers.

"But then you have got loads of them every second day and you give something on the minor ailments and you're getting paid for the cost of the drugs and not for the hassles it is causing."

Male, 66 Years, Independent

"...[many pharmacies] have not dispensed as many [they] have more people registered. They are registering but not actually prescribing [supplying] so much for them."

Female, 25 Years, Large Multiple

A fee per consultation was suggested as an improved method of remunerating pharmacies.

"...you are sort of driven by the amount of people that have signed up for. Back home in Ireland, the person, the one signed to any particular pharmacy, it was just per consultation which worked out a lot better you know."

Female, 27 Years, Independent

The reimbursement which pharmacies received for any medicines supplied was also criticised for not accounting for profits which pharmacies would have otherwise made through the over the counter sales.

"I have worked out and I'm not sure if any pharmacist have worked out if the, the capitation fee you get each month makes up for any loss of profit you've got over the counter."

Male, 37 Years, Independent

With the proposed abolishment of prescription charges across Scotland in 2011, participants were keen to learn, if at all, how far the patient eligibility criteria for the service registration, would be extended by the Scottish Government. They noted that this would have implications for the over the counter sales of medicines.

"I don't know how is going to remain viable when prescription charges are abolished...If everybody is eligible for e-MAS, people are just going to demand stuff and if there's nothing to take, then they just go empty handed and how can you make a profit if you have to give everything away? We don't get a dispensing fee for e-MAS. We just get reimbursed with the cost of the product that we've given out. But it's a trade cost that we're reimbursed, it's not the profit that we would normally make in things."

Female, 25 Years, Large Multiple

7.3.2.2 Financial rewards for individual pharmacists

Financial incentives were explained by a few participants to have been used by some pharmacies as an impetus for pharmacists to register more patients. Such incentives were mostly based on the number of patients they could register. Such incentives were regarded

as an acknowledgement of the professional service pharmacists were working hard to deliver.

"I have to say though, we are tasked in my company with hitting a certain amount of professional service income and one of the methods of doing that is the number of [e-]MAS registrations we have. So, that's an incentive to us to try and boost that... our pay size is actually very good. I think, one of the reasons for this is when we are doing with minor ailment [service]. ...you can shine, you can actually show that you are working hard, you're doing this, you're using the professional knowledge, you are dealing with the trust of the public, you are benefiting from it. If I can actually demonstrate that what I am doing is generating this amount of professional service, then I can hold my head up. I can't blame for the credit crunch, but you know at least I am doing what I was trained to do."

Male, 39 Years, Large Multiple

However, a few objected providing monetary incentives for employees with the notion that that such practice could potentially encourage competition across pharmacies for patient registration. This was deemed to vie against the non-competitive norm of this innovative service.

"And in some multiples and all, you know not naming names, but you know a staff had been sent to sign up as many people as they can for the minor ailment scheme and some of the incentives that they have, they get rewarded if they do it and some of them have to do it. Their company requires them to sign up, may be fifty a week or you know, and that's not allowed."

Female, 27 Years, Independent

7.3.2.3 Time and workload

The need for personal involvement of a pharmacist in every aspect of e-MAS consultations generated comments. Such level of involvement was deemed impractical for routine practice. Moreover the requirement was also noted to be in contrary with non e-MAS related non-prescription medicines supplies, where, pharmacy support staff often undertook consultations and made supply decisions under pharmacists' supervision.

"It is quite time consuming and now, when you have somebody coming in to buy Calpol [paracetamol] when their kid when they have got teething, you get now the staff kind of say..., getting on their minor ailments for their child's name or whatever, goes in for a while for prescriptions or waiting or whatever, when I get down, I have to go out and talk to them

whereas prior to that the girls could have done the WWHAM^e questions and sold it. So, yeah..., has increased my workload."

Female, 46 Years, Small Multiple

Some commented about the additional processes involved in e-MAS supplies.

"Just because [now] you have to go onto the computer system more frequently. Whereas before, you just had hand over the bit of advice, now you actually have to go right down to the advice and print off the prescription. So that takes more time."

Female, 26 Years, Small Multiple

A few participants from independent pharmacies shared their experiences of difficulty in ensuring personal involvement in e-MAS consultations and supplies in the light of limited staff capacity.

"... tryin' [to] produce a prescription rather than just a sales [for e-MAS medicines supply]. So it does, take a pharmacist. Like some shops have got two pharmacists which does make easier. A lot of shops are one pharmacist, so the pharmacists goin' stop doing a repeat prescriptions, prescriptions, to go and do the [e-MAS] consultations... Ah! cause you know, we are small community [pharmacy], its just the extra bit of paper work involved."

Male, 37 Years, Independent

Such concerns were noted to be exacerbated by a lack of cooperation from patients who wanted prompt services.

"I think when people come in, they want to be seen immediately and they don't appreciate that we still have prescriptions and extra responsibility. But most people are happy enough to wait. But the only thing that benefits...is they don't need appointment but at the same time if people ...as...everybody comes in and may be have a rush when parents dropping children off to school and again its 3 o' clock when they pick them up. Everybody...coming at those times, it gets busy. That's the only thing. You know a consultation may take between 10 and 20 minutes. So that's the only sort of thing, time pressures."

Female, 44 Years, Small Multiple

^e A list of questions presented to patients to assess the suitability of medicines supply in pharmacy. Refers to Who is it for?; What are the symptoms?; How long have the symptoms been present?; Any other medication being used at present?; and what Medication has been tried already? Chapter 7: Pharmacists' adoption of e-MAS (Qualitative)

E-MAS guidelines requiring pharmacists to generate a prescription for each consultation also drew criticism. This was considered problematic when medicine supplies were not made. Participants also explained that patients were reluctant to wait longer to sign the computer generated e-MAS prescriptions; implying potential loss of capitation payments.

"I only use the prescriptions when I am dispensing [supplying the medicines]. I don't, I don't do blank ones [generate prescriptions when medicines not supplied]...because you have to go on to the file on the computer, finding them up to do and then you print it sign off and then, all you saying is go to your doctor. That will just take a long time, they're [patients] not going to wait us doing that...Customers don't want it either, they got to go through big [hassles], they don't worry."

Female, 46 Years, Small Multiple

Some suggested that current procedures requiring patients to sign e-MAS prescriptions following consultation be amended to allow pharmacists to obtain patient signature prior to the consultation. This would allow pharmacists to obtain the appropriate remunerations for the service provision.

"It could be that, someone wants to get advice using the service, they, may be have to sign something first. Same as if you go to the dentist, you sign a form at the start."

Male, 39 Years, Large Multiple

While some participants stated that they did not 'bother' to document 'advice only' consultations, others were torn between the need to complete documentation to ensure that patients registration numbers were maintained for capitation payment and the strain such processes were exerting on resources within the pharmacy.

"...and yes, they will be registered with me longer if I print off the form and get them to sign it to show that they've been given advice or they've been referred to the GP. But it's just, it's not feasible to do that... time is the main contributing factor."

Female, 25 Years, Large Multiple

Some had adopted alternative strategies to fulfil the need for personal involvement. Where expertise of their support staff was known or could be demonstrated, pharmacist involvement in every aspect of consultation or supply was deemed less essential. Participants also suggested that current guidelines be amended to allow more speedy documentation.

"We've elected within the pharmacy that I've worked for. If there's any request for anything on the minor ailments, it's handled by a pharmacist. Initially, we go, you know, the counter staff come for us, I like to say go back to basics, what are the symptoms etc. And if we decide something that is appropriate, then we'll say so..., choose it and then I pass back for the actual physical part of it to be labelled and all the forms produced etc and then it comes back to me for a final check. One of us finally checks before it actually goes over to the patient... We have moved away from that [requirement].... nine times out of ten, I mean, the dispensers and the healthcare assistants have been doing, they have been recommending products for years, years and years. So often, they do have an idea that what's gonna be best... the dispensers know absolutely what to do."

Female, 25 Years, Large Multiple

7.3.2.4 'Shopping List': Issues of service misuse

The potential of service misuse by certain members of public was deemed a barrier. Misuse was often cited to be the case relating to consultations, where a patient requested specific medicines for reasons suspected by the pharmacist to be other than clinical need.

""Or is it, or we're just actually created another group of ill people, that would have either bought it [medicines] before or would've just left it or would have actually cleared up on its own... we've had three teenagers tryin' to sign up the minor [e-MAS] and the smoking cessation scheme. And we reckon... what they're needing, we reckon they're using it for other motives"

Male, 37 Years, Independent

Lists of medicines presented by patients to pharmacists suspected to be for storage purposes were often depicted by participants as 'shopping lists'; and the patients presenting such requests were often the 'worried well'. Participants often expressed 'anger' and 'frustrations' at these situations. Irrational uses of medicines were deemed to be leading to potential patient safety implications.

"...a lot of people think they can just come with the shopping list and I don't know if you have that experience... a lot of people do come in and say that I need paracetamol and I need ibuprofen and, I want this all in this e-MAS scheme."

Female, 54 Years, Independent

"In the case of e-MAS, all these worried well and parents..., sort of all bloody shopping list.

That's difficult..."

Male, 66 Years, Independent

Themes also reflected that some respondents were keen to educate patients to preclude future encounters of a similar nature.

"So it's trying to get round them, it's [e-MAS] not the service that they use as and when needed, it's for a child who must be ill or..."

Female, 56 Years, Large Multiple

The issue of some patients switching registration across pharmacies in response to pharmacists' reluctance to entertain 'inappropriate' requests was deemed a key challenge. Such switches had adverse implications for remuneration.

"They just go some place... You know because we've somebody asking for some irrelevant items, sorry...then they re-register [at another pharmacy] and then they don't come back."

Female, 46 Years, Small Multiple

7.3.2.5 Communication with GPs and practice nurses

The need for greater inter-professional communication to enable pharmacists to curb e-MAS misuse was highlighted by some participants.

"So there seems to be no communications between GP and pharmacy. I'm managing same things [ailments], two or three times in a space of a week, to treat the same condition [of one patient]. There's nothing near to say right they have been round the corner that morning and got the same thing or something similar to treat that condition and they are not, you know, they are getting something in the morning and if its not works, they are going somewhere in the afternoon to try and see if they get something else. 'Cause again its back to this, we need something that will treat it and cure it."

Male, 37 Years, Independent

7.3.2.6 Direct requests for medicines by patients

Participants' responses to patient direct requests for medicines raised similar concerns to the requests received out-with e-MAS, as presented in Chapter 3. Any specific requests for medicines were construed as being contrary to the aims of the service and were considered by participants to indicate a lack of respect or awareness of the professional expertise of pharmacists.

"So if you are living in that sort of society [where] there's not enough respect for the role of pharmacists and then coming in and asking for something in e-MAS rather than coming and asking, say - can you give me something to treat for athlete's foot? And that indicates to me a lot of respect. I will say I will prescribe you what I think is suitable for you. I won't say as quite bluntly to the patient as this but, you tell me what your condition is and I will tell you what is suitable in a much friendly way as to..."

Male, 55 Years, Large Multiple

Ironically, some participants indicated that decisions to deny 'inappropriate' specific medicine requests within e-MAS, were more common than with the sales of medicines over the counter.

"... if we don't feel that it is [appropriate], we won't be supplying it [the medicine], you know. If you want to buy it yourself, then fair enough but it's based basically on the [e-MAS] consultation, you know that we have to go by that.

Female, 27 Years, Independent

One quote reflected how respondents often had to go through 'awkward' conversations in an attempt to demonstrate their 'control' over the supply of medicines to the patients.

"We've got you know, same time... we want this, the minor ailment [service], and I tend out to go the way we can go. Like what it is for? Take them right back to the beginning and go out the way to prescribe something different what we are asked just to be awkward and just to show I am in control."

Male, 37 Years, Independent

Participants mentioned that patients often shifted their registration to another pharmacy when direct request for medicines were denied.

"That's not what it [e-MAS] is for. I've had a patient.... I said you can't [have this product]. It wasn't set up to be like this. What he did was to turn around to another chemist [pharmacist] and register wherever they want."

Male, 66 Years, Independent

Verbal directions from doctors and practice nurses to patients were also deemed to be contributing to the high number of specific product requests for medicines. Participants reflected antipathy over GPs and practice nurses sending patients to the pharmacy with verbal prescriptions of medicines to be supplied under the service. Such verbal orders again were construed as lack of respect for pharmacists' expertise in decision making and lack of awareness of the requirements of the e-MAS service.

"Annoying thing is, they come in to the pharmacies, can I have something and you start questioning about and discover that NHS 24 has referred them and that really irritates me. Because, in some cases telling me what I've got to prescribe by NHS 24 and that one is very irritating."

Female, 56 Years, Large Multiple

"And you feel that if you are a piggy in the middle [between the doctors and the patients]. The baddy..."

Female 53 years independent

Participants also recalled situations where referrals made by GPs were challenging due to therapies being off-label or out-with the non-prescription license.

"....they have sat in the doctors... got their antibiotics and they have been told to go to the pharmacy to get a bottle of Calpol [paracetamol] or ibuprofen and we go ok, there's, we can give you a 100 ml [bottle], but it's to do them for two weeks and they [patients] go: - well, why didn't the doctor write the prescription?- I don't know and that creates a wee bit, 'cause obviously the GPs don't understand fully what the minor ailment service is about. It was supposed to take the pressure off them in the first place, filter the consultations and they should still be prepared to write prescriptions, I suppose to be for long time or a longer period [of therapy]."

Male, 39 Years, Large Multiple

Patient safety implications arising from so deemed 'irrational' advice by other health professionals were also highlighted, reflecting the importance of pharmacists as the ultimate medicines decision makers.

"What I see recently... and again it's linked to minor ailments [service] is, so many mums come and asking for paracetamol suspension and ibuprofen at the same time. And whether its right or not, I only recently discovered that, that apparently is information that NHS 24

give to mums when they call in with kids with high temperature but you know now it seems to be almost as you say that run of the mill they come in with looking for something for teething etc and they want both [paracetamol and ibuprofen]. And that's, that's where they're new to me. You would have stuck to probably one or the other, and with the situation with asthma. The amount of ibuprofen suspension that's, that's being sold or supplied over the counter, we just wonder."

Female, 53 Years, Independent

7.3.2.7 Technical elements of the service

The computerisation of documentation associated with e-MAS consultations was the basis of complaints from some respondents. Such complaints mainly surrounded the resources and expertise required as procedures were 'taxing'. One deemed computerisation of documentation activities within e-MAS as a major 'change' in the way non-prescription medicines were supplied.

"It was quite a major change for us, sort of paperwork side of things and putting it through the computer was quite difficult for us to start with."

Female, 47 Years, Small Multiple

Discomfort with the 'radical' change deemed to be required for the pharmacists and pharmacy support staff needed were expressed.

"They're trying to get away from the paper. I've had an argument at other meetings and they're trying to get away from the paper based. 'Electronics is the way is the way to go, we should be going into electronic messages and checking on you, e-MAS computers, check some kind of statistics'...I'm not interested...A paper thing coming through, then I would open it and you could take it home"

Female, 46 years, Small multiple

However, others were supportive of computerisation and perceived benefits owing to increased efficiency. Nevertheless, there were complaints that technical errors with the current electronic system were frequently encountered, a common one being lack of recognition of the generic versions of medicines by the e-MAS computer systems.

"They were on the e-MAS formulary but my computer system didn't have that [generic medicine] listed as a drug file, so I couldn't physically prescribe it because it didn't come up

in the system. So, that has been the single biggest influencing factors on my prescribing practices..."

Female, 25 Years, Large Multiple

Complaints were also noted around computer systems not allowing pharmacists to correct any errors made during the supply process.

"It's a nightmare...because, you picked, for some reason the wrong pack size, you cannot go back and amend one either. Once you've pressed that button, it's away and if somebody has put in a wrong figure, a, a wrong letter in some of the boxes, back it [the medicine] comes disallowed [for reimbursement]."

Female, 53 Years, Independent

7.3.2.8 Access to patient medical records

Helping pharmacists curb the potential service misuse was highlighted as the benefit of greater access to patient medical records for e-MAS, in addition to other benefits of such access presented in Chapter 3.

"I think, if we could get to see the patients' histories, as you know towards e-MAS, as to into everything they've got in any pharmacy, that the pharmacy can obviously be, you know, blanked diced. You know, what they are getting, to pick up the people that have abused it, that also pick on the people that, you know, have problems or do you need to be referred on?"

Female, 27 Years, Independent

7.3.2.9 Formularies

The availability of a user friendly e-MAS formulary was deemed imperative to assist pharmacists with rationale decision making when making medicine supplies. This was also important to ensure that items supplied were within the list of medicines eligible for reimbursement. However, both positive and negative opinions about existing formularies were expressed. Supportive participants referred to clear lay-out and user friendly presentations as positive features.

"it's [formulary] very easy to use and access. It's good, it kind of have certain categories of the different kind of minor ailments, enlists the drugs in each category..., it's so quite easy to use."

Female, 29 Years, Small Multiple

Those negative referred to the restrictive nature, mainly for the limited ranges of medicines included.

"There's not enough choice of products in there [formulary], I would see but ...the groupings is okay"

Female, 44 Years, Small Multiple

Comment was also made on the restrictions placed within e-MAS formulary for the duration of the supply of certain medicines.

"The other Health Board projects that we are involved in.., the head lice project where we can supply a full treatment whereas we are told under the minor ailment service, we can only give one supply. For most products you need to repeat them after 7 or 14 days. So, it's kind of ridiculous under the minor ailment service saying that you could have that one bottle, you can come back in 7 days to get your next one. That's not appropriate."

Male, 39 Years, Large Multiple

Concerns around lack of inclusion of generic medicines in e-MAS formularies were also raised. Participants rued the missed opportunities to produce further NHS savings.

"...it's easier to prescribe everything by brand, you can save things getting thrown back [rejected for reimbursement]."

Male, 37 Years, Independent

Participants voiced that e-MAS formularies should ideally include only those medicines that are eligible for reimbursement. This would require amendment of the current guidelines which, in principle, claims that pharmacies are reimbursed for any P and GSL medicines supplied.

"I mean did we, did we make the formulary bigger and scrap everything else and just allow the things on this formulary, allowed in the minor ailment [service], which, I think is a great idea because it would restrict a whole lot of things but as it stands just now with all these P and GSLs..."

Female, 46 Years, Small Multiple

Because of the fear of missing out on reimbursements, some participants stressed the need to adhere to formularies while making medicines supply decisions.

"...you know but what you have given is one of the things in the formulary any way. You're not, you're not going out with the formulary to give something sort of.., differently."

Female, 23 Years, Small Multiple

In contrast, others regarded formularies 'just as a guide' considering it not essential to adhere as long as the medicines belonged to either the P or GSL categories.

"I mean..., its fine because of the fact that its not entirely rigid. I think..., the fact that we can go off the formulary using our professional discretion. But, in the same aspect, having a formulary in itself is also useful... I like the formulary, I also like going off the formulary if I need to."

Male, 39 Years, Large Multiple

The need to update formularies on a regular basis was also voiced, keeping abreast of the changes taking place such as the inclusion of newly reclassified medicines and new brands of existing non-prescription medicines.

"The formulary is out of date. There are things we don't agree with.., the things being there under...,things with.., I'm not saying that's a wholesale thing, we want to make wholesale changes to the formulary but formulary is designed as products on the market, now when, the products is being released... [formulary]"

Male, 55 Years, Large Multiple

Participants from one of the Health Board valued recent formulary updates that were taking place.

"Well, the formulary we've got now tell you generic names and brand names that can be prescribed. So its clearer."

Female, 28 Years, Small Multiple

Participants expressed a lack of acquaintance with the methods and processes for feedback to Health Boards around updates in formularies. In addition, some participants voiced that the formularies being produced at the Health Board level should be scrapped so as to

enable universal implementation of the national formulary. This would remove any ambiguities arising from multiple formularies across the Health Boards.

"There is now scope from massive differences between as to what we can supply what we can't, how you supply, will we be paid for it?... how do we feed in, can we feed into the, the Government bodies for what we would like to see in formulary?... Here it's now Scottish system and but, why do we need local formularies and why then, say, how dare do you get hold of people to say, we think this should be in the formulary now."

Male, 55 Years, Large Multiple

7.3.2.10 Clinical guidelines for decision making

The need for further clinical guidelines to support decision making was also voiced. Participants reflected that current guidelines were less explicit in areas around decision making in relation to management of minor ailments.

"So, is it minor? You know, there are a lot of grey areas about what is minor and what's not. Hay fever have been one of the crackers, as you know by August, it should hopefully have died down. But how often do you go and treat em'? Or when do you tell them to go to the doctor?...There's not enough guidance."

Male, 37 Years, Independent

7.3.2.11 Opportunities to advertise the service

Patient targeted promotional materials were highlighted as key to promoting patient registration. Some appreciated the advertising materials designed by NHS National Education Scotland in raising public awareness.

"With us it's a case of, it's great when they actually put the poster up in the window to advertise because we weren't basically allowed to advertise the scheme before that or promoted it in any sense. But when the advertisement went up in the windows, I'm not too sure what you call that, you know with the health promotion window that all pharmacies have. That went up and then, basically we're sort of rural community and people do talk to each other more so, probably than the time when they'd have come in and sort of asking about it and then you're able to tell them but you weren't actively allowed to promote it before this advertisement came about." Perhaps cut this down?

Female, 27 Years, Independent

On the contrary, others complained that current advertising materials were insufficient to promote the service and wished the Health Boards to legitimise the use of privately sponsored campaigns by pharmacies relevant to their community needs.

"When it [e-MAS] was first launched, I think everyone in the pharmacy was excited about it. Because it was the first step towards moving away from volume dispensing, in terms of payment. I suppose we were, initially slightly disheartened. Head office provided lots and lots of promotion material for it which the Health Board, then the NHS said you can't use because we need a levelled playing field. Having worked for a big company, you know, then recycling of the information pack which the public, I think would have found useful and we could have used that to promote it. It's disappointing the fact that even now after a lapse of time, mothers of, of children are coming in and going, no, I don't know what you are talking about."

Male, 39 Years, Large Multiple

Participants described encounters with patients registered with the service who were still naive about their registration status, implying a lack of awareness.

"...folks don't seem to know one what they signed the form for. I've had several occasions where they've got, oh, have you heard the minor ailment scheme? No, and then you go, you will find them registered in another pharmacy. So, I'm not sure if that's been the city they signed it up. They just don't know, they just don't know what they've signed."

Male, 37 Years, Independent

The need for further promotion was highlighted with pharmacists recognising that many patients eligible to register were yet to do so. Such shortcomings were attributed by participants to the lack of opportunities to promote the service.

"...how many people actually know about it. 'Cause I think, the information we have is that only about 20% of the people that could be registered, are registered."

Male, 39 years, Large Multiple

Participants also identified the role for GPs in helping to promote the service.

"Well, like saying to patients, Oh! you could go and get this [medicine] from you pharmacy without coming to see me sort of things. Not I am aware of, very occasionally, I think I've had people coming in and say oh my GP said I could just get that here. So, obviously one or

two GPs are [promoting at the moment] but..., I don't know that many are [doing] at the moment."

Female, 55 Years, Small Multiple

7.3.2.12 Training

The importance of formal training to facilitate adoption of innovative services and medicines was presented in Chapter 4. This was not raised as an issue by participants in relation to e-MAS. However one participant recounted 'not any training' (*Female, 28 Years, Small Multiple*) when e-MAS was first introduced. However, despite this the same participant expressed no difficulty in 'getting used to' the system.

7.3.3 Pharmacists' views on future provision of feedback of performance as a potential facilitator to adoption of e-MAS into practice

Key themes identified within this category related to: awareness and experience of feedback of practice performance; participants' preferences on the types of data from e-MAS usage; issues of privacy and confidentiality around dissemination of feedback; preferred method of data presentation and delivery from e-MAS and data from other areas of e-Pharmacy. These key themes and subthemes are presented with illustrated quotes.

7.3.3.1 Awareness and experiences of feedback of practice performance

Participants reflected varying levels of awareness and experience of the use of feedback of practice performance around e-MAS. Some explained that they were already receiving feedback from their Health Boards, limited to either one or some of the following categories: the cost of items supplied; medicines allowed and disallowed for reimbursement; adherence with formulary; and data on patient registration.

"The Health Board, I think is responsible for generating that sorts of [data]...We get feedback in terms of our number of [patient registration]...and also in terms of the number of [e-MAS] prescriptions that we are writing so we can see whether we are over performing, or if we are one of the better ones or we are less or so. That feedback is good...[but] we don't get it all the time"

Male, 39 years, Large Multiple

Participants already receiving such feedback, however, complained that the data were mostly outdated. A few demonstrated awareness of GPs' use of feedback from electronic prescribing systems.

"This is like the SPA [Scottish Prescribing Analysis] data, the doctors get back from the prescribing, is that right?...GPs have a lot information they get feedback from prescriptions but they then have targets to reach so many seventy year, seventy years olds with whatever conditions to protect them from heart problems and in the long term it's saving NHS loads of money, hospital beds and whatever."

Female, 46 years, Small multiple

7.3.3.2 Participants' preferences on the types of data from e-MAS usage: supply of non-prescription medicines

Feedback in the following areas around medicine supplies within e-MAS were of interest to participants.

Number of medicines supplied

The total number of medicines supplied from each pharmacy via e-MAS within a retrospective time frame was of interest. Such feedback would enable pharmacists to move away from manual counting of the labels if they wanted to reflect on their own practice. In addition, benefits to stock controls within the pharmacy were highlighted.

"Total number of items we've dispensed, I suppose I can count the labels, but it'd be interesting to get back, what, what we've done previous months."

Female, 46 Years, Small Multiple

• Therapeutic categories of medicines supplied

Details of the therapeutic categories of medicines supplied classified according to British National Formulary (BNF) were desired by participants. Only the individualised feedback to pharmacies/pharmacists was expressed as being potentially more useful for their direct relevance to pharmacists.

"Yeah, it would be good to know, wouldn't it, to really know you have been prescribing right things for the right reasons, isn't it? Its good for CPD..."

Female, 26 years, Small Multiple

There was a low level of interest in receiving nationwide or Health Board aggregated data sets. Such low interest was mainly attributed to the lack of relevance to individual practice.

"It would just be of interest really. I don't think it would make any difference to our own practice."

Female, 55 years, Small Multiple

Aggregated data sets were only deemed relevant if comparisons of practice were made with individual pharmacies/pharmacists.

"It would be nice to see region wide analysis and that of specific shop analysis and the two could be laid, literally one on top of the other..."

Male, 66 Years, Independent

Others explained that, as every pharmacy is unique in terms of patient demography and hence the types of ailments, comparisons of individual pharmacist/ pharmacy performances with local or national e-MAS performance could not be justified, unless the comparisons were made between areas of similar demography.

"Obviously, I think, every pharmacy is different. You know we are a small independent in a local community and you know, so comparing our data to a busy city centre pharmacy is pointless, I would think. But other pharmacies in a similar situation would perhaps ...kind of similar to yourself, [with] similar GP surgeries, similar sort of social, deprivation or affluence in an area. You know these would be the things I would want to compare with. So, there is no point..."

Female, 44 years, Small Multiple

Only a few saw participants benefits in receiving aggregated data sets alone without any comparisons to individual pharmacists/pharmacies. In relation to individualised feedback, however, benefit of reflecting on practice where individual practice appeared to be very different from national or local performances was highlighted.

"What I prescribe [supply medicines under e-MAS], which I kind of already know but seeing it in writing, you know makes you more aware. And may be also look at areas where you don't prescribe enough. May be because we don't understand or you know... just not many patients are coming in for that ailment."

However, aggregated data sets relating to Health Boards or locales were deemed to benefit pharmaceutical public health initiatives by enabling pharmacies to set up and work around certain targets, for example, in containing locally prevalent problems.

"...because you obviously have all these sort of seasonal problems, cold and flu, hay fever, things like that, possibly sort of head lice things. So I think that would be of benefit to reflect on perhaps to organize yourself to the next sort of phase."

Female, 44 Years, Small Multiple

"...to increase your work effort into promoting...thinking about head lice or something similar, and then quantify how much that effort was rewarded with how many prescriptions you received, getting close to business targets. ...yeah, you could review your performance, you could review your individual pharmacy's performance how it is done ..."

Male, 28 Years, Large Multiple

Some expressed high levels of confidence in their decision making in practice. They perceived that although feedback data would be potentially 'interesting', it would be unlikely to serve any benefits.

"...we know what we are prescribing [supplying]. It's interesting, but it's not something I would need to look at."

Female, 46 Years, Small Multiple

• List of medicines allowed/ disallowed for reimbursement

Losing out on reimbursement for certain medicines supplied within e-MAS was a key issue, as presented earlier in section 7.3.2.1. A timely breakdown of the list of medicines allowed and disallowed for reimbursement was deemed potentially useful in informing future practices.

"...you know we tend to quite a lot of...prescribe things which we do get sent back, just to see things which we haven't been paid for that. So, that's useful."

Female, 28 Years, Small Multiple

"Certainly would be worthwhile...so that we don't do it [supply disallowed medicines] again."

• Adherence with the formulary

Those who advocated the need for adherence to the formulary expressed a desire to obtain individualised feedback around formulary adherence to identify any training or educational needs. The importance of such data was also particularly noted to be useful to impress upon 'locums' who may potentially lack familiarity with the formulary, hence possibly responsible for skewing pharmacy formulary adherence.

"...your compliance relation, compliance to the formulary related to anti-infective skin preparations and emollients and corticosteroids, for example, even if it is split down even further than that, but you just then knew that there was an area where I'm really not that compliant. So, let's go and review the formulary, review that what should I be giving out. So, you then know that, that's the area which I need to do some CPD and do some training to review what I, I thought I knew or what the store, where the store going.., may not going quite right."

Female, 25 Years, Large Multiple

Data around formulary adherence was considered more relevant if formulary adherence was to be incentivised.

"The GPs get incentivized for being percentage over guidelines [for cost effective prescribing]. We don't. But, if we get incentive payments, it'll be very helpful."

Male, 37 years, Independent

• Generic versus branded medicines supply

Participants were aware of the potential NHS cost savings arising from generic medicine supplies through e-MAS. Given that e-MAS computer systems could, in the future, allow supplies of generic versions, participants were very keen to obtain feedback on how much each pharmacy was saving the NHS.

"list of figures in terms of prescribing generically, what kind of percentage [generic supply is ours] as compared to kind of national average is... quite useful to see."

Female, 29 years, Small Multiple

Some, however, explained that cost saving had less relevance if pharmacist decision making was ethical, hence in the best interests of the patient.

"I don't think that's [feedback on generic medicines supplies] of any benefit because if you are prescribing ethically, anyway, then the price shouldn't be an issue. The number of items shouldn't either be, and I'm prescribing something because it's necessary not [for other reasons]."

Male, 55 Years, Large Multiple

7.3.3.3 Participants' preferences on the types of data from e-MAS usage: Patient registration

Number of patients registered

Although data around the number of patients registered within a pharmacy could be retrieved through the pharmacy computer system, some participants commented that there were anomalies between the number shown by the pharmacy computers and capitation payments received from the Health Boards. Feedback data would therefore enable pharmacists to ensure fairer remuneration.

"With the system..., that you have just generated information saying how much, many people we have registered [for e-MAS]. But when we compare it with what the Health Board said we had, there's always a difference... Our computer thought it was registered but when you actually check, nothing had got through... in fact, then we had an issue because we couldn't re-register them because our computer thought they were registered even though the Health Board didn't think that they were registered. So, knowing what the Health Board, are paying us for each month would be a benefit to us"

Male, 39 Years, Large Multiple

Participants were asked to comment on whether local and national patient registration data would be of use. Some deemed such information to be important for Health Board and the Government but not for individual practitioners.

"Yes, that's interesting to the Government and the Health Board, but that's not interesting to the individual community pharmacist."

Female, 46 Years, Small Multiple

Others, however, commented that such data would be an 'eye opener', for example to identify any need for greater effort in getting more patients to register. A few, however, raised objections around dissemination of such data with the notion that it could incite competition between pharmacies to increase patient numbers.

"It's always good to have a good criticism to be able to affect yourself. If you don't have the information, you don't know where you could improve...So, it will be good to see where we are over performing or underperforming or doing well."

Female, 43 years, Small Multiple

"I don't think minor ailment is a competitive thing. Its not you know you are trying to do more than just down the road. We are trying to serve our customers as best as we can."

Female, 47 years, Small Multiple

• Number of 'active' patients in the e-MAS register

Some reflected on the need to provide feedback to pharmacies with data on number of patients that are being seen repeatedly for the service provision along with the numbers not 'active' in the system after initial registration. These data were deemed to have potential to encourage pharmacies to focus on continuity of care.

"..if people [pharmacists and support staff] are just purely signing people [patients] up, it really makes that meaningless. You really what you want to know is who is actually using it."

Female, 53 Years, Independent

Number of patients lapsed from the register and those transferred to other pharmacies

These two specific areas again had direct bearing on pharmacy remuneration. Participants deemed data would serve as timely updates on the specific band of capitation remuneration the pharmacy received through their Health Boards.

"...it will be good to know which patients are still on and which patients have lapsed. It obviously helps. Higher the number of patients you have, the more, you know the, remuneration you get. So we would have a way of knowing who is still on and who is not."

Female, 43 years, Small Multiple

7.3.3.4 Feedback of performance relating to changes in practice guidelines

Participants were asked their opinions on receiving feedback around how changes in national practice guidelines, such as amendments in formularies or changes in legal status of non-prescription medicines, affected their own e-MAS performance. Very low interests in such feedback were observed.

"POMs to Ps, I would just kind of know myself, how that was going. I wouldn't see really any major need for...[this]"

Female, 29 years, Small Multiple

"I don't need to be informed up to date. Your practice, don't think changes dramatically over short space of time."

Male, 28 years, Large Multiple

7.3.3.5 Issues of privacy and confidentiality around dissemination of feedback

Participants reflected on issues around privacy and confidentiality that might arise with the gathering and dissemination of feedback of e-MAS performance data. Participants were strongly against the use of feedback data by either pharmacy management or Health Boards to mandate practice changes at the individual practitioner level; for example, in setting undue targets aimed at increasing performance. Participants further advised that information should only be disseminated for supportive reasons. Apprehension around the potential misuse of data by pharmacy management was mostly noted with respondents from multiple chain ownerships.

"I'll be little bit worried about one angle of having this. Now working for multiple [pharmacy ownership], this may or may not happen but if..., put on e-MAS further up the chain, so, well you, you have to achieve X numbers products in this category you supply in given period of time. Why you are not doing 'cause there are so many folk registered, you're, you're below, below the national average or something like that."

Male, 28 years, Large Multiple

However, a few had no issue with privacy or confidentiality and were happy for their performance within e-MAS to be disseminated to others, including other pharmacists.

"Not, certainly not, where I am working at the moment. I don't think that [disseminating information to others] would be an issue. I think possibly if you are working for the big multiple, then that would be more of an issue. Certainly, in my situation, I don't think that really is an issue..."

Female, 47 years, Small Multiple

7.3.3.6 Preferred method of data presentation and delivery from e-MAS

Most participants explained that they worked in a busy environment and hence feedback should use formats and presentations able to deliver key messages at a glance. Participants were divided on the issue of whether electronic or postal methods of delivery would be more appropriate.

"Four of us here will say paper [based feedback] and one will say computer [based]. This is the age gap..."

Female, 54 Years, Independent

7.3.3.7 Data from other areas of e-Pharmacy

Participants were asked if there were any areas of practice other than e-MAS, which could benefit from performance data feedback. Participants' interests were mostly around the activities within Acute Medication Service (AMS) such as the number of medicines dispensed for each GP practice in a local area so as to estimate which of the GP contractors were contributing to pharmacies' income; demographics of patients using pharmacy specific pharmacy and total medicines including prescription and non-prescription medicines supplied to individual patients.

"The amount of prescriptions dispensed....sent from specific surgeries sent every month sort of across the area."

Female, 23 Years, Small Multiple

One quote also reflected the usefulness of data relating to, but not limited to minor ailment management, around how innovative services are progressing in Scotland as compared to the rest of the UK nations.

"...it's interesting to see how pharmacy is progressing in this country compared to the rest of the UK because it is something that nobody else is really doing... I do want to see pharmacy progressing and moving on..."

Female, 25 years, Large Multiple

7.4 DISCUSSION OF KEY FINDINGS

This is the first qualitative evaluation around pharmacists' adoption of e-MAS and associated barriers and facilitators associated since Scotland wide e-MAS rollout in 2007.

Chapter 7: Pharmacists' adoption of e-MAS (Qualitative)

Participants' attitudes towards the nationwide rollout of the service and key facilitators/barriers to service adoption were identified to answer the study objectives.

7.4.1 Attitudes towards the service

Participants identified benefits to both professional practice and patients. The service was commended for enabling pharmacists to make supplies of medicines, including the so deemed 'pricy' newly reclassified, many of which certain patient groups might otherwise find inaccessible.

Service regulations requiring patients to register at one pharmacy of their choice were also noted, facilitating greater acquaintance between professionals and patients. However, extension of the need for patient registration to other services may contradict health policies which aim to increase patient choices [6].

Participants raised awareness of potential NHS savings through e-MAS and regarded such savings as a motivation to service adoption. A few studies have demonstrated cost minimisation brought about by similar minor ailment schemes. These economic savings models are based on the reduced cost of pharmacy consultations as opposed to GPs [111,113,337,338]. Such services have also been shown to be effective in reducing GP workload specific to minor ailments [111,113], although overall GP workload has been mostly shown to have been unaffected [113,339]. The long term economic impact of nationwide rollout is yet to be explored. There are several factors which should be considered and these are discussed in Chapter 9.

7.4.1 Facilitators and barriers to the adoption of e-MAS

Both 'context' and 'content' related facilitators/barriers were identified from the qualitative data; many of these being similar to the adoption of innovations of reclassified medicines into practice. Appropriate remuneration and reimbursement was regarded as a key facilitator to adoption of the service. Although some deemed that service implementation was leading to financial benefits to the pharmacy, many did not support the current e-MAS remuneration patterns. These differences could be related to how implementation was affecting individual pharmacies' businesses relating to non-prescription medicine sales. It may be that in rural pharmacies, with the predominance of elderly patients exempt from prescription charges, e-MAS could reduce profits generated through either the over the counter sales, or remuneration from dispensing prescriptions.

Debates about the benefits of capitation-based versus 'fee-for-service' system need to be considered. Criticisms of capitation-based systems as compared to fee-for-service systems in general include the former encouraging a focus on new patient registration, shorter consultation times and higher workloads and hence potentially compromising continuity of patient care [340]. However, the published studies mostly relate to doctors' practices and the evidence itself has been suggested to be poor, limiting generalisability to other areas of primary care [340]. Any issue about pharmacists' potential disinterest in continuity of care has been partly dealt under e-MAS which requires at least one consultation per registered patient per year for the pharmacies to be eligible for the capitation payment. However, it penalises the pharmacy for less than one and does not reward for more than one consultation per year [341]. This lack of sufficient reward for repeated care accounting to more than one consultation per year was deemed unfair by participants. Models that would pay pharmacists per consultations were suggested as fairer by some participants. This type of remuneration pattern was utilised in the feasibility study prior to the nationwide service roll out, which paid pharmacists with a fee per consultation. Complaints around lack of enough financial reward for service provision were also raised [342]. In other areas, where such remuneration patterns for similar minor ailment schemes exist, for example in some PCTs of Northern Ireland [343] and some PCTs in England [344], research into pharmacists' attitudes towards such remuneration patterns have not been yet published. A qualitative study into pharmacists' perspectives of a similar minor ailment scheme in Nottingham PCT also reported pharmacists' dissatisfaction with the remuneration structure, but did not detail the nature of remuneration [123]. The need for further evaluation around the effect of different remuneration systems in pharmacists' adoption of new services; and the effect of these systems on clinical and economic outcomes has been recently outlined in a recent systematic review on effectiveness of diverse remuneration structures [345]. The author noted difficulties in concluding which was the most appropriate remuneration system.

Lack of patient willingness to countersign the e-MAS prescriptions due to time implications was thought to have affected pharmacy remuneration. Alternative means of recording consultations such as the use of automatic cards carried by patients and readable by the e-pharmacy system could be an efficient technique to replace the counter signature requirements. In addition, the current restriction placed on advertising e-MAS, which is limited to leaflets and a poster designed by NHS Scotland [341,346] was also considered to

limit patient numbers and hence remuneration. The potential role of GPs and practice nurses in promoting the service as identified by participants was worth noting.

The walk in nature of the service was deemed by some to be leading to excess workload. Although an appointment based system was deemed a possibility by some participants, the walk in nature of the service is unlikely to be changed, as enhancing the image of community pharmacy as the first point of contact for unscheduled care remains a priority for the Scottish Government [347].

The mandate within e-MAS which requires pharmacists' personal involvement in every aspect of supply was deemed to contrast with the processes for non-eMAS supply of nonprescription medicines. The cognitive elements involved in the service, for example the systematic patient assessment, medicines supply and referral [94,95] might be the reason why greater pharmacists' involvement is mandated. However, a study in the UK has demonstrated that as many as 90% of pharmacy consultations around non-prescription medicines purchases are handled by support staff, covering conditions such as head lice and acne [348]. Many participants in this study reported to have deviated from such personal involvement requirements and putting alternative measures in place. On one hand, such measures are likely to free up pharmacists' time. Alternatively it might give patients a negative impression; especially those moving from GP managed minor ailments. Perceived expertise of health professionals has been identified as a key trigger in patients' decisions around which professionals from whom they choose to receive care [101,105,120]. Amendments in the current provisions around personal involvement requirements should be based on the balance between what is appropriate for patients against what is feasible to undertake in a pharmacy environment.

Enhanced access to patient medical records was also considered necessary to enable informed decision making around minor ailment management and issues around reclassified medicines. Access to patient medical records is also important to enable pharmacists to adopt other services integrated within e-pharmacy such as the Chronic Medication Service (CMS). This is a service whereby pharmacists can manage patients' long-term medication for up to 48 weeks under a shared-care arrangement with GPs [349]. A concept of an emergency card summary has been recently introduced in Scotland which details the annual record of chronic and acute medicines prescribed to the patients. It is anticipated that pharmacists will be able to obtain access by telephoning NHS24 [347].

However, such access by pharmacists will require patient consent, and in addition is not available at the point of care. Further debate about acquisition, use and governance of patient medical records in pharmacy is urgently warranted.

The need for enhanced access to patient medical records and better inter-professional communication were also voiced by participants to support pharmacists dealing with suspected service misuse. Although the pilot e-MAS in Scotland showed an average of one consultation per patient per year [350], respondents reflected concerns that some customers might be tempted to misuse the service. Participants were strongly opposed to the issue of direct medicine requests received from patients, many of which were initiated via by GP and practice nurse referrals.

Opinions around the usefulness of e-MAS formularies were mixed. Some appreciated the layout and content whereas others voiced that formularies were too restrictive. Restrictive formularies might potentially lead to a greater number of GP referrals by pharmacists and contribute to barriers to patient utilisation of the service. Some Health Boards seemed to have updated their formularies frequently and recently, reflected in participant satisfaction. Very limited evidence generated through qualitative interviews with seven GPs from Nottingham PCT, England, reflects that GPs are also in favour of increasing the range of medicines within e-MAS formularies including the inclusion of antibiotics [351]. There is a need for further discussion among stakeholders regarding formulary extension.

The benefits, barriers and facilitators around the adoption of e-MAS by community pharmacists identified in this study are consistent with previous studies, most of which used qualitative methodology. Barriers to service adoption that were reported during the feasibility study in England [342] are still being experienced by pharmacists. These also match literature reports around evaluation of another similar scheme in Nottingham PCT in England [123,352]. Positive aspects reported by others were: the contribution to extending pharmacists' skills; greater patient accessibility to minor ailment management, improved relationships with GPs and patients; and reduced GP workload and financial benefits for pharmacists [123,342]. Key barriers reported were the limited scope of the formulary and restrictive protocols [123,342,352]; lack of privacy for consultations in the pharmacies [123,342]; lack of support from local medical practices [123,342]; lack of opportunity to advertise the service [123,342]; excessive paperwork [123,352]; ambiguous scheme protocols [123,342]; abuse and misuse of the service by some customers [123,342]; lack of access to

patient medical records [342]; presentation of proxy consultations [342]; and patient pressure to prescribe medications for every consultation [352] thereby regarding pharmacy as a place to obtain medicines without any patient assessment [342]. Compared to the findings of other studies [123], the participants in this survey, however, did not raise the issue of privacy as a concern. Lack of patient willingness to undergo detailed consultation might have made the issue of privacy redundant. Further training for support staff was not raised in this study as compared to previous findings [123], however, it should be borne in mind that support staff currently have little role in the Scottish scheme.

Three studies around patient views of minor ailment schemes have been published. A study of 143 patients (response rate: 14%) conducted in Nottingham PCT reported that ease and convenience of access was the most important benefit of the scheme [353]. Interestingly, higher patient satisfaction was related with lower patient income status which could indicate that those of lower income are more likely to use the service. Patients voiced that the 'physical environment' was the most important barrier. The very low response rate limits the usefulness and generalisability of the findings. Vohra surveyed patients who had accessed Minor Ailment Scheme in the Chorley and Ribble PCT (123 replies, response rate: 40%) [121]. Of those using the service, almost all were positive about the scheme and would use it again. No appointment and the 'free' nature of the service were the key reasons for planned reuse. Langley et al investigated patients in the Eastern Birmingham PCT who were given the option to use the scheme instead of visiting their GPs for managing minor ailments but had refused the offer [114]. Of the 24 out of 30 patients approached, common concerns were related to privacy available in pharmacies, pharmacists' expertise in diagnosing minor ailments and expression of greater trust in doctors. These findings suggest that many benefits, barriers and facilitators to service adoption are similar among pharmacists and patients.

7.4.2 Performance feedback data as a potential facilitator to e-MAS adoption by pharmacists

Diverse areas of practice were identified by participants where feedback could support service adoption, such as by allowing review of performances around patient registration. Feedback around formulary adherence was related to ensuring that reimbursements were received for future medicines supplies made through the service. In addition, the e-MAS computer system allowing, many participants were keen to follow cost effective medicine supply practice and receive feedback around how much savings each practitioner was

bringing to the Health Boards. Nevertheless, participants expressed a need to incentivise the cost effective non-prescription medicine supplies through e-MAS. There is a considerable amount of evidence from the medical literature that cost effective and guideline adherent medicine supplies could be influenced by the use of feedback of performance data recorded through the electronic prescribing systems [334,354-356]. A recent systematic review around the benefits of audit and feedback to health care practitioners suggests that changes in practice brought about by such feedback are largest when baseline adherence to the guidelines or standard to practice is low [357]. Hence those pharmacists who deemed adherence to formularies and service guidelines important and those least adherent at baseline are most likely to benefit. Some examples of electronic systems through which such feedback data has been used to support rationale medicine supply practice of doctors include the Scottish Prescription Analysis (SPA) [358] and PACT [359] in the UK, COMPASS in the Republic of Ireland and South Africa [360]. Similar electronic systems are known to be in place to support electronic medicine prescribing by doctors in Australia [361], Sweden [362], Canada [363] and the Netherlands [364]. Although some evidence suggests that feedback information alone can be as effective as interventions such as reminders, outreach, incentives and opinion leaders [333], evidence also reflects that feedback of performance alongside educational outreach visits and computers reminders are more effective than using feedback alone [361-367]. Future provision of feedback hence would benefit from accompanying other educational intervention to support pharmacists' service adoption where required.

Many participants expressed a desire for feedback around the total number of medicines supplied and types of medicines supplied through e-MAS. Many related these to identifying personal educational needs through reflection of areas where they would find themselves 'overprescribing' or 'under prescribing'. In many instances where feedback around medicine supply practice and patient registration was sought, the importance of comparison of performance with local/national service data was highlighted. Evidence from the medical literature again suggests that feedback is most effective in encouraging practice change where the receiver's own practice is inconsistent with those of peers [357].

Feedback around individual practice was deemed by participants to be more desirable than aggregated feedback to groups of pharmacies. It has been suggested that individualised feedback, particularly because of the capacity to highlight individual need for change is more consistent in bringing about change [361,363,368]. Participants' concerns around

'aggregated' feedback of performance related to a potential lack of relevance to individual practitioners. The evidence around the importance of identifying the information needs actually required at the level of patient care [335,369] is further strengthened by this qualitative study.

The lack of expectations of any potential 'advantage' from feedback could explain why some expressed little interest. The usefulness of feedback has been shown to be greater once practitioners become familiar with the information [370]. Fears about the inappropriate use of feedback by 'head office' are worth noting. Feedback which does not mandate use or change , as desired by most participants, is known as 'passive' feedback [357]. This is contrary to 'active' feedback associated with mandated use and change. It is important that pharmacists' wishes around feedback are respected. Evidence stresses that practitioners need to agree about whether they want to review their performance [357], hence forcing change is likely to have negative consequences.

Other barriers to accessing performance feedback as a tool to facilitate innovation adoption in this study mostly reflect those identified in the literature around doctors' use of feedback. Barriers to the use of electronic feedback reported by the literature relate to: doubts about the application of information to practice [371], lack of time in using the information [371-373], convenience of access [371,374], issues about reliability of the source [373], difficulty in interpreting the available information [371,374] and lack of individual motivation [375].

The desire for timely feedback as highlighted by the participants in this study is important given that feedback is more effective in changing professional practice if provided when recollection of actions and experiences are fresh in practitioners' minds [376].

Limited evidence around the applications of performance feedback in enabling the adoption of new behaviour by pharmacists exists. Most studies have used a mystery customer approach to collect and report on the performance of pharmacists or support staff [376-379]. One study compared the accuracy of guideline adherent counselling by 30 pharmacies in Australia receiving and not receiving regular feedback [378]. Those receiving feedback were found to demonstrate greater adherence to practice guidelines than those not receiving feedback. Another study with 20 community pharmacists from London investigated the potential of feedback in enabling pharmacists to identify drug-related problems (DRPs) through a clinical medication review programme; those who regularly

received feedback of performance were more likely to have identified the DRPs more accurately than those who had not received feedback [380]. Those receiving feedback were also more likely to suggest appropriate courses of actions to the patients. Feedback collated and reported through mystery customer studies is less likely to reflect long term performance. This method is more suited to investigating pharmacists' and support staff's communication and counselling skills [377]. Benefits around feedback relating to long term performance collected and disseminated through external sources is hence a novel area of research within community pharmacy.

Anecdotal evidence suggests that pharmacists currently receive feedback resulting from various audits taking place within their pharmacy organisations, especially larger chain organisations [381]. However, there is a lack of detail on the audit processes, content and outcomes [381]. Further research in this area is warranted.

7.4.3 Factors associated with innovation adoption

Analysis of the results around pharmacists' adoption of e-MAS into practice revealed very similar findings to the qualitative data around factors associated with adoption of reclassified medicines innovations. In relation to e-MAS, themes around benefits to professional role development and pharmacy; benefits to the patients; opportunity to have feedback of practice performance, and greater acquaintances with patients all relate to perceived advantage of innovations as per the diffusion model [131]. Desire to see whether their effort had been worthwhile to save Government resources through service provision as a source of motivation relates to observability. Complaints around technical elements, the so deemed lengthy consultation recording process relates to perceived *complexity* of innovation adoption [131]. Adjustments made by practitioners to suit their workload demands such as by delegating certain tasks to support staff relates to re-invention [131]. Service roll out matching the need of pharmacies and their business interests related to compatibility [131]. Again the importance of trialability was not identified [131], which may be due to the fact that participants had already passed the stage of trilability when this investigation was carried out. In addition, patient acceptance and use of the service; issues of clear practice guidelines; and issues around communications with GPs related to external factors associated with innovation adoption [131]. The resource issue within pharmacy relates to internal 'contextual' factors [131]. These factors will be quantified for their importance to service adoption in the next phase of the research.

7.5 SUMMARY OF CHAPTER 7

Key benefits, facilitators and barriers to the adoption of e-MAS into practice by community pharmacists were identified. Benefits of e-MAS to professional role development, to the patients and to Government were explained by participants. Innovative features within the service such as the concept of 'one pharmacy registration' were also noted for contribution to minor ailment management. Participants were hence; supportive of the service, but its adoption into practice was hindered by issues such as remuneration, reimbursements, formulary restrictions, and technical elements of the service, lack of access to patient medical records and patient abuse and misuse of the service. Feedback of practice performance through e-pharmacy received a cautious welcome from participants as a potential information source to encourage service adoption. With the issues such as resolving the ownership of such performance feedback data, privacy and confidentiality, pharmacists' confidence; feedback in the long term could potentially be a useful tool to facilitate service adoption by pharmacists and could be extended to other areas of epharmacy. These facilitators and barriers identified relate to factors associated with innovation adoption as described by Rogers [131]. These findings are important on their own to inform service development. Key themes and illustrative quotes will also be used to develop the questionnaire items to quantify factors associated with the service adoption by pharmacists using a wider sample of the population of community pharmacists in Scotland.

CHAPTER 8: PHARMACISTS' ADOPTION OF E-MAS (QUANTITATIVE)

8.1 INTRODUCTION TO THE CHAPTER

This chapter presents data collected from the mailed survey around pharmacists' adoption of e-MAS. Since the nationwide rollout of the service in 2006, there has been no large scale evaluation of this service from any stakeholders' perspective [96]. The following were the research objectives.

8.2 OBJECTIVES

- 1. To quantitatively investigate the adoption of e-MAS into practice by community pharmacists.
- 2. To quantify facilitators/barriers associated with adoption of e-MAS by community pharmacists.
- 3. To investigate the utility of Rogers' diffusion model in exploring objectives 1 and 2 above.

8.3 DEVELOPMENT OF QUESTIONNAIRE ITEMS

Pharmacists' adoption of e-MAS was the main outcome measure. An eight item facilitator scale, mainly measuring benefits to professional practice and patients; and a 10 item barrier scale were designed based on the literature review (Chapter 1), qualitative interviews (Chapter 7), and theoretical model of diffusion of innovations [131] (table 8.1 and table 8.2). Respondents were asked to indicate which of the listed facilitators and barriers applied to them, with multiple selections allowed. Two open questions encouraged respondents to list any other facilitators/barriers not included in the scale.

Table 8.1: Development of eight item e-MAS 'facilitator' scale

Scale measure	Practice relevance	Supporting statement from interviews	Rogers' description of the theme	Rogers' broader category
Financial benefits to me	Financial benefits	"Our pay size is actually very good. I think, one of the reasons for this is when we are doing with minor ailment [service]. "	Advantage	Attributes of innovations
Financial benefits to my pharmacy	Financial benefits	"I just hope that the funding for it continues and makes [our time] worthwhile."	Advantage	Attributes of innovations
Opportunity for enhanced working with GPs	Inter- professional relationship	"GPs don't understand fully what the minor ailment service is about."*	Advantage	Attributes of innovations
Opportunity for more effective patient treatment	Enhanced access to medicines	" I've been quite delighted when I can actually help people [in need] feel all right"	Advantage	Attributes of innovations
Opportunity to know my patients better due to registration process	Benefits to practice	"You definitely do get to know people, patients more efficiently."	Advantage	Attributes of innovations
Opportunity to better meet patient expectations	Relevance to local needs	"Where we are here, it's not a very well to do area. Things like Zanprol [omeprazole]are too expensive for people to buy herethat would more come under the minor ailment [service] "	Compatibility	Attributes of innovations
Opportunity to extend my professional role	Role development	"I'm happy that our role isgetting bigger"	Advantage	Attributes of innovations
Availability of electronic feedback relating to my practice	Feedback of practice performance	"Its always good to have a good criticism to be able to affect yourself."	Advantage	Attributes of innovations

^{*}positive quote not identified

Table 8.2: Development of 10 item e-MAS 'barriers' scale

Scale measure	Practice relevance	Supporting statement from interviews	Rogers' description of the theme	Rogers' broader category
Lack of satisfactory reimbursement	Financial benefits	"But it's a trade cost that we're reimbursed, it's not the profit that we would normally make"	(Dis)Advantage	Attributes of innovations
Lack of satisfactory remuneration	Financial benefits	"if the capitation fee you get each month makes up for any loss of profit"	(Dis)Advantage	Attributes of innovations
Time for recording consultations or supply	Resource implications	"they're [patients] not going to wait us doing that [record consultations and countersign]"	Complexity	Attributes of innovations
Lack of access to patients' medical records	Patient medical records	"I think, if we could get to see the patients' history, as you know towards e-MAS"	Complexity	Attributes of innovations
Technical components of the electronic service	Technical component	"that has been the single biggest influencing factors on my prescribing practices"	Complexity	Attributes of innovations
Inadequate resources of my pharmacy	Organisational resources	"A lot of shops are one pharmacist"	Organisational	Organisational
Lack of opportunity for enhanced working with GPs	Inter- professional relationship	"GPs don't understand fully what the minor ailment service is about."	External factor	External factor
Lack of clear practice guidelines	Practice guidelines	"it's easier to prescribe everything by brand, you can save things getting thrown back [rejected for reimbursement]	External factor	External factor
Low number of patients presenting for the service	Patient acceptance of service	"how many people actually know about itonly about 20% of the people that could be registered, are registered."	External factor	External factor
Suspected misuse/overuse of the service by some customers	Misuse/overuse	"sometimes they [patients] are just coming in and looking for cough bottles for the cupboard"	External factor	Attributes of innovations

8.4 DATA ANALYSIS

Descriptive analysis was performed on the outcome measure; and to quantify responses to the facilitator and barrier scale. Binary logistic regression was performed to identify key factors associated with the level of service adoption using similar analytical procedures as in Chapter 6. Responses to open questions were analysed using content analysis as detailed in Chapter 2.

8.5 RESULTS

Demographic characteristics of respondents (N=563) appear in Chapter 6 (section 6.3). Only the results relevant to e-MAS are presented here.

8.5.1 Level of e-MAS adoption

A high majority (over 84%) of the participants ranked their level of adoption of e-MAS at either 4 or 5 (the highest adoption ranking) on the five point ordinal scale. The results are summarised in table 8.3.

Table 8.3: Pharmacists' adoption of e-MAS

Please indicate how often do you or your support staff deliver e-MAS service (N= 490)

1*	2	3	4	5†
n (%)	n (%)	n (%)	n (%)	n (%)
2	15	60	135	278
(0.4%)	(3.1)	(12.2)	(27.6)	(56.7)

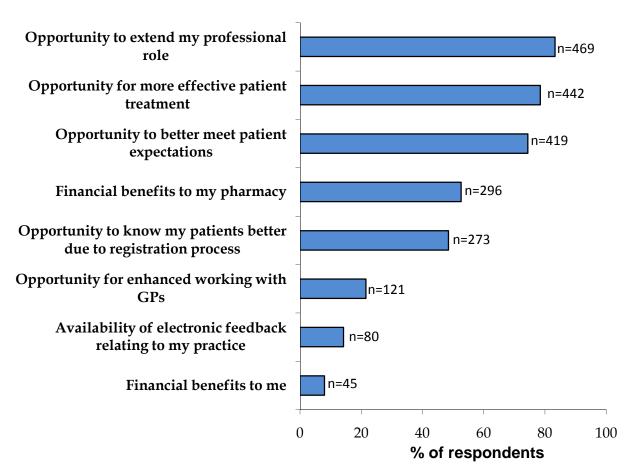
^{*1} represented 'not at all'; †5 represented 'very frequently' in the questionnaire.

8.5.2 Responses to facilitator scale

Among the eight listed facilitators of e-MAS, the opportunity to extend professional role was the most frequently highlighted by the respondents (469, 83.3%). Three other benefits of e-MAS were also highly rated: the opportunity for more effective patient treatment (442, 78.5%); the opportunity to better meet patient expectations (419, 74.4%); and financial benefits to the pharmacy (296, 52.6%). A minority of around one in five perceived the opportunity for enhanced working with GPs to be a benefit, as shown in figure 8.1.

Figure 8.1

Responses to e-MAS facilitator scale (N= 563)*



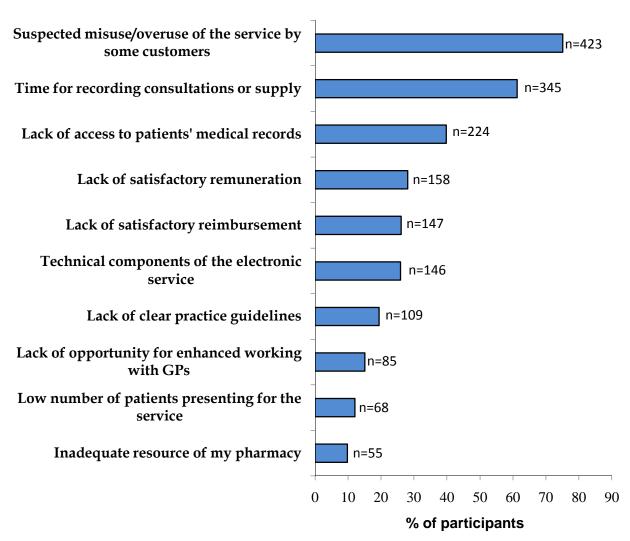
^{* %} add up to >100% as multiple selections were allowed; arranged in descending order of %.

8.5.3 Barriers to the provision of e-MAS

Key barriers noted by most participants were the suspected misuse/overuse of the e-MAS service by some customers (423, 75.1%) and the time required for recording customer consultations and/or supply (345, 61.3%). Approximately 40% (224) perceived the lack of access to patients' medical records a barrier (figure 8.2).

Figure 8.2

Responses to e-MAS barrier scale (N=563)*



^{* %} add up to >100% as multiple selections were allowed; arranged in descending order of %

8.5.4 Responses to open questions

A total of 33 and 60 respondents respectively provided comments on the two open questions around any other facilitators and barriers.

Most of the themes that were identified related to the items already presented within the eight-items facilitator scale and hence merely reinforced the validity of the scale. The most prominent theme was enhanced patient access to medicines contributed by e-MAS. Two quotes around the theme 'role development' were not realised through the review of literature or qualitative focus groups and interviews (Chapter 7). The requirements around pharmacists' personal involvement in every aspect of consultation and generation of e-MAS prescription after each consultation were perceived as enhancing pharmacists' images in society. These comments contradict those identified in the qualitative phase where the impracticality of such personal involvement was criticised by most participants.

Ten respondents considered that e-MAS offered no benefits to either pharmacists or patients (table 8.4).

Table 8.4: Benefits identified by the respondents through responses to open questions*

Response	Number of	Exemplar quotes (Respondent code)
categories	responses	Exemplar quotes (respondent code)
Enhanced patient access to non-prescription medicines	12	"Ability to supply whatever treatment is required without worrying whether customer can afford it, or that I am trying to increase my sales." R63 "Encourages health care of "lower class" as they get advice and free goods to their own benefit." R358
		"benefit in supplying to children for certain products." R200
No benefits, very much against the service	10	"E-MAS is a mistake, one of the worst ideas so far. Reinforcing bad mentality of getting everything for nothing." R11
		"I have nothing positive to say about e-MAS." R358
Role development	6	"Increased perception among patients of pharmacists' expertise in drugs and treatment." R52
		"Utilising clinical knowledge/skills obtained at university plus by doing CPD plus training to be independent prescriber" R121
		"Pharmacist to counsel patients rather than some untrained person selling products." R305
		"Able to counter prescribe bit on prescription so enhanced role in patient eyes." R407
Benefits to the Health Board/ Government	3	"Less NHS time/ money wasted on unnecessary visits to the Drs, appointments more readily available to patients more ill." P309
Financial benefits	1	"Business growth, negotiation in OTC purchase price due to increased purchase volume." R184
Patient acquaintance	1	"Keep customers coming to my pharmacy." R46
Other	1	"Accuracy" R131

^{*} Some respondents provided more than one comments

Responses to the open question around 'additional barriers' also related to the issues covered by the 10-item barrier scale. Lack of clear practice guidelines and restricted formularies was the most prominent theme. Lack of consistent guidelines and SOPs to deal with inappropriate requests were blamed by a few to have encouraged misusers to shift their registration status across pharmacies to obtain the desired medicines. Issues around lack of support from other health professionals and resources were also raised by a few respondents.

Table 8.5: Barriers to provision of e-MAS identified by respondents through responses to open questions* (note: this table extends to two pages)

-		Exemplar quotes (Respondent code)
categories responses		
Practice	16	"Need clear list of products allowed on e-MAS service."
guidelines/ formularies		R339
formularies		"Staff unsure when Ok to supply + product to supply." R342
		"Widespread inconsistency in how different pharmacies deliver service e.g. some do not promote it or are very strict in what they prescribe. Some pharmacists only prescribe what is on local 'guidelines' even though they will be reimbursed for supplying any non-black listed GSL or P product." R139
		"Other pharmacies supplying contra the requirements, patients expecting similar from us." R358
Misuse/ abuse	13	"Patients demanding a particular product without
of the service by		satisfactorily justifying the need-leading to stockpiling
some customers		and unnecessary use of medicines." R319
		"Patients not interested in pharmacists' clinical advice or input they just want their list of medicines supplied." R47
		"Aggressive customers e.g. furious plasters are not allowed + verbally abusive because plasters are on the leaflet!" R195
Lack of support from GPs and practice nurses	12	"GPs/ nurses referring patients for this service with a note specifying what I should prescribe. This defeats totally the intended purpose of e-MAS." R73
		"1. GPs and Health visitors etc sending patients to pharmacy rather than deciding with 'it' at the end of the consultation. 2. Wouldn't it be great if you could do the prescribing course then set up your own practice in the pharmacy, rather than the patient still registered at the G and you work for them!" R404
		"GPs/ nurses referring patients to me for painkillers on e MAS after prescribing antibiotics on GP10." R186
Resource issues	7	"Not enough staff in shop." R295
		Poor stock control, Stock what they [head office] like, not what's on the formularies." R305
		"Lack of trained staff" R272

^{*}some respondents provided more than one comment

Categories	Number of responses	Exemplar quotes (Respondent code)
Reimbursement/	5	"Causing decrease in profit as slower payment plus
implications for		decreased cost of medicines." R273
over the counter		
sales		"Loss of OTC sales which is more profitable." R87
Time issues around	4	"Find it difficult to ask patient to sign form when only
recording		advice given." R102
consultation		
Lack of opportunity	3	"Leaflets and advertising doesn't explain service
to advertise		properly." P513
Technical	3	"IT issues e.g. those affecting pack selection for
component of the		endorsement and e-transfer of details." R471
service		
		"Slow computers" R305
Remuneration	3	"Lapsing- waste of time. Very difficult to retain numbers" R193
Language barriers	1	"Lack of language resources when dealing with non-
with patients		English speaking patients" R10
Other	2	"Have the people who introduce new schemes even worked in a pharmacy." P459
		"Patients not knowing postcode/ GP name etc." R471

8.5.5 Multivariate analysis

Binary logistic regression analysis was performed to identify the key facilitators/barriers associated with respondents' ratings of adoption of the service. Responses to the barriers, facilitators and demographic characteristics were used as explanatory variables. Responses to the barrier scale were reversed scored to make all items positive before the analysis so as to ease interpretation of the output. Scores on the adoption scale were used as the outcome measure. Based on the distribution of responses, the five point e-MAS implementation scale was converted to two point (binary) scale whereby points 1, 2 and 3 in the five point scale were labelled as 'low implementation' with points 4 and 5 in the scale merged and labelled as 'high implementation'. Categories within demographic characteristics: the age, number of years registered with RPSGB and size of pharmacy ownership, were also combined to form binary variable as explained in Chapter 6 (section 6.6.2). Univariate cross tabulation analysis was performed on the outcome measure with all the explanatory variables. Those variables showing significant association with the outcome measure based on Chi-square statistics P value ≤0.05 were entered into stepwise logistic regression using the Forward LR method.

Univariate analysis showed that six items from the facilitator scale, four items from the barrier scale and four demographic characteristics were significantly associated with the outcome 'adoption' (table 8.6-8.8). Approximately 91% of the respondents who agreed with e-MAS as having financial benefits to their pharmacy were likely to rank their adoption as 4 or 5 in the five point scale as compared to only approximately 77% of the respondents who did not agree with the financial potential of the service. The other associations should be interpreted similarly. Only the significant associations are presented below. The rest appear in Appendix VIII.

Table 8.6: Cross tabulation analysis of facilitators with the outcome 'adoption' of e-MAS into practice showing significant associations

Scale items	Categories	Low adoption n(%)*	High Adoption n(%)*	P value
Financial benefits to my	Yes	23	231	< 0.001
pharmacy (N= 490)		(9.1)	(90.9)	
	No	54	182	
		(22.9)	(77.1)	
Opportunity for more	Yes	45	335	< 0.001
effective patient treatment		(11.8)	(88.2)	
(N=490)	No	32	78	
		(29.1)	(70.9)	
Opportunity to know my	Yes	21	212	< 0.001
patients better due to		(9.0)	(91.0)	
registration process	No	56	201	
(N=490)		(21.8)	(78.2)	
Opportunity to better	Yes	44	316	< 0.001
meet patient expectations		(12.2)	(87.8)	
(N=490)	No	33	97	
		(25.4)	(74.6)	
Opportunity to extend	Yes	56	356	0.005
my professional role		(13.6)	(86.4)	
(N=490)	No	21	57	
		(26.9)	(73.1)	
Availability of electronic	Yes	3	64	0.011
feedback relating to my		(4.5)	(95.5)	
practice (N= 490)	No	74	349	
		(17.5)	(82.5)	

^{*} Represent values within each row categories; Low adoption: Score 3 or below; High adoption: Score 4 or above

Table 8.7: Cross tabulation analysis of barriers with the outcome 'adoption' of e-MAS into practice showing significant associations

Scale items*	Categories	Low adoption n(%)†	High Adoption n(%)†	P value
Technical component of the electronic service	Yes	47 (13.1)	313 (86.9)	0.011
(N= 490)	No	30 (23.1)	100 (76.9)	
Lack of clear practice guidelines (N=490)	Yes	56 (14.0)	343 (86.0)	0.048
	No	21 (23.1)	70 (76.9)	
Low number of patients presenting for the	Yes	43 (10.0)	388 (90.0)	<0.001
service(N=490)	No	34 (57.6)	25 (42.4)	
Lack of access to patient medical records (N=490)	Yes	37 (12.6)	256 (87.4)	0.031
	No	40 (20.3)	157 (79.7)	

^{*} Items reversed scored † represent values within each row categories; Low adoption: Score 3 or below; High adoption: Score 4 or above

Table 8.8: Cross tabulation analysis of demographic characteristics with the outcome 'adoption' of e-MAS into practice

Scale items	Categories	Low adoption n(%)†	High Adoption n(%)†	P value
Innovativeness (481)	Cautious or	57	228	0.004
	deliberate	(20.0)	(80.0)	
	Role model or	19	177	
	venturesome	(9.7)	(90.3)	
Age (N= 482)	39 years or	32	264	0.001
	under	(10.8)	(89.2)	
	40 years and	42	144	
	over	(22.6)	(77.4)	
Number of years	10 years or	27	221	0.004
registered with RPSGB	under	(10.9)	(89.1)	
(N=483)	11 years or	49	186	
	over	(20.9)	(79.1)	
Size of pharmacy ownership (N= 473)	Independent or small multiple	31 (21.2)	115 (78.8)	0.045
	Medium sized or large multiple	44 (13.5)	283 (86.5)	

[†]represent values within each row categories; Low adoption: Score 3 or below; High adoption: Score 4 or above

Regression analysis resulted in five explanatory variables making a significant contribution to the outcome- pharmacists' levels of e-MAS adoption, as presented in table 8.9. The highest impact on e-MAS adoption was with the statement 'low number of patients presenting for the service'. Those agreeing with this statement being a barrier to service provision were approximately 15 times less likely to have scored 4 or 5 in the five-point adoption scale than those disagreeing with this statement. Other factors found important were: financial aspects; perceived opportunities provided by the service for more effective patient treatment; greater acquaintance with the patients due to registration requirements; access to patient medical records; and pharmacists' younger age. (Table 8.9)

Table 8.9: Binary logistic regression model of the outcome e-MAS adoption with the explanatory variables

		-	Exp(B)		C.I. for P(B)	Mod	el if item remov	ved .
Items retained in the model	Wald	P value	(odds ratio†)	Lower	Upper	Model Log likelihood	Change in -2 Log likelihood	P value of the Change
Financial benefit to my pharmacy	6.704	.010	2.357	1.232	4.512	-144.425	7.013	.008
Opportunity for more effective patient treatment	5.339	.021	2.230	1.129	4.402	-143.530	5.223	.022
Opportunity to know my patient better due to registration process	4.716	.030	2.074	1.074	4.006	-143.361	4.886	.027
Low number of patients presenting for the service*	55.227	<.001	14.502	7.163	29.360	-170.609	59.381	<.001
Lack of access to patients' medical records*	5.246	.022	2.049	1.109	3.784	-143.561	5.285	.022
Age (39 years and under or 40 years and over)	8.452	.004	2.532	1.353	4.736	-145.285	8.733	.003
Constant	13.391	<.001	.128					

^{*}Items reversed scored; †for score 4 or above

The highly significant model (chi-square value <0.001) in table 8.10 below suggests that the multivariate model, with the addition of the six variables, significantly improved the outcome prediction over when only the regression constant was included. Both the Cox and Snell R square and Nagelkerke R square values suggest that explanatory variables were useful (a value close to 0 suggests that the variables are useless and close to 1 indicates that the outcome is predicted perfectly) [295]. The Hosmer and Lemeshow test goodness of fit statistic was not significant suggesting that the observed data are not significantly different from the values predicted by the model; justifying that the variables retained through analysis were very reliable.

Table 8.10: Regression model summary (Note: this table is divided into three parts within this page)

Omnibus Tests of Model Coefficients

	Similar de l'este de Model Coefficients					
	Chi-					
	square	Df	P value			
Step	3.985	1	.046			
Block	112.579	7	< 0.001			
Model	112.579	7	< 0.001			

Df: Degree of freedom

-2 Log likelihood ratio and R square values.

-2 Log	Cox & Snell R	Nagelkerke R
likelihood	Square	Square
281.837	.219	.378

Hosmer and Lemeshow Test statistics

Chi-square	P value
6.628	0.577

8.6 SUMMARY AND DISCUSSION OF KEY FINDINGS

8.6.1 Adoption of e-MAS into practice

Over 84% of the respondents rated their level of e-MAS adoption 4 or above on the five point ordinal scale. Only two respondents rated their level of adoption as 'not-at-all' and this was despite the service being a core component of the community pharmacy contract [96]. The results showing an overall high level of adoption of the service is encouraging to stakeholders given that this survey was undertaken when nationwide rollout was still in its infancy.

8.6.2 Facilitators/barriers to service adoption

The opportunity for pharmacy role development offered by e-MAS was supported by approximately four out of five of the respondents. Three out of four perceived that this service had enhanced the opportunity to meet patient expectations and to treat them more effectively, than prior to the service introduction. A similar proportion also accepted that there had been a financial benefit realised with the service. This is worth noting in the light of findings from the qualitative interviews and literature review, where dissatisfaction around the current remuneration and reimbursement patterns were very strongly expressed by most participants. In responses to the barrier scale, approximately 28% and 26% of respondents reflected concerns around remuneration and reimbursements respectively. This dissatisfaction with remuneration is most likely to be related to preference for fee per consultation over a capitation payment as well as the issue associated with lapsing of patients not using the service at least once a year. Issues around lack of satisfaction with reimbursement are most likely to be related to e-MAS not accounting for the profit of the medicines supplied as was realised in the qualitative phase.

One response reflected that financial benefits resulted from the opportunity to negotiate the purchase price of medicines with the wholesalers due to an overall increase in volume of medicines supplied since the inception of e-MAS. This might indicate that whether the nationwide rollout of e-MAS is leading to increased overall supply of medicines within some communities. Evidence from grey literature suggests that some 87% of patients have been known to use self care for minor ailments and would not seek any health care professionals' advice [382]. If nationwide rollout of the service is encouraging these individuals to abandon self care, this would be contrary to Government aims to strengthen patient self care (Chapter 1). 'Sensitivity' analysis in economic studies suggests that increased use of pharmacy services due to enhanced access by those previously least Chapter 8: Pharmacists' adoption of e-MAS (quantitative) 273 interested in seeking health care services for minor ailment management, can eliminate any cost savings that are supposed to be brought about by the service roll out [344]. However evidence around long term economic and patient clinical outcomes brought about by pharmacy services usage versus self care or other models of care for minor ailment management remains poorly understood [383,384].

Approximately 8% of respondents suggested that e-MAS had improved financial benefits to individual pharmacists. This might reflect the proportion of organisations incentivising e-MAS performance. Nonetheless, many respondents owned their pharmacy who might interpret financial benefit to pharmacy as their own.

Greater inter-professional working remains one of the key aims of the service with pharmacists able to directly refer patients to their GPs or out of hour primary care services [96]. However 4 out of 5 respondents were yet to realise enhanced collaboration. The need for further measures to enable greater inter-professional working is supported by this finding.

Results also indicate that the majority of respondents were yet to receive any individualised feedback of performance around e-MAS activities from the NSS. At the time this survey was conducted, individual Health Board e-MAS utilisation data were, however, available to all pharmacists via the NHS NSS Website [222]. Future strategies to deliver such feedback relating to performance of individual pharmacists/pharmacies are under development [385].

The issue of misuse/overuse of the service by some members of public was regarded a barrier to service adoption by a large proportion of respondents. A few referred to the lack of or ambiguities within e-MAS practice guidelines on how to handle these patients. Inconsistent responses from pharmacies around customer requests relating to suspected of misuse/overuse were deemed to be encouraging patients to register with other pharmacies in an attempt to gain access to these medicines. Comparison of previous studies undertaken in Scottish community pharmacy reflects that convenience of access to medicines may contribute to this issue. A survey undertaken in all 1,091 community pharmacies in Scotland in 2000 (response rate: 79.1%), reported that approximately 68% of respondents acknowledged experiencing requests for medicines with potential for abuse/misuse [386], a proportion less than identified in this survey. As greater numbers of patients are registering

with e-MAS [222], it is imperative that pharmacies are given appropriate strategies and training around how to effectively deal with these issues. Research to date on such pharmacy related strategies mostly relate to substance misuse [386,387]. A survey of 180 community pharmacies from South Wales (response rate: 89%) found refusing sales, claiming that medicines were 'out of stock' (63%), or referring patients to GPs (25%) as among the most common strategies. Future research is needed to broaden these issues by considering how pharmacists can minimise e-MAS requests from those trying to stockpile medicines for future use. Appropriate measures are also important from an economic perspective. A recent national audit around wastage due to stockpiling of unwanted prescription medicines by patients was estimated to cost the NHS in England £100m [388]. Results of this survey prompt the need to counteract the likely increase in medicine misuse associated with increased access.

The lengthy process of recording each patient consultation or medicines supply was cited as the second most common barrier to service adoption. A retrospective data analysis of seven PCTs in England involved with similar schemes reported as few as 1% of the claims made for remuneration related to 'consultation only' activities [344]. Such figures could imply that pharmacists are under pressure (from patients and themselves) to supply medicines after each consultation, hence resulting in very few consultations without medicine supplies. The qualitative data (Chapter 7) shows that such low number of claims around 'consultation only' could also be attributed to difficulty in recording this activity due to resource implications and patient reluctance to wait for stages requiring patient signature.

Inadequate resources within the pharmacy setting as a barrier to service adoption were identified by approximately only one in ten respondents. Such resource constraints might be related to issues such as lack of pharmacists to adequately deal with personal involvement or strain on existing staff created by the walk in nature of the service.

8.6.3 Factors associated with innovation adoption

The multivariate analysis further allowed quantification of the factors associated with adoption of the innovative e-MAS service by community pharmacists. E-MAS is a core component of the community pharmacy contract in Scotland. From the perspective of diffusion of innovations, the core contract represents 'authority' decisions from the Government to adopt the service rather than 'optional' or 'contingent' types of decision

making discussed in earlier Chapters around reclassified medicines. Hence every pharmacy should be in a position to offer the service when eligible patients present. The importance of patient acceptance having the most determinant influence on e-MAS adoption into practice within multivariate analysis was hence less surprising from this view point.

Approximately 12% of the respondents had agreed that low number of patients presenting for the service was a problem in service adoption. Lack of the so deemed enough opportunity to promote the service as raised by the interview participants could be one of the reasons for low number of patients presenting for the service. In addition, this issue could also be explained by the deprivation of the geographical areas the pharmacies represented. The Scottish Index of Multiple Deprivation (SIMD) report 2009 showed that approximately 10% of Scottish population live in the least deprived areas with deprivation indexes 19 and 20 (1= most deprived, 20= least deprived) [389] where relatively low number of patients are likely to fulfil the eligibility criteria for service registration. A recent analysis of nationwide e-MAS utilisation data found area deprivation significantly related to numbers of patients registered and medicines supplied [390]. Findings from the multivariate analysis of the data within this study are further endorsed by this latest report.

Apart from the above, perceived benefits of the innovative service such as financial benefits, opportunity for more effective patient treatment; and low perceived complexity associated with need for patient medical records were strongly associated with the outcome. Younger pharmacists had higher levels of adoption; however, perceived innovativeness again, did not show influence. Many of these findings resemble factors associated with pharmacists' adoption of innovative reclassified medicines as presented in Chapter 6. The association of these factors around their importance in innovation adoption by adopters were found to be in the direction as suggested by Rogers [131].

8.7 SUMMARY OF CHAPTER 8

E-MAS was found to be adopted into practice by community pharmacists in Scotland. Perceived benefits agreed by the majority related to financial advantage, professional role development, the opportunity to offer more effective patient treatment and to meet patient expectations. Barriers to adoption were issues of service misuse by some patients and, the timely process for recording consultation or supply. Multivariate analysis indicated that: number of patients presenting for the service was most strongly related to pharmacists' level of adoption of the service.

CHAPTER 9: GENERAL DISCUSSION

9.1 INTRODUCTION TO THE CHAPTER

This Chapter summarises key aims, objectives and findings identified throughout the thesis with emphasis on the achievement or otherwise, of the research aim and objectives.

Research strengths and limitations are highlighted by critically appraising the methods employed at different stages. Relevance of the findings to policy, practice and theory, future directions and final conclusions are presented.

9.2 REVIEW OF THE THESIS

The general literature review was undertaken and presented as two distinct sections. Within the first section, the literature around Government policies enhancing opportunities for new pharmacy services around minor ailment management was reviewed. Foundations of modern pharmacy practice development were laid by the Nuffield report [31] which highlighted the need for reform of the nature of community pharmacy services, funding and research in the forthcoming decades. Subsequent key White and Green papers from the UK Health Departments, prior to and post devolution, were reviewed. It appears that all of the devolved Governments were keen to enhance pharmacy's role in minor ailment management and to support self care through professional advice and guidance. The policy documents that were identified repeatedly promised extra funding and professional development opportunities for pharmacy and also identified that enhanced minor ailment management would bring: professional role development opportunities; extended use of professional skills; enhance reputation with the society; as well as contribute to freeing up GPs thus reducing waiting times; and bringing about significant health benefits in the longer term. This enhanced minor ailment management was proposed through two key policy interventions, both of which would mainly enhance patient access to nonprescription medicines. The first was the ongoing reclassification of medicines which would allow more medicines previously available only on prescription to be reclassified to P and GSL status and thus available for over the counter purchase. However, those patients who could not afford these medicines were deemed to benefit less. Hence minor ailment services such as the e-MAS in Scotland were piloted and subsequently introduced throughout Scotland around the time of the commencement of this PhD. This service allows those patients exempt from prescription charges to be eligible to obtain non-prescription medicines free of charge.

A review of peer reviewed, published research literature from the UK around enhanced management of minor ailments from community pharmacy was conducted. This review identified that the current literature was limited in the key policy intervention areas identified above, especially around community pharmacists' perspectives of new services adoption and associated barriers and facilitators. Core limitations of the published literature related to a general lack of robust qualitative studies as well as lack of large scale quantitative evaluation of new services. These limitations aided the formulation of research aims, objectives, choice of methodologies and methods of this study resulting in the generation of original, novel data which contribute significantly to the published literature.

The importance of theoretical frameworks allowing the researcher to systematically collect, generate, interpret and analyse the data to facilitate understanding of the change process and factors affecting innovation adoption was realised in the latter phase of the literature review in Chapter 1. Through critical appraisal of the available theoretical frameworks, application of Rogers' diffusion of innovations model [131] was deemed an appropriate foundation to support this research. The diffusion model was used to interpret the findings of the qualitative phase of this research followed by its application in designing the quantitative research instrument.

The overall aim of this PhD was to investigate Scottish community pharmacists' adoption of innovative medicines and services aimed at enhanced minor ailment management. Data were generated and collected to: evaluate the process related aspects of innovation adoption from community pharmacists' perspectives; investigate pharmacists' adoption of newly reclassified medicines and e-MAS; and from these to extract key factors affecting innovation adoption thereby allowing consideration of the wider relevance of these factors to new pharmacy services. A critique of available methodologies in undertaking the research and justification of the choice of a mixed methodology was presented in Chapter 2.

Current developments around enhanced minor ailment management were deemed by pharmacists participating in the qualitative interviews as contributing to their role development and image in society. The twenty participants, who were identified through a two staged sampling process, mostly agreed that inception and implementation of e-MAS and the ongoing reclassification of medicines were key changes around enhanced minor ailment management within pharmacy. However, participants reflected diverse attitudes towards embracing change. Where current changes were embraced reluctantly by many

who deemed the current pace as fast and furious, others were keen to contribute to developments taking place within pharmacy and were excited about ongoing changes. The eagerness of these individuals to play a more proactive role in leading and introducing change to the public was noted. Regardless of practice setting and ownership model, the merits of each innovation appeared to be considered at the individual level. Hence an organisational level decision to implement an innovation did not necessarily translate to adoption at the individual level.

Facilitators/barriers specific to pharmacists' adoption of both key innovations were identified. Where many of these facilitators/barriers were similar for both, a few were unique to the medicines/service evaluated. The importance of pharmacist perceived benefits to patients, to pharmacists' role development, training opportunities, sources of information, access to patient medical records, new service/medicines fitting local needs, 'good' patient behaviour, clear practice guidelines, support at organisational and external level were highlighted. Certain newly reclassified medicines were deemed to have been highly adopted into practice by the interview participants, and others least adopted or not adopted at all based, based on the above key facilitators/barriers. Detailed investigation of the feedback of practice performance relating to the adoption of e-MAS was also undertaken. Interestingly, participants voiced a cautious welcome to such information sources.

When considered from the theoretical point of view, the facilitators and barriers identified in the qualitative phase matched closely to the factors associated with innovation adoption as suggested by Rogers' diffusion of innovations model [131]. Most of the perceived attributes of innovations; organisational and external contextual factors as suggested by Rogers were observed.

The results of the qualitative interviews led to the emergence of research objectives for the next phase of the research. Key objectives of the cross sectional survey were to: quantify pharmacists' adoption of the above innovations around enhanced minor ailment management from pharmacy; quantify the importance facilitators/barriers to the adoption; and from these to derive factors associated with pharmacists' adoption of innovations. A systematic review of international peer reviewed literature, mainly around pharmacists' adoption of newly reclassified medicines, undertaken prior to the survey enabled the strengths and limitations of the existing literature to be addressed, aiding design of the

quantitative research instrument. Twenty-eight facilitators/barriers specific to pharmacists' adoption of newly reclassified medicines were identified from the systematic review. The systematic review provided evidence from the existing literature that decision making by professionals is a complex phenomenon and that multivariate research designs are most appropriate in researching innovation decision making. Rather than evaluating all innovations as one development, factors associated with the adoption of innovations would best be quantified by evaluating as diverse innovations as possible using the same population.

Four newly reclassified medicines and e-MAS were evaluated in the cross sectional survey of all community pharmacies in Scotland. The survey was piloted with a sample of 50 community pharmacies prior to the main survey. The reclassified medicines selected for evaluation had been adopted into practice to varying degrees. Chloramphenicol eye drops for bacterial conjunctivitis had most support and were adopted highly, whereas simvastatin for the prevention of coronary events in adults with moderate risk was least supported and adopted. Adoption of omeprazole aimed at management of peptic disorder was higher compared to studies undertaken immediately post reclassification [122]. Naproxen, the most recent medicine to be reclassified for the management of dysmenorrhoea had already been adopted by over four out of five respondents and its non-prescription status was also supported by the majority. Results from descriptive, bivariate and multivariate analyses provided the conclusions that: perceived benefits to pharmacy, professional role and to patients; observability of such benefits; compatibility of therapeutic area to existing ranges of pharmacy medicines, pharmacists' expectations and to pharmacy business interests; confidence and perceived complexity of adoption process; and patient acceptance and affordability of the medicines were the most consistent and strongest factors associated with pharmacists' adoption decisions regarding reclassified medicines. Adoption of e-MAS was also influenced by similar factors with patient acceptance showing the strongest association.

Rogers' diffusion of innovation model was useful in content development and interpretation of the quantitative data. However, the items that measured pharmacists' facilitators/barriers belonging to each of the theoretical factors did not correlate well enough to constitute 'one factor' in principal component factor analysis. Hence, each barrier and facilitator was interpreted as a separate factor for relevance to practice.

The findings from both the qualitative and quantitative phases have key relevance to the practice of pharmacy around and beyond the area of enhanced minor ailment management. It is important to discuss the rigour and weaknesses of the method that were adopted in this study before such relevance is discussed.

9.3 DISCUSSION OF METHOD: QUALITATIVE INTERVIEWS AND FOCUS GROUPS

Although debates exist as to whether the concept of 'rigour' applies to qualitative research as it does to quantitative, qualitative research conducted without sufficient consideration of rigour is often labelled as being 'no different than fictional journalism' [391]. The following section highlights strengths and limitations of the qualitative focus groups and interviews undertaken within this research.

9.3.1 Internal validity

Internal validity in qualitative research refers to whether the findings are 'correct' and 'precise' [392] or the extent to which findings represent reality, so 'issues of credibility and truth take prominence' [393]. Criteria to establish internal validity in the qualitative phase of this PhD are based on Creswell's validity framework [169] and Paterson's reactivity framework (figure 9.1) [394]. Each of these is discussed below.

Figure 9.1: Framework to enhance the internal validity of qualitative study*

- Clarifying researcher bias from the outset of the study (reflexivity)
- ♣ Engagement and observation in the field
- Peer review or debriefing
- ♣ Triangulation
- External audits
- Reactivity

9.3.1.1 Clarifying researcher bias from the outset of the study

In qualitative research, the researcher acts as an 'instrument' of data generation and hence it is imperative that the background of the researcher be explicitly stated as this might influence choice of research design, data generation and analysis [169]. The student researcher is a pharmacist registered with the Nepal Pharmacy Council and had no previous experience of Scottish community pharmacy. This means that the researcher had Chapter 9: General discussion

^{*}adapted from [169,394]

no bias to any potential outcome of the studies or had any preconceived ideas about what is happening or should be happening in pharmacies. Background knowledge and experience around minor ailments and non-prescription medicines was gained through undergraduate and postgraduate pharmacy training, work experience as an industrial pharmacist and lecturer in Nepalese academia. However, review of the literature allowed the researcher to become acquainted with the hopes and expectations of pharmacy stakeholders in Scotland and other UK nations. Two key stakeholders of community pharmacy partly funded this research. These were: the Community Pharmacy Scotland (CPS) an organisation representing Scottish community pharmacy owners; and NHS NSS, a non-departmental public body which provides national strategic support service and expert advice to the NHS. However, neither had any influence on study design, methodology, method, data collection/generation, analysis or dissemination.

The researcher's interest in diffusion of innovations arose after commencing the PhD. There was no pressure on the part of the researcher to justify or refute the theoretical framework applied to this research. Participants were never aware of the theoretical assumptions during the interviews; and similarly the topic guide was not designed to 'impose' on the participants the need to support or refute theory. It has been argued that preconceptions about theoretical lenses used to review the data are not 'biased' as long as the researcher acknowledges them prior to undertaking the research [204]. One approach to enhancing reflexivity is by considering the data from different theoretical viewpoints.

The researcher very much agrees with this in Chapter 1 saying that no theoretical framework is right or wrong to undertake research as long as there appears a sound basis to utilise the theory. Had any other theoretical framework been adopted, it is likely that some of the findings and interpretations would have matched to those identified in this study, whereas others might have not.

The topic guide was designed in accordance with the research aims and objectives. Although the researcher sought views from one of the funding bodies, the NHS NSS, the final decision lay with the researcher, under the guidance of the supervisory team. In addition, participants were provided with the opportunity to share views and experiences on related items not covered by the topic guide but relevant to the subject area being investigated.

Data analysis methods were selected following critique and consideration of available methods. The student received formal training from many different sources listed in Appendix X (General) around both the qualitative and quantitative and mixed methodology research, and evidence syntheses through systematic review of literature. Given the information gleaned from the literature reviews it was considered inappropriate to utilise a grounded theory approach as theories and hypotheses were not being generated or a semi-quantitative technique such as content analysis, which may have led to the omission of important information.

9.3.1.2 Engagement and observation in the field

Engagement and observation should be undertaken to allow the researcher to 'learn from the culture' where the research is to be undertaken [169]. This criterion was partially fulfilled by conducting field visits to three community pharmacies located within two Scottish Health Boards, prior to undertaking the qualitative work. This allowed the researcher to become acquainted with the practical constraints relevant to 'real life' working situations of community pharmacy that could never have been realised solely through the literature review. This also provided a glimpse of day to day activities in Scottish community pharmacies, encompassing e-MAS and supply of newly reclassified medicines. To an extent, these visits allowed the researcher to build empathy with community pharmacists. Pharmacies were also clearly told that such observations in any way did not include data collection hence eliminating any need for ethical review. A pilot focus group conducted prior to the actual focus groups and interviews with four locum community pharmacists allowed the researcher to further build empathy and gauge reaction to specific questions. However, it should be acknowledged that these participants were university lecturers and as such their understanding of the researchers' questions might have been different from 'full study' participants. Nonetheless, this experience provided valuable changes to the topic guide. These experiences of conducting focus groups by the researcher were gained in addition to two previous experiences as a focus group note taker at the commencement of the PhD.

9.3.1.3 Peer review or debriefing

Peer review or debriefing are known to keep a 'check' on the research process by asking the researcher hard questions about the methods, meaning and interpretations [169]. University regulations require that students regularly present at informal settings of school research student symposia, allowing the student to be 'challenged'. In addition, the researcher

presented poster and oral communications at several national and international pharmacy practice conferences. The student had meetings with his principal supervisor approximately once per week; and with other members of the supervisory team approximately once per month or when needed. Emerging research issues and directions as well as the interpretation of emerging findings were regularly discussed within these meetings.

9.3.1.4 External audit

A number of peer reviewed papers including conference proceedings and a project report submitted to the NHS NSS were rigorously peer reviewed with feedback. Of note, one full paper around the quantitative evaluation of e-MAS adoption by pharmacists was published in the International Journal of Pharmacy Practice [395] and several others are in draft form.

9.3.1.5 Triangulation

The findings from the systematic review of literature (Chapter 4) and the cross sectional survey (Chapter 6 and 8) were compared with those obtained from the qualitative phase (Chapter 3 and 7) to identify similarities and differences thereby facilitating triangulation of the results.

9.3.1.6 Member checking

Member checking is also known as respondent validation [396] and requires the transcripts and reports of data analysis to be sent back to the participants for verification. However, the feasibility of this process was carefully debated by the researcher. Issues considered were the tremendous demand this process places on participants, and that there are potential issues of recall bias [396]. Respondent validation is of particular use in action research where the researcher and participants work co-operatively to facilitate ongoing changes [396]. For these reasons, member checking was not undertaken.

9.3.1.7 Reactivity

Reactivity relates how the research participants and the researcher respond to each other during the research process; or the negative or unintended effect on research subjects because of the experience of being investigated [394]. There are five sources of reactivity in qualitative research involving face to face interactions. 'Emotional valence' [394] which arises from the lack of trust of participants with the researcher could determine the nature of the data shared with the researcher. The telephone contact by the researcher with

participants prior to the scheduled focus groups was intended to minimise this effect. In addition, participants were given background information about the researcher. They were also given ample opportunity to contact the researcher and supervisory team members to clarify any issues. The researcher took great care not to directly empathise or disagree with participants' points of view.

It has been stated that physical characteristics of the researcher such as appearance, age, race and personality are taken into account when determining emotional valence. However, participants appeared highly comfortable and relaxed in the face to face interactions and although this is more difficult to gauge over the telephone, there appeared to be no major issues in the telephone interviews. Another important consideration in reactivity is the importance of the 'distribution of power' which arises from the perceptions of the participants or the researcher that the other has more or less status of authority than themselves [394] and these perceptions could either be occupational or social. One pharmacist who was sent an invitation to participate expressed the feeling that she would feel intimidated while facing a researcher and chose not to participate. Hence it is likely that those participating had either not consider this or were more relaxed and comfortable. In addition, the researcher tried to be as friendly and keen as possible by engaging before the interviews, sharing his background as well as by comforting the participants asking 'how was your day?'; sharing researcher's own experiences of the day, and his research; considering calling later if they were having a 'bad day' or a busy session (during telephone interviews). The lunch session prior to the focus groups further provided an opportunity to build relationships just prior to data collection. It is also worth stressing that the researcher was a trained 'novice' in qualitative research, and himself had apprehensions about conducting the interviews 'to the best of his ability'. However, it is still possible that nerves might have reduced some depth and breadth of questioning. This effect was minimised as the interviews progressed.

A further bias around reactivity relates to the importance of 'lively interactions' during data collection. A bored, tired and discouraged researcher is known to pass his/her disinterest to the research participants [394]. The researcher had sufficient gaps between interviews and hence fatigue was not an issue. In addition these gaps provided opportunities to review reflect and learn from the experiences. The use of standardised participant information and the opportunity to discuss research aims and objectives also minimised the fourth factor

contributing to reactivity arising from the lack of understanding on part of the participants about 'goal of the interaction' [394].

The last issue around reactivity arises from the 'shoulds' of behaviour expected from research participants [394]. Participants were informed at length that there were no right or wrong answer to any question and were given assurance about the confidentiality and anonymity of the data. The researcher was keenly interested to identify both barriers and facilitators of practice change and hence did not in any way seek to influence the participants as either advocates or cynics of change.

9.3.2 Reliability

Reliability can be defined as the degree to which findings are independent of accidental circumstances of the research [397]. This requires the researcher to reassure the readers that similar results would have been produced if the research were to be repeated using same or similar methods [392]. Reliability is sought both in terms of the consistency or replicability of the original data as well external reliability, as well as whether the interpretations obtained from the analysis would be reproduced if performed by an independent analyst (internal reliability) [392].

Debate exists over whether qualitative research can be truly tested for reliability as rigorously as quantitative approaches. However, it has been argued that it should still be possible, for example conducting and analysing social interactions in a way that can be subjected to empirical testing [397]. Although it is almost impossible for an independent researcher to come up with a completely identical set of results and conclusions, the data collection and analysis processes should convince the reader of transparency and replicability. Perakyla [397] reviews two ways of doing so.

Firstly, reliability is enhanced by ensuring good quality recording of the conversations between researcher and participants, ensuring that the whole of conversations are subjected to analysis. Analysis based only on field notes could be vulnerable to speculation about their integrity and reliability [397]. The recording of all interviews and focus groups in this study was conducted using digital and audio recorders of high quality. In addition, experienced researchers undertook note taking during face to face interview settings, although this was not feasible during telephone interviews. The transcribing of all focus groups and interviews was performed by the student researcher himself without any

secretarial support. Transcripts were reviewed and cross checked for reliability by the principal supervisor. This was important given that English was a second language of the researcher and that different dialects, slang and accents of participants from diverse geographical areas. Ambiguities were identified and rectified, some of which may have significantly altered the meaning of the data and subsequent interpretation.

Secondly it is important to guarantee accountability of the process of how interpretation was achieved. In doing so, the process of inter-rater reliability [396] was used to enhance the rigour of the data analysis process. This inter-rater reliability check was performed in the transcripts of one of the focus groups of greatest duration. The researcher used both the 'top bottom' as well as 'bottom top' approach to analysis using framework technique [248]. The second coder used only the 'bottom top' approach and was unaware of the main coding framework developed by the researcher. No disagreements that could significantly alter the meaning were identified. The student also had opportunities to discuss and defend the coding with two other supervisors. Although these did not code the data independently, checks were performed to ensure that analysis was dependable, consistent and 'making sense'. No major disagreements were identified although analysis was an iterative process. Notes taken by more experienced researchers during the focus groups as well as the discussions that had taken place between researchers were also considered for the basis of analysis to ensure the reliability of the data coding.

9.3.3 External validity

External validity relates to the degree of generalisation of the results to other contexts, which in this study could be to other pharmacists or pharmacies in Scotland, UK or elsewhere. The term theoretical generalization is often used instead of empirical generalization when describing the external validity of qualitative research [396].

Researchers who use qualitative research to inform the development of quantitative research instruments (as the case with this study) might be less interested in the external validity of the qualitative data. However, many of the results obtained within the qualitative phase, such as evaluation of the process related aspects of innovation adoption, in this thesis, are 'main', independent findings in their own right. The issue of external validity hence needs to be considered separately here.

Sampling is often raised as an important point when considering the external validity of qualitative research. The focus groups and interviews in this study used a two staged sampling process whereby the Health Boards were purposively sampled followed by random sampling of the pharmacies within those boards. Anticipated difficulty in pharmacy recruitment was the main drivers behind random sampling. The random sampling method did not inflict disadvantages over a purposive sampling method. The diversity of the respondent demography that was observed perhaps justifies that a random sampling approach was as appropriate as a more 'truly 'qualitative approach of purposive sampling. Recruitment of focus groups and interview participants across different Health Boards was staged, with a few weeks in between them. This allowed the researcher to confirm that diverse experiences and demographic characteristics were being achieved through the recruitment process.

The issue of participants' interests in the subject area might limit the external validity of the findings. It is likely that only those who had either very strong positive or very strong negative opinions around pharmacy change and innovation might have participated in the research resulting in non-respondent bias. The theoretical saturation that was assumed to have been achieved during latter stage of data collection allowed the researcher to propose that the whole spectrum of opinions had been captured. However, one can never be 'certain' of theoretical saturation given the low sample size in the qualitative study.

The dominance of some focus group members is relevant to external validity. Some levels of dominance were unavoidable despite efforts of the researcher and facilitators. It was often as difficult dissuading dominant speakers from speaking as persuading the 'shy' participants to speak.

Considering these weaknesses and strengths, the external validity of the findings most likely extends to pharmacies operating in similar contexts to the participants. This also extends to other pharmacies of those represented Health Boards followed by pharmacies in other Health Boards in Scotland, and finally in the other UK nations and beyond with similar socioeconomic conditions and pharmacy regulations.

9.4 DISCUSSION OF METHOD: SYSTEMATIC REVIEW OF LITERATURE

Discussion around the systematic review method has already been presented in Chapter 3.

9.5 DISCUSSION OF METHOD: MAILED SURVEY

This section will discuss how the issue of rigour was addressed during the quantitative phase of this research.

9.5.1 Internal validity

Aspects of internal validity are deemed particularly important in quantitative studies when measurements depend on personal responses to questions [210]. The following types of internal validity are applicable to the quantitative research instrument used in this study namely: face validity, content validity, criterion validity and construct validity.

9.5.1.1 Face validity

Face validity is a superficial subjective assessment of the presentation and relevance of the questionnaire [190]. The assessment is mainly around: whether the questions within the questionnaire appear to be relevant, reasonable, unambiguous and clear. The use of an expert panel from within and out with the school allowed for the face validity of the questionnaire to be assessed. Some of the expert panel were practising pharmacists, a few had much experience with pharmacy practice research and, one external reviewer contributed expertise around innovations research. The content and wording of the questionnaires were carefully selected to avoid ambiguity and the items were derived from the quotes from the transcripts of the qualitative interviews. All these measures allowed reassurance that the questionnaire would be successful in enabling the collection of information required for the research aims and objectives to be answered.

9.5.1.2 Content validity

Content validity refers to the extent to which the items within a questionnaire adequately cover the domains under investigation [210]. The thorough review of the literature undertaken prior to the survey, the results of qualitative interviews, the systematic review of literature and the theoretical framework applied to this study were used to enhance the content validity of the questionnaire. Given the level of background research that was undertaken prior to the survey instrument development, it is less likely that any important issues associated with innovation adoption around ongoing reclassification of medicines Chapter 9: General discussion 289

were missed. However, content focused around the evaluation of e-MAS had to be limited to make the evaluation 'brief' and also owing to the constraints in space within the questionnaire. One example, highlighting this issue is around e-MAS formulary and treatment protocols, which were both evaluated within the item 'practice guidelines'.

One important criterion in enhancing content validity where associations are being explored relates to considering and accounting for all known confounders. To that end, a range of demographic characteristics were measured alongside the 24 items facilitator/barrier scale.

The number of innovative medicines and services evaluated in this study also merit discussion in terms of their adequacy to inform factors associated with decision making. There is no minimum number of innovations that need to be evaluated for the derivations of these important factors. However, similar research with innovative services with doctors' adoption of innovations utilised five new medicines licensed for primary care [328]. The number of innovations evaluated within this study is hence justifiable.

9.5.1.3 Criterion validity

Criterion validity refers to the extent to which a method of measurement of outcomes agrees with the results which would be obtained if measurement of the outcomes were conducted by using alternative objective measures or 'gold standards' [210]. The semantic differential scales have been widely validated in other health service research and pharmacy practice settings; for example, in assessing the degree of pain in a scale of 1 to 10 [398]; or to measure pharmacists' satisfaction with their profession [399]. Although measuring the actual packs of the newly reclassified medicines that were supplied by the respondents or by asking for the number of patient consultation with e-MAS would have been more objective measures of the outcomes; adjusting these for size of pharmacy, location, population served and so on would have been hugely challenging. For example, five packs of omeprazole a day could be rated as a very high level of adoption by a pharmacist in a rural settings given the size of the population; whereas this may not be so for a pharmacist located in a urban high street setting. These relative differences were best handled by using the semantic differential scales. Nonetheless, due to the cross sectional design the responses were prone to recall bias. Assessment of criterion validity for the outcome acceptance is perhaps less relevant as objective measures are less applicable to measure support for the given innovation.

Predictive utility is often described as the ability of a questionnaire to predict the outcomes through gold standard or objective measurement of the similar outcomes in the future within the same population. Such a process was not feasible to undertake within a time and resource constraints of a PhD.

9.5.1.4 Construct validity

Construct validity refers to substantiation that the instrument is measuring the underlying concept it intends to measure. This was relevant to the 24 item scale measuring barriers and facilitators to adoption, the constructs of which were deemed to be belonging to factors affecting innovation adoption by Rogers' diffusion of innovation model [131]. The validity of the theoretical constructs could not be fully established in terms of both 'convergent validity', which requires that the scale should correlate with other related variables; and 'discriminant validity', which requires that the items within the construct should not correlate with dissimilar variables. The conclusion that was derived from the results of the factor analysis was that although each of the 24 item scale could still be related to the theoretical concepts of diffusion of innovations model as described in Chapter 4; in practice, they still represent unique barriers and facilitators. Downsizing the 24 item scale that has been developed in this study to smaller number of items for future research with pharmacists' adoption of reclassified medicines is not recommended.

9.5.2 Reliability

As many as seven different reliability tests have been proposed to be applicable for quantitative research [190]. However the following three are relevant for the questionnaire that was used in the survey and are discussed in detail:

9.5.2.1 Test re-test reliability

This relates to assessing the stability of a measure over a time which is not expected to change. It is conducted by taking repeated administration of the same questionnaire to the same participants and is done by measuring the weighted kappa coefficient for the ordinal data and Cohen's kappa coefficient for the nominal data [190]. In the main survey, this was not feasible to undertake due to the resource and time constraints this process would have demanded. The higher sample size above 100 required to estimate the kappa statistics [400] meant that this would require additional strain even to establish this reliability in the pilot

study. Respondent identification requirement for the test retest reliability meant that this was also against the anonymity clause on the research as advised by the NoSREC.

9.5.2.2 Split half reliability

Split half reliability relates to dividing an item within a construct into two halves and then measuring the correlation between the items [190]. The lack of interpretable outcomes from the factor analyses meant that this could not be undertaken.

9.5.2.3 Internal consistency reliability

Test of internal consistency reliability was performed on the outputs of factor analysis. This measures whether items within a construct produce similar scores and are computed by values such as Cronbach's alpha as described in Chapter 4. The dismissal of factor analysis meant that internal consistency reliability was also less relevant for this survey.

9.5.3 External validity

Two measures were conducted to estimate the external validity of the survey results. The estimation of sample size that was conducted prior to the survey is one measure to confirm the external validity of the findings. The non-respondent analysis that was also conducted reflected that there were no significant differences in the late and early respondents in terms of outcomes; as well as the demographic characteristics that were retained as important in univariate, bivariate and multivariate analysis. This reflects that external validity of the results of this survey, from a statistical point of view, was established. However, given that one is never certain about how the non-respondents might behave, one cannot be certain of this.

The external validity of the findings of the survey most importantly extends to the pharmacies located within Scotland followed by the rest of the UK nations and beyond depending upon the similarity of pharmacy regulations and socioeconomic status of other countries with Scotland. In addition, the findings are most relevant to the medicines and the service that were evaluated.

The cross sectional nature of the survey to identify factors associated with innovation adoption also contributes to limitations around generalisability of the findings. As the outcomes and factors were measured in the same time point, it is difficult to confirm, for example whether the opinions that were measured informed the innovation adoption

decisions; or that whether decisions to adopt or reject the innovations followed the opinions. This provides the conclusion that prospective designs best suit innovation adoption research.

In addition only one pharmacist from each pharmacy was asked to respond. It is likely that those least interested in the issues around innovations might not have responded. However, the three introductory questions used in the opening page of the questionnaire booklet (Chapter 5, section 5.8.2) tried to minimise the bias by asking those participants who may not necessarily be 'innovative' but were interested in the issues about innovations to participate. This might have minimised non-response bias in terms of innovativeness of respondents.

9.6 RELEVANCE TO PRACTICE

This section describes the relevance of the findings of this study to the area of enhanced minor ailment management from community pharmacy; and beyond where appropriate. The relevance to practice discussed here is grounded in the study findings.

9.6.1 Relevance to the process of new service introduction in community pharmacies

9.6.1.1 Bridging the gap between policy makers and practitioners

There is a need to bridge any communication gaps existing between community pharmacists and policy makers surrounding decisions made around future pharmacy innovations. Pharmacists need to be involved in discussions ideally prior to piloting and implementation of new pharmacy services. All pharmacists need to be notified of developments in a timely and appropriate manner so that they can prepare themselves and their staff by acquiring new knowledge and skills. The lack of acquaintance with, for example, the, reclassification of medicines and inadequate time to prepare the necessary knowledge and skills were often highlighted as a matter of concern during the qualitative interviews and responses to open questions in the survey. This is also key to avoiding the 'embarrassment' arising through lack of timely notifications as experienced by the participants in this study. Consultations that are usually organised by the Royal Pharmaceutical Society (RPS) and the MHRA around future pharmacy innovations could be further strengthened by actively involving more practitioners in consultations. However, this assumes that a majority of pharmacists will indeed follow through in participation.

9.6.1.2 Importance of strengthening diffusion network

Pharmacists who are keen to actively contribute to any developments need to be given an appropriate forum and process to express their views. A few participants in both the qualitative interviews and surveys strongly advocated that they embraced change in a positive way. There is a need to identify these pro-active pharmacists who can act as 'movers and shakers' or assume the role of opinion leaders within their organisations and local practices forums to persuade others less interested in innovations to also become involved.

9.6.1.3 Importance of strengthening pharmacist patient communications

Strengthening of pharmacist patient communication is warranted. Patients need to be made more aware of the benefits of following pharmacists' advice around medicines supply/non-supply decisions. Revisions of currently available tools such as the WWHAM approach [401] to dealing with medicine requests might be necessary, especially in enabling pharmacists and pharmacy support staff to deal with excessively demanding customers. This may be warranted with new services with which patients may not be familiar with service requirements or limitations. Enhancing the image of the pharmacy as a health care centre is also necessary. From pharmacists' perspectives most patients regarded pharmacies as places to obtain medicines rather than undergoing consultation for the appropriateness of supply. Although not raised by the participants in this study, greater involvement of patients in decision making around pharmacy innovations could also generate future research questions around whether such moves could address the communication issue.

9.6.1.4 Advertising and naming of newly reclassified medicines

Wider discussions around the need for changes in regulations around media advertisements of newly reclassified medicines are required. Advertising should emphasise the importance of the pharmacy consultations as well as product limitations. In addition, very distinct names should be used for P and POM versions of medicines to reduce patient and pharmacist confusion and associated potential medication errors. This may also simplify training needs and promoting support staff undertaking supply.

9.6.2 Key facilitators/barriers to innovation adoption

9.6.2.1 Benefits to the profession and enhanced image in society

Future services should enable pharmacists to undertake new roles and enhance their image in society. Role development could be best facilitated by maximising the utilisation of pharmacists' current skills or by training pharmacists to undertake new roles. The new roles within innovative services need to be compatible with existing resources, pharmacy environment and pharmacists' desires. New services will not guarantee role development unless pharmacists are convinced of the benefits of the innovations to patients, as realised with the case of newly reclassified simvastatin.

9.6.2.2 Benefits to patients

It is important that pharmacists are convinced of the benefits of innovative services to patients. Lack of evidence of efficacy is likely to deter pharmacists from supplying newly reclassified medicines. Belief in the evidence base enables high acceptance and adoption of medicines. These issues were realised in the qualitative phase and systematic review of literature; and further substantiated in the mailed survey where tendency to supply and support the reclassified status of medicines were consistently associated with belief in evidence base or vice versa in bivariate/multivariate analyses. Patient feedback was often expressed as an indicator of evidence base as well as the reports in journals which they consider as 'unbiased'; and two studies identified in the systematic review [228,283]. Future decisions to reclassify medicines, where possible, should be substantiated through evidence of efficacy which has been generated in over the counter settings and for the licensed indications and dosages licensed for such settings. Appropriate mechanisms to provide feedback to pharmacists about emerging evidence are also important. Importance of benefits to patients in decision making also appeared important in relevance to e-MAS; further substantiating the importance of this innovation attribute.

9.6.2.3 Sources of information and training opportunities

Pharmacists should be provided with full information about innovative medicines and services to support knowledge gain and skills development to enhance their competence and confidence to undertake the adoption. Although perhaps an issue for minority pharmacists in the population, a few participants in this study expressed difficulties in accessing sufficient information sources, for example, around the adoption of newly reclassified medicines. Pharmacists' use of information sources that have been designed for patients can raise concerns, as such sources are likely to be less appropriate and

comprehensive from a professional point of view. Pharmacies can also benefit from external sources such as the professional body and proprietor organisations taking greater responsibilities to train pharmacy support staff. Appropriate training around new services for pharmacy support staff is a vital part of adoption and will facilitate pharmacists in undertaking new and cognitive roles.

In terms of new innovative services and the process of change there is also a case for greater pharmacist training around leadership, organisational and motivational skills than just those relating to the specific service. Such training will allow pharmacists to delegate routine tasks to support staff with greater confidence; with such delegation being key to undertaking future innovative roles. Hence limiting such access to certain pharmacy services could be more appropriate within existing constraints.

9.6.2.4 Access to patient medical records

Greater access to patient medical records is important in enabling community pharmacists undertaking new roles or to undertake existing roles more effectively. Indeed, access is important for services other than minor ailments, such as for the chronic medication service, and to facilitate the practice of pharmacists with non-medical prescribing qualifications that are located within the community. Electronic sharing of patient data held by general practitioners, at least for the services that are integrated within e-pharmacy, could be the way forward. Results from various phases of this study have substantiated that pharmacists' perceived needs for access to patient medical records is more likely to be greater for some medicines and services than others.

9.6.2.5 Resources within the community pharmacy setting

Differences in the perceived adequacy of pharmacy resources were not strongly associated with adoption of innovative services and medicines. However, with pharmacists focusing more time towards direct patient care, smaller pharmacies with potentially less available infrastructure and resource may have less capacity for development of the infrastructure in the future. In addition, the busy working environment within community pharmacies was often cited in the qualitative phase as being unsuited for lengthy patient risk assessment activities, such as those required for the supply of sumatriptan and simvastatin. Resource barriers to undertaking risk assessment activities could be diminished by remunerating pharmacies for undertaking such activities thereby reducing pressure to make sale or supply after each consultation. Nevertheless, many of the risk assessment requirements

highlighted by participants reflected gaps between stakeholders and pharmacists; as the guidelines often state such requirements are often not mandatory.

9.6.2.6 Availability of service guidelines

Clear and explicit clinical and process guidelines are important in supporting pharmacists to adopt innovative roles. Within services around enhanced minor ailment management, for example, points of patient referral to GPs could be made more explicit. For the Government funded services such as e-MAS, user friendly pharmacy guidelines could be related to ensuring that pharmacists are remunerated and reimbursed appropriately. Guidelines are also likely to enable pharmacists avoid litigation issues around any errors attributed by the confusions. Guidelines need to be regularly updated for recent changes in the pharmaceutical market. In addition, harmonisation of service guidelines across the Health Boards are likely to benefit pharmacists working as locums, where any such differences are rooted around local public health problems or to local Health Board policies.

9.6.2.7 Financial benefits

New services should confer financial benefits on pharmacies or at least should not diminish existing financial situations. These benefits were often associated with high regard and adoption into practice. When implementing Government funded services that are anticipated to generate savings, pharmacies could be incentivised with a fraction of such savings. Capitation based payments could be argued to be an effective means of remunerating pharmacies for future services. However, the criticism of this type of remuneration structure as discussed earlier in Chapter 7 and 8, such as lack of focus on quality and consistency of patient care need to be addressed.

9.6.2.8 Patient acceptance of service

As identified by participants in this research, high patient cost implications of new services are likely to deter many patients who may prefer using GP services and hence are key to patient acceptance and utilisation of innovative pharmacy services. Such cost implications might even lead to pharmacists voluntarily referring patients to their GPs as seen with the case of treatment with medicines such as simvastatin indicated for long term conditions . As pharmacy services benefit from the advantage of increased access, balance between 'reasonable' service fees (for services not funded by the Government) so as to ensure sustainability of pharmacy as business entities; and relevance to prescription charges or GP waiting times need to be maintained. New services should also be compatible with local

patient demography as these are associated with potential interest/disinterest to pharmacy businesses.

Direct to consumer advertisements, although found to have high a bearing on patient acceptance of new medicines/services, were deemed by participants to be inappropriate. Future changes in regulations around advertising of newly reclassified medicines needs to gather greater consensus from diverse stakeholders.

9.6.3 Post diction versus prediction of innovation adoption by pharmacists

Although this study evaluated recently introduced services, factors identified as associated with innovation adoption could be used to predict the success of future services. Medicines belonging to therapeutic categories such as β -blockers, diuretics, calcium-channel blockers, angiotensin-converting-enzyme inhibitors, HMG-coenzyme A reductase inhibitors, inhaled corticosteroids, short- and long-acting β 2-adrenergic agonists and bisphosphonates are among over 100 candidates for reclassification to P status [402]. Acceptance and potential adoption of innovative services can be predicted by asking pharmacists several questions around the key factors associated with decision making identified from this study as follows:

- 1. Is the service/medicine novel to the existing range of medicines/services?
- 2. Are service elements likely to see benefits pharmacists' role development and image in society?
- 3. Are pharmacies likely to financially benefit from the innovations?
- 4. Is there a need for further training to enhance capacity development in pharmacy?
- 5. Are pharmacists likely to have sufficient knowledge and expertise to be able to train their support staff and develop SOPs?
- 6. Will every pharmacy be able to resource capacity developments required for the delivery of the new medicines/services? If not how can they be resourced?
- 7. Are service delivery procedures too complex to be carried out in a retail pharmacy environment?
- 8. Do pharmacists perceive that the benefits of innovations to patients are sufficient and are based on evidence?
- 9. Is the service compatible with pharmacy business interests and practice environment in diverse settings?

- 10. Are patient cost implications likely to deter patient use of services?
- 11. Are pharmacists likely to adopt the service without access to patient medical records even if the requirements say otherwise?
- 12. Will there be a need for greater inter-professional collaboration and communication and how can they be ensured?

9.7 FUTURE WORK

The following research questions are proposed which are grounded in the findings and limitations of this study.

- 1. What are the barriers and facilitators to pharmacists' adoption of innovative services specific to different stages of adoption into practice and organisational implementation, such as during the launch of medicines into the market and at times removed from launch. Such investigations will further illuminate the relevance of the facilitators/barriers at distinct stages and could aid direction of future interventions. Potential methods: Case studies around specific innovations.
- 2. What are the key indicators of 'role development' and 'novelty' within new services? Identification of these key indicators could enable anticipation of their acceptance and adoption by pharmacists.

Potential methods: In depth qualitative studies.

- 3. What are the key factors leading to non-adoption/rejection of innovations after an initial decision to implement/adopt them? Research could provide further answers to disinterests in provision of services like reclassified simvastatin after the so stated heavy 'push' by some organisations during the initial stages of this pharmacy innovation. Potential methods: Prospective qualitative/quantitative studies.
- 4. Why are certain practitioners less interested and supportive of change? Research could provide further perspectives on resistance to change. Limited evidence suggests that intensive educational strategies can facilitate innovation adoption.
 Potential methods: Qualitative in depth studies, case studies of least innovative community pharmacists.

- 5. If and how could feedback of practice performance from electronic sources such as e-pharmacy facilitate adoption of innovative services or bring about changes within individual areas of practice? These types of studies could further generate evidence around whether such costly procedures are worthwhile in pharmacy settings and to distinguish between the transient and real long term applications of such information. Potential methods: Large scale controlled trials measuring both short term and long term outcomes.
- 6. What are stakeholders' opinions about the ownership of pharmacy feedback data? Resolving these issues could aid future provision of any personalised feedback to practitioners. Potential method/s: Delphi studies involving major stakeholders of pharmacy practice changes.
- 7. Is service delivery affected by incentivising pharmacists for performance based payments, and if so how? Findings from such studies could explore the usefulness of such incentives in encouraging pharmacists adopt innovative services, without compromising the ethical underpinnings.
 Potential methods: Mixed method studies combining case studies with quantitative evaluation of service delivery.
- 8. What are the triggers to patient acceptance and adoption of innovative pharmacy services, a factor that was so consistently and strongly shown to influence pharmacists' adoption of innovative services in this study? What are the triggers to use and non-use of pharmacy or other health care professionals for minor ailments? These studies can benefit development of future interventions to directing patients for appropriate care services and to enable service development in pharmacy so as to encourage patient utilisation.

Potential methods: Mixed method studies utilising in-depth interviews, patient responses to vignettes around minor ailment scenarios, household diary studies. Prospective funding for this study is already being sought by the researcher.

9. How do perceptions of minor ailments match/differ across pharmacists, other health care professionals and patients? Answer to this question could enable further

identification of triggers to patients seeking health care, focusing on disparities in concepts across the health care professionals.

Potential methods: Case studies, qualitative in depth interviews

- 10.What is the long term impact of innovative pharmacy oriented services around minor ailments in terms of economic and humanistic outcomes? These studies require consideration of the negative impact of increased access such as misuse of e-MAS as identified in this study and to date no considered by current economic evaluation models. Participants in this study were keen to be aware of the economic savings to diverse stakeholders to understand whether or not their efforts had been worthwhile. Potential method/s: Patient cohort studies, long term cost effectiveness, cost benefit and full economic evaluation
- 11. What are the financial impacts on pharmacies of innovative services funded by the Government such as the e-MAS? How can sustainability of the service be assured? Which remuneration system best promotes the sustainability of pharmacy services? Potential methods: Prospective case studies, prospective quantitative economic evaluation studies.

9.8 CONCLUSIONS

This doctoral research has investigated community pharmacists' adoption of innovative medicines and services aimed at minor ailment management. In doing so, a range of methods were applied constituting a mixed methodology, including systematic review of the literature. These generated original data which can inform future developments in services both related and unrelated to minor ailment management. To date, findings have been presented at national and international conferences and one peer reviewed paper published.

Pharmacists regarded the ongoing changes in practice around enhanced minor ailment management to be contributing to their role development and enhanced image in society. However, many factors were found to be key to individual pharmacists' positive and negative perceptions about such innovative medicines and services. The four newly reclassified medicines studied and the Scottish minor ailment service (e-MAS), were adopted into practice by participants of this study to varying degrees. For example, chloramphenicol eye drops for bacterial conjunctivitis had most support for the reclassified

status and were adopted highly; whereas simvastatin for the prevention of coronary events in adults with moderate risk and, despite five years of reclassification was least supported and adopted. Descriptive, bivariate and multivariate analysis of the cross sectional survey data evaluating the five innovative medicines/services revealed that the following factors were key to pharmacists' decision making in relation to adoption of innovative medicines and services aimed at minor ailment management:

- 1. pharmacists' perceived benefits of innovations to pharmacy (financial);
- 2. pharmacists' perceived benefits of innovations to professional role;
- 3. pharmacists' perceived benefits to patients;
- 4. pharmacists' perceived compatibility of innovations to existing medicines/services; to pharmacy business interests; and to pharmacists' expectations;
- 5. patient acceptance and affordability of medicines/services;
- 6. pharmacists' confidence and low perceived complexity of adoption;

Differences in the adoption of the medicines and services evaluated across respondents were less explained by differences in adequacy of resources or sources of information. This might indicate that the new services around minor ailments have not yet demanded reorientation of existing services; and hence in most cases, it is likely that diverse pharmacy organisations are coping well with the resource implications raised by these innovations. Hence the issue of how pharmacists' perceive the characteristics of innovations such as potential for financial benefits to pharmacy are key to predicting whether future innovations in similar areas will be successfully adopted.

In addition to the factors associated with innovation adoption decisions, many issues around process related aspects of innovation adoption were also identified in this study. In particular, participants identified the need to be given a more effective voice around how and which pharmacy innovations are introduced in pharmacy in the future. Innovative pharmacists expressing interest in contributing to ongoing changes within the profession were also identified. Pharmacists like these can act as movers and shakers within their organisations and local practice forums to persuade others less comfortable about the issue of innovations. Timely notifications, information and training around future innovations are essential to prepare pharmacists for service delivery. A need for greater efforts from wider stakeholders to enhance public respect for the profession was also identified.

The theoretical framework of Rogers' diffusion of innovations model was applied in this study to interpret the research findings as well as to aid the design of the research instrument. However, the facets of practice elements consisted within the theoretical factors as proposed by Rogers model did not collate together in statistical analysis. Hence, although many of the practice elements were relevant to theoretical factors as proposed by Rogers' diffusion of innovation model, future evaluation using this theoretical model should not collapse the scale items designed in this study. As suggested by Rogers' diffusion model, however, attributes of innovations such as the *relative advantage* of innovative medicines/services, *observability* of benefits such as observable treatment outcomes of medicines, *compatibility* to pharmacy ranges of medicines and business interests; were positively associated with innovation adoption. *Complexity* of innovation adoption was negatively associated. Not all attributes of innovations such as the *trialability* were identified. External contextual factors such as patient acceptance of innovative service also had a high place in pharmacists' decision making.

The limitations of this study, mainly the low response rates in both qualitative and quantitative studies; limited number of innovations evaluated; and the perspective of only one stakeholder of change means that the results and recommendations need to be taken cautiously by the readers.

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An Exploration of Scottish Community Pharmacists' Adoption of Innovative Services and Products relating to Minor Ailment Management

Vibhu Paudyal

A thesis submitted in partial fulfilment of the requirements of Robert Gordon University

for the degree of Doctor of Philosophy

(Appendix to the thesis)

March 2011

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Appendix

APPENDIX I (CHAPTER 1)

Table 11.1: Example of search strategy employed for review of literature II in Ovid MEDLINE (R)

#	Search History
1.	Minor ailment\$
2.	Self care
3.	Drugs, Non-prescription/ or OTC\$.mp.
4.	over the counter\$.mp.
5.	over-the-counter\$.mp.
6.	pharmacy only.mp.
7.	general sales list\$.mp.
8.	1 or 2
9.	3 or 4 or 5 or 6 or 7
10.	Pharmacist\$.mp. or Pharmacists
11.	Community Pharmacy Services/ or community
	pharmacist\$.mp.
12.	10 or 11
13.	8 and 12
14.	9 and 12

Date: 17-01-2008

Description of databases used

Ovid MEDLINE (R)

Produced by the US National Library of Medicine and is a source for bibliographic and abstract coverage of biomedical literature. MEDLINE encompasses information from the areas of allied health. It claims to have more than 9.5 million records from more than 4,800 journals until 2008 (1).

International Pharmaceutical Abstracts (IPA)

International Pharmaceutical Abstracts is produced by the American Society of Health-System Pharmacists. This has an index of more than 750 pharmaceutical, medical, and health-related journals (1).

CINAHL

This provides coverage of literature related to allied health related topics (with a focus on nursing literature) and also provides access to selected conference proceedings. Until 2008, it had index of over 2,900 journals from the fields of nursing and seventeen allied health disciplines (1).

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EMBASE

EMBASE provides access to biomedical and pharmacological literature. It has index of more than 7,000 peer reviewed journals (2).

PsychINFO

This database covers published literature originated from various disciplines since the 1800s, including coverage of several pharmacy practice and related journals.

Approximately 2400 journals were indexed until 2008 of which over 99% of the journals are

References to descriptions of databases used

claimed to be peer reviewed (3)

- (1) EBSCO. EBSCO support. Available from: http://support.ebscohost.com. Accessed 03 March 2008.
- (2) Elsevier B.V. EMBASE Biomedical answers. Available from: http://www.info.embase.com/about/what.shtml. Accessed 02 March 2008.
- (3) American Psychological Association. PsycINFO. Available from: http://www.apa.org/psycinfo/. Accessed 05 June 2008.

Appendix - 2 -

APPENDIX II (CHAPTER 2)

A comparison of the merits and demerits of telephone interviews and focus groups.

Telephone interviews and focus groups are known to differ in the following key areas.

Items	Discussion
Response rate	Telephone interviews offer better response rate than focus groups (1,2).
Bias	Telephone interviews are claimed to possess smaller interviewer effect
	(3) and a lower tendency for socially desirable effect bias (1,3); both due
	to lack of face to face interaction of participants and the researcher
	within the former method.
Data collection	Distraction of participants by the activities of work environment are
	more prone to telephone interviews (4).
	Telephone interview method could be less effective in collective data
	with participants with language or hearing problems such as the
	elderly where focus groups can be more effective (3).
	Telephone interviews can allow researcher to collect data from
	geographically dispersed population (4).
Nature of data	Telephone interviews are likely to miss the interaction among the
	participants due to the one to one approach of interviewing (4).
	Exploration of similarities and differences in the views of the
	participants can hence be better undertaken with focus group data (5).
Confidentiality	Greater confidentiality and anonymity for discussing sensitive topics is
	aided by telephone interview approach as compared to focus group
	approaches.
Cost	Telephone interviews tend to incur lower resource implications to
effectiveness	researcher minimising costs associated with travel and venue
	arrangements associated with focus groups (6).
Minimising harm	Telephone interviews can offer greater personal safety for both
to participants	interviewer and interviewee and thus could benefit researchers where
	such risks are anticipate (3).

References to Appendix 2.

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- (5) Morgan DL, Scannell AU. Planning focus groups. London: SAGE Publications; 1998.
- (6)Kaplowitz MD, Hoehn JP. Do focus groups and individual interviews reveal the same information for natural resource valuation? Ecological Economics 2001;36:237-247.
- (7) Musselwhite K, Cuff L, McGregor L, King KM. The telephone interview is an effective method of data collection in clinical nursing research: a discussion paper. International Journal of Nursing Studies 2007;44: 1064-1070.

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APPENDIX III (CHAPTER 3)

(No appendix to chapter 2 exist)

Focus group invitation letter



Date as postmark

Dear

Community pharmacists' views on changing practice in relation to non-prescription medicines.

I am a PhD student at The Robert Gordon University and am currently doing a research study on the above title.

Recently, changes in practice have arisen in relation to the non-prescription medicines due to ongoing reclassifications and the introduction of the electronic-Minor Ailment Service (e-MAS) and linked formularies.

The aim of this project is to investigate community pharmacists' views on changing practice in relation to non-prescription medicines. In particular, we are interested in the factors affecting decision making processes, the role of initiatives such as e-MAS and information services as practice support. Your views will help us understand the practice support needs of community pharmacists and will play an important role in the design of information feedback on e-MAS use from NHS National Services Scotland (NSS).

Taking part will involve coming to a focus group discussion session, not lasting longer than 90 minutes, with some other community pharmacists from your area. This will take place on <u>3rd of June, 2008 at 6.30 pm</u> for 7:15 pm start at(see the map attached). All travelling expenses will be reimbursed and light supper will be provided from 6.30 pm.

Enclosed are further details of the study and about information regarding your participation in the focus group. If you are willing to take part, please complete and send the reply slip in the pre-paid envelope or via fax at 01224-262555 by 26th of May, 2008.

If you have any questions, please do not hesitate to contact myself (01224-262559 or v.paudyal@rgu.ac.uk) or any members of the research team below.

Yours sincerely,

Vibhu Paudyal,

PhD Student

School of Pharmacy & Life Sciences

Research team: Mr Vibhu Paudyal, Dr Derek Stewart, Dr Denise Hansford, (01224-262509 or d.hansford@rgu.ac.uk), Dr Scott Cunningham (01224-262533 or s.cunningham@rgu.ac.uk).

Appendix - 4 -

Focus group reminder letter

Date as postmark

Dear

This is a reminder to the invitation we had sent you regarding a request to take part in a focus group session. To date, I have not received a reply from you. I apologize if you have recently returned the reply slip.

If however, you have not, as I mentioned to you in the first letter, the aim of this project is to investigate community pharmacists' views on changing practice in relation to non-prescription medicines. In particular, we are interested in the factors affecting decision making processes, the role of initiatives such as e-MAS and information services as practice support. Your views will help us understand the practice support needs of community pharmacists and will play an important role in the design of information feedback on e-MAS use from Information Service Division Scotland (ISD), a division of NHS National Services Scotland (NSS).

The focus group will last no longer than 90 minutes and will also involve some other community pharmacists from your area along with you. This will take place on <u>3rd of June</u>, <u>2008 at 6.30 pm</u> for 7:15 start at(see the map attached).

If you are willing to take part, please complete and send the reply slip in the pre-paid envelope or via fax at 01224-262555 by 26th of May 2008.

All travelling expenses will be reimbursed and light supper will be provided from 6.30 pm. If you have any questions, please do not hesitate to contact myself (01224-262559 or email: v.paudyal@rgu.ac.uk) or any members of the research team below.

Yours sincerely,

Vibhu Paudyal

PhD student,

School of Pharmacy & Life Sciences

Research team: Mr Vibhu Paudyal, Dr Derek Stewart, Dr Denise Hansford (01224- 262509 or d.hansford@rgu.ac.uk), Dr Scott Cunningham (01224-262533 or s.cunningham@rgu.ac.uk)

Appendix -5-

Focus group confirmation letter

Date as postmark

Dear

Thank you for agreeing to take part in the focus group discussion to be held inon 3rd

of June at 6.30 PM. We will be meeting in room number PA7 on the ground floor.

As I have explained to you earlier, the aim of the project is to investigate community

pharmacists' views on changing practice in relation to non-prescription medicines. In

particular, we are interested in the factors affecting decision making processes, the role of

initiatives such as e-MAS and information services as practice support. Your views will

help us understand the practice support needs of community pharmacists and will play an

important role in the design of information feedback on e-MAS use from Information

Service Division Scotland (ISD), a division of NHS National Services Scotland (NSS).

We will provide you with a light supper and reimburse your travel expenses.

We eagerly look forward for your participation on the day. Please bring along the consent

form and the copyright clearance form with you or alternatively they will be available in

the venue. If you cannot attend for any reasons, please call us at:

Mr Vibhu Paudyal: 01224-262559 or v.paudyal@rgu.ac.uk

Thank you again for agreeing to take part. We look forward to meeting you on 3rd of June.

Yours Sincerely,

Vibhu Paudyal

PhD student

School of Pharmacy & Life Sciences

Version no: FG01; Date: 01-May- 2008

Appendix - 6 -

Focus group participant information sheet

Before you decide to take part in the study, I kindly request you to take some time to read the information provided below relating to the project. It is important for you to understand why the research is being done and what it will involve. Please feel free to discuss this with others or to ask us about matters you find difficult to understand after reading this. Take time to decide whether you wish to take part. Thank you for reading this.

1. What is the purpose of the study?

The aim of this project is to investigate community pharmacists' views on changing practice in relation to non-prescription medicines. In particular, we are interested in the factors affecting decision making processes, the role of initiatives such as e-MAS and information services as practice support. Your views will help us understand the practice support needs of community pharmacists and will play an important role in the design of information feedback on e-MAS use from Information Service Division Scotland (ISD), a division of NHS National Services Scotland (NSS).

ISD aims to provide community pharmacists with information feedback relating to the non-prescription medicine supply through e-MAS in the near future for your practice support. Your views will play important role in the way these services will be delivered to you in order to support your practice.

2. Do I have to take part?

No. It is up to you to decide whether to take part. If you do decide to take part, you will be requested to keep this information sheet for your record and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect your relation with the university or the National Services Scotland.

3. Why have I been chosen?

You have been selected from a random list of community pharmacies from your health board.

4. If I decide to take part what should I do?

If you are willing to take part, please complete the reply slip and return in the pre-paid envelope provided or via fax at 01224-262555. We will then send you with a consent form and copyright clearance forms which you can bring along in the focus group or alternatively you could sign them on the venue just before the commencement of the focus group.

5. What will happen to me if I take part?

You will be invited to participate in a group interview session that will last no longer than 90 minutes which will be audio recorded and transcribed into a paper document. There will be some other community pharmacists along with you to discuss the matters as mentioned above in item 1 above. All such transcripts, subsequent data analysis and all reporting of the study results will be anonymous.

6. What will happen to the results of the research study?

The results of the research study will be disseminated through publication at conferences and in journals. A brief report of the result of the study will be available by December, 2008 and you may obtain a free copy from the RGU contact list provided below.

7. What are the possible benefits of taking part?

You will have a chance to share your views among other colleagues related to the issues around the topics and the way you would like to see information feedback to be presented

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to you for your practice support. Your views may play an important role relating to the future provision of methods of medicine use data feedback to community pharmacists.

8. What are the possible disadvantages and risks of taking part?

You may feel discomfort with some issues if other members of the group divulge any confidential matters about themselves or about other participants. Participants will be reminded about this at the beginning of the session and in the consent form. You can request to stop discussing any matter which you find uncomfortable or you can withdraw at any time.

9. Will my taking part in this study be confidential?

All information collected will remain strictly confidential and your name will not appear in any transcript, report or other publications. Audio records of the group discussions will be destroyed after submission of the final research paper from the project. In addition, all data will be stored securely in a password/lock protected facilities within the School of Pharmacy at all times and access will be restricted to members of the research team.

10. Who has reviewed the study?

North of Scotland Research Ethics Committee decided that this study does not need to go through full ethical review process. The study has been peer reviewed by the Robert Gordon University Research Degrees Committee.

11. Who is organising and funding the research?

This research is organized and funded jointly by the School of Pharmacy at The Robert Gordon University, Aberdeen and ISD. The PhD student is also supported by a grant from Community Pharmacy Scotland (CPS).

12. Contact for further information

If you have any questions or require any further information, please contact:

at the School of Pharmacy & Life Sciences, The Robert Gordon University

Mr Vibhu Paudyal v.paudyal@rgu.ac.uk 01224 262559
Dr Denise Hansford d.hansford@rgu.ac.uk 01224 262509
Dr Scott Cunningham s.cunningham@rgu.ac.uk 01224 262533

Appendix -8-

Focus group consent form

Title of the project: Community pharmacists' views on the changing practice in relation to non-prescription medicines.

Name of the principal researcher: Vibhu Paudyal, school of Pharmacy & Life Sciences, The Robert Gordon University, Aberdeen

1	I confirm that I have read and understand the information sheet dated 01/05/08 version FG01 for the above study.				
2	I understand that my participation includes my involvement in a group interview session lasting 90 minutes or less.				
3	I agree that the interview will be audio recorded and transcribed into a paper document.				
4	I understand that my name will not be included anywhere in the report of the findings.				
5	I understand that I have an obligation to respect the privacy of other members of the discussion group by not disclosing any personal information that they share during the discussion.				
6	I understand that my participation in this study is entirely voluntary and I am free to withdraw at any time without giving a reason.				
7	7 I agree to take part in the above study.				
Nam	ne of participant	Date	Signature		
Name of Person taking consent (if different from researcher) Date		Date	Signature		
Rese	archer	 Date	- Signature		

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Focus group copyright clearance form

Research Project: Community pharmacists' views on	changing practice in relation to non-		
prescription medicines.			
Date: 03/06/08			
Location:			
The purpose of this agreement is to ensure that your or practice and in strict accordance with your wishes. All of the research project and may be used in publication and on the internet.	material will be preserved for the life		
All contributions will be anonymised and all identifyir to preserve anonymity and confidentiality.	ng materials will be stored separately		
I hereby assign the copyright in my contribution to The Robert Gordon University School of Pharmacy and Life Sciences research project.			
Signed Dat	re		
Name in Block Capitals			
Signed for Project Da	ate		

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Telephone interview invitation letter

Date as postmark
Dear Pharmacist,
Community pharmacists' views on e-MAS performance feedback requirements.
I am a PhD student at The Robert Gordon University and am currently undertaking a research study on the above title.
The aim of this project is to investigate community pharmacists' views on the role of information services in the context of changing practice in relation to non-prescription medicines. Your views will help us understand the practice support needs of community pharmacists and will play an important role in the design of information feedback on e-MAS use from NHS National Services Scotland.
Taking part will involve a telephone interview , not lasting longer than 20 minutes.
Enclosed are further details of the study and information regarding your participation. If you are willing to take part, please complete the research ethics form/reply slip stating a convenient date, time and phone number to call you and post it in the pre-paid envelope provided or via fax to 01224-262555 by
If you have any questions, please do not hesitate to contact myself (01224-262559 or v.paudyal@rgu.ac.uk) or any members of the research team below.
Yours sincerely,
Vibhu Paudyal, PhD Student School of Pharmacy & Life Sciences
Research team: Mr Vibhu Paudyal, Dr Derek Stewart (d.stewart@rgu.ac.uk 01224 262432),
Dr Denise Hansford (01224- 262509 or d.hansford@rgu.ac.uk), Dr Scott Cunningham (01224-
262533 or <u>s.cunningham@rgu.ac.uk</u>).

Appendix -11 -

Telephone interview reminder letter

Date as postmark

Dear Pharmacist,

This is a reminder to the invitation we had sent you regarding a request to take part in a telephone interview. To date, I have not received a reply from you. I apologize if you have recently returned the reply slip.

If however, you have not, as I mentioned to you in the first letter, the aim of this project is to investigate community pharmacists' views on the role of information services in the context of changing practice in relation to non-prescription medicines. Your views will help us understand the practice support needs of community pharmacists and will play an important role in the design of information feedback on e-MAS use from NHS National Services Scotland.

Taking part will involve a **telephone interview**, not lasting longer than 20 minutes.

If you have any questions, please do not hesitate to contact myself (01224-262559 or email: v.paudyal@rgu.ac.uk) or any members of the research team below.

Yours sincerely,

Vibhu Paudyal

PhD student,

School of Pharmacy & Life Sciences

Research team: *Mr Vibhu Paudyal, Dr Derek Stewart* (d.stewart@rgu.ac.uk 01224 262432), *Dr Denise Hansford* (01224- 262509 or d.hansford@rgu.ac.uk), *Dr Scott Cunningham* (01224- 262533 or s.cunningham@rgu.ac.uk)

Appendix - 12 -

Telephone interview participant information sheet

INFORMATION SHEET

16/07/08 version T-1

Before you decide to take part in the study, I kindly request you to take some time to read the information provided below relating to the project. It is important for you to understand why the research is being done and what it will involve. Please feel free to discuss this with others or to ask us about matters you find difficult to understand after reading this. Take time to decide whether you wish to take part. Thank you for reading this.

1. What is the purpose of the study?

The aim of this project is to investigate community pharmacists' views on changing practice in relation to non-prescription medicines and the role of information services in this context. Your views will help us understand the practice support needs of community pharmacists and will play an important role in the design of information feedback on e-MAS use from NHS National Services Scotland.

ISD (Information Service Division, NHS) aims to provide community pharmacists with information feedback relating to the non-prescription medicine supply through e-MAS for your practice support. Your views will play important role in the way these services will be delivered to you in order to support your practice.

2. Do I have to take part?

No. It is up to you to decide whether to take part. If you do decide to take part, you will be requested to keep this information sheet for your records and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect your relation with the university or the National Services Scotland.

3. Why have I been chosen?

You have been selected from a random list of community pharmacies from your health board.

4. If I decide to take part what should I do?

If you are willing to take part, please complete the research ethics form/reply slip and return in the pre-paid envelope provided or via fax at 01224-262555.

5. What will happen to me if I take part?

You will be invited to participate in a telephone interview session that will last no longer than 20 minutes which will be audio recorded and transcribed into a paper document. All such transcripts, subsequent data analysis and reporting of the study results will be anonymous.

6. What will happen to the results of the research study?

The results of the research study will be disseminated through publication at conferences and in journals. A brief report of the result of the study will be available by December, 2008 and you may obtain a free copy from the RGU contact list provided below.

7. What are the possible benefits of taking part?

Your views may play an important role relating to the future provision of methods of medicine use data feedback to community pharmacists.

8. What are the possible disadvantages and risks of taking part?

You may feel slight discomfort with the issue of confidentiality of the telephone interview and the recording of the conversation. A high level of security in relation to the access of the

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audio recordings and transcripts will be maintained. Only the principal researcher and the members of the supervisory teams will have access to the data and audio recordings.

9. Will my taking part in this study be confidential?

All information collected will remain strictly confidential and your name will not appear in any transcript, report or other publications. Audio records of the interview will be destroyed after submission of the final research paper from the project. In addition, all data will be stored securely in a password/lock protected facilities within the School of Pharmacy at all times and access will be restricted to members of the research team.

10. Who has reviewed the study?

North of Scotland Research Ethics Committee advised that this study does not need full NHS ethical review. The study has been peer reviewed by the Robert Gordon University Research Degrees Committee.

11. Who is organising and funding the research?

This research is organized and funded jointly by the School of Pharmacy at The Robert Gordon University, Aberdeen and ISD. The PhD student is also supported by a grant from Community Pharmacy Scotland (CPS).

12. Contact for further information

If you have any questions or require any further information, please contact:

at the School of Pharmacy & Life Sciences, The Robert Gordon University

Mr Vibhu Paudyal v.paudyal@rgu.ac.uk 01224 262559

Dr Derek Stewart d.stewart@rgu.ac.uk 01224 262432

Dr Denise Hansford d.hansford@rgu.ac.uk 01224 262509

Dr Scott Cunningham s.cunningham@rgu.ac.uk 01224 262533

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Telephone interview consent, copyright clearance form and reply slip

Title of the project: Community pharmacists' views on e-MAS performance feedback requirements.

Name of the principal researcher: Vibhu Paudyal, school of Pharmacy & Life Sciences, The Robert Gordon University, Aberdeen

Please tick($\sqrt{}$) in the box

		ave read and understa Γ-1 for the above study.	nd the information sheet dated	Ш	
4		at my participation in w session lasting 20 min	ucludes my involvement in a utes or less.		
5	I agree that the interview will be audio recorded and transcribed to a paper document.				
6	I understand that my name will not be included anywhere in the report of the findings.				
7	I understand that all materials will be preserved for the life of the research project and may be used in publication, education, lectures, broadcasting and on the internet.				
6		my participation in this s w at any time without g	study is entirely voluntary and I iving a reason.		
7 I			ereby assign my contribution to narmacy & Life Sciences research		
Name	e of participant	Date	Signature		
Resea	nrcher	Date	Signature		
I will	be available on the f	ollowing date, time and	telephone number		
Date:		Time:	(8AM to 5:15 PM)		
Telep	hone number:	(work/	mobile/home)		

Appendix - 15 -

Focus group Topic Guide June 2008

Introduction

My name is Vibhu and I am a PhD student here in the school of pharmacy. With me is our experienced colleague for my support. She is Focus group is a research method by which a particular topic of interest is discussed to collect the views and experience of people by sitting together in a group setting. Let me refresh you with the topics we are going to discuss tonight. We will be talking about your experiences of the things that have influenced your practice with non-prescription medicines and your views about some aspects of performance data feedback relating to these medicines.

Housekeeping

I will make an audio recording of the conversation to make sure that I do not miss important points that you have to say by not relying only on my memory or the notes. If you find it uncomfortable at any stage just give me a shout so that I can turn off the recorder for you. Also important is not to disclose each others private matters, things which could be uncomfortable in a group setting. We will allow the person to finish what he or she has to say before we express our own views for some technical reasons with the recording.

Great, welcome again and thank you very much for coming. We expect to finish this session within 90 minutes time from now and will try not to exceed the limit. It would be perfect if everyone has a chance to say something about each of the topics.

Areas of discussion

- -Great, let's start the session by simply introducing each other? (Will depend on situation) 2 min
- -Could you please describe an occasion where you dispensed a non-prescription product today or last time? **3 min**
- -In your experience, what are the things that have changed/influenced your practice with regards to non-prescription medicines? **5 min**
- (Probes: EBM, CPDs, Drug industry literature, peer influence, feedback, remuneration/reclassification)
- -Could you please explain in what way the things that you found useful helped support your practice in this context? **5 min**
- -How about the things that you found least useful or the things that you found were lacking? **7 min** (*Ask for specific examples if they do not appear in the discussion*)
- -Let us now move into areas of reclassified medicines, how do you decide whether to adopt or not a newly reclassified medicines? **8 min**
- -Does it vary from medicines to medicines? (Simvastatin, Omeprazole, chloramphenicol etc) 3 min
- -How about information support when it comes to recently reclassified medicines. Were they enough and supportive? **5 min**

(Ask what do they expect and what were lacking if it does not appear in the discussion)

-Let's get into e-MAS now. How did you feel about it when it was first introduced and how is it affecting your practice now? **8 min**

(*Probe a bit about decision making*)

- -Now I just would like to inform you that National Services Scotland are trying to support your practice by giving you feedback about non-prescription medicine supplies through e-MAS. To do this they need to understand the needs in this particular area. This means basically showing you the performance feedback regularly about how you or your company/ health board is doing. What sort of data would you think would be most useful to you? 5 min
- -Now I will take you through preliminary feedback information generated on e-MAS usage. How do you think these sorts of information could support your practice? (You could think of any data you would like to see, for example relating the medicines, pharmacies, patients/patient populations etc.) 10 min
- -What could be the best way to deliver the information to you so that it can be easily accessible to look when you require? **7 min**
- -Which other areas of NPMs might be worth getting such performance feedback?
- 5 min

- -Would feedback on individual medicines be any useful? 3 min
- -Summary of the discussion (If time allows) 4 min

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Telephone interview topic guide, June 2008

Introduction

Hi ******, Hello, good morning/afternoon/evening. Just to remind you, I am Vibhu calling from Aberdeen. I am a PhD student in Robert Gordon Uni, School of Pharmacy. So, how was the day? Great, *****, thank you again for your willingness to participate. We will be talking about information support relating to non-prescription medicine supply. This is specially focussed on the e-MAS performance feedback data to be provided to you in the future by NHS National Services Scotland.

Housekeeping

As you are aware, this conversation is being audio recorded to make sure that I do not miss important points that you have to say by not relying only on my memory or the notes. If you find it uncomfortable at any stage, just give me a shout so that I can turn off the recorder for you. Great, we expect to finish this session within 20 minutes time from now and will try not to exceed the limit.

Demography:

So, *****, may I get a few details about your demographics. Ok, could I ask your...(Fill in the demography table form) **1 min**

Areas of discussion

- -Are there any areas where you need more information/literature/training support in the context of decision making for non-prescription medicine supply? **2.5min**
- -How about the support tools for decision making when it comes to newly reclassified medicines? (Probe with individual products) 3.5 min
- -How do you think performance feedback can help you in your practice with NPMs, such as giving you a report of performance of the last few days/month relating to your product supply or other activities? **3 min**
- -Now I just would like to inform you that National Services Scotland are trying to support your practice by giving you feedback about non-prescription medicine supplies through e-MAS. To do this they need to understand the needs in this particular area. This means basically showing you the performance feedback regularly about how you or your company/ health board is doing. What sort of data would you think would be most useful to you? 4 min
- -How about the examples of data I sent you and the examples of how GPs are using it. How do you think you could make use of your performance feedback in the context of your own practice? **3 min**
- -What could be the best way to deliver the information to you so that it can be easily accessible to look when you require? 2 min
- -Which other areas of NPMs might be worth getting such performance feedback? 1min

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Ethics committee reply in response to initial queries around process of obtaining ethical approval

Dear Vibhu

Thank you for your email.

I will try and answer all your queries

- 1 Yes you can use the new form.
- 2 You can come through the Nosres committee
- 3 You will need to book your application through the Central Allocation System (you can get the number on the NRES website)
- 4 The R&D form should be almost completed using the new form but you have to complete bits which are only relevant to R&D.
- 5 When you are ready to submit you send everything to the North of Scotland Research Ethics Office Summerfield House

2 Eday Road

Aberdeen

AB15 6RE

You only need to submit one copy of everything as we have to photocopy it about 20 times.

6 If you want to send an informal query to myself that is no problem at all. Put it in an email providing as much information as possible and I will get back to you as soon as possible.

I am not in the office until Thursday but if you need clarification on any of the above points just let me know.

Kind regards

Rachel

Dr Rachel Venables
Acting Scientific Advisor
North of Scotland Research Ethics
Summerfield House
2 Eday Road
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Monday - Thursday 8.00am - 4.00pm

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Research Project outline for initial Research Ethics Committee

Robert Gordon University Faculty of Health & Social Care School of Pharmacy & Life Sciences

Implementation of electronic-Minor Ailment Service in Scotland: Study of community pharmacists' early views, experiences and challenges.

Electronic minor ailment service (e-MAS) refers to a service introduced in the new community pharmacy contract in Scotland. E-MAS allows members of the public who are exempt from prescription charges to register with a community pharmacy of their choice and receive non-prescription treatment for minor ailments supplied by pharmacists free of charge or where appropriate to get advice or onward referral to other health practitioners. Introduction of this service has arisen through implementation of Scottish Government's policy to ensure that a safe culture for self care practice is established even among those that cannot afford to buy non-prescription medicines. This project will be carried out in collaboration with the National Medicine Utilization Unit (NMUU) of NHS Scotland. The NMUU are responsible for planning the medicine data feedback provision to healthcare practitioners in Scotland.

Objectives:

- 1. What are the views, experiences and challenges faced by the community pharmacists (CPs) concerning the introduction and ongoing operation of e-MAS?
- 2. What quality mechanisms are in place to support and develop the practice by individual CPs including the supply data feedback that is currently provided on non-prescription drug management supply through e-MAS?
- 3. For the future, what are community pharmacists' preferences regarding the type, method of presentation, and additional support related to data feedback provision for the supply of non-prescription medicines through e-MAS?

Methodology: This research has been designed in two parts.

- **A. Focus groups:** Four focus groups will be held in different Health Boards of Scotland consisting of 8-12 NHS contracted community pharmacists in each group. Focus groups are planned to last not more than 90 minutes and will conducted using a semi-structured approach utilising a predefined topic guide Health Boards will be selected based on different levels of e-MAS utilisation, from which random sample of pharmacies will be selected. An invitation letter with study information including extent of participation will be sent to each potential pharmacist participant. Those willing to participate will be returning a consent form. Data will be analysed using qualitative framework analysis to identify consequent themes.
- **B. Postal questionnaire:** Results of data analysis from the focus groups will be used to inform questionnaire development. This will be sent to all community pharmacists' premises in Scotland. This will aim to quantify and correlate the differences in the views of community pharmacists across several groups of interests (for example job nature of community pharmacists, geographical deprivation area in which they work etc). The questionnaire should take no more than 10-15 minutes to complete. Data will be analysed using univariate /multivariate statistical methods. Research practice and data storage throughout all parts of the study will comply with the RGU Research Governance & Ethics Policy.

Other relevant information: Chief Investigator: Vibhu Paudyal (B Pharm, MSc Clin. Pharmacology); Funding/Collaborators: Community pharmacy Scotland (CPS), NMUU NHS Scotland); Nature of Project: PhD Research supervised by Dr D Hansford and Dr S Cunningham; Project peer reviewed by: Robert Gordon University Research Degrees committee. This will be the first study to be undertaken in this particular area since the new contract for Scottish community pharmacists came into effect in 2006.

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Further correspondence with the Ethics Committee

Dear Vibhu

Thanks for your email.

Could I just clarify a few points with your regarding your proposal.

How will the focus group participants be recruited?

Do you intend to use consent forms, if so can you let me see a copy?

How will the questionnaires be returned will the be anonymous or anonymised and if so why.

I look forward to hearing from you soon.

Kind regards

Rachel

Dr Rachel Venables
Acting Scientific Advisor
North of Scotland Research Ethics
Summerfield House
2 Eday Road
Aberdeen
AB15 6RE
Tel: 01224 558480
Monday - Thursday 8.00am - 4.00pm

Dear Vibhu

Thanks for your email and clarification there are a few issues that I have with your documentation.

Letter of Invitation/PIS

I think you need to supply more information about the study. I have attached a model PIS which you may wish to adapt for your study.

You can not say that it has been approved by the Ethics Committee, you could say that the study is classed as a service evaluation and has not had to go through ethical review (or something similar).

Questionnaires

It would be better if the questionnaires were anonymous and no study ID number was placed on them. If you are going to send reminders, then it is better that it is a blanket reminders and only one reminder gets sent. Then you do not need to collect any identifiable information.

Consent Form

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I have attached the standard format that we usually recommend. Also I don't think you need to have I do not agree to take part in the study. If participants want to take part then they should just sign the consent form and if they don't they should not need to respond to you.

I look forward to hearing from you soon.

Kind regards

Rachel

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Ethics committee decision

Dear Vibhu

Thank you for responding to my queries, I think we have covered everything!

After review of your information and discussion with the Vice Chair of Committee 1 we feel that your project is a service evaluation and would not require a formal ethics application.

If you need any further information, please don't hesitate to contact me.

Good luck with your project.

Kind regards

Rachel
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Monday - Thursday 8.00am - 4.00pm

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Ethics committee responses to request for the conduction of telephone interviews

Dear Vibhu

My apologies that you have not received a reply from us sooner. We have had staffing shortages in the office and I am just back from annual leave.

I will review your proposal and get back to you by the end of the week.

Again, my apologies for the delay in the response time.

Kind regards

Rachel

North of Scotland Research Ethics Summerfield House 2 Eday Road Aberdeen AB15 6RE Tel: 01224 (5)58474

01224 (5)58503

Office Hours: Mon-Fri 9am-4pm

Dear Vibhu

Thank you for your email.

Can I ask you to clarify the following please:

The information does not make it clear that you are asking them to take part in a telephone interview rather than focus group.

After you have transcribed the interview are you going to send them a copy of the transcript for verification.

I look forward to hearing from you soon.

Kind regards

Rachel

North of Scotland Research Ethics Summerfield House 2 Eday Road Aberdeen AB15 6RE Tel: 01224 (5)58474

01224 (5)58503

Office Hours: Mon-Fri 9am- 4pm

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Ethics committee decision

Dear Vibhu

Thank you for clarifying the points requested.

After further review we feel that the changes to your project still ensure that this is a service evaluation and would not require a formal ethics submission.

If you need any further information, please don't hesitate to contact me.

Good luck with your project

Kind regards

Rachel

Rachel Venables PhD
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Monday - Thursday 8.00am - 4.00pm

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An exemplar focus group transcript

C: Ok, this is working perfect. F1: Frightened to say anything, just listening (Laughs from other participants)

C: Well, this is working as well. So lets just start with a brief introduction. *****, shall we start from you?

M1: About myself then?

C: Please,

M1: *****, I live in ***(Name of a place), qualified in 1976. So, therefore, been community pharmacist for nearly 30, 32 years (Laughs). And, and I am employed by ****(Name of a pharmacy). I have worked all my career for ****(Name of a pharmacy) person employees butbut..not financial, now, I am at the stage where, pension, important, is there anything else? And I got family in... So, em... I'm qualified Manchester University. Did much of it from ****(Name of a place) but did most of my early years down in **** (name of a place) in various managing positions in*** (name of a place). Then went to **** (name of a place) as manager and I think, bad to get out there, out there for the sake of my sanity, to be honest em... and came back to ****(Name of a place) on relief, as, came in as a relief pharmacist in the branches in the ****(Name of a place) area. That was about 14 years ago, stayed there ever since. I'm technically relief but at the moment I am spending quite a lot of time in ***(Name of a place), simply because there's a vacancy there, so I'm covering the vacancy. Will be on relief later somewhere else, think so and Em... supplementary prescriber, but not much opportunity to use it at the moment particularly being on relief but hoping when things settle down, em.. can make conversion to independent prescriber.

C: Ok, *****,

F1: *****, community pharmacist in ***(Name of a place) but I have worked in a rural community for quite a number of years, em...just working in an independent pharmacy rather than a big companies. ...

C: Right, Mr *****,

M2: ****, first, I worked for a hospital for sometime, then, worked in retail. Then, I'm for about for about 30 years, in a rural pharmacy now.

C: ****

F2: *****, I settled working ***(Name of a pharamcy) for many, quite a few years. Then went to do locums when my children were young, did locums about, may be, 12 years or something, near about. And, I've, I am now working in ***(Name of a place) as a manager with the ***(name of a pharmacy).

M3: I'm *****, I qualified in 2003, em.., spent my, my career so far in community pharmacy in and around ***(Name of a place)shire. Most of been it rural setting until the last year or so when I've moved into a, an urban setting within ***(Name of a place), much busier environment. And, I've, only worked for two companies. A small to medium sized chain and I've moved to a large chain of the Cooperative group and, just, still, still a learning curve for me just now.

C: Good, so, just to enter into the topics of non-prescription medicines, could you describe an occasion where you supplied or dispensed a non-prescription medicine today or last time?

We'll go round about in first occasion and then...

M3: Head lice seems to be popular within ***(Name of a place) now, it's only today, I've had couple of eMASes to, to, to supply, if you're meaning from any title?

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C: yes, from any title,

F2: Head lice treatments and paracetamol for children.

M1: For me in the last few days has been, coming quite strong antihistamines, the season starting to allergic children, children, with, reactions, groin obviously, the small children (smiles)

C: So, you see a lot of seasonal changes, in relation to demand of these....

M1: Starting to change now,

M3: yes.

F1: As I said, purely minor ailments scheme you are talking about, or just?

C: No, anything, anything,

F1: People, people buying things at the counter as well, in general, the sale and supply.

C; yes, in general, yes.

F1: Yes, I've had a dry skin, head lice, paracetamol, anti-histamines and I think, I've had all of them today. And, mouth ulcers... I don't know is this endless working in a chemist shop everyday without thinking about it So, ya, lots of things.

M2: I agree with, ah,.. head lice. I had two patients at work today, keep with the season Piriton, quite a lot of that, two complaints about the cetrizine, which I supplied, that it doesn't work, so supplied 2 lots of Priton and em..., we put on e-MAS, so, Calpofren, Calpol, Eumovate, did, couple of hydrocortisone steroids, those on e-MAS, as well as Aunguentum-N for trial, child, 2 year old, had, very, very allergic skin, she is allergic to milk, so, I supplied with special formula, Neocode, and so, so that's a job in order she was also heaping, received the Eumovate and doctors are off today and I dispensed it.

C: Great, let's enter to the main area of discussion now. Ah, have you seen in recent years, changes, any changes, significantly affecting your practice in relation to non-prescription medicines?

F1: Possibly pseudoephedrine sales pack size em.., prior to that paracetamol..., these are the regulated changes you have to implement.

C: yes, anything, regulatory or anything significant, you would like to

M3: Changes, lot, lot of areas have been fairly steady.., stream..., fairly settled down, in a recent while, accounting for past two three years, seems to be reasonably fairly predictable level of demand.

M1: The second concern for the level of demand, may be driven by the level of advertising, not for, not for e-MAS, but, I wasn't even aware that, there was, there was an OTC naproxen coming out until, until it was pointed out on television. To me, I would think I would read in my journal and chemist but its not as early, for cover to cover. But, that, I would, then coming and asking for OTC naproxen which I wasn't even aware. I might, I don't know if I'm alone.

F2: I knew it was coming.

M1: the, em, I must have missed the...

M2: It's a great help to have that but its, em, difficult to explain to a man, without insult him (smiles and laughs by other participants).

(Too many speaking at a time, loss of conversation, 5 seconds)

M1: So, just highlighting the point here that changing from POMs to Ps is fine if it's given us an extra, a weapon in the armoury if you're like but if its driven by television advertising, not quite so sure, that people coming and asking for potent medication, I might not be satisfied. I think, it should be, led by us (supported by F1), not led by television.

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F2: TV advert, I think, is appropriate for them, so they make decision for the things they want......

F1: I think, Curanail must be on the teli (TV) just now as well. 'Cause, 'cause I've had somebody asking for that and that's such an expensive item, something I would not generally recommend first line, but, because its on the television, advertise.....

M3: (overlap of conversation)

F1: yes, also, sorry, I also don't want that anymore.

C: So, do you mean when changes do happen, from POM to P or P to GSL, this, do these television advertisement and things are

F1: From POM to P, is, is the big one, because it's the thing, people couldn't purchase earlier, gets advertised on teli, oh... this is great, this is great stuff and they come in and, they ask for, they don't come in and what've you got for period pain? What've you got for fungal nail infection? This is just can I say, can I have the stuff that's advertised on the television? The power of advertising is quick, and you negotiate with your patient. Put something else in there, you didn't want it there in the first place. Yes, I can treat your nail infection if you leave it just up to me, let me decide how I going to treat you. This is you get the same, you can't walk into a GP practice and say to the doctor, I come on with such and such I saw on teli. The GP wont listen to it. And, I found that quite frustrating, generally changes from POM to Ps is, is, is the main one, which you get Coronia advertised on the teli, Askits for whatsoever, may be on GSL for ages and people buying them on Tescos, there, that doesn't really affects me so much as the, ones that can only be get from pharmacies, from a POM to P where they come in to up to our door...

M2: I think, chloramphenicol has been best POM to P (agreed by al others)
F1: That's really good one, ya (agreed by others)

F2: What a demand from the customers.....

(Lost data due to many speaking at a time) for few seconds

C: So, what do you think should be done to make things easier for you to actually make people understand the rationale behind reclassifications and the evidence based supply from pharmacies? Are there anything that...

M1: Just cut the advertisings (smiles)

F2: You'll see things like Chloramphenicol, I think its purely...

M2: That's the worse thing

F1: And then they wonder when you're asking them all the questions. So I just thought why the teli could not have it like..........

F1: So, the difficult area has been adverts. I think people will see them and buy past from another place.

M1Yes...

F2: And if they not get it, then just try up somewhere else

F1: they just go some place yes, yes.. and that's with minor ailments as well. You know because we've somebody asking for some irrelevant items, sorry but I need to register for minor ailment before we can treat you. And then they re-register and then they don't come back (smiles). C: So, how about the information support you get when things get reclassified from POM to P?

(silence)

Looking into specific examples of recent reclassifications like Simvastatin and Omeprazole?

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F1: What did you say that? Sorry,

C: Information support, materials like trainings as well as information materials for supply?

M1: You do get trainings

11:47

M3: You do get trainings but it seems to be driven by the company who is about to make a small fortune of promoting the products themselves , its its not standardized. So it can be difficult to integrate to your own, your own branches.

F1: We have the ***** (a health board) Prescriber, when new drugs come in the market, ***** health board look at it and evaluate them and they tell the GPs that this is the new product and this is gonna be OK for such and such but don't use it for.... They have some kind of evaluation process when new drugs are coming out for the prescribers. But if there's a new things come out for pharmacists itself whether its from POM to P or what.. its the drugs companies that do all the training and ..., there is no sort of evaluation thing there

M2: Usually the products which are established, we find out from like what the truth is about it.

F1: We usually see in the Chemist and Druggist, or from the reps

F1: Sometimes you have to actively look out, seek out that information, even for the standardised...., oh by the way this one which is coming out, is that not something that is in the journal about reclassification which tells you all, its quite muddled isn't it? There's a lot of stuffs that haven't changed for ages, there's not something specific new things...highlighted in the colour or something.

C: So are there any ideal ways of delivering you the information when reclassification happens? F1: Yeah.., we know that going to be in pharmaceutical journal, all that sort of....

M2: They can send us a sort of standardized card with all the information instead of all promotional information, you got to fight the way through to find the information you really want. The card would then allow to acquiesce the change and secondly would give you the standard information. I think you would have to put the cost against the company. Its unfair to ask pharmaceutical journal to bear the cost.

M1: Its also a problem..., before launch its often in glossy magazines or newspapers whether it is news or whether it is promotional. I have been asked for something that appears on daily mail or whatever, newspaper that does a new medical drug. Now if I don't read that particularly newspaper, I won't have a clue what they are talking about. Its often there before its says its available from.... These, these, if you like editorials are often set up months before paper goes to press, months before magazines goes to press. Often its not on the shelf at all or often I don't know anything about it. I don't have any datasheet on it. So, I think.., that, that doesn't only happen with over the counter drugs, it can also happen with prescription drugs. People asking about new wonder drug for rheumatoid arthritis, which they read about in the Sunday post, doctor on Sunday post. I think they come back to something, might be there's not enough respect for medicines in the country. They still got, I still have got people asking for Coproximol, doctor could in theory prescribe it or.... So if you are living in that sort of society there's not enough respect for the role of pharmacists and then coming in and asking for something in e-MAS rather than coming and asking say can you give me something to treat for athlete's foot?, coming and asking for... And that indicates to me a lot of respect. I will say I will prescribe you what I think is suitable for you. I won't say as quite bluntly to the patient as this but, you tell me what your condition is and I will tell you what is suitable in a much friendly way as to...

M3: you felt like you are an obstacle to the patient to get what they want.

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M2: With e-MAS, you do have patients coming with virtually the shopping list and that is wrong.

M1: that's not what it is for

M2: Thats not what it is for. I've had a patient.... I said you cant., it wasn't set up to be like this. What he did was to turn around to another chemist and register wherever they want.

C: We'll get into e-MAS later (laugh from the participants). So, relating to reclassified products, were there or are there any products that have (been) welcomed much in the community pharmacy and are there any products which haven't been throughso well?

F1: Oh, well, Chloramphenicol, has been fantastic,. I would say Imigran has been a waste of time (agreed by others)

M3: Zocor?

F1: Zocor has been a waste of time as well.

M3: omeprazole,... that's the price

F1: yeah very expensive

M2: Price sensitive, yeah.., exactly.

M3: Absolutely, well the thing like Feminax Ultra, that have got into swing... it seems to be very well received, I mean, that's what I sampled, about three people have came back and said, its wonderful.

M1: I haven't had a chance to sell it but yeah it's a kind of product that you'd like to watch what you're using it for (Laughs)

M2: I've never used it for many years, but em.., exactly what you said

M1: Naproxen, is for, for Migraine, I haven't been able to sell it yet because Buccostem is not particularly migraine product but, that would be one I might welcome. I don't see why can I sell it for migraines but cant sell it for any other conditions. So, that would be one I might think should go or should be less restricted. I don't know if anybody else think the same.. the same I think the license is restricted on that. Chloramphenicol will certainly go along with that, would have wished that for years..

F1: Getting back to what you were saying that the trainings before these products come out. It's the reps doing it, 'cause it's the only one that we get for POM to P for certain conditions. Its not that we are allowed to use the actual drug for what we want to use it for. We cant do it (agreed by others). migraines, sickness thing. I mean, I mean, the naproxen is another one, they could just bring in naproxen off POM to P ... generic naproxen tablets but ... specific product, its not for migraine or whatever, what was it called again? Feminax Ultra, that was it. We are, we're restricted to what we can actually, I mean where naproxen is the drug to use for over the counter restricted in what we can use it for.

M1: I do have a concern about using the brand names for the existing, put a different product. I have a concern on that for a long time that, when you get ..., the name...extra ... plus and told that its confusing for the hospitals if there is an overdose because, basically the database will actually show ... as being Salicylate product. And of course, you can actually have everything now with under the sun under its product name and I don't, I'd have liked to call some other than Feminax Ultra to be honest because now its ... we have people are coming in and requesting it, then its totally different product, you are talking about from the traditional ...? I'm not really very keen on hanging a new product on an old well excepted, well excepted name, I think they should call it something, there's, must be plenty of options to call it something else. (Two speaking at a time for few seconds, doesn't seem to be a data)

F2: Its quite confusing, when they have fancy products like Cansten and they bring out counter pack which is obviously..., it's the same but its misleading

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F1: oh yeah, god, yeah.. you see, you see Sudafed, I've seen people looking at Sudafed in the supermarket, I felt like, its not Pseudoephedrine, its phenylephrine and that's not the same as you buy in the chemist shop, you go to your chemist, you can't, ... looking at the packet, thinking it's the same, its not. But as you said, because it's a branded the same, the pack looks almost the same, it's called Sudafed, they called Sudaphed...,

F2: very similar to....just now ' 'cause I got mixed up myself, my staff got an stuck with it and

F1: sometimes its Sudafed and sometimes its Sudafed non-drowsy congestions or something, there's two...

F2: They are two different packs and all look the same.

M3: Is it decongestion, decongestion relief?

F1: Its something like that, two different.., for decongestion but the packs look very similar. And I think its very misleading, its obviously a marketing ploy for big brands.

M1: Once you got a good brand name, you hang something else on to it and....

F1: And as you said the Feminax one 'cause its completely different ingredient and

C: So, are there any other products which haven't been going really well in pharmacy that have been reclassified in the past?

M1: have or haven't?

C: Haven't.

M2: Sold cheaper Colpermin and ..., didn't go at all. M3: What happened to Zantac when it first came out?

F2: That gets called, I don't know... why

F1: You get it generic or Pepcid AC

M2: Yeah...

C: How about Simvastatin, is it doing well?

M2: no.

M3: I don't think, we even stock it anymore.

F1: No.

M2: So expensive, the doctor's formula and they get points for getting so many people on statins (laughs)....

M3: 10 milligrams just do for two weeks. If, if its hitting target audience of....., I'm sure when it was first sent out, it was targeted towards the working, it may all 40s, 50s GPs but stayed on 40 milligrams depending on weight. Ten's not gonna really cut it.

M1: I think that was targeted..., they worried well rather than, which is the reason it didn't work well as even if you were doing cholesterol testing in the pharmacy.

F2: When you're doing cholesterol testing, did you sell any...or...?

F1: No, did referrals

M1: No, I either offered dietary advice because the cholesterol testing wasn't, wasn't even differentiating high density and low density, so....and they didn't look into anything else, I mean, the..., whether the patient had a history of or a family history of stroke, whether diabetic. So, I mean..., in isolation, I think it was pretty much useless exercise. (F2: You stopped doing it?) I stopped it long time ago. I did it if somebody demands, we stock as a matter of policy. I didn't agree with it. I did it when it was contractually required me to..... but I've..., ah..., never sold a pack of Simvastatin in life. Never had any intention to ...do it.., I was quite happy to offer advice to people if they had a high total cholesterol read and as to whether people benefit and if

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they come back after certain amount of time to see if it had improved doing that. But, no I think, my time is really devoted elsewhere really honest in that one.

C: Is it the same experience you had Mr *****?

M2: Yes, oh yes, I was looking at one pack of Zocor, the retail pack.., the heart.., one more..... F2: I think it depends as well on what area you are targeting, because if you are in a, an affluent area, probably, ***(Name of a place), people may be motivated to pay twelve pounds or whatever, canna remember. But if you're in a poorer area like ***(Name of a place).. (interrupted)

M1: Don't think I sold very much when I was on relief on ***(Name of a place) earlier ,...people say.., London perhaps might be somewhere..... but ...

F2: People may be motivated in that situation because they could probably afford it.

M1: They're worried, they're worried

(Loss of conversation for a couple of seconds due to too many speaking at a time)

F1: they're worried well, things like that they're worried well

C: So, are there any other factors than cost, do you think is responsible for its..?

M3: A big factor for me at least, if, if I'm ..pressed for time filling out whole Imigran or, or, I cant remember if Zocor had, had the same problem, but... I find that, I find that taxing if I have to even find..

F1: Customers don't want it either, they got to go through big ..., they don't worry.

M3: they just, just want to get quick service

C: So, what could be done to encourage, this chronic medications to be brought into community pharmacy in the future? Are there any support lacking or is that the whole idea behind such reclassification not very good? What do you think can be done in the future?

F1: Chronic long term medications like the, Simvastatin?

C: Yes.

F1: So, what would make us..?

C: Yes, be, you know more, make public more trust, you know or make community pharmacists more equipped or more competent to supply these kind of, products in the future?

M1: Sorry, coming back to.., sort of , not to be worried about...,but you have to have some more access to records, some access to patient records to actually be aware of what you actually treating someone actually, actually..,needs treatment. There's a....,at the moment we would have people coming and asking for Zocor and they need treatment. We wouldn't have people coming in....did...yes, they are worried well. But its should be targeted towards what is appropriate, not, not desired (smiles).

M2: Unless you have the, em.., access to records.... to see what we want to., some can been treated with statin or ... and come in and if you are able to sell for example at reasonable price...Simvastatin..., and ask for Simvastatin..and they have already treatment with statin, give another one and the only way we could have be possible is only if we had access to the records, kind of dangerous in a sense if you think about it.

M3: Seems to be more successful, hearing the names, seems to be more successful with shorter and acute conditions rather than going...

M1: The successful ones as I say is the ones Zovirax, Chloramphenicol, first the Loperamide, I can remember when that came OTC, so those three products were successful because...

F1: We're really kind of first port of call for acute things and they, really people are coming if there's something wrong with them but if it's a long term chronic thing, they come in and we can direct into their GP for the long term chronic thing.

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F2: I think most people are probably more comfortable anyway with the long term chronic conditions to be seen by their GPs. Most of these, well, not, not Simvastatin, that, lot of these products have short term license which...quite use for more than five days before we refer them to GPs, so we're quite restricted by product license to, to what we can do and what we cant do.

M1: There's problem with..., when things go from P to GSL, Are they been restricted or controlled enough when they are sold outside pharmacy? I mean paracetamol are sold in local garage, I mean, em..., number of items.....

M2: I think your point..,... interesting about the Sudafed and phenylephrine, you got glaucoma, you don't have ... phenylephrine from Tesco.

F1: From Tesco? Yeah.., everybody is worried about it, can I have six packets Madam? M2: Yeah

M1: I have seen it but a lot of the major supermarkets will have enforcement in, in another terms. I don't know, I never have tried to go through, Tesco, Tesco to see how many paracetamol you get, get through there but that will, anyway its not got computerized.

F1: Paracetamol

F2: paracetamol, but I don't think, sudaphed.

F1: But they only do it for paracetamol because it's a suicide risk isn't it.

M1: So, I limit to sell X as being a professional but Tesco can sell 2X, 3X,

F2: Well, paracetamol, they don't sell two packets,

F1: yeah, but you can go and buy two packs of sudaphed.

F2: yeah, you are right and....just try it

F1: Just try it?

(Loss of data due to too many people speaking at a time)

C: Going back to the information support, when there the reclassification happens (do occur), do you prefer some source of information over others, depending upon where the information is coming from?

M3: A, a, an impartial source, not the manufacturers. I always get sceptical when I see their, their, their, their data coming through. Its usually, a good journal would be the pharmaceutical journal. When I happen to see it,,it looks like that I might not pick it up but when I do, I want to read about it....that's, that's usually the source.., will be happy to..,

F1: The announcements in pharmaceutical journal is usually what I pick up....yeah...And you do look at the manufacturers thing, so that thinks about bias,

F2: Chemist and Druggists

M1: Yeah, Chemist and Druggists...

C: So, lets move into another area now. How about the influence of this..., literature surrounding evidence based medicine supply, affecting your practice with non-prescription medicines? Do you see, them.., affecting your practice a lot? For example literatures coming up in journals and new information supports..., suggesting evidence based supply and things?

F1: Tryin' to think of any example.

(Silence)

M3: Only slight, most of the medicines available as non-prescriptions are so well established.It tends to almost..,the..,evidence is something we actually know, whether, whether...,its.., occasionally.., those are..,Simethicone being more effective over Dimethicone for headlice?

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F1: Yeah, I was thinking something about the paracetamol, Ibuprofen, evidence base about the kids treatment, not to give together or something. And where, where did that information came from? I can't remember where that came from. Things about using paracetamol and Ibuprofen together

M2: If you give them, they tend to reinforce the renal toxicity F1: But did that come through the health board or...?

F2: I saw that, I don't think..,

M2: Journal,

F1: A journal?

M2: I think so.

F1: yeah.., evidence based, as you said.., what else was you.....?

M3: There is one, one of the Dimethicone related products which was in a study which was seen to be X percent more effective than, than than, than..., I can't remember..., permethrin or something like that.

F1: When I see in a journal something like that, you get a sort of sort of clock it. I mean by the time you flick through the journal, you see titles, I mean interesting titles and then you, if you read something that somebody done some study on.., and they don't mean a brand, they talk about dimethicone base on.., or a Malathione base and then you kind of read that oh..,OK, I will start recommending Malathione base instead. So I suppose if you do read something and its an evidenced base paper on, on the things that you can sell over the counter, its not all something you're looking for, its just something you have to see.. and then that would may be affect what you recommend.

C: Are these CPDs and things affecting your decision making? CPDs?

F1: Whats a CPD?

(A laugh from other participants)

C: continued professional development, training and things.

M3: I, still,..because..,, related to recent POM to Ps, because I'm still sceptical of the CPD, because they provide the CPD articles on, on, on the recent switch. But I'm still sceptical, specially on the CPD things...that's lovely, thanks for telling that but I'm still not quite necessarily choose that product over, over something which has been successful for, with other patients or customers before.

M1: not occasions, presumably with head lice but, the health board has a formulary. Now, I do try to stick to that, what the recommendations are from that and it doesn't include any preparations that are designed to be used in 20 minutes or applied and washed off again. And that, I've had few arguments in that particular circumstance where the ***(Name of a place) formulary certainly says it should be left over the night, washed off in the morning...which rules out the (F1: See on the telis and its on the teli...). Yes..., If you're asking me to write on e-MAS, I am writing what, what, what I believe is going to, sort of.., I wont have an arguments. Well, argument probably is too strong a word, a debate shall we say, em..., patients who want what is quicker to use and I've refused prescribing because may be quick to use but the evidence doesn't back up its use. Now, that's I think what we should be doing. But, it can be quite difficult. We also have problems, if going to be honest, with doctors sending the patients down, asking for the things on e-MAS. Now, em..,probably, it is saving the doctor's budget, the whole point of e-MAS was, was to actually, prevent people having to go to see doctors with minor ailments. If they're already in the doctor's surgery receiving an antibiotic, then why does is the doctor telling patients to come to us for..., paracetamol?

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C: Great, well, lots of interest in e-MAS. Now, lets get into e-MAS now. (Big laugh from all the participants). So, how big this was a change in your contract when it first came? *****, may I start with you please?

F2: We piloted in ***(Name of a place), so we've been doing MAS for seven, over seven, seven years now. Em.., I think initially, people didn't understand if its available. Its quite hard work to register patients. But now, more people know about it. Not, not everyone knows about it, I think we still have got ground work to tell people about it and how it does affected work? It can be very annoying some days, (agreed by M2), very busy and you've got lots of them and in other days, you don't see them at all. And I think...(smiles), ..., when you're really busy, there's lots of people turn out and looking for something, see e-MAS ...

M1: its not a very stable programme, isn't it?

F2: not its not, its not (smiles), but people tend to have their..., have their..., I suppose their aspirations to what they want. A... said that.., I'd been to the doctor and he's told them to come down for paracetamol which he ... handle well or recommend and they just want paracetamol. So its trying to get round them, its not the service that they use as and when needed, its for a child who must be ill or...

M2: I want paracetamol, paracetamol, Ibuprofen, I don't want to pay for it (laughs)

F1: I've run out of paracetamol for my _____ can I have some more please? There's wrong with the child, I've just run out of it. Why you give me paracetamol. I use it every night.

M3: That's.., em.., I've only...em, they kind of keep.., em.., the paper based, the minor ailments or 'Direct Care' or something, came in force for about a year into my having qualified. So, its just another thing which was easy to...., what I studied in....but... Firstly, that I was trying to treat it as a normal day to day pharmacy life, if, if I am dealing with the prescriptions are done in line But we have a sort of customer who wants to speak to me, , Oh, come in, speak to me. But, when ..,minor ailments..., direct care.., treated it as a (F1: Prescription).., well, no, not immediately, I, I made a mistake while I was trying to deal with it, then, they are back it they are not..., They then took me, it took me sometime to think.., you know, actually.., I couldn't have to tell these people, this, this, is the service gonna be, twenty minutes wont.., and these other people who...

F2: That's what I said, I suppose, if you go and speak to the person, first, the.., usually, the girls will take it quite quicker, the information. Then you go down and speak to them andI want paracetamol and then, you have to say, well, no.... (too many speaking at a time) ...give you what you aiming, em..., and then see, well, now be 15-20 minutes because..

F1: I think, kind of..., when it was first introduced, people were coming in and they wanted their paracetamol. Because you, because it was a pilot project, we were trying to encourage people to use the service and tell them about and everything was like and "oh, do you know the minor ailments?", we are introducing the minor ailments service for them. When they were coming and asking for something, normally they would have just come in and asked, they would have done the WHAAM questions then sell it the way I ... But because we have been used to the pilot project to encourage people to do the minor ailments service, get people registered on it, telling them about of being free or whatever. It is quite time consuming and now, now, when you have somebody coming in to buy Calpol when their kid when they have got teething, you get now the staffs kind of say...,getting on their minor ailments for their child's name or whatever, goes in for a while for prescriptions or waiting or whatever, when I get down, I have to go out and talk to them whereas prior to that the girls could have done the WHAAM questions and sold it. So, yeah..., has increased my workload.

C: How about getting paid for it advice with this..e-MAS?

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(Laugh from participants)

F1: Just a little bit on the minor ailments, we...,referral or advice only or something. No, its so much hassles. I only use the prescriptions when I am dispensing. I don't, I don't do blank ones for... Do you do blank ones for advice or referral only? (asking other participants)

F2: No, I do very very little but not as we should...

F1: I've never done it, not at all.

C: why don't you do it regularly?

F1: because you have to go on to the file on the computer, finding them up to do and then you print it sign off and then, then all, all you saying is go to your doctor. That will just take a long time, they're not going to wait us doing that.

(Too many participants speaking at a time for a couple of seconds)

M1:referral mean piece of paper on to the doctor. That might be a different issue.....I have, I have seen this, this patient and ...

F1: but what about advice? You give people advice all the time...

M1: I, I think, its more.....

F2: It depends, the.., how ill the person is? It will be wee while that I go and phone the doctor saying that this person here, what I feel.., needs to be seen and they get an appointment. Whereas if they go across themselves, might be until next week..

C: How about formulary support for this e-MAS?

F1: What is that support?

C: Formulary

F1: Formulary

F2: Bad (Smiles)

M2: Yes.

M1: well again I think, 'cause the health, probably the same because a test..., ***(Name of a place) was a test belt. It was one of the two original sites. So it's the same formulary now as it was when ...(F2: years ago).... and also the difficulty is that, that you can't prescribe anything that's, that's got P license on it, ...? not in the formulary. So you're getting variations between pharmacies as to what and what is not being prescribed. We also get the situations, sort of strange ones where branded names are allowed to be picked. The flocona, the fluconazole issue (agreed by other participants). If you're, if you prescribe a particular drug fluconazole under PGD, you can supply it but its, its only endorsed and put through the computer in a certain way only. So you are actually giving a more expensive product(too many speaking at a time)...even if we have cheaper drugs on the shelves.

F1: I've had so many things refused for picking up wrong things off the computer as I do everything branded one. I don't do anything generic anymore. I do branded, apart from paracetamol and Ibuprofen. The stuffs.... because you are allowed to do it and not getting, not paid for it.

(Loss of transcript due to too many people speaking at a time)

F1: ...it picked up the second things like off the computer, things like beclomethaosone nasal spray because it's printed off in 200 which is damn this cheap, which is cheaper than the OTC thing as I wasn't getting paid for it, ...? doing that. Fluconazole nasal spray..

C: Sorry, I interrupt you here, how about the definitions of minor ailments as listed in the formulary? Do they cover the ailments you see everyday?

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M1: Pretty well, pretty much, there's not enough choice of products in there I would see but there is.., the groupings is OK.

C: Could you shade more light on that. How is there not enough choices relating to the products?

F1: Well, the formulary is just there as a guide 'because you can prescribe any P or GSL medicine, almost everything, except the blacklisted....

F2: More Patient Group Directions for... em.., Naproxen (laugh by F1).., Naproxen or in fluconazole. I mean why we given Diflucan if we give ..., when we can give Fluconazole generic reduced price. So the Patient Group Directions for some of these products over acyclovir another ones. So, you that there are lots of products that have Patients Group Directions where we could give the generic version and save the Health board some money. But you've got to prescribe the branded product.

M3: that's what the GPs have been, bashed overhead for prescriptions...for seventy percent generic prescribing rate . It's the target they have to reach.

M1: The thing is that we don't have PGDs, of course we cant give the POM version, which, which is, which is what the problem. You are talking round the samples because you have to, somebody have to write the PGDs. That means saves money for the long term ... long term because we ... supply

F2: Things like Canesten, as I mentioned early, ...right pack because you've got POM pack and P pack, identical. I'm not always convinced (Laughs) ... lots and lots of people...I've given the POM pack you know,

F1: but its just, its just paperwork, patients getting the treatment as needed. Its purely the endorsement, endorsement, the computer system and things, if you are handwriting you are all right. (Laughs)

F2: But then do they pay attention to your endorsement?

F1: Yeah

F2: Are you sure?

F1: Yeah

F2: I don't think they do.

F1: I've got picked up......for something not allowed

C: Earlier we discussed that in some occasions cost actually is a factor, where you cant supply the product you wanted to because patients cant afford it. Is e-MAS helping you in that context?

F1: me, yes (agreed by all), mine is a quite deprived area, so yeah...

M3: It also makes it quite prone to abuse (agreed by all) but I've been quite delighted when I can actually....., to help people feel all right remedy ... conditions to what you're already looking for 'cause that helps me further.

M2: In the case of e-MAS, all these worried well and parents...,sort of all bloody shopping list (Laughs). That's difficult...

M1: That might've been due to the fact that the surgeries are closed on Saturdays 'cause quite a lot of e-MAS in my case comes in on Saturdays for acute things because they have occurred on Saturdays and either patient decided to come to pharmacy first although we referred to NHS 24 who recommended going into the......

F2: Annoying thing is, they come in to the pharmacies, can have something and you start questioning about and discover that NHS 24 have referred them and that really irritates me. Because, in some cases telling me what I've, what I've got to prescribe (agreed by others) by NHS 24 and that one is very irritating.

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M1: I don't know that's, that's, the thing what they are calling and saying.....

F2: NHS 24 probably have told them to go to the pharmacy and get something from e-MAS. M1:I have worked I have worked on the couple of occasions on the, on the, outlines of the NHS 24 lines in each of the three (smiles from everybody) as an adviser, I walked the floor of each of the NHS 24 centres and never heard actually anybody say, go to, go to pharmacy and ask for advice and see if he could help.....

F2: These people come in and say they are told to get such and such but that means, I mean....

M1: Well, I mean as I see, nobody ever says that but.., em...., what people come in and say to you is that, somebody saying, somebody actually saying, may be, may be two different things and that, as I said, they're quite good at referring and, and what they do, problem is for right supply as they don't think NHS 24 knows what ... emergency supply prescriptions and that their definitions might not be the same So, em.....

C: So, are there any support you would like to see in relation to e-MAS in the future? Anything, any support information related?

F2: Clarification to the doctors that they see patients they prescribe and not send them over to the pharmacy.

M1: particular problems with products we can only sell them on specific situation. Say, hydrocortisone, for, not for a face relief, for example. Doctors send them down leaving, Hydrocortisone can either be prescribed by us or sold by us under the same term as we can. We kind of find that quite difficult, it's quite difficult to refuse as well to be honest.

M2: Also be nice if the formulary let us do just generic (agreed by others), dispensing, that would be nice.

F1: yes, that would be, that would be a big help actually. Generic dispensing for the minor ailments formulary, yeah..

M1: But also I mean, how do we feed in, can we feed into the, the government bodies for what we would like to see in formulary.

F1: Yes, that's why they are doing that.

C: How would generic prescribing through e-MAS would help you?

M1: No, no, I am saying the, what I think OK, got Chloramphenicol or Fucithalmic can we prescribe that? How, who do we I take that to, to as a suggestion? Definitely, expand the formulary. Yes, I think, hold on well this would be useful, I would, just, just on top of my head but...

M2: something to expand the formulary

F1: more PGDs to use POMs

M1: But yeh, how, belong to, its, its national?

F2: Because it's a local formulary, a local group working on a formulary in ***(Name of a place) because we have new formulary coming out.

M1: But its now gone national, so I mean, is there any way we should be sort of saying to national

F2: I mean why do we have the national formulary and the local formulary, can we not just have one?

M1: Ya, interesting, when you say information feedback, information service division Scotland, so we are actually talking Scotland. Here its now Scottish system and but, why do we need local formularies (agreed by others) and why then, say, how dare do you get hold of people to say, we think this should be in the formulary now. Its, the formulary is out of date. There are things we don't agree with..., the things being there under...,things with..., I'm not saying that's a

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wholesale thing, we want to make wholesale changes to the formulary but formulary is designed as products on the market, now when, the products is being released.....now.....

F1: There's a lot of products that are available an allowed on e-MAS that are not in the formulary (agreed by M1). In fact, I don't pay even much attention to the formulary any more. If it just says its allowed, then do it and I...

M1: So they go to your pharmacy and they come to mine, say...,my my husband got from *****'s and ...

F1: I found the formulary quite restricting, cause the things that I recommend fairly regularly weren't in the formulary. So, how do you get things put in the formulary or makes the formulary much bigger and better and then, and then ban everything else.... (smiles) M1: Oh, just haven't I thought really is, that's, its be

(Loss of transcripts as people speaking on top of each other).

C: Ok, lets get into another area of information supp, support related to e-MAS. As we know this is electronically managed, managed system, every performance relating to e-MAS is recorded in Edinburgh. So its possible to give you feedback relating to how e-MAs is performing in your shop and how products are being dispensed. Are there any areas where you'd like to see those data feedback given back to you in the future relating to e-MAs?

F1: This is like the SPA data, the doctors get back from the prescribing, is that right? So you wondering if we're interested in getting the information like how much it has cost or things like that?

C: Any, any information you can think of.

F2: Do not get at least in a month or we used to get least in a month what the cost was...of the things what we supplied, what cost was in a month. I don't know... from prescription pricing.....

M3: may be because you were one of the pilots (smiles).

F2: No,

F1: How many things you prescribed that , how may times you prescribed ? (this participant asking question to F2 to make sure)

F2: I told you a list of everything what we are prescribing. What the total cost, I mean, the total cost of as paid is (loss of data) 100 pounds or something like that.

F1: Its interesting because its just not a lot of money.

F2: We used to get that but I don't think we get it now.

C: Yes, can you think of any areas you would like, you think would be helpful to look at the picture of how e-MAS is performing?

F1: Total number of items we've dispensed, I suppose I can count the labels, but it'd be interesting to get back, what, what we've done previous months.

F2: ...What we are prescribing.... Just what we've actually prescribed in preceding months, and what was..., may be, may be more feedback (Loss of data)

M1: If it would be just by BNF groupings, perhaps, I wouldn't say every single line but as I said, X number of histamines or X analgesics,

F2: And may be a trend overall what's been prescribed, would that be helpful? From all, all the pharmacies in ***(Name of a place)s, in different lines, I don't knowing,

F1: They are collecting that already I would think, for what we've prescribed , from somebody, some place and why is

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F2: It would make nice, to see how we compare to other people,

F1: Ah, business, that's private,

F2: I know, not individually, I mean as a comparison to ***(Name of a place), all the......

F1: And then you'll see how the head lice are fleeing at the door, because the e-MASes....

C: Interesting, why would you like to see, compare with other people, how does that help your practice or decision making?

F2: I just like to be nosy and (laugh from everbody). Know whats happening in the world. Well, may be I'm quite insular when they gave me some restricted formulary and we all might think oh, thought using that particular product and information (by M2), yes 'cause I do restrict the availability of the limited number of products.

C: So, looking into what peers are doing (yes by F1 and F2), does that help you making future decision making? *****,

M3: May be interesting in public health capacity, to see if there any particular spikes in any particular areas of geographical region, any problems and..... To me, to me as a pharmacist, dealing with what's coming in your door at that particular time, so it may be more strategic level interesting. But just from, perhaps to see, may be open eyes a little, (smiles), to look at other options, perhaps, wonder why there's, I'm prescribing so much of a particular item.

Ya, may be useful, especially, evidence based changes perhaps allowed.

M1: It'd be interesting to know if its, if it's saving any money. Because the whole idea was to save doctor's surgery time. Has it actually happened? Has the waiting time decreased, to be seen by doctors, has gone down, for, for minor ailments? And if it has and is saving money, and I'm not saying this because I am one from multiple but are we going to more loaded onto us simply to save doctor's and it's unfair its working at the moment.

F1: It's not fair, no, no. You know, they pay for the dispensing fees and they pay for the cost of the drugs and the number of people on your list.

F2: Not, certainly not, both the number of patients that is following, because a lot of these people has been in my list since day one are now off the list... The, the initial people in my list have been on it for seven years. A lot of them, some of them have moved away, no longer around but they are certainly not paying or not using the service and ...

M2: But then you have got loads of them every second day and you give something on the minor ailments and you're getting paid for the cost of the drugs and not for the hassles it is causing.

M1: But that's what I was coming to..... really, if, if I'm doing doctor's role he is getting paid. That's why I see in... once a month or once in ten years (agreed by other participants), its, its, still, its better for the patient to be honest and I don't see why someone who registered and haven't moved to, to somewhere else which is fair enough to go to another doctors, re-register and then ...? Can't stay on and then, by the time, I'm still available to write prescription for that patient. And then I've to re-register them if they disappeared if there's, well, renew their registration.

F2: If you are talking about registration with e-pharmacy, then, just, in general, you go to that pharmacy for everything you do at the doctor's.

M1: And that, may get this with the chronic, chronic medications being computerized (agreed by F1).

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F2: As I just said, people who are registered with me, they may get prescription with you. But that, they don't realize that they can take their e-MAS to..., stop coming to me for their e-MAS, things like that.

M1: They change it round, change it round (smiles from everybody), somebody's rota but somebody re-registered with me simply because I was the only one..., on the Sunday rota. You've got to keep coming to me-you can't keep jumping backwards and forwards.

F2: you can't.

C: Are there any trends of data you'd like to see relating to product supply in specific?

F1: Specific to your individual....business?

C: yes, individual... business, your practice, your pharmacy or you as a pharmacist?

M1: I'm quite happy, that sort of...... measures the number which we are in much control of and...to be honest.

M3: I'll be little bit worried about, one, one angle of, of, of having this. Now working for multiple..., this may or may not happen but if..., put on e-MAS further up the chain, so, well you, you have to achieve X numbers products, products in this category you supply in given period of time. Why you are not doing 'cause there are so many folk registered, you're, you're below, below the national average or something like that.

F1:Head office using the information of the individual pharmacists for their prescribing. The information that we get back from what we are prescribing would be used by some head office some place, rather than each individual pharmacist who is doing it. Somebody else looking at it may be thinking, as you said, oh, it looks so many people registered...? so many scraps. 'Cause (smiles)

C: If that information be provided to you in confidence, would, would that be better rather than your company or boss, say...?

F1: It could be actually, 'cause you get locums or relief, because they should sign on the minor ailments, you have to put registration under it, so doesn't matter which branch or whatever you are, may be collate that for each individual person so you can see what you've been prescribing. But you already know what you have been prescribing, so...,

M1: I don't think that's of any benefit (agreed by F1) because if you are prescribing ethically, anyway, then the price shouldn't be an issue. The number of items shouldn't either be, and I'm prescribing something because its necessary not...

F1: a list of disallowed items, 'cause when I get the old ones back, and when I came in the shop and when I see its coming back but a locum or a relief person say what they'll do wouldn't see that

M3: That, that'd be interesting.

F2: community pharmacy, not just something ...

M3: there seems to be a little bit...

(Overlapped conversation)

F2: I'm sure its not the only...

C: Mr *****, you own the shop and are there any business, may be data of any business interests you would like to see, e-MAS performance from you shop?

M2: Because, I am just a sale trader, I would like to see what the, analysis of, for example, the group is, the area, ***(Name of a place), and then, see mine, little bit (smiles), as that, oh, is that what... oh...just what you said ...perhaps, I am actually more closely, this allergy question, because there's so much of that being prescribed over the whole area, what am I doing wrong? or am I right. Or I may come to the conclusion we haven't got this particular problems, so am I

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doing anything wrong? It would be nice to, to, to see region wide analysis and that of specific shop analysis and the two could be laid, literally one on top of the other. Gives you some clues (agreed by one of the female participants which seems to change her position).

M3: We could even see, em.., if there's a new pharmacy, for, say, the staffs weren't automatically picking up, this should be an e-MAS referral rather than, turning straight to the counter...

M2: But unfortunately, have colleagues here...but.., problem of head office (This participant is from independent pharmacy), may be, em..., misuse this information (agreed by one female participant). Therefore have to specifically addressed to the pharmacist, so they don't go to the head office, only to the Practioner.

C: Right, Will it be interesting to see such data, I mean when changes happen, for example when you think that Simvastatin is not doing well in my shop. Would you like to see what others are doing?

M2: Yes,

C: Are there any individual products you can think of, getting feedback in the future about how is it performing in your shop relating to any specific product supply?

M2: Well, just of interest, if you're saying that, that, to expand the thing, I would like to see what happens generally region wide to, em..., UTI products. Trimethoprim (called by F1), Exactly, this is what I was trying to get out.

C: So, I've some data from e-MAS generated recently, not very recently but last year (smiles from participants) from e-MAS warehouse which will be hopefully, be given back to you in the near future. I'll show you some slides and graphs and we can discuss further things about what might be interesting to look at or get information feedback in the future.

***(Note taker), would you like to ask anything in the mean time I log on this computer?

N: Not really, I'd like to make comment on something we spoke about earlier. Em..just, 'cause had a situation recently which happened to a doctor, who went to GP and was told she had a psoriasis and told she should go to her pharmacy and ask for hydrocortisone because you work in a pharmacy and I, I said, is that the best thing to do? And he said, well, if you go in and tell her, tell them, its for your doctor who has got which is for psoriasis, they wont give it to you and I thought that was really interesting because for me, that just highlighted a lack of communication, not well acknowledged from GP but also the lack of communications between the two disciplines.

F1: The GPs don't realise that we're restricted to the license whereas they can prescribe whatever they want.

C: So these are few of the slides from e-MAS. Can you see *****, Yes? Em, this is the number of patients registered during this period, July 2006 to June 2007 from e-MAS. So each bar actually represents different health boards. So as we're saying earlier, ***(Name of a place) is T,

F1: This is percentage of the population, is this not?

C: Ya, percentage of the population eligible to register e-MAS.

F2: Ayrshire and Arran has got a bigger population than ***(Name of a place), it is

M1: They were on the test as well, so there..... Percentage of the population.

F2: I think, it's morehighly populated.

M3: The pharmacies are bigger, greater coverage, 'cause the Arbraoth and Forfar?

F1: So, the number of patients registered for e-MAS in Scotland and then registrations, what's?...

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(This shows difficulty of interpreting the graphs as designed, multiple questions about the first graph)

M1: As a percentage, F1: Percentage of what? C: Eligible, eligible patients.

F1: So, the number of the eligible, patients, there's only, in the best, there's only quarter of them who are actually registered. There's a lot of people out there where they don't have a..... Yes, that's interesting to the government and the health board, but that's not interesting to the individual community pharmacist. (This participant is talking about the slide showing number of people registered on e-MAS).

F2: It is really, 'because you can register a few more. (Conflict between the participants) M1: only thing, is of course is......

F1: The health boards only have to...Its up to them 'cause they don't like to advertise..
F2: Ya...but there's some concern and you know that eligible to join, you could may be

F1: Well, I still think that the health boards are the ones that should be really interested in these figures but not individuals... . These figures are not on individual basis. (expressed views before second slide was shown).

(Loss of transcript due to too many speaking at a time)

M1: But its also, I mean, since it is only two people that are entitled to free prescription, so, then its not a true....., 'cause obviously the richer areas of the country, the poorer areas of the country, obviously, em... people pay for their prescriptions and they cant register for e-MAS. So, therefore, I don't understand...

F1: That's the percentage of eligible population. So....

M1: Number of patients registered, is it?

F1: Number of, percentage of eligible people.

M1: So, registration, sorry I am just taking it as a, sorry is its only the people who don't pay for the prescription or...? (Agreed by the moderator). So, that's the fact that there is no skewing because of it.

C: so, would you to, this to be broken down into individual pharmacies, further? When each bar would represent....?

F1: No, that's very sensitive. If you get that, that's very sensitive if you break it down into individual pharmacies and show it to everybody...

F2: I don't think they could do it for individual pharmacy, cause you will know....

F1: They can do it..they can get the statistics and do it but is it the right thing to get out to everybody? That's quite sensitive information when you...

F2: But then, when you have how many eligible patients, in ***(Name of a place) to join e-MAS because some will go to *****'s, some will come to me, some will go to the other pharmacies, and we have other people who don't get prescriptions at all.

F1: But you're gonna way to show the number of eligible people registered at each pharmacy? C: No, not, I don't have that, it will be there if you ask for, so.....

M3: If you, if you're to receive to your pharmacy solely, the number of patients registered compared to the mean...

F1: Ya, that would be all right.

F2: the number of people that were registered against the number of "could be registered" per pharmacy

M3: But, that would just be a sniff of information, but it wouldn't, it wouldn't be for practical use other than say, oh right, I'm doing right, I'm doing badly. You'd, probably be, just to see, whether or not, although the mean is well, you're above the mean, you're still miles off for what

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you should really be for, in terms of national. It might, ya, suppose... I don't , I don't know the depth of.....

C: So, this is the total number of items dispensed during that period in Scotland, this is the pooled data for Scotland. And, this is the top ten items dispensed through e-MAS during that period. So, are these, these sort of data interesting to see, to compare whether your shop...? M2: Yes, interesting

F1: ya, this one is particularly interesting

(Laugh from M3)

I mean you could tell them that what's your most popular items, paracetamol, ibuprofen, head lice treatment, we already know that, we know what we are prescribing. Its interesting, but its not something I would need to look at. You're trying to cut down...

M1: If you ask me is that right then top ten, I would have got most of it.....

M3: That, that'd would be something, em..almost..... annual basis, that'd would be nice to see....I don't, I don't need to be informed up to date . Your practice, don't think changes dramatically over short space of time.

F1: Yes, probably once a year or something.

C: And this is the gross ingredient cost of the items

F1: No interest at all, not bothered. (this is about the GIC graph) Smiles from other participants.

C: So, this is again comparing each health board with Scottish average, the items dispensed per thousand MAS registrations.

F1: That's interesting, isn't it, ***(Name of a place), wherealong there.. (Silence)

M1: going over the average, you know, is that the average, dotted..?

C: Yes, the dotted is the Scottish average. This is the items dispensed per thousand MAS registrations.

F1: So, we all are doing the same amount of work.

(Participants analysing the graphs keenly)

C: If instead, this, your shop's data is compared with the Scottish average, how that data be useful to you?

F2: Not very much,

M1: Not very much, the Scottish average, 'cause, 'cause, looking at some of the ones up there, can't understand why Border and Fife would be substantially less than ***(Name of a place) or em... Dumfries and Galloway, for example, it seems to...

M3: Going at a tangent but I remember, when it was rolled out in Fife, it was just a huge push to register and very little in terms of follow up. Now you're registered when going to do something, and don't know what the colleague, em...... is interested.... He has a , had a huge drop off because most people simply registered on the, in June, July something and then they thought...

M1: It seems to me, just looking there, why in certain parts of the country, they could do with a push (advertising by M3), advertising in December. So they can't really, don't, the actual, if they don't work in those parts of the country, it really wouldn't be

M3: It wouldn't be for any help.....

F1: So, the number of items dispensed per every thousand registrations, so that tells you sort of how much work you are doing, So its just sort of....

M3: how many active people you have

F1:That, that's because I was always thinking about Fife. They probably have thousands and thousands people registered but they probably are doing the same amount of work as us. But, because its per thousand, it shows you that they're low but they are not actually doing the same

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amount of work as us. But they have far more, far more, thousands people registered. (agreed by M3)

M3: That's true, ya,

M1: you know, in ***(Name of a place), the percentage..., the two spins back, then, em.. Fife... isn't it

(Participants trying to understand the slides, Laugh)

(Laughter from all participants)

F1: These things are all interesting, ya.

M1: Ayrshire and Arran and ***(Name of a place) is one and two, isn't it?, in terms of number of people registered. So, why is, why is ***(Name of a place)

M3: ..Quite large multiples....., thy might be quite interested to see that.

F2: Because ***(Name of a place) have got quite restrictive

F1: These kinds of figures are interesting to health board, health board level.

M2: Other thing, and..,that, that, number of items per thousand registration, six hundred seems to be an awful lot

M3: Six hundred items per thousand registrations?

F1: Ya,

F2: That'smore than half of the registered, isn't it.....

C: So, in average, one patient was supplied with one product during this nine months which is

C: So, this is e-MAS data for an individual shop which we were discussing earlier. So, this is the number of items dispensed as per BNF chapters.

So, this shows the skin preparations, sorry..

F1: Oh yes, chapter in BNF

C: yes,

F1: Right, and the different colours are ...

C: Ya, the top colour, the top number of items dispensed in this chart is skin preparations, I think. So, this sort of data can be possibly generated from your shop and given back to you. (Long silence)

So will this be something helpful or alerting or useful in any way?

M3: Well, the only two ways you could see that it should be for over a long period of time to see a trend. So, perhaps over a short period of time, ... formats of the ...? target to, to increase your, your work effort into promoting your,thinking about head lice or something similar, that would be a big push towards.... Promoting antihistamine use, trying to think some drugs...., and then, then quantify how much that effort was rewarded with how many prescriptions you received, getting close to business targets. Money... ya, you could, you could review your performance, you could review your individual pharmacy's performance how it is done but...

F1: So, they've got ear at the bottom, is that ear and they have put the number of items dispensed in whichever part of BNF and so that.... I don't know which one is which (shows difficult in interpreting the data as is shown in the slides F1 discussing with M1).

M1: I think, in terms of estimating work load might be useful, in terms of negotiating with my boss to say I need more staff to ... (Smile from all participants). I've actually got evidence here, how much the work load of e-MAS is. In terms of actually anything else, its probably store of items what I would hope I would know anyway (agreed by F1). Em...again, see, looking at it.....

F1: Things like that might be useful for the health board if they, kind of ..., public health campaign on, such and such..., if there were something we could do on minor ailments to help that public health..., then they could then look at that and see for individual groups but... for individual pharmacist, I don't see, not much interesting (smiles).

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M1: And again as I said, we want to prove how much we are saving the country's money by doing this, instead of going to the doctors'. That sort of data is interesting.

F1: how much you saved on an individual GP's cost by seeing so many of their patients, cause they're registered at that practice.

F2: How many patients that come in to see us would actually have gone to GP in the first place and how many still we've got in each....

M1: That's, that's an interesting question. Do we have the data to say how many head lice they've got in a surgery? Cause, that, that sort of converse data you've got there, are we writing new scripts or are we writing scripts that the doctors or practice nurses would have been responsible for writing. Therefore we are saving the country money, because we're doing it cheaper than the cost of a doctor. Doctor's consultation been cheaper than our time....

F1: Why we're doing it cheaper? Because we are mugs.

C: So, means linking GP data with e-MAS?

M1: Yes trying to tie the two up, because in isolation, it doesn't mean actually anything, I don't think.

M3: I'm sure, it would be perfect either way 'because we, we will have some new patients which have never gone to the GP practice for that condition before and.... So,

M1: yes, or he couldn't, he couldn't do, couldn't get an appointment for that...

M3: yes, it could be.

M1: This information might be useful to the people who negotiate the contracts for..., the chemists contractors bodies because it can prove, the, the workload that has been, we're taking on, as I said, the doctors used to take them. And, what we should be paid for it. As, on an individual basis, probably I wouldn't say, not to me personally,

F2: Ya, probably interesting, but I don't think it'll be of much use.

F1: Exactly, interesting but not of much use.

M1: I mean, I don't mind being sort of more available on the......, I don't mind you know what I am doing, quite well censored (smiles quite happy to send a few more troubles someone around you. (Smiles). But, em..., I, I don't think it'll be much, unless you going to change the practice by having the data available, as I see, that would change

F1: I mean, GPs have a lot information they get feedback from prescriptions but they then have targets to reach so many seventy year, seventy years olds with whatever conditions to protect them from heart problems and in the long term it's saving NHS loads of money, hospital beds and whatever. You know minor ailments, the little irritating things, nothing as big as the low cost things. And I think, really the most I would be interested in it is, how much times are we saving the GPs in a particular practice, we are saving a lot more time for the anothers, who we're helping the best to make my time valuable because we're getting paid c**p for it basically (smiles).

And I think, that, that would be more interesting to me to find about the GP practice who we are working better with, which of their patients...

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M1:.....what ***** said comes to me as a pharmacist, fine I can choose to read it or, or, not read it or pick the buttons out of what I want to read. I wouldn't want to go into the management of the company who would then be comparing me with next branch, branch of.. I don't, I don't mind being compared to colleagues who is in the same street. But, I don't want to be compared, I don't want to be compared to Montrose or Forfar where, two totally different communities but they could be the next branches I'd probably be compared to. Forfar doing this or, em.... or they might be compared to me if I was better than that. I don't think that's a, a fair comparison to make. But that'd be either......

F2: ...they could judge you based on how good you are on those figures. You are prescribing for what you have need to prescribe for whereas somebody else might be prescribing, you know, because they want to get the figures up or something. Whereas, you are prescribing professionally and...I think you've got your professional conscience you're prescribing, what you should be prescribing, you're doing it appropriately, you know just to see the Joe Bloggs up the road just given any old drugs somebody comes in and asks for (agreed by other participants).

F1: They come with shopping list and ...

M1: even, even within the same company, (F2:you cant compare, I don't think) but I mean, ah.., as I said, you're trying to ... the bosses ... (Smiles)

(Loss of transcripts due to too many speaking at a time)

C: So, are there any interesting things in terms of patient outcomes, for example whether your advice or referral did work, were the diagnosis same from the GPs, linking.... (The moderator actually meant to ask do you want to see these sorts of data but its articulated it in the way are there any currently? my mistake)

M1: Are there any of that.

F1: Very rarely...

F2: I think, occasionally, somebody come back and say- that product you sold me is so good (smiles)

F1: that stuff you gave me on e-MAS really worked for me.....what was that? Can you remember?

(Loss of data as many participants speaking at a time)

M2: The product... this morning, no they said they were c***p...(Laughs)

M3: Suppose, we might have some benefit, you may, may see more with..., single pharmacist, single GP practice, one small town without any influence from pharmacies, fifteen, twenty miles away...

F1: Twenty different, yeah...health centres

M3: Yeah, but if you're in a centre of the town, very difficult to ..., because if they, even if they had a prescription,..., the only way, normally you can check is either by sheer luck by the patient coming back to prescription or perhaps telling you, they, they go somewhere else, you see....

M1: The only feedback you get is very good or very bad. (Agreed by all participants)

F1: That's right, yes.

F1: if there is something allergic reaction, they come back and tell you and if it wont when the previous, the doctor previously hadn't prescribed, that hadn't worked, they come back and ,oh, it's a..., my experience since..., only...

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M3: There would be benefit having a means of the GP seeing what you have done, em, with the piece of paper or with, with, sorts of access to an electronic records to see, to see what the pharmacist has prescribed already, the two connect....

M2: That would be great idea, that's what you were saying about..., having access to records....

M1: Two way access, yeah..., they need to know what we are, we're doing just now as.....

F1: That'd soon be ...? with e-MAS. Patient will go out into the same day and then appear at doctor's surgery what we've been doing.

F2: You think so?

F1: Oh, big brother is watching us (Laughs)

(Loss of transcript due to too many people speaking at a time)

C: So, yeah, this is the data from the same shop, em, the individual preparations broken down for individual preparations. No we can see the anti-infective items have shown the most....., in these four quarters.

So, these sorts of data GPs are getting, more used to of it, I mean...,to encourage generic prescribing as well as to see whether they are sticking to guidelines. And also when changes happen in guidelines or legislations and things.

So, for example, this is a compliance, percentage compliance, graph, bar graph of GPs. This is a threshold, so we can see some GP contractors are yet to achieve the target while some of them are well beyond the target. So, I mean, each bar represents different GP contractors.

So, what do you think, in which forms would you like these data, if to be provided to you would be most beneficial or most easier to interpret and

M3: That, that would be useful.

F2: Well, that's right, to find out what we've been prescribing...,

(Well the participants change their views here after being shown that the GPs are utilizing these data a lot, before they were saying we know what we prescribe)

F1: We don't stick to the formulary because the, the national formulary, is different from the local one. (Agreed by M3). So, compliance with the national formulary is what we'll get back I would think.

M3: Oh yeah, absolutely, exactly, its not, its not standardized enough...

F1: I mean did we, did we make the formulary bigger and scrap everything else and just allow the things on this formulary, allowed in the minor ailments, which, I think is a great idea because it would restrict a whole lot of things but as it stands just now with all these P and GSLs...

F2: I think... the... national formulary which is, more usable and, and everybody used the same formulary.

F1: But, then, that could be quite interesting. But then, you wouldn't be not allowed to do it with formulary because you're only to prescribe the things on the list...

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C: Physically, what way would you like these information to be provided to you, electronically, paper or in training, as a training material or CPD material?

F1: Four of us here will say paper and one will say computer (Laugh from other participants). This is the age gap...

M3: Its very very easy to press delete, and specially if great deal of electronic information afterwards... going over the bins....

F1: They're trying to get away from the paper. I've had a argument at other meetings and they're trying to get away from the paper based, electronics is the way is the way to go, we should be going into electronic messages and checking on your, on your e-MAS on your, your computers, checking you registrations, may be go in and check some kind of statistics...that are..Its just going to be, if it just would be some kind of annual thing that you know analysis and it ...I'm not interested in monthly, just looking it too frequently, but may be once a year or once every six months. A paper thing coming through, then, then I would open it and you could take it home, you never look at it. Its just a time, time consuming, you want to analyse these type of things, you need time to look at

M1: No, I would, I would go for computers. See, I wouldn't

F1: I wouldn't think you were a computer man

M1: Oh yes, yes, its just....I could just press the start button and scroll the mouse

(Loss of transcription due to too many people speaking at a time)

M1: (talks about NHS.net) So, I mean, the IT has got to travel on a pace

(Loss of transcript due to too many people speaking at a time)

F2: I was just wondering how electronic transfer of prescriptions, obviously you can do that....

M1: And, and, and, and.., yes, I've got, because I was a prescriber, I have actually at home NHS net. So, actually I can use from a home PC, NHS net address. But I cant, I can't use it at work.

C: So, would graphs be more helpful or texts, numbers?

M1: I think bar charts or graphs (Agreed by all)

story in your mind. I think its got to be graphical.

M3: Yes

F1: yes, visual

C: I mean, in real situation, when you are in shop, would you have time to interpret all these data and you know, look at it? What would be the best way to deliver it, so that you ...

M2: As, for the graphs ... good... axis is, no, its not difficult to, understand but fundamentally, if its graphically produced. Whereas if it is text, I don't think.....,when you read it again, different

M1: I think, its got to be graphical

M3: But the head lice stuff, she really want to know more. I'm sure if they wanted to produce graph, they could, information services, then produce ... raw data

M1: Cutting back on computer if you like to...

C: Yeah, one last question, we are nearly end of the discussion. How do you perceive change in general em..., in your practice?

M1: Right, Ok the, with, sorry I'll go first. Em..., I think the difficulty, may be in the future is the services have been cut, funds are going out much more localized. So its been costed locally. So, ***(Name of a place) health board is getting ...ah, a pool of money. Some of that is going to Angus, some of that is going to ***(Name of a place) and Kinross, some of that is going to ***(Name of a place). Within those areas, even the same schemes that are coming out or not coming out identical myself as a pharmacist to travel across borders, I can dispense, I've got, don't know if you gave up baby scheme, its different in Angus from what is it in ***(Name of a place). And in Angus, the ID you require is different from ***(Name of a place). In ***(Name of a

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place) you need Scottish, or a ***(Name of a place) local ID card. In Angus, you just need photographic proof. And I can supply the morning after pills, in anywhere in Angus, because done the training scheme that covers Angus, but can't in Fife because you have to be, registered, you've done the fife training which is, there are slightly different age groups so, whether its free or not to supply to children under the age of 16 is different. And I've got a concern that people start moving, may working on Grampian on Saturday and they go working in Fife next month. Just, just odd day here and there, (F1:you got to sign all these PGDs) but I can't, I can't, I can't possibly be signed to all these different PGDs and always very good that local means of being addressed of, specific example Chlamydia testing because ***(Name of a place) has particularly problem of teenage pregnancies and it's, it's an issue. But the, the funds available locally for them to decide how to spend it but it does make it quite difficult for us if we got local formularies all over the place and if Angus is doing one thing and even within ***(Name of a place) we've got three different CHPs doing three totally different, em..., things. So, em..., I've concerns about sort of going from (C: one place to...), well, again, even within Britain now, we have the English doing MURs, Scotland doesn't. We've got minor ailments and urgent supply PGDs, they don't, we are charging five pounds they are charging £7.10 or the exemption rates, may be good, may be not but it doesn't mean that we're having pharmacists who move across areas totally, it may be minor differences between areas and countries in the past. There is now scope from massive differences between as to what we can supply what we can't, how you supply, will we be paid for it?

C: *****, how do you perceive change in general, do you welcome or....?

F1: Oh yeah, I welcome change in general if its gonna be advantageous for us. I don't like these excess paper working things. At the moment, we have this smoking cessation programme and has gone on to the computer and I don't know if you guys have got loaded on your computer? Now the people in NHS ***(Name of a place) can log you in into, em..., even open clinics, just people just can come in and book people into it. I don't like extra paperwor... why does I have to book in for sometime. In some clinics, some ...which to me is just a pain in the b*** and excess computer garbage for me to look at ... thing and that

We can go into say have had a heart attack in ***(Name of a place) smoking cessation programmes up in your area, where do you live, you know... you know, every Thursday. And they done it and I don't even go and look at it personally. So the things change is good if there's an advantage but change sometimes is just extra paper work for statistics and such things like that.

C: Mr *****,

M2:For, to, the, em..., list of products been expanded we can use on e-MAS. What from my... has been good and switch from POM to have been adequate but Trimethoprim, I 'm really looking forward to, a lot and ya, I think, its and its going to get better. C: *****,

F2: Em...., well quite like change but I sometimes feel that, feel that, actually a lot of different things is happening in different areas and particularly, these locums are coming out and you're not sure who is signed up for what and which, what each person can do. And I think, sometimes people don't realize what they can do and what they can't do and do their own things sometimes.... And I'm quite for change, but I do find that there's lot happening, its quite fast and furious and I think in a busy working day when you're, you're particularly busy, you don't always have time to absorb it. In that day, at the moment, right I'll need to do, what's the things then,.... So there's a lot happening that, we, we've to understand and put into practice for the staffs to make sure that they're all understanding what's happening. So, I think all these things are done in our own time when you are very busy.

F1: Please don't choose the minor ailments service for quite a wee while, acute medication, the electronic thing, the

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M3: Right, yeah, ...generally change, I am quite happy to, it's the, it doesn't, it doesn't upset me too much. Occasionally found, especially when there is excess bureaucracy or this, em..., or agreed to put it in a great deal of work trying to achieve the minimum amount of work required to meet the change. And, when I feel, does ... sometimes doing embarrassing trying to tackle something.....,but I don't... I do like inform ... NHS, that I have achieved this and that I shall send the performa ... At at least appreciate the targets to enforce..., got to get this done by certain point.... em..,and tick, that's done, but probably wont be quite. I will get round to it eventually. I do need to prodding with a stick from time to time to

But its all coordinated through NHS Scotland or so, ... it has to be done and that's the only people that are going to annoy you about change and

M1: Perhaps, so it could be, em.., super pharmacies, not super-pharmacies, who do every single, not the ...super-pharmacies as we are here just now, em..., I'm thinking about the pharmacies that will have walk in clinics, the big pharmacies have got walk in clinics, neo-vaccinations (agreed by F1), they've been doing EHC, Chlamydia testing, they've been ...? Some in the middle are doing bit ..., somebody in there are purely, simply dispensing. F1: and I believe that we're tryin' introduce some kind of enhanced Methadone service as well, so, like the community pharmacies..., I mean the key workers, there is a lot.....,

M1: so, is there a source that we have to take on of these changes things? Honestly, honestly, the single pharmacist, without the complete ... prescribing, vaccination,

(Loss of data due to too may people speaking at a time)

F2: I struggled with one pharmacist... I'm on own

M1: And that's not including those that are doing nursing home, MDS or compliances dispensing, so

(Participants laughing, Loss of transcripts due to too many people talking at a time) C: Ok, we're into 90 minutes. Thank you very much for the discussion and I would like to turn off the recorder now.

(Participants in good mood, still amusing among themselves).

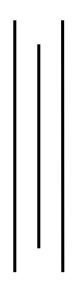
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APPENDIX IV (CHAPTER 4)

Systematic review protocol

Robert Gordon University: Aberdeen Faculty of Health and Social Care School of Pharmacy and Life Sciences

Exploring community pharmacists' decision-making relating to new non-prescription medicines



SYSTEMATIC REVIEW PROTOCOL

Research Student:

Vibhu Paudyal BPharm, MSc, PG Cert (Research Methods)

Supervisors:

Dr Derek Stewart, Dr Denise Hansford, Dr Scott Cunningham and Prof. Dennis Tourish

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Title Exploring community pharmacists' decision-making relating to new nonprescription medicines **Background** Community pharmacies are among the key providers of health care services to members of the general public. In the UK, new community pharmacy services are being introduced alongside revised contractual frameworks. New non-prescription medicine services, which constitute a large proportion of these changes, are aimed at increasing the role of the community pharmacist in patient care, encouraging self care and hence potentially reducing general practitioner (GP) waiting times (1-3). The ongoing reclassification of prescription only medicines (POM) to pharmacy (P) medicines is one of such initiatives (4-5) taking place in Scotland. Reclassification of medicines is an ongoing process and allows customers to buy reclassified medicines in a community pharmacy under the direction of a pharmacist, without the need of a prescription. One of the fundamental, and perhaps obvious, minimum requirements for these services is that they are adopted into practice by community pharmacists. Such adoption decisions are not always straightforward and may require learning new behaviours and new ways of working. Pharmacists' adoption decisions relating to new services have, to date, been given little attention by researchers. In particular there is a lack of studies on newly reclassified medicines. Research on adoption decisions in health care in general is dominated by studies focusing on the medical profession. Of note is the emphasis on the facilitated diffusion of the emergent evidence base into standard medical practice (6-8). It is important that a similar evidence based focus is given to community pharmacy related developments. There is a need to facilitate community pharmacy practice change by identifying key elements that influence the adoption decisions at individual practitioner level. An initial review of the pharmacy-based literature, carried out by the researcher, has demonstrated that there is a dearth of publications and hence research in this area. Of the few published literature reviews relating to practice change, the focus has largely been on organizational implementation issues. In addition, some reviews have focused on a wide range of pharmacy related services, on subjects such as challenges encountered when implementing 'extended services', 'cognitive services' and 'new services' in community pharmacy (9-11). It would appear that there are several reasons for carrying out a systematic review of the pharmacy based literature: few studies on different elements of practice change; lack of a standard methodological approach; the constant stream of innovations, reclassified medicines and services. It is key that we understand fully this adoption decision process. In addition, focus on individual practitioner issues is also justified, given the centrally important role of their involvement in delivering new services and associated roles in preparing the organization in doing so. It is therefore particularly relevant at the outset to systematically review the published literature in this field of community pharmacy practice.

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methodology for the systematic review.

The remainder of this protocol describes the specific objectives and proposed

Ohiastinas	2. To provide and onitions the mostle delegies mostle de and models to
Objectives	3. To review and critique the methodologies, methods and models to investigate factors associated with community pharmacists' decision
	making around reclassified medicines described in peer reviewed
	published literature.
	4. To enlist and describe the importance of facilitators/barriers
	identified from the peer reviewed published literature to community
Inclusion	pharmacists' decision making around reclassified medicines.
criteria	Study population, sites
criteria	No set criteria of study sites.
	Study design
	No set criteria for type of studies. For illustration, both qualitative and
	quantitative including interventions and mixed methods will be
	considered.
	Reviews and systematic reviews of studies
	Reviews and systematic reviews of studies
	Language
	English
	Date limit
	1990 to date
Exclusion	Literature based only on conceptual models/basis, i.e without
criteria	empirical evidence will be excluded.
	Studies based on patient or GP perspective of new services will be
	excluded.
	Studies focusing only on extended service delivery with no particular
	relevance to non-prescription medicine services will be excluded.
Databases	PsychINFO
Databases	MEDLINE
	• CINAHL
	EMBASE
	• IPA
	Cochrane library
Other	Business source premier NHCC
Other literature	NHS Scotland community pharmacy e-library search fields
search tools	Conference abstracts (International social pharmacy workshop,
search tools	International Pharmaceutical federation FIP congress and manual
	search for BPC abstracts, Health Services Research and Pharmacy
	Practice conference (published in International Journal of Pharmacy
	Practice), European Society of Community Pharmacy (ESCP), United
	Kingdom Clinical Pharmacy (UKCPA, published in Pharmacy World
	and Science)
	Bibliography of identified literature
T 1 . 1 . 1	Google and Google Scholar
Journal titles	International Journal of Pharmacy Practice
for manual	Pharmacy World and Science The state of the state o
searching	Family Practice
	BMC Family Practice
	Annals of Pharmacotherapy
	Journal of Clinical Pharmacy and Therapeutics
	Journal of Social and Administrative Pharmacy
	American Journal of Health Systems Pharmacy

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0 1 .	
Search terms	Reclassified medicine
(To be used with	Non prescription medicine
appropriate wild card and	Over the Counter (OTC) medicine
truncation)	Minor ailment
	Self medication
	Pharmacy
	Pharmacist
	Self care
	Practice change
	Service adoption
	Service implementation
	Factor
	Decision
	Decision making
	Barrier
	Facilitator
	Diffusion
	Pharmaceutical care
	Pharmacy practice
	Driver
	Extended service
	Change
	Change management
	Change agent
	Social network
	Champion
	Management
	Leader
	Leader
Search term	Combination 1
combinations	Compination 1
for scoping	Non-prescription medicine or over the counter medicine or minor ailment
search	or reclassified medicine or self care or self medication
	AND
	Pharmacy or pharmacist
	Combination 2
	Non-prescription medicine or over the counter medicine or minor ailment
	or reclassified medicine or self care or self medication
	AND
	Decision or decision making or adoption or implementation or change or
	practice change or innovation or diffusion
	Combination 3
	Non-prescription medicine or over the counter medicine or minor ailment or reclassified medicine or self care or self medication AND
	AND Barrier or facilitator or driver or motivator or factor
	Combination 4

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	Non-prescription medicine or over the counter medicine or minor ailment or reclassified medicine or self care or self medication AND	
	Leadership or management or social network or influence or champion or change agent	
	Combination 5	
	Extended service or practice change or change management	
	AND	
	Community pharmacist or community pharmacy	
Software to	Refworks	
manage		
references		
Quality assessment	Quality assessment forms have been developed appropriate for each research design likely to be encountered. However studies will not be excluded based on poor quality as eliciting the current methodological trend in the subject area is one of the set objectives.	
Study	This will be conducted in three stages	
selection	Initial screening of titles to be carried out against the inclusion criteria	
	to look for potentially relevant papers	
	Screening of full papers	
	Removing any duplicate publications of same studies	
Number of	Principal investigator (VP) to screen for titles and abstracts	
researchers	2. VP and DS (as a second reviewer) to screen full papers	
involved	3. Any conflicts to be resolved by discussion with SC, DS and DT	
Data	1. A detailed form to be developed	
extraction	2. Data extraction to be cross checked for reliability by second reviewer	
	(DS).	
	3. Any disagreements will be resolved by discussion with SC, DS and	
	DT.	
	4. If not resolved, the disagreement will be reported in the final review.	
Strategies to	None (due to time constrains)	
deal with		
missing data		
from		
published		
papers		
Data	It is difficult to anticipate strategies for data synthesis in the beginning due to	
synthesis	uncertainty of the potential data that will be retrieved. Depending on the data	
C1 1 1	that will be retrieved, it is most likely that syntheses could be narrative.	
Strategy for dissemination	PhD thesis, conference abstracts and a publication in peer reviewed journal	
of results		
	Any deviation from the set strategy will be well recorded after being a great	
Strategy to deal with any	Any deviation from the set strategy will be well recorded after being agreed	
amendments	by the research team.	
in the		
protocol		
during the		
process		
Potential	Policy makers, pharmacy practitioners and researchers	
audience	y	

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References to systematic review protocol

- (1) The NHS Plan: a plan for investment, a plan for reform. London: Department of Health; 2000.
- (2) Pharmacy in the future implementing the NHS plan. London: Department of Health; 2000.
- (3) The Right Medicine: A Strategy for Pharmaceutical Care in Scotland. Health Department Stationery Office; 2002.
- (4) A vision for pharmacy in the new NHS. London: Department of Health; 2003.
- (5) Scottish Executive. National Health Service (Scotland) ACT 1978 Health board additional pharmaceutical services (Minor Ailment Service) (Scotland) Directions. Edinburgh: Primary Care Division; 2007.
- (6) Denis JL, Hébert Y, Langley A, Lozeau D, Trottier LH. Explaining diffusion patterns for complex Health Care innovations. Health Care Management Review. 2002; 27(3):60.
- (7) Prosser H, Almond S, Walley T. Influences on GPs' decision to prescribe new drugs-the importance of who says what. Family Practice. 2003; 20(1):61-68.
- (8) Steffensen FH, Sorensen HT, Olesen F. Diffusion of new drugs in Danish general practice. Family Practice. 1999; 16(4):407-413.
- (9) Bond CM, Laing AW, Inch J, Grant A. Evolution and change in community pharmacy. Royal Pharmaceutical Society of Great Britain: London. 2003.
- (10) Roberts AS, Benrimoj S, Chen TF, Williams KA, Aslani P. Implementing cognitive services in community pharmacy: a review of facilitators used in practice change. International Journal of Pharmacy Practice. 2006; 14(3):163-170.
- (11) Roberts AS, Benrimoj SI, Chen TF, Williams KA, Aslani P. Implementing cognitive services in community pharmacy: A review of models and frameworks for change. International Journal of Pharmacy Practice. 2006; 14(2):105-113.

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Description of databases used for literature searching in systematic review

International Pharmaceutical Abstracts, PsychINFO, Ovid MEDLINE (R), CINAHL, EMBASE (as in Appendix I)

Business Source Premier (BSP)

This database contains literature from management and marketing journals and is a good source of evidence from business and management sources. This database claims to have an index of more than 2,300 journals dating back from 1886 (1).

Cochrane Library

The Cochrane Library contains intervention related literature. Searching this library provides functionality of accessing several databases simultaneously, which include Cochrane Database of Systematic Reviews (CDSR), Database of Abstracts of Reviews of Effects (DARE), Cochrane Central Register of Controlled Trials (CENTRAL), Cochrane Methodology Register (CMR), Health Technology Assessment Database (HTA) and NHS Economic Evaluation Database (NHS EED) (2).

References to descriptions of databases

- (1) EBSCO. EBSCO support. Available from: http://support.ebscohost.com. Accessed 03 June 2008.
- (2) Cochrane Collaborations. Cochrane Handbook for Systematic Reviews of Interventions 2008. Available from: http://www.mrc-bsu.cam.ac.uk/cochrane/handbook500/.Accessed 03 June 2008.

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Table 3.2: Search strategies used for systematic review literature retrieval

(Note: this table extends has four parts)

Search strategy I employed for databases IPA, BSP and CINAHL

Search Terms	Search Options	Actions
S1	Decision or adopt or implement or	Limiters - Published Date from:
	diffusion or barrier or facilitator or driver	19900101-20091231; Publication Year
	or motivator or leader or network or	from: 1990-2009; English Language;
	champion or change agent	Expanders - Apply related words
		Search modes - Boolean/Phrase
S2	Non-prescription or nonprescription or	Limiters - Published Date from:
	over the counter or deregulation or	19900101-20091231; Publication Year
	reclassified or self care or self medication	from: 1990-2009; English Language;
	or extended service or change management	Expanders - Apply related words
	or practice change or new service or	Search modes - Boolean/Phrase
	innovation	
S3	Pharmacy or Pharmacist	Limiters - Published Date from:
		19900101-20091231; Publication Year
		from: 1990-2009; English Language;
		Expanders - Apply related words
		Search modes - Boolean/Phrase
S4	S1 and S2 and S3	Search modes - Boolean/Phrase

Search strategy II employed for databases IPA, BSP and CINAHL

Search Terms	Search Options	Actions
S1	pharmacy or pharmacist	Limiters - Published Date from:
		19900101 -20091231; Publication Year
		from: 1990-2009;
		English Language;
		Expanders - Apply related words
		Search modes - Boolean/Phrase
S2	Non-prescription or nonprescription or over	Limiters - Published Date from:
	the counter or minor ailment or reclassified	19900101-20091231; Publication Year
	or self care or self medication or extended	from: 1990-2009; English Language;
	service or change management or practice	Search modes - Boolean/Phrase
	change or new service or innovation seems	
	very in focus	
S3	S1 and S2	

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Search strategy I employed in Medline, EMBASE and PsychINFO

#	Search Options	#	Search Options
1	nonprescription\$.mp	17	implement*.mp
2	over the counter\$.mp	18	diffus*.mp
3	non-prescription\$.mp	19	barrier\$.mp
4	minor ailment\$.mp	20	facilitat*.mp
5	reclassif*.mp	21	driver\$.mp
6	self care.mp	22	motivat*.mp
7	self medicat*.mp	23	leader*.mp
8	extend* service\$.mp	24	network*.mp
9	chang* manag*.mp	25	champion\$.mp
10	practice chang*.mp	26	change agent\$.mp
11	new service\$.mp	27	13 or 14
			7 or 12 or 3 or 4 or 8 or 10 or 2 or 9 or 1 or 5 or 11 or
12	innovat*.mp	28	6
			26 or 22 or 18 or 21 or 16 or 15 or 23 or 20 or 25 or 24
13	pharmacy\$.mp	29	or 17 or 19
14	pharmacist\$.mp	30	28 and 27 and 29
15	decision\$.mp	31	28 and 27
16	adopt*.mp		

[mp= ti (title) \$ truncation * wildcard]

Search strategy II employed in Medline, EMBASE and PsychINFO

#	Search Options	#	Search Options
1	non prescription\$.mp	8	pharmacy\$.mp
2	over the counter\$.mp	9	non-prescription\$.mp
3	minor ailment\$.mp	10	6 or 4 or 1 or 3 or 9 or 2 or 5
4	reclassif*.mp	11	recommend*.mp
5	self care.mp	12	supply*.mp
6	self medicat*.mp	13	8 or 7
7	pharmacist\$.mp	14	11 or 12
		15	13 and 10 and 14

[mp= ti (title) \$ truncation * wildcard]

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Systematic review quality assessment form (Quantitative and mixed method studies) (A completed example- Blenkinsopp et al 2004)

A. Appraisal item: Aim

Appraisal question: Is the research explicit about its aims and objectives

Quality indicators	Quick answers if any	Notes/ Details
Was there a clear statement of the aims of	Yes	
the research?		
Was there a clear statement of the	Yes	
objectives of the research		
If there a mention of why the aim was	Yes	
important?		
Any basis of how aims and objectives	Yes	
emerged?		

B. Appraisal item: Design

Appraisal question: How defensible is the research design?

Quality indicators	Quick answers if any	Notes/ Details
Is there a clear mention of study design?	Yes	
Is there a discussion for the rationale of study design?	No	
If the study is carried out in multiple phases or multiple method, is there a clear mention of the reason for doing so?	No	
Is there a discussion of the limitation of study design?	No	
Is there a discussion of strength of study design?	No	

C. Ethics

Quality indicators	Quick answers if	Notes/ Details
	any	
Was ethics committee advice sought	No	

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D. Appraisal item: Sample/ Participants

Appraisal question: How defensible is the selection of participants/ cases/ documents

Quality indicators	Quick answers if any	Notes/ Details
Is there a mention of study location, how and why they have been chosen?	Yes	
Is there a description of any population of interest and how sample selection relates to it?	Yes	
Is there a justification of sample size?	No	
Is the recruitment strategy clearly explained?	No	No mention of how many further samples were recruited to reach the desired number
Is there documentation of reasons for non-participation among sample approached or any efforts being made?	No	

E. Appraisal item: Data collection

Appraisal question: How well was the data collection carried out?

Quality indicators	Quick answers if any	Notes/ Details
Is there a justification of the procedure of data collection?	No	
Are the issues about validity of the data collection tool addressed?	Yes	Piloted and reviewed by academic committee. However pilot sample was very low
Is there a discussion of who conducted the data collection and was there any bias likely? If so. how did the researcher addressed the issue?	Unclear	Not clear about the contribution of each author, bias likely due to conflicting interest, mentioned clearly
Is there a clear mention of procedure of data collection?	Yes	·
Was it likely that study settings may have influenced data collection?	Yes	Authors familiarity to the pharmacists in the area
Were the data collection method modified during the study, if so are the reasons clearly stated?	Yes	Following pilot, questionnaire was modified but does not mention what was modified

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F. Appraisal item: Data analysis

Appraisal question: Was the data analysis sufficiently rigorous?

Quality indicators	Quick answers if any	Notes/ Details
Is there a mention of clear procedure for data management and/or analysis?	No	No mention of software used
Has the procedure been justified?	No	
Is there a mention of what the tests applied intend to measure?	No	

G. Appraisal item: Findings/results

Appraisal question: How credible are the findings?

Quality indicators	Quick answers if any	Notes/ Details
Are findings/ conclusions supported by		
the study		
Are P values and other relevant values provided?	Yes	
Is there a discussion of why particular significance was issued to specific sets of	No	Does not indicate if there were qualitative data that
data?		might have been important
Are key messages highlighted or summarized in the report?	Yes	
Is there a discussion on how the findings add to what is already known about the topics? (supported by literature review)	No	Perhaps due to no previously available studies
Are any new areas of interest emerged	Not explained	
during the research mentioned?	Not explained	
Is there a discussion of any practice, policy implications of the findings?	Yes	
Is there a discussion of limitation of the findings presented?	No	
Are findings discussed in relation to the	Yes	
aims/ objectives of the research?		
Is there a discussion of generalizability of	No	
the findings or how far are the findings		
transferable to wider population?		
Could researcher's position may have biased conclusions that were drawn.	Yes	Lead author paid advisor to Johnson & Johnson MSD on the switch of simvastatin
		10mg reclassification

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Quality assessment form (Qualitative studies)

Appraisal item: Aim

Appraisal question: Is the research explicit about its aims and objectives

Quality indicators	Quick answers if	Notes/ Details
	any	
Was there a clear statement of the aims of		
the research?		
Was there a clear statement of the		
objectives of the research		
If there a mention of why the aim was		
important?		
Any basis of how aims and objectives		
emerged?		

B. Appraisal item: Design

Appraisal question: How defensible is the research design?

Quality indicators	Quick answers if	Notes/ Details
	any	
Is there a clear mention of study design?		
Is there a discussion for the rationale of		
study design?		
If the study is carried out in multiple		
phases or multiple method, is there a clear		
mention of the reason for doing so?		
Is there a discussion of the limitation of		
study design?		
Is there a discussion of strength of study		
design?		

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C. Appraisal item: Sample/Participants

Appraisal question: How defensible is the selection of participants/ cases/ documents

Quality indicators	Quick answers if	Notes/ Details
	any	
Is there a mention of study		
location, how and why they have		
been chosen?		
Is there a description of any		
population of interest and how		
sample selection relates to it? (eg		
typical, extreme etc)		
Is there a description of how		
particular participants, documents		
or cases were chosen?		
Is the recruitment strategy clearly		
explained?		
Is there documentation of reasons		
for non-participation among		
sample approached/ non-		
inclusion of selected cases/		
documents?		

D. Appraisal item: Data collection

Appraisal question: How well was the data collection carried out?

Quality indicators	Quick answers if	Notes/ Details
	any	
Is there a justification of the procedure of		
data collection?		
Is there a discussion of who conducted the		
data collection and was there any bias		
likely? If so. how did the researcher		
addressed the issue?		
Is there a clear mention of procedure of		
data collection?		
Was it likely that study settings may have		
influenced data collection?		
Were the data collection method modified		
during the study, if so are the reasons		
clearly stated?		

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E. Appraisal item: Data analysis

Appraisal question: Was the data analysis sufficiently rigorous?

Quality indicators	Quick answers if	Notes/ Details
	any	
Is there a mention of clear procedure for		
data management and/or analysis?		
Has the procedure been justified?		
Is there a mention of how descriptive		
categories, themes and category emerged?		
Are contradictory data, extreme cases or		
alternative positions explained?		
Are association of data with any typology		
created justified?		
Has the researcher explained potential		
bias/influence arising from analyst		
position?		

F. Appraisal item: Findings/results

Appraisal question: How credible are the findings?

Quality indicators	Quick answers if	Notes/ Details
-	any	
Are findings/ conclusions supported by		
the study		
Is there a discussion of why particular		
significance was issued to specific sets of		
data?		
Are key messages highlighted or		
summarized in the report?		
Is there a discussion on how the findings		
add to what is already known about the		
topics? (supported by literature review)		
Are any new areas of interest emerged		
during the research mentioned?		
Is there a discussion of any practice, policy		
implications of the findings?		
Is there a discussion of limitation of the		
findings presented?		
Are findings discussed in relation to the		
aims/ objectives of the research?		
Is there a discussion of generalizability of		
the findings or how far are the findings		
transferable to wider population?		
How does researcher's position may have		
biased conclusions that were drawn. Any		
alternative explanations suggested?		

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Quality assessment form (Reviews of literature)

Review:	
Article ID:	Quality assessor:

A. Appraisal item: Aim

Appraisal question: Is the research explicit about its aims and objectives

Quality indicators	Quick answers if any	Notes/ Details
Was there a clear statement of the aims of the review?		
Was there a clear statement of the objectives of the review?		
If there a mention of why the aim was important?		
Any basis of how aims and objectives emerged?		

B. Appraisal item: Review method

Appraisal question: How defensible is the review method adopted?

Quality indicators	Quick answers if	Notes/ Details
	any	Details
Is there a clear mention of review method such as		
narrative, systematic or general review?		
Is there a discussion for the rationale of method adopted?		
Were the inclusion and exclusion criteria of the		
literature reviewed clearly explained and how		
appropriate are they?		
Is there a mention of search strategy employed for		
literature search mentioned and are they		
appropriate?		
Is there a mention of database used to search		
literature and were they		
Were personal contacts with experts made to		
retrieve more literature		
Were unpublished literature searched?		
Were literature other than in English language		
included?		
Were hand searching used to retrieve literature		
from core journals in the field?		
Were there more than one assessor for the studies?		
Is there quality assessment criteria mentioned?		
Is there a discussion of the limitation of method		
selected?		
Is there a discussion of strength of review method?		

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C. Appraisal item: Data analysis

Appraisal question: Was the data analysis sufficiently rigorous?

Quality indicators	Quick answers if	Notes/ Details
	any	
Is there a mention of clear procedure for		
data management and/or analysis?		
Has the procedure been justified?		
Is there a mention of what the tests applied		
intend to measure?		
Has the researcher explained potential		
bias/influence arising from analyst		
position?		

D. Appraisal item: Findings/results

Appraisal question: How credible are the findings?

Quality indicators	Quick answers if	Notes/ Details
	any	
Are findings/ conclusions supported by		
the study		
Are key messages highlighted or		
summarized in the report?		
Is there a discussion of any practice, policy		
implications of the findings?		
Is there a discussion of limitation of the		
findings presented?		
Are findings discussed in relation to the		
aims/ objectives of the research?		
Is there a discussion of generalizability of		
the findings or how far are the findings		
transferable to wider population?		
How does researcher's position may have		
biased conclusions that were drawn. Any		
alternative explanations suggested?		

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Systematic review data extraction form (A completed example- Blenkinsopp et al 2004)

Review:				
Article ID:	1	Reviewer:	VP	

General Information	Data extracted	Any comment
Title:	OTC simvastatin supply- what changes in	
	practice and education do pharmacist want	
First author	Blekinsopp,J	
Author affiliation	Univ. of Bradford, UK	
Publication type	Journal peer reviewed	
Source of article	Pharmaceutical Journal (Vol 273) 7 Aug 2004	Database search

Aims and objectives	Data extracted	Any comment
Aim	Investigate and appraise the changes required in	
	practice and the training requirements of	
	community pharmacists to enable them to supply	
	simvastatin 10mg over the counter appropriately.	
Objectives	1. To investigate and appraise the changes	
·	required in practice to enable the	
	appropriate supply of simvastatin.	
	2. To investigate pharmacists' training	
	requirements for the appropriate supply of	
	OTC simvastatin.	

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Method	Data extracted	Any comment
Study design	Structured questionnaire (Both qualitative and quantitative research aspects)	_
Recruitment	200 random pharmacists, postal questionnaire (piloted to 10 pharmacist)	Not clear how further samples were selected to reach the targeted sample of 200. Low number of pilot participants
Place of study	Leeds/ Bradford area UK	
Piloting and any modification	To 10 pharmacists, modification done	Modification not reported
Inclusion criteria	Those who agreed to participate through telephone interview	•
Exclusion criteria	Not agreeing to participate during pre-contact	
Any interventions	None	
Any reminders used	None	
Analysis method used	Descriptive analysis, Cross tabs	
Any statistical	Chi-square tests	
technique used		

Results	Data extracted	Any comment
Number of	50%	-
participants or		
response rate		

Quantitative results	Data extracted	Any comment
Views on changing	61% believed profession is ready for the	
practice	additional responsibility of the supply of	
	medicines through greater prescribing role, 25%	
	disagreed and 14% unsure.	
	Views on whether reclassification was a good	
Views on	idea: 40 % agreed, 24% disagreed, 36 % unsure.	
reclassification	Those having consultation area were more likely	
	to agree (P=0.028) than those without one. Those	
	agreeing that this was a good idea were more	
	likely to agree profession being ready for more	
	prescribing role.	
Adoption of	If made available over the counter 60% stated	
reclassified medicine	they would be happy to supply, 18% would not	
	and 22% unsure	

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Facilitators/barriers to adoption of reclassified medicines

Facilitators/barriers to decision making	Data extracted	Any comment
Risk assessment Guideline	67% willing to take blood cholesterol test in pharmacy, 18% would not and 15% unsure With risk factors identified, 63% willing to identify the need for statins, 19% would not and 18% unsure Protocol and guidelines should be in place (100% agreed)	
Training	96% agreed or strongly agreed that additional trainings are required. 63% preferred Centre for Pharmacy Postgraduate Education, RPSGB by 40% and National Pharmaceutical Association by 20%. Desirable contents of training package were pharmacology, adverse effects (100%), other interventions to reduce risk (97%), pathophysiology and major risk factors (94%) and advice on counselling about statins (91%).	
Competence/ confidence	39% believed examination of competence is required, 45% disagreed and 16% unsure.	
Access to patient records	50% would like patient records to be available with 16% wanting records of past two years, 20% for past five years, 6% did not believe that patient medical records not needed	
Record of supply	66% agreed supply should be recorded, 22% said should not and 12% unsure Method to keep record: 57% mentioned PMR was the best option to keep record, 35% favoured patient held records	
Need for communication with GPs	34% said GPs should be notified of the supply	
Resources	Views on whether reclassification was a good idea: 40 % agreed, 24% disagreed, 36 % unsure. Those having consultation area were more likely to agree (P=0.028) than those without one.	

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Data extracted	Any comment
Pharmacists additional comments displayed concerns not related to the proposed simvastatin product highlighting gaps in knowledge about the proposed switch. Verbatim comments on importance of training requirements	Qualitative results appears only in discussion section

Conclusions and future direction suggested		Data extracted	Any comment
Conclusions	1.	Need for consultation area highlighted for	
		proposed switch.	
	2.	Need for recording the supply highlighted	
		because long term products currently on	
		non-prescription status are very few and	
		as opposed to other existing short term	
		OTC products where patients may not	
		inform health professionals, this should	
		not be the case for simvastatin.	
	3.	Though PMR system was the most	
		popular, authors argue this is least	
		effective when it comes to sharing with	
		others and therefore, Patient held records	
		are recommended.	
	4.	Presents CPPEs as well established, known	
		for providing well-presented and effective	
		training packages.	

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List of studies excluded after full text screening

S.N	Title and source	Reason/s for exclusion
1	Soon, J.A, Levine, M. Ensom, M.H.H; Gardner, J.S; Edmondson, H.M; Fielding, D.W. The developing role of pharmacists in patient access to emergency contraception. Disease Management & Health Outcomes 2002;10:601-11.	Community pharmacists' perspectives of medicines reclassification not presented
2	Achanta, A.S; Temkin, C.W; Rhodes, C.T. Attitudes and opinions towards regulatory aspects of non-prescription medicines. Clinical Research & Regulatory Affairs 2003;20:1-14. DOI 10.1081/CRP-120018736	Results section do not distinguish the opinions of community pharmacists against others
3	Scott E.M; Paschalides, S.C. Pharmacists' views on emergency hormonal contraception one year after deregulation. HSRPP Conference 2003, Belfast.	Does not specify whether pharmacist participants were based in community.
4	Chapman, J.L; Zechel, A; Carter, Y.H; Abbott, S. Systematic review of recent innovations in service provision to improve access to primary care. British Journal of General Practice 2004; 54: 374-381.	Community pharmacists' perspectives of medicines reclassification not presented
5	L.A. Conard and M.A. Gold, Emergency contraceptive pills: A review of the recent literature, Current Opinion in Obstetrics & Gynecology 2004: 16: 389–395.	Community pharmacists' perspectives of medicines reclassification not presented
6	Sutkin, G; Grant, B; Irons, B.K; Borders, T.F. Opinions of West Texas pharmacists about emergency contraception. Pharmacy Practice 2006;4(4): 151-155.	Results section do not distinguish the opinions of community pharmacists against others
7	Taylor, J.G; Berger, B.A; Anderson-Harper, H.M; Pearson, R.E. Pharmacist readiness for greater involvement in OTC product selection: implications for education. American Journal Pharmaceutical Education 2000;64:133–40.	Community pharmacists' perspectives of medicines reclassification not presented

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APPENDIX V (CHAPTER 5) Copy of main questionnaire



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?	Section A: About reclassified medicines 1. Please indicate how much you appreciate having these reclassified products available for your OTC practice?	4. Please rank the following statements from 1 to 5 based on your agreement levels for each product where 1 = strongly disagree 2 = disagree 3 = neither agree or disagree 4 = agree 5 = strongly agree					
	(Please tick one box for each product) Not at all Very much OTC omeprazole	omeprazole omeprazole omeprazole omeprazole omeprazole oorc oorc oorc oorc oorc oorc oorc oor					
	OTC simvastatin	(Example) I feel confident about my ability to supply this product 5 4 5 3					
	OTC chloramphenicol eye drops	This is/was a good opportunity to extend my role as a health professional					
	2. To what extent do you and/or your support staff <u>supply</u> these products? (Please tick <u>one</u> box for each product)	This product matches with the business/service ambitions of my pharmacy					
П	Not at all Very frequently	This product has potential for good financial returns for my pharmacy					
	OTC omeprazole	My customers often complain about					
	OTC naproxen	the cost of this product (not					
	OTC simvastatin	including e- MAS supply)					
	OTC chloramphenicol eye drops	Insufficient resources (e.g. staff, space etc) within my pharmacy has limited the practice of this product					
	Which source(s) of information do you find useful for making decisions about adopting newly reclassified medicines? (Please tick <u>all</u> that apply)	It is likely that customers could misuse this product					
	□ My pharmacy management □ Journals □ Drug Company training sources □ Television □ RPSGB □ Newspapers	Customers not accepting my advice around this product makes me less likely to adopt this product I find the processes involved in the					
	☐ Patient information leaflets ☐ Senior colleagues ☐ Professional leaders ☐ Fellow pharmacists	supply of this product complex					
	☐ National/Local formularies ☐ Contract champions ☐ Other sources not listed (please list/detail)	I am happy to delegate the task of supplying this product to support staff					
		Many customers ask for this product by name					
Q,		I feel confident about my ability to supply this product					
0							
%							

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1= strongly disagree 2= disagree 4= agree 5=st	3= neither ag crongly agree	ree or disagree	Please explain if any other factors that affects your adoption of new popular expeription products into your practice?
Statements I believe that this product is a welcome addition to the range of pharmacy medicines I have access to sufficient sources of information relating to this product I believe that the OTC regimen for this product is likely to be effective The similarity of POM and P packs of this product could create confusion It is easy for me and/or my customers to know if treatment with this product is effective I believe this product has potential to engender patient satisfaction I believe there are high risks of adverse events associated with this product	OTC	OTC simvastatin OTC OTC of the control of the contr	Section B: About the electronic Minor Ailment Service (e-MAS) 1. Please indicate how often do you or your support staff deliver e-MAS service? (Please tick one box) Not at all Very frequently 2. Which of the following have been benefits of e-MAS? (Please tick all that apply) Financial benefits to me Financial benefits to my pharmacy Opportunity for enhanced working with GPs Opportunity for more effective patient treatment Opportunity to know my patients better due to registration process Opportunity to extend my professional role Availability of electronic feedback relating to my practice Other (Please list/detail)
introduction of this product may have represented a 'step too far' for OTC products It has been my management's decision rather than my own as to if/ how far to adopt into practice I get adequate support from my professional body to adopt this product Lack of proper way to communicate with the local medical practice is a barrier to adopt this product Lack of access to patient medical records makes it difficult to adopt this product into practice I am/would be comfortable going off guidelines to supply this product			3. Which of the following are barriers to the provision of e-MAS? (Please tick all that apply) Lack of satisfactory reimbursement Lack of satisfactory remuneration Time for recording consultations or supply Suspected misuse/overuse of the service by some customers Technical components of the electronic service Inadequate resources of my pharmacy Lack of opportunity for enhanced working with GPs Lack of clear practice guidelines Low number of patients presenting for the service Lack of access to patients' medical records Other (Please list/detail)

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	Click to show one page aca ume
-	
?	Section C: About yourself
	Please tick <u>one</u> of the following that best describes you in relation to your professional practice. I resist new ways of working I am cautious in relation to new ways of working; tend to change once most peers have done so I deliberate for sometime before adopting new ways of working I serve as a role model for others in relation to new ways of working I am venturesome and willing to take risks with new ways of working
	2. What is your gender?
	3. How old are you?
	☐ 29 years and under ☐ 30-39 ☐ 40-49 ☐ 50-59 ☐ 60 or above
	4. How many years you have been registered as a pharmacist? ☐ 5 years and under ☐ 6-10 ☐ 11-15 ☐ 16-20 ☐ 20 or above
	5. What type of pharmacy do you work in?
	☐ Independent (1 store) ☐ Small multiple (2-4 Stores) ☐ Medium sized multiple (5-25 stores) ☐ Large multiple (over 25 stores)
	6. What best describes your employment status? (Please tick all that apply) Owner
	7. Are you a pharmacist prescriber registered with RPSGB? \square Yes \square No
	8. Do you have any postgraduate qualifications?
	9. What best describes the location of the pharmacy you work? ☐ Urban ☐ Suburban ☐ Rural
	Please return the completed questionnaire in reply paid envelope provided.
	Thank you for your cooperation.
0)	
Ĭ	

Post it note message attached to questionnaire

Dear Pharmacist, Your
input into this research is
very valuable to us. It
would be great to get the
questionnaire back from
you by ______(date)
Signature

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APPENDIX VI (CHAPTER 6)

I. Factor analysis of 24-item scales belonging to naproxen

Kaiser-Meyer-Olkin measure of sampling adequacy (KMO) was 0.818 and Barlett's test of sphericity was significant (p= <0.001)

Visual inspection of Scree plot and tabulation of the factors having Eigenvalues greater than 1 showed that seven components were extracted (table 5.1-5.2, figure 5.1).

Table 16.1: % Variance of components explained (naproxen)

Component	Initial Eigenvalues			Rotation Sums of Squared Loadings				
		% of	Cumulative		% of	Cumulative		
	Total	Variance	%	Total	Variance	0/0		
1	4.617	19.239	19.239	3.283	13.681	13.681		
2	2.415	10.062	29.301	1.961	8.169	21.850		
3	1.379	5.744	35.045	1.654	6.893	28.743		
4	1.316	5.485	40.530	1.649	6.872	35.615		
5	1.174	4.893	45.423	1.630	6.792	42.407		
6	1.124	4.685	50.108	1.463	6.095	48.502		
7	1.008	4.200	54.308	1.393	5.806	54.308		

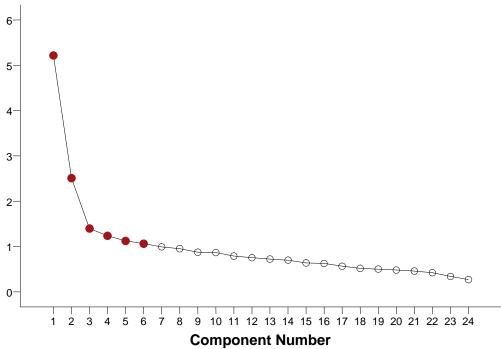
Extraction Method: Principal Component Analysis.

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Figure 16.1: Scree plot (naproxen)

Scree plot (naproxen)





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Table 16.2: Rotated component matrix (naproxen)

		Component					
	1	2	3	4	5	6	7
This is/was a good opportunity to extend my role as a health professional	.788						
This product matches with the business/service ambitions of my pharmacy	.811						
This product has potential for good financial returns	.679						
for my pharmacy I believe that this product is a welcome addition to the	.739						
range of pharmacy medicines I believe that the OTC regimen for this product is likely	.739						
to be effective	.598						
My customers often complain about the cost of this product (not including e-MAS supply) †		.613					
Insufficient resources (e.g. staff, space etc) within my pharmacy has limited the practice of this product †		.523	.423				
It is likely that customers could misuse this product †		.596					
Customers not accepting my advice around this product makes me less likely to adopt this product †		.573					
I find the processes involved in the supply of this product complex [†]		.432					
Introduction of this product may have represented a 'step too far' for OTC products †			.542				
It has been my management's decision rather than my			.764				
own as to if/ how far to adopt into practice † I get adequate support from my professional body to			., 01				
adopt this product I feel confident about my ability to supply this product				.577			
I have access to sufficient sources of information				.741			
relating to this product It is easy for me and/or my customers to know if				., 11	5 40		
treatment with this product is effective Lack of proper way to communicate with the local					.548		
medical practice is a barrier to adopt this product †					.710		
Lack of access to patient medical records makes it difficult to adopt this product into practice †					.432	.590	
I believe this product has potential to engender patient satisfaction						- .457	
I believe there are high risks of adverse events						.757	
associated with this product † I am happy to delegate the task of supplying this						., 0,	
product to support staff							.729
I am/would be comfortable going off guidelines to supply this product							.650
Many customers ask for this product by name*							
The similarity of POM and P packs of this product could create confusion † *							
Extraction Method: Principal Component Analysis Rotat	:	J. 17		ul. I/a:			

Extraction Method: Principal Component Analysis. Rotation method: Varimax with Kaiser Normalization. †: items reversed scored; Values below 0.4 are suppressed. * with values less than 0.4

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II. Factor analysis of 24-item scales belonging to simvastatin

Kaiser-Meyer-Olkin measure of sampling adequacy (KMO) was 0.805 and Barlett's test of sphericity was significant (p= <0.001)

Visual inspection of scree plot and tabulation of the factors having Eigenvalues greater than 1 showed that six components were extracted (tables 5.3-5.4, figure 5.2).

Table 16.3: % Variance of components explained (simvastatin)

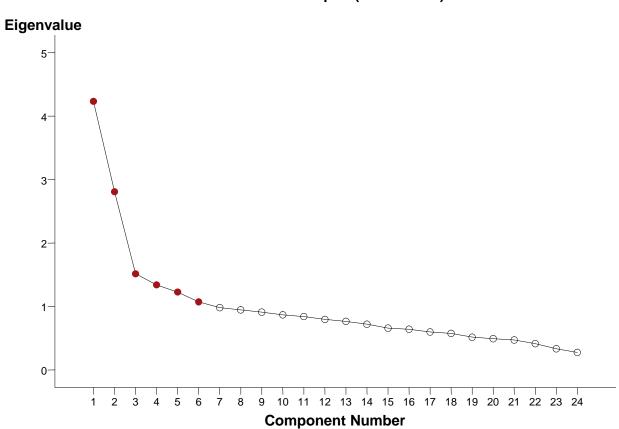
Component		Initial Eigenv	alues	Rotation Sums of Squared Loadings				
		% of	Cumulative		% of	Cumulative		
	Total	Variance	%	Total	Variance	0/0		
1	4.233	17.639	17.639	3.537	14.737	14.737		
2	2.808	11.702	29.340	2.255	9.395	24.132		
3	1.515	6.313	35.654	1.925	8.020	32.152		
4	1.340	5.584	41.238	1.741	7.252	39.404		
5	1.227	5.114	46.352	1.537	6.406	45.810		
6	1.072	4.468	50.819	1.202	5.009	50.819		

Extraction Method: Principal Component Analysis.

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Figure 16.2: Scree plot (simvastatin)

Scree plot (simvastatin)



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Table 16.4: Rotated component matrix (simvastatin)

Items	Component					
	1	2	3	4	5	6
This is/was a good opportunity to extend my role as a health professional	.777					
This product matches with the business/service ambitions of my pharmacy	.820					
This product has potential for good financial returns for my pharmacy	.651					
It has been my management's decision rather than my own as to if/ how far to adopt into practice †	.803					
I feel confident about my ability to supply this product	.622					
Lack of proper way to communicate with the local medical practice is a barrier to adopt this product †	.480		.427			
I believe this product has potential to engender patient satisfaction	.516					
I believe that the OTC regimen for this product is likely to be effective		.539				
My customers often complain about the cost of this product (not including e-MAS supply) †		.526				
Insufficient resources (e.g. staff, space etc) within my pharmacy has limited the practice of this product †		.643				
I believe there are high risks of adverse events associated with this product †		.541				
I am/would be comfortable going off guidelines to supply this product		.446				
Many customers ask for this product by name		.485				
Introduction of this product may have represented a 'step too far' for OTC products †			.621			
I get adequate support from my professional body to adopt this product			.758			
I am happy to delegate the task of supplying this product to support staff			.694			
It is likely that customers could misuse this product † Customers not accepting my advice around this				.487		
product makes me less likely to adopt this product † The similarity of POM and P packs of this product				.674		
could create confusion † * I find the processes involved in the supply of this				.599		
product complex † I have access to sufficient sources of information					658	
relating to this product					.606	
Lack of access to patient medical records makes it difficult to adopt this product into practice †					.495	
I believe that this product is a welcome addition to the range of pharmacy medicines						.787
It is easy for me and/or my customers to know if treatment with this product is effective*						

Extraction Method: Principal Component Analysis. Rotation Method: Varimax with Kaiser Normalization. Component scores less than 0.4 are suppressed; †: items reversed scored * has value below 0.4.

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III. Factor analysis of 24-item scales belonging to chloramphenicol

KMO measure of sampling adequacy was 0.807 and Barlett's test of sphericity was significant at <0.001. Eight components could be extracted (tables 5.5-5.6, figure 5.3).

Figure 16.3: Scree plot of chloramphenicol

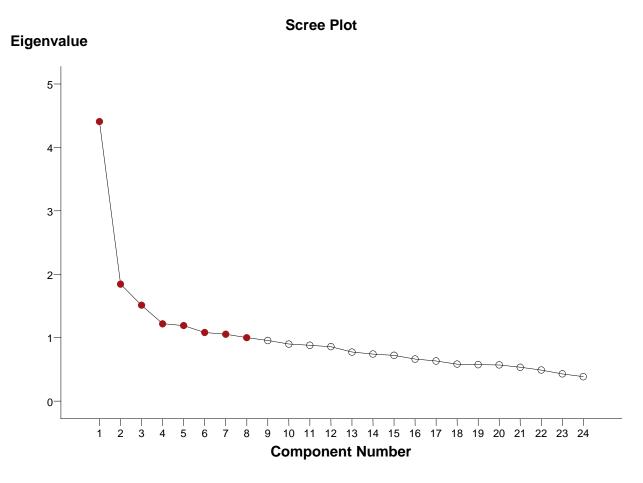


Table 16.5: % Variance of components explained (chloramphenicol)

Component		Initial Eigenvalues		Rotation	Sums of Squa	red Loadings
		% of	Cumulative		% of	Cumulative
	Total	Variance	%	Total	Variance	0/0
1	4.407	18.362	18.362	2.622	10.926	10.926
2	1.844	7.683	26.046	2.139	8.911	19.836
3	1.511	6.298	32.344	1.849	7.706	27.542
4	1.219	5.079	37.423	1.736	7.235	34.777
5	1.191	4.962	42.385	1.304	5.433	40.211
6	1.082	4.507	46.892	1.293	5.388	45.598
7	1.055	4.394	51.286	1.207	5.029	50.628
8	1.000	4.167	55.454	1.158	4.826	55.454

Extraction Method: Principal Component Analysis.

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Table 16.6: Rotated component matrix of chloramphenicol

Items	Component							
	1	2	3	4	5	6	7	8
My customers often complain about the cost of this product (not including e-MAS supply) [†]	.444							
Insufficient resources (e.g. staff, space etc) within my pharmacy has limited the practice of this product †	.649							
I find the processes involved in the supply of this product complex [†]	.609							
I believe there are high risks of adverse events associated with this product [†]	.575							
Introduction of this product may have represented a 'step too far' for OTC products [†]	.502							
I feel confident about my ability to supply this product		.564						
I believe that this product is a welcome addition to the range of pharmacy medicines		.661	.408					
I have access to sufficient sources of information relating to this product		.656						
I believe that the OTC regimen for this product is likely to be effective		.672						
This is/was a good opportunity to extend my role as a health professional			.794					
This product matches with the business/service ambitions of my pharmacy			.811					
I get adequate support from my professional body to adopt this product				.625				
Lack of proper way to communicate with the local medical practice is a barrier to adopt this product [†]				.671				
Lack of access to patient medical records makes it difficult to adopt this product into practice [†]				.547				
It is likely that customers could misuse this product [†]	.488				.562			
I am happy to delegate the task of supplying this product to support staff					.455			
Many customers ask for this product by name This product has potential for good financial					.773	-		
returns for my pharmacy It has been my management's decision rather than						.535 .742		
my own as to if/ how far to adopt into practice [†] Customers not accepting my advice around this						./ 12	.599	
product makes me less likely to adopt this product [†] I am/would be comfortable going off guidelines to								
supply this product The similarity of POM and P packs of this product							.741	_
could create confusion† I believe this product has potential to engender								.519
patient satisfaction It is easy for me and/or my customers to know if								.771
treatment with this product is effective* Extraction Method: Principal Component Analysis Rota			**		1 75 1			

Extraction Method: Principal Component Analysis. Rotation Method: Varimax with Kaiser Normalization; †: items reversed scored Values below 0.4 are suppressed. * with values less than 0.4

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Table 16.7: Univariate statistics of 24-item scale items and demographic characteristics with the outcome 'omeprazole acceptance' showing non-significant associations (Note: this table extends up to two pages)

Scale items/ variables	Categories	Low acceptance n (%)	High acceptance n (%)	P value
My customers often complain	Low agreement	160	276	0.187
about the cost of this product	0	(36.7)	(63.3)	
(not including e-MAS supply) †	High agreement	33	79	
(N= 548)		(29.5)	(70.5)	
Insufficient resources (e.g. staff,	Low agreement	78	119	0.124
space etc) within my pharmacy	0	(39.6)	(60.4)	
has limited the practice of this	High agreement	115	237	
product† (N= 549)	0 0	(32.7)	(67.3)	
It is likely that customers could	Low agreement	93	145	0.130
misuse this product † (N= 549)	0	(39.1)	(60.9)	
1 /	High agreement	101	210	
	0 10 11	(32.5)	(67.5)	
The similarity of POM and P	Low agreement	57	90	0.358
packs of this product could		(38.8)	(61.2)	
create confusion† (N= 549)	High agreement	137	265	
,		(34.1)	(65.9)	
I believe there are high risks of	Low agreement	79	126	0.208
adverse events associated with	zow ugreement	(38.5)	(61.5)	0.200
this product [†] (N= 546)	High agreement	112	229	
ins product (iv 510)	111611 ugreemen	(32.8)	(67.2)	
It has been my management's	Low agreement	77	134	0.714
decision rather than my own as	zow ugreement	(36.5)	(63.5)	0.711
to if/ how far to adopt into	High agreement	113	214	
practice [†] (N= 538)	i iigii agreemen	(34.6)	(65.4)	
I get adequate support from my	Low agreement	99	153	0.054
professional body to adopt this	Low agreement	(39.3)	(60.7)	0.001
product (N=545)	High agreement	92	201	
product (14 010)	i iigii agreemen	(31.4)	(68.6)	
Lack of proper way to	Low agreement	(01.1)	(00.0)	0.051
communicate with the local	Low agreement	94	142	0.001
medical practice is a barrier to		(39.8)	(60.2)	
adopt this product [†] (N=542)	4			
adopt this product. (14 342)	High agreement	96	210	
		(31.4)	(68.6)	0.010
I am/would be comfortable	Low agreement	164	291	0.363
going off guidelines to supply this product (N=544)		(36.0)	(64.0)	
	High agreement	27	62	
		(30.3)	(69.7)	
Innovativeness (N= 544)	Cautious or	115	212	1.00
	Deliberate	(35.2)	(64.8)	
	Role model or	76	141	
	venturesome	(35.0)	(65.0)	
Gender (N= 545)	Male	65	146	0.090
		(30.8)	(69.2)	
	Female	128	206	
		(38.3)	(61.7)	

[†]Items reversed scored

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Variables	Categories	Low acceptance n (%)	High acceptance n (%)	P value
Age (N= 546)	39 Years and	131	209	0.074
,	under	(38.5)	(61.5)	
	40 years and over	63	143	
	•	(30.6)	(69.4)	
Relief (N= 554)	Yes	12	27	0.652
		(30.8)	(69.2)	
	No	184	331	
		(35.7)	(64.3)	
Second (N= 554)	Yes	5	16	0.369
,		(23.8)	(76.2)	
	No	191	342	
		(35.8)	(64.2)	
Locum (N= 554)	Yes	7	9	0.656
,		(43.8)	(56.3)	
	No	189	349	
		(35.1)	(64.9)	
Non-store (N= 554)	Yes	0	1	1.00**
,		(0.0)	(100.0)	
	No	196	357	
		(35.4)	(64.6)	
Prescriber (N= 551)	Yes	48	97	0.569
,		(33.1)	(66.9)	
	No	147	259	
		(36.2)	(63.8)	
Postgraduate (N= 549)	Yes	28	60	0.503
(, , ,)		(31.8)	(68.2)	
	No	167	294	
		(36.2)	(63.8)	
Location*** (N= 497)	Urban	53	101	0.929
((34.4)	(65.6)	
	Suburban	77	137	
	2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	(36.0)	(64.0)	
	Rural	47	82	
	_ 1911 911	(36.4)	(63.6)	
Size of ownership (N= 536)	Independent or	51	114	0.211
(1 · 500)	small multiple	(30.9)	(69.1)	
	Medium or large	137	234	
	multiple	(36.9)	(63.1)	

 $^{^{\}ast}$ % represents proportion within row categories; ** Fischer's exact test *** Locums/relief excluded

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II. Regression analysis univariate outputs

Table 16.8: Univariate statistics of 24-item scale items and demographic characteristics with the outcome 'omeprazole adoption' (note: this table extends up to four pages)

Scale items	Categories	Low adoption n (%)	High adoption n (%)	P value
This is a good opportunity to	Low agreement	237	27	<0.001
extend my role as a health	zow ugreement	(89.8)	(10.2)	0.001
professional (N= 548)	High agreement	163	121	
F	111611 1161 001110111	(57.4)	(42.6)	
This product matches with the	Low agreement	283	45	<0.001
business/service ambitions of	O	(86.3)	(13.7)	
my pharmacy (N= 548)	High agreement	117	103	
	0 0	(53.2)	(46.8)	
This product has potential for	Low agreement	297	61	< 0.001
good financial returns for my	O	83.0)	(17.0)	
pharmacy (N= 542)	High agreement	100	84	
	0 0	(54.3)	(45.7)	
My customers often complain	Low agreement	326	110	0.048
about the cost of this product	O	(74.8)	(25.2)	
(not including e-MAS supply) †	High agreement	72	39	
(N=548)	0 0	(64.9)	(35.1)	
Insufficient resources (e.g. staff,	Low agreement	161	35	< 0.001
space etc) within my pharmacy	O	(82.1)	(17.9)	
has limited the practice of this	High agreement	238	114	
product† (N= 548)	0 0	(67.6)	(32.4)	
It is likely that customers could	Low agreement	174	63	0.855
misuse this product † (N= 548)	Ü	(73.4)	(26.6)	
	High agreement	225	86	
	0 0	(72.3)	(27.7)	
Customers not accepting my	Low agreement	238	77	0.087
advice around this product	Ü	(75.6)	(24.4)	
makes me less likely to adopt	High agreement	157	72	
this product† (N= 544)		(68.6)	(31.4)	
I find the processes involved in	Low agreement	171	35	< 0.001
the supply of this product	Ü	(83.0)	(17.0)	
complex † (N= 545)	High agreement	226	113	
	0 0	(66.7)	(33.3)	
I am happy to delegate the task	Low agreement	293	78	< 0.001
of supplying this product to	, and the second	(79.0)	(21.0)	
support staff (N= 545)	High agreement	104	70	
·		(59.8)	(40.2)	
Many customers ask for this	Low agreement	372	118	< 0.001
product by name (N= 546)	-	(75.9)	(24.1)	
	High agreement	26	30	
		(46.4)	(53.6)	

^{* %} represents proportion within row categories; †Items reversed scored

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Scale items	Categories	Low adoption n (%)	High adoption n (%)	P value
I feel confident about my ability	Low agreement	70	2	<0.001
to supply this product $(N = 547)$	9 - 1	(97.2)	(2.8)	
	High agreement	329	146	
	0 0	(69.3)	(30.7)	
I believe that this product is a	Low agreement	204	16	< 0.001
welcome addition to the range	_	(92.7)	(7.3)	
of pharmacy medicines (N= 548)	High agreement	196	132	
		(59.8)	(40.2)	
I have access to sufficient	Low agreement	95	17	0.002
sources of information relating		(84.8)	(15.2)	
to this product (N= 545)	High agreement	302	131	
		(69.7)	(30.3)	.0.004
I believe that the OTC regimen	Low agreement	224	25	< 0.001
for this product is likely to be	TT: 1	(90.0)	(10.0)	
effective (N= 547)	High agreement	175	123	
The similarity of DOM and D	T ariv a ama ama amt	(58.7) 110	(41.3) 35	0.416
The similarity of POM and P packs of this product could	Low agreement	(75.9)	(24.1)	0.416
create confusion† (N= 547)	High agreement	289	113	
create confusion: (14–347)	riigii agreemeni	(71.9)	(28.1)	
It is easy for me and/or my	Low agreement	205	43	<0.001
customers to know if treatment	Low agreement	(82.7)	(17.3)	0.001
with this product is effective	High agreement	190	105	
(N=543)		(64.4)	(35.6)	
I believe this product has	Low agreement	238	48	<0.001
potential to engender patient	O	(83.2)	16.8)	
satisfaction (N= 527)	High agreement	144	95	
	0 0	(60.3)	(39.7)	
I believe there are high risks of	Low agreement	156	47	0.124
adverse events associated with	Ü	(76.8)	(23.2)	
this product† (N= 544)	High agreement	240	101	
		(70.4)	(29.6)	
Introduction of this product	Low agreement	121	22	< 0.001
may have represented a 'step		(84.6)	(15.4)	
too far' for OTC products† (N=	High agreement	276	126	
545)		(68.7)	(31.3)	
It has been my management's	Low agreement	160	48	0.121
decision rather than my own as	1	(76.9)	(23.1)	
to if/ how far to adopt into	High agreement	231	97	
practice [†] (N= 536)	T	(70.4)	(29.6)	0.002
I get adequate support from my	Low agreement	198	51 (20.5)	0.002
professional body to adopt this	TT:=1	(79.5)	(20.5)	
product (N= 543)	High agreement	197	97	
titams reversed scored		(67.0)	(33.0)	

[†]Items reversed scored

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Scale items/ variables	Categories	Low adoption n (%)	High adoption n (%)	P value
Lack of proper way to	Low agreement	191	45	<0.001
communicate with the local	C .	(80.9)	(19.1)	
medical practice is a barrier to	High agreement	202	102	
adopt this product† (N= 540)		(66.4)	(33.6)	
Lack of access to patient medical	Low agreement	244	67	0.001
records makes it difficult to		(78.5)	(21.5)	
adopt this product into practice†	High agreement	153	81	
(N= 545)		(65.4)	(34.6)	
I am/would be comfortable	Low agreement	338	115	0.033
going off guidelines to supply		(74.6)	(25.4)	
this product (N= 542)	High agreement	56	33	
7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7		(62.9)	(37.1)	2 222
Innovativeness (N= 543)	Cautious or	251	74	0.008
	Deliberate	(77.2)	(22.8)	
	Role model or	145	73	
C 1 01 540	venturesome	(66.5)	(33.5)	0.107
Gender (N= 544)	Male	143	65	0.136
	г 1	(68.8)	(31.3)	
	Female	252	84	
A /NT	20.3/	(75.0)	25.0)	0.711
Age (N= 545)	39 Years and	252	89	0.711
	under	(73.9)	(26.1)	
	40 years and over	147	57	
Esmariana (NI- E46)	10 rrooms and	(72.1)	(27.9) 73	0.469
Experience (N= 546)	10 years and under	212		0.469
		(74.4) 186	(25.6) 75	
	11 years or over	(71.3)	(28.7)	
Owner (N= 553)	Yes	59	36	0.016
Owner (N= 333)	168	(62.1)	(37.9)	0.010
	No	343	115	
	INO	(74.9)	(25.1)	
Manager (N= 553)	Yes	306	94	0.002
Manager (14 300)	103	(76.5)	(23.5)	0.002
	No	96	57	
	140	(62.7)	(37.3)	
Relief (N= 553)	Yes	26	14	0.342
	100	65.0)	(35.0)	0.012
	No	376	137	
	0	(73.3)	26.7)	
Second (N= 553)	Yes	13	8	0.378
()	- +-	(61.9)	(38.1)	1.010
	No	389	143	
	0	(73.1)		

[†]Items reversed scored

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Variables	Categories	Low	High	P
	· ·	adoption	adoption	value
		n (%)	n (%)	
Locum (N= 553)	Yes	14	2	0.257**
		(87.5)	(12.5)	
	No	388	149	
		(72.3)	(27.7)	
Non-store (N= 553)	Yes	0	1	0.273**
		(0.0)	(100.0)	
	No	402	150	
		(72.8)	(27.2)	
Prescriber (N= 550)	Yes	102	44	0.425
		(69.9)	(30.1)	
	No	298	106	
		(73.8)	(26.2)	
Postgraduate (N= 549)	Yes	59	31	0.115
		(65.6)	(34.4)	
	No	341	118	
		(74.3)	(25.7)	
Location*** (N= 494)	Urban	113	41	0.68
		(73.4)	(26.6)	
	Suburban	158	53	
		(74.9)	(25.1)	
	Rural	91	38	
		(70.5)	(29.5)	
Size of ownership (N= 535)	Independent or	122	41	0.451
,	small multiple	(74.8)	(25.2)	
	Medium or large	265	107	
	multiple	(71.2)	(28.8)	

^{**} Fischer's exact test; *** Locums/ Relief excluded

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Table 16.9: Univariate statistics of 24-item scale items and demographic characteristics with

the outcome 'naproxen acceptance' (note: this table extends up to four pages)

Scale items	Categories	Low	High	P
	O	acceptance	acceptance	value
		n (%)	n (%)	
This is a good opportunity to	Low agreement	95	108	< 0.001
extend my role as a health	· ·	(46.8)	(53.2)	
professional (N= 547)	High agreement	29	315	
	0 0	(8.4)	(91.6)	
This product matches with the	Low agreement	103	163	< 0.001
business/service ambitions of		(38.7)	(61.3)	
my pharmacy (N= 547)	High agreement	21	260	
		(7.5)	(92.5)	
This product has potential for	Low agreement	98	220	< 0.001
good financial returns for my		(30.8)	(69.2)	
pharmacy (N= 542)	High agreement	25	199	
		(11.2)	(88.8)	
My customers often complain	Low agreement	91	274	0.072
about the cost of this product	_	(24.9)	(75.1)	
(not including e-MAS supply) †	High agreement	32	149	
(N=546)		(17.7)	(82.3)	
Insufficient resources (e.g. staff,	Low agreement	53	123	0.006
space etc) within my pharmacy		(30.1)	(69.9)	
has limited the practice of this	High agreement	71	301	
product† (N= 548)		(19.1)	(80.9)	
It is likely that customers could	Low agreement	69	204	0.205
misuse this product † (N= 548)		(25.3)	(74.7)	
	High agreement	56	219	
		(20.4)	(79.6)	
Customers not accepting my	Low agreement	79	226	0.036
advice around this product		(25.9)	(74.1)	
makes me less likely to adopt	High agreement	43	196	
this product† (N= 544)		(18.0)	(82.0)	
I find the processes involved in	Low agreement	59	119	< 0.001
the supply of this product		(33.1)	(66.9)	
complex† (N= 544)	High agreement	64	302	
	0 0	(17.5)	(82.5)	
I am happy to delegate the task	Low agreement	91	232	< 0.001
of supplying this product to	· ·	(28.2)	(71.8)	
support staff (N= 545)	High agreement	33	189	
		(14.9)	(85.1)	
Many customers ask for this	Low agreement	106	339	0.281
product by name (N= 544)	<u> </u>	(23.8)	(76.2)	
- , , , ,	High agreement	18	81	
		(18.2)	(81.8)	

^{* %} represents proportion within row categories; †Items reversed scored

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Scale items	Categories	Low acceptance n (%)	High acceptance n (%)	P value
I feel confident about my ability	Low agreement	29	27	< 0.001
to supply this product (N= 547)	O	(51.8)	(48.2)	
	High agreement	95	396	
	0 0	(19.3)	(80.7)	
I believe that this product is a	Low agreement	83	81	< 0.001
welcome addition to the range	J	(50.6)	(49.4)	
of pharmacy medicines (N= 549)	High agreement	41	344	
		(10.6)	(89.4)	
I have access to sufficient	Low agreement	29	61	0.024
sources of information relating		(32.2)	(67.8)	
to this product (N= 545)	High agreement	94	361	
		(20.7)	(79.3)	
I believe that the OTC regimen	Low agreement	80	108	< 0.001
for this product is likely to be		(42.6)	(57.4)	
effective (N= 547)	High agreement	44	314	
		(12.3)	(87.7)	
The similarity of POM and P	Low agreement	39	98	0.069
packs of this product could		(28.5)	(71.5)	
create confusion† (N= 547)	High agreement	84	326	
		(20.5)	(79.5)	
It is easy for me and/or my	Low agreement	61	129	< 0.001
customers to know if treatment		(32.1)	(67.9)	
with this product is effective	High agreement	63	290	
(N= 543)		(17.8)	(82.2)	2 221
I believe this product has	Low agreement	82	178	< 0.001
potential to engender patient	TT: 1	(31.5)	(68.5)	
satisfaction (N= 527)	High agreement	34	233	
T.L. 12 d 1.2 . 1	T	(12.7)	(87.3)	0.200
I believe there are high risks of	Low agreement	95	305	0.399
adverse events associated with	III: ala a anno anno ant	(23.8)	(76.3)	
this product† (N= 546)	High agreement	29	117	
Introduction of this must dust	I over a comp comb	(19.9)	(80.1)	~ 0.001
Introduction of this product	Low agreement	54 (40.0)	78 (50.1)	< 0.001
may have represented a 'step too far' for OTC products† (N=	Uigh agraement	(40.9) 70	(59.1) 344	
546)	High agreement	(16.9)	(83.1)	
,	Low agroomont	57	152	0.037
It has been my management's decision rather than my own as	Low agreement	(27.3)	(72.7)	0.037
to if/ how far to adopt into	High agroomont	(27.3) 63	265	
practice [†] (N= 537)	High agreement	(19.2)	(80.8)	
I get adequate support from my	Low agreement	76	177	<0.001
professional body to adopt this	Low agreement	30.0)	70.0)	10.001
product (N= 542)	High agreement	46	243	
product (1 (012)	THEIT agreement	(15.9)	(84.1)	
†Items reversed scored		(10.7)	(04.1)	

[†]Items reversed scored

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Scale items/ variables	Categories	Low acceptance n (%)	High acceptance n (%)	P value
Lack of proper way to	Low agreement	58	166	0.150
communicate with the local		(25.9)	(74.1)	
medical practice is a barrier to	High agreement	64	252	
adopt this product† (N= 540)		(20.3)	(79.7)	
Lack of access to patient medical	Low agreement	69	215	0.366
records makes it difficult to		(24.3)	(75.7)	
adopt this product into practice†	High agreement	54	207	
(N=545)		(20.7)	79.3)	
I am/would be comfortable	Low agreement	108	359	0.445
going off guidelines to supply	_	(23.1)	(76.9)	
this product (N= 543)	High agreement	14	62	
	0 0	18.4)	(81.6)	
Innovativeness (N= 542)	Cautious or	79	246	0.321
	Deliberate	(24.3)	(75.7)	
	Role model or	44	173	
	venturesome	(20.3)	(79.7)	
Gender (N= 543)	Male	52	158	0.408
		(24.8)	(75.2)	
	Female	71	262	
		(21.3)	(78.7)	
Age (N= 545)	39 Years and	76	263	0.999
	under	(22.4)	(77.6)	
	40 years and over	47	159	
	•	(22.8)	(77.2)	
Experience (N= 546)	10 years and	60	223	0.382
-	under	(21.2)	78.8)	
	11 years or over	65	198	
	•	(24.7)	(75.3)	
Owner (N= 552)	Yes	21	75	0.949
,		21.9)	78.1)	
	No	104	352	
		(22.8)	(77.2)	
Manager (N= 552)	Yes	94	304	0.444
		(23.6)	(76.4)	
	No	31	123	
		(20.1)	79.9)	

[†]Items reversed scored;

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Variables	Categories	Low acceptance n (%)	High acceptance n (%)	P value
Relief (N= 552)	Yes	10	29	0.791
		(25.6)	(74.4)	
	No	115	398	
		(22.4)	(77.6)	
Second (N=552)	Yes	2	19	0.187**
		(9.5)	(90.5)	
	No	123	408	
		(23.2)	(76.8)	
Locum (N= 552)	Yes	2	14	0.544**
		(12.5)	(87.5)	
	No	123	413	
		(22.9)	(77.1)	
Non-store (N= 552)	Yes	0	1	1.00**
		(0.0)	(100)	
	No	125	426	
		(22.7)	(77.3)	
Prescriber (N= 549)	Yes	33	111	0.956
		(22.9)	(77.1)	
	No	90	315	
		(22.2)	(77.8)	
Postgraduate (N= 547)	Yes	18	70	0.687
		(20.5)	(79.5)	
	No	106	353	
		(23.1)	(76.9)	
Location*** (N= 495)	Urban	33	121	0.646
,		(21.4)	(78.6)	
	Suburban	47	166	
		(22.1)	(77.9)	
	Rural	33	95	
		(25.8)	(74.2)	
Size of ownership (N= 534)	Independent or	51	114	0.004
1 ()	small multiple	(30.9)	(69.1)	
	Medium or large	71	298	
	multiple	(19.2)	(80.8)	
data Tit. 1 / data T	/ D 1: 6 1 1 1	\ ' /	\/	

^{**} Fischer's exact test; *** Locums/ Reliefs excluded

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Table 16.10: Univariate statistics of 24-item scale items and demographic characteristics with the outcome 'naproxen adoption' (note: this table extends up to four pages)

Scale items	Categories	Low	High	P
	O	adoption	adoption	value
		n (%)	n (%)	
This is a good opportunity to	Low agreement	156	48	< 0.001
extend my role as a health	O .	(76.5)	(23.5)	
professional (N= 551)	High agreement	134	213	
		(38.6)	(61.4)	
This product matches with the	Low agreement	193	74	< 0.001
business/service ambitions of	O	(72.3)	(27.7)	
my pharmacy (N= 551)	High agreement	98	186	
		(34.5)	(65.5)	
This product has potential for	Low agreement	206	114	< 0.001
good financial returns for my	O	(64.4)	(35.6)	
pharmacy (N= 546)	High agreement	82	144	
	0 0	(36.3)	(63.7)	
My customers often complain	Low agreement	215	152	< 0.001
about the cost of this product	O	(58.6)	(41.4)	
(not including e-MAS supply) †	High agreement	74	109	
(N= 550)	0 0	(40.4)	(59.6)	
Insufficient resources (e.g. staff,	Low agreement	114	63	< 0.001
space etc) within my pharmacy	O	(64.4)	(35.6)	
has limited the practice of this	High agreement	177	198	
product† (N= 552)	0 0	(47.2)	(52.8)	
It is likely that customers could	Low agreement	153	122	0.231
misuse this product † (N= 552)	O	(55.6)	(44.4)	
,	High agreement	139	138	
		(50.2)	(49.8)	
Customers not accepting my	Low agreement	171	136	0.138
advice around this product	O	(55.7)	(44.3)	
makes me less likely to adopt	High agreement	118	123	
this product† (N= 548)		(49.0)	(51.0)	
I find the processes involved in	Low agreement	120	59	< 0.001
the supply of this product	O	(67.0)	(33.0)	
complex† (N= 548)	High agreement	170	199	
, ,	0 0	(46.1)	(53.9)	
I am happy to delegate the task	Low agreement	199	127	< 0.001
of supplying this product to	O	(61.0)	(39.0)	
support staff (N= 549)	High agreement	`92 [′]	131	
` '	0 0	(41.3)	(58.7)	
Many customers ask for this	Low agreement	255	192	<0.001
product by name (N= 548)	O	(57.0)	(43.0)	
. ,	High agreement	36	65	
	0 0	(35.6)	(64.4)	

^{* %} represents proportion within row categories; †Items reversed scored

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Scale items	Categories	Low adoption n (%)	High adoption n (%)	P value
I feel confident about my ability	Low agreement	47	9	<0.001
to supply this product (N= 551)	O	(83.9)	(16.1)	
,	High agreement	244	251	
	0 0	(49.3)	(50.7)	
I believe that this product is a	Low agreement	135	30	< 0.001
welcome addition to the range		(81.8)	(18.2)	
of pharmacy medicines (N= 552)	High agreement	155	232	
		(40.1)	(59.9)	
I have access to sufficient	Low agreement	60	30	0.004
sources of information relating		(66.7)	33.3)	
to this product (N= 548)	High agreement	227	231	
		49.6)	(50.4)	
I believe that the OTC regimen	Low agreement	139	50	< 0.001
for this product is likely to be	TT: 1	(73.5)	(26.5)	
effective (N= 549)	High agreement	151	209	
TI : 11 11 (PO) (ID	T .	(41.9)	(58.1)	0.011
The similarity of POM and P	Low agreement	86	52	0.011
packs of this product could	III: ala a anno anno anno	(62.3)	(37.7)	
create confusion† (N= 550)	High agreement	203	209	
It is easy for me and / or my	I are a ama ama ami	(49.3) 131	(50.7) 59	<0.001
It is easy for me and/or my customers to know if treatment	Low agreement			<0.001
with this product is effective	High agreement	(68.9) 156	(31.1) 200	
(N= 546)	High agreement	(43.8)	(56.2)	
I believe this product has	Low agreement	164	98	<0.001
potential to engender patient	Low agreement	(62.6)	(37.4)	\0.001
satisfaction (N= 530)	High agreement	117	151	
satisfaction (14 555)	Then agreement	(43.7)	(56.3)	
I believe there are high risks of	Low agreement	228	174	0.002
adverse events associated with	0.00	(56.7)	(43.3)	
this product [†] (N= 549)	High agreement	61	86	
, ,	0 0	(41.5)	(58.5)	
Introduction of this product	Low agreement	95	38	< 0.001
may have represented a 'step	o .	(71.4)	(28.6)	
too far' for OTC products† (N=	High agreement	194	222	
549)	0 0	(46.6)	(53.4)	
It has been my management's	Low agreement	112	97	0.557
decision rather than my own as		(53.6)	46.4)	
to if/ how far to adopt into	High agreement	167	163	
practice† (N= 539)		(50.6)	(49.4)	
I get adequate support from my	Low agreement	161	93	< 0.001
professional body to adopt this		(63.4)	(36.6)	
product† (N= 545)	High agreement	125	166	
		(43.0)	(57.0)	

[†]Items reversed scored;

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Scale items/variables	Categories	Low adoption n (%)	High adoption n (%)	P value
Lack of proper way to	Low agreement	135	91	0.009
communicate with the local	O	(59.7)	(40.3)	
medical practice is a barrier to	High agreement	152	165	
adopt this product† (N= 543)	0 0	(47.9)	(52.1)	
Lack of access to patient medical	Low agreement	169	117	0.002
records makes it difficult to	Ü	59.1)	(40.9)	
adopt this product into practice†	High agreement	119	143	
(N=548)		(45.4)	(54.6)	
I am/would be comfortable	Low agreement	252	218	0.189
going off guidelines to supply	Ü	(53.6)	(46.4)	
this product (N= 546)	High agreement	34	42	
	0 0	(44.7)	(55.3)	
Innovativeness (N= 542)	Cautious or	199	129	< 0.001
,	Deliberate	(60.7)	(39.3)	
	Role model or	91	127	
	venturesome	(41.7)	(58.3)	
Gender (N= 547)	Male	123	88	0.038
,		(58.3)	(41.7)	
	Female	164	172	
		(48.8)	(51.2)	
Age (N= 548)	39 Years and	163	178	0.003
,	under	(47.8)	(52.2)	
	40 years and over	127	80	
	•	(61.4)	(38.6)	
Experience (N= 549)	10 years and	133	152	0.002
-	under	(46.7)	(53.3)	
	11 years or over	159	105	
	•	(60.2)	(39.8)	
Owner (N= 556)	Yes	62	35	0.020
		63.9)	36.1)	
	No	231	228	
		(50.3)	(49.7)	
Manager (N= 556)	Yes	206	195	0.361
,		(51.4)	(48.6)	
	No	87	68	
		(56.1)	(43.9)	
Relief (N= 556)	Yes	18	22	0.397
		(45.0)	(55.0)	
	No	275	241	
		53.3)	(46.7)	

[†]Items reversed scored;

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Scale items / variables	Categories	Low adoption n (%)	High adoption n (%)	P value
Second (N= 556)	Yes	8	13	0.253
,		(38.1)	(61.9)	
	No	285	250	
		(53.3)	(46.7)	
Locum (N= 556)	Yes	11	5	0.293
·		(68.8)	(31.3)	
	No	282	258	
		(52.2)	(47.8)	
Non-store (N= 552)	Yes	1	0	1.00**
,		(100.0)	(0.0)	
	No	292	263	
		(52.6)	(47.4)	
Prescriber (N= 553)	Yes	80	66	0.606
		(54.8)	(45.2)	
	No	211	196	
		(51.8)	(48.2)	
Postgraduate (N= 547)	Yes	39	51	0.064
		(43.3)	(56.7)	
	No	252	209	
		(54.7)	(45.3)	
Location*** (N= 497)	Urban	77	77	0.742
		(50.0)	(50.0)	
	Suburban	114	100	
		(53.3)	(46.7)	
	Rural	70	59	
		(54.3)	(45.7)	
Size of ownership (N= 534)	Independent or	114	51	< 0.001
	small multiple	(69.1)	(30.9)	
	Medium or large	167	206	
	multiple	(44.8)	(55.2)	

^{**} Fischer's exact test; *** Locums/ Reliefs excluded

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Table 16.11: Bivariate analysis showing correlations of the outcome 'simvastatin acceptance' and 'simvastatin adoption' with the 24-items scale displaying Kendals' T values of of <.2

Statements	Kendal's T correlation values with 'simvastatin acceptance'	Kendal's T correlation values with 'simvastatin adoption'
I am happy to delegate the task of supplying this product to support staff	¥	.118***
I find the processes involved in the supply of this product complex [†]	.135***	.142***
I feel confident about my ability to supply this product	.164***	.150***
My customers often complain about the cost of this product (not including e-MAS supply) †	0.028	.070
Insufficient resources (e.g. staff, space etc) within my pharmacy has limited the practice of this product [†]	080*	.002
It is likely that customers could misuse this product [†]	077*	060
Customers not accepting my advice around this product makes me less likely to adopt this product [†]	0.003	.036
I have access to sufficient sources of information relating to this product	.097**	.088*
The similarity of POM and P packs of this product could create confusion [†]	-0.065	085*
I believe there are high risks of adverse events associated with this product [†]	.115***	.026
It has been my management's decision rather than my own as to if/ how far to adopt into practice [†]	084*	.137***
Introduction of this product may have represented a 'step too far' for OTC products [†]	¥	099***
I get adequate support from my professional body to adopt this product	.113***	.078*
Lack of proper way to communicate with the local medical practice is a barrier to adopt this product [†]	-0.053	.062
Lack of access to patient medical records makes it difficult to adopt this product into practice [†]	.094**	.140***
I am/would be comfortable going off guidelines to supply this product	.113***	.093*

^{*}P≤0.05; ***P≤0.01;***P≤0.001 †Items reversed scored 4 Correlation values ≥.2 and appears in Chapter 6

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Table 16.12: Bivariate analysis showing correlations of the outcome 'simvastatin acceptance' and 'simvastatin adoption' with self innovativeness and demographic characteristics displaying Kendals' T values of of <.2

Variables	Kendal's T correlation values with 'simvastatin acceptance'	Kendal's T correlation values with 'simvastatin adoption'
Innovativeness	0.047	0.040
Gender	-0.040	085*
Age	0.048	0.048
Experience	0.025	0.034
Type of pharmacy	0.049	0.072
Owner	-0.012	0.011
Manager	.095*	0.072
Relief	-0.022	-0.077
Second	-0.048	-0.006
Locum	-0.055	-0.001
Non-store	-0.019	0.019
Prescriber	0.032	-0.005
Postgraduate qualification	-0.010	-0.052
Location	-0.038	0.013

^{*}P≤0.05

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Table 16.13: Bivariate analysis showing correlations of the outcome 'chloramphenicol acceptance' and 'chloramphenicol adoption' with the 24 items scale displaying Kendals' T values of <.2

Statements	Kendal's T correlation values with 'chloramphenicol acceptance'	Kendal's T correlation values with 'chloramphenicol adoption'
This product has potential for good financial returns for my pharmacy	.166***	¥
It is likely that customers could misuse this product [†]	.154***	.074
My customers often complain about the cost of this product (not including e-MAS supply) †	.091	.150***
Customers not accepting my advice around this product makes me less likely to adopt this product [†]	.098*	.112***
I am happy to delegate the task of supplying this product to support staff	.004	.196***
Many customers ask for this product by name	.098*	.130***
Insufficient resources (e.g. staff, space etc) within my pharmacy has limited the practice of this product [†]	.156***	.161***
I find the processes involved in the supply of this product complex [†]	.181***	¥
I have access to sufficient sources of information relating to this product	.119***	.134***
The similarity of POM and P packs of this product could create confusion†	.104***	.129***
It is easy for me and/or my customers to know if treatment with this product is effective	.132***	.174***
I believe there are high risks of adverse events associated with this product [†]	.195***	.129***
I believe this product has potential to engender patient satisfaction	.083*	.016
It has been my management's decision rather than my own as to if/ how far to adopt into practice†	.105***	.004
Lack of access to patient medical records makes it difficult to adopt this product into practice [†]	.132***	.148***
Lack of proper way to communicate with the local medical practice is a barrier to adopt this product [†]	.119***	.134***
I get adequate support from my professional body to adopt this product	.095*	.070
I am/would be comfortable going off guidelines to supply this product	.041	.052

^{*}P≤0.05; ***P≤0.001; †Items reversed scored [¥] Correlation values ≥.2 and appears in Chapter 6

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Table 16.14: Bivariate analysis showing correlations of the outcome 'chloramphenicol acceptance' and 'chloramphenicol adoption' with innovativeness and demographic

characteristics displaying Kendals' T values of <.2

Variables	Kendal's T correlation values with 'chloramphenicol acceptance'	Kendal's T correlation values with 'chloramphenicol adoption'
Innovativeness	0.073	.147***
Gender	0.032	.098*
Age	-0.039	184***
Number of years registered with the RPSGB	-0.032	154***
Type of pharmacy	0.009	.126***
Owner	-0.012	0.028
Manager	-0.009	0.014
Relief	0.071	-0.040
Second	-0.058	-0.043
Locum	-0.012	0.029
Non-store	-0.012	-0.019
Prescriber	-0.021	-0.051
Postgraduate qualification	0.000	-0.073
Location	0.019	-0.013

^{*}P≤0.05; ***P≤0.001;

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Non-respondent analysis

Table 16.15: Non-significant univariate **associations relating to non-respondent analysis** (Note: this table extends up to eight pages)

Respondent category with age

					Age			Total
			29 and under	30-39	40-49	50-59	60 and above	
Category as per time of response	Early respondents	Count	167	104	81	80	14	446
		% within Category as per time of response	37.4%	23.3%	18.2%	17.9%	3.1%	100.0%
	Late respondents	Count	46	26	11	21	4	108
	1	% within Category as per time of response	42.6%	24.1%	10.2%	19.4%	3.7%	100.0%
Total		Count	213	130	92	101	18	554
		% within Category as per time of response	38.4%	23.5%	16.6%	18.2%	3.2%	100.0%

P=0.387

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Respondent category with number of years registered with the RPSGB

				Number in years				Total
			5 years and under	6-10	11-15	16-20	20 or above	
Category as per time of response	Early respondents	Count	144	82	40	44	138	448
	•	% within Category as per time of response	32.1%	18.3%	8.9%	9.8%	30.8%	100.0%
	Late respondents	Count	44	16	12	7	28	107
	·	% within Category as per time of response	41.1%	15.0%	11.2%	6.5%	26.2%	100.0%
Total		Count	188	98	52	51	166	555
		% within Category as per time of response	33.9%	17.7%	9.4%	9.2%	29.9%	100.0%

P=0.318

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Respondent category with type of pharmacy ownership

,				Type of pharmacy				
			Independen t	Small multiple (2- 4 stores)	Medium sized stores (5-25 stores)	Large multiples (over 25 stores)		
Category as per time of response	Early respondents	Count	82	55	79	221	437	
	1	% within Category as per time of response	18.8%	12.6%	18.1%	50.6%	100.0%	
	Late respondents	Count	17	14	13	62	106	
	-	% within Category as per time of response	16.0%	13.2%	12.3%	58.5%	100.0%	
Total		Count	99	69	92	283	543	
		% within Category as per time of response	18.2%	12.7%	16.9%	52.1%	100.0%	

P=0.376

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Respondent category with owner status

I I	-	•	Owner		Total
			Yes	No	
Category as per	Early	Count	79	375	454
time of response	respondents	% within Category			
		as per time of	17.4%	82.6%	100.0%
		response			
	Late	Count	18	90	108
	respondents	% within Category			
		as per time of	16.7%	83.3%	100.0%
		response			
Total		Count	97	465	562
		% within Category			
		as per time of	17.3%	82.7%	100.0%
		response			

P=0.968

Respondent category with manager status

			Manager		Total
			Yes	No	
Category as per	Early	Count	328	126	454
time of response	respondents	% within Category			
		as per time of	72.2%	27.8%	100.0%
		response			
	Late	Count	79	29	108
	respondents	% within Category			
		as per time of	73.1%	26.9%	100.0%
		response			
Total		Count	407	155	562
		% within Category			
		as per time of	72.4%	27.6%	100.0%
		response			

P=0.945

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Respondent category with relief status

			Relief		Total
			Yes	No	
Category as per	Early	Count	32	422	454
time of response	respondents	% within Category			
		as per time of	7.0%	93.0%	100.0%
		response			
	Late	Count	8	100	108
	respondents	% within Category			
		as per time of	7.4%	92.6%	100.0%
		response			
Total		Count	40	522	562
		% within Category			
		as per time of	7.1%	92.9%	100.0%
		response			

P=1.000

Respondent category with 'second' status

			Second		Total
			Yes	No	
Category as per	Early	Count	17	437	454
time of response	respondents	% within Category			
_		as per time of	3.7%	96.3%	100.0%
		response			
	Late	Count	4	104	108
	respondents	% within Category			
		as per time of	3.7%	96.3%	100.0%
		response			
Total		Count	21	541	562
		% within Category			
		as per time of	3.7%	96.3%	100.0%
		response			

P=1.000

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Respondent category with locum status

			Loc	um	Total
			Yes	No	
Category as per	Early	Count	14	440	454
time of response	respondents	% within Category			
		as per time of	3.1%	96.9%	100.0%
		response			
	Late	Count	2	106	108
	respondents	% within Category			
		as per time of	1.9%	98.1%	100.0%
		response			
Total		Count	16	546	562
		% within Category			
		as per time of	2.8%	97.2%	100.0%
		response			

P=0.711

Respondent category with non-store status

		•	Non-store		Total
			Yes	No	
Category as per	Early	Count	0	454	454
time of response	respondents	% within Category			
		as per time of	.0%	100.0%	100.0%
		response			
	Late	Count	1	107	108
	respondents	% within Category			
		as per time of	.9%	99.1%	100.0%
		response			
Total		Count	1	561	562
		% within Category			
		as per time of	.2%	99.8%	100.0%
		response			

P=0.434 (Fisher's exact test)

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Respondent category with prescriber status

			Prescriber		Total
			Yes	No	
Category as per	Early	Count	116	333	449
time of response	respondents	% within Category			
		as per time of	25.8%	74.2%	100.0%
		response			
	Late	Count	30	78	108
	respondents	% within Category			
		as per time of	27.8%	72.2%	100.0%
		response			
Total		Count	146	411	557
		% within Category			
		as per time of	26.2%	73.8%	100.0%
		response			

P=0.772

Respondent category with postgraduate qualification status

,g	<i>y</i> yy	•	Postgraduate qualification		Total
			Yes	No	
Category as per	Early	Count	76	374	450
time of response	respondents	% within Category as per time of response	16.9%	83.1%	100.0%
	Late	Count	15	92	107
	respondents	% within Category as per time of response	14.0%	86.0%	100.0%
Total		Count	91	466	557
		% within Category as per time of response	16.3%	83.7%	100.0%

P=0.564

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Respondent category with pharmacy location

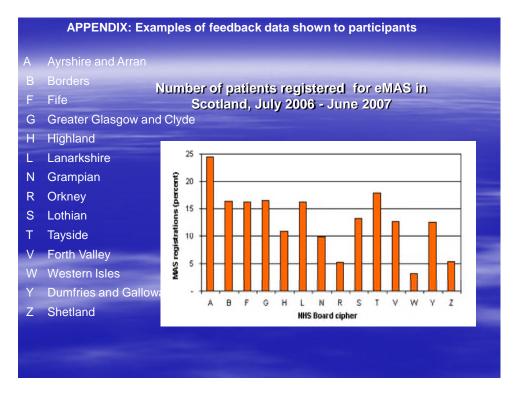
			Location			Total	
				Sub-		Locum/	
			Urban	urban	Rural	Relief	
Category as per	Early	Count	138	179	120	16	453
time of response	respondents	% within Category					
		as per time of	30.5%	39.5%	26.5%	3.5%	100.0%
		response					
	Late	Count	30	52	21	5	108
	respondents	% within Category					
		as per time of	27.8%	48.1%	19.4%	4.6%	100.0%
		response					
Total		Count	168	231	141	21	561
		% within Category					
		as per time of	29.9%	41.2%	25.1%	3.7%	100.0%
		response					

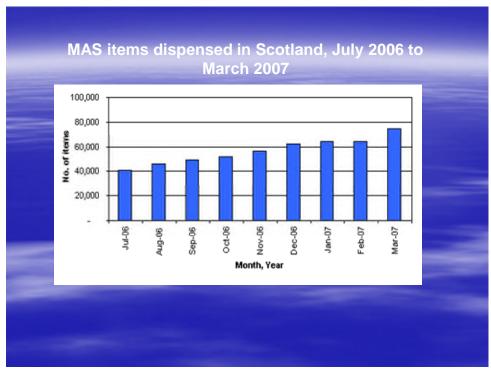
P=0.285

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APPENDIX VII (CHAPTER 7)

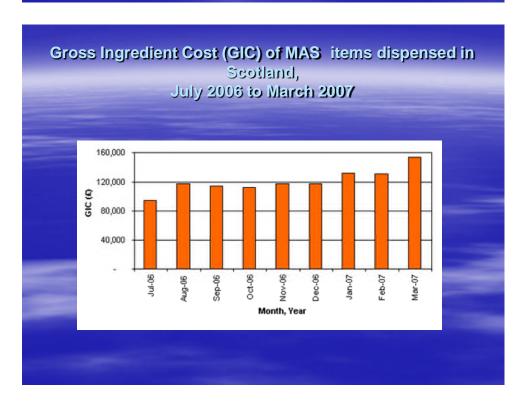
Examples of e-MAS performance feedback data presented to focus groups and interview participants as vignettes



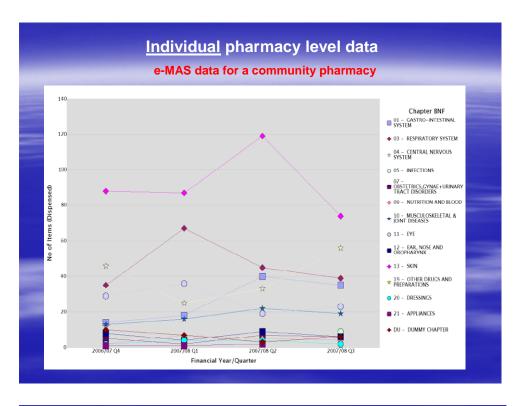


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	TOP 10 MAS items dispensed in Scotland July 2006 to March 2007					
	Drug Name	Examples of use in MAS	No of items			
	Paracetamol	Pain, fever	84,609			
	Ibuprofen	Pain, fever, inflammation	32,230			
	Simple Linctus	Cough	32,096			
	Malathion	Scabies, head lice, crab lice	24,877			
	Chloramphenicol	Eye infections	17,698			
	Pholcodine	Cough	17,315			
Ē	Clotrimazole	Vaginal thrush, athlete's foot	16,179			
-	Pseudoephedrine Hydrochloride	Nasal congestion	15,855			
	Emollients	Dry scaly skin	13,229			
	Aciclovir	Cold sores	12,556			



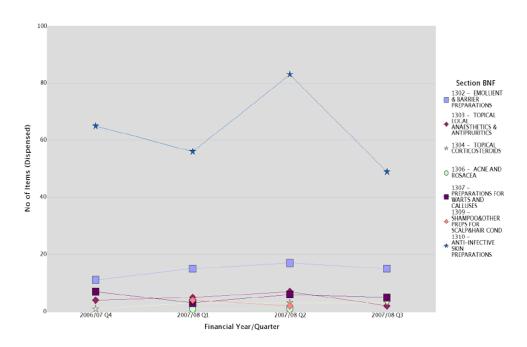
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Individual pharmacy level data

e-MAS data for a community pharmacy

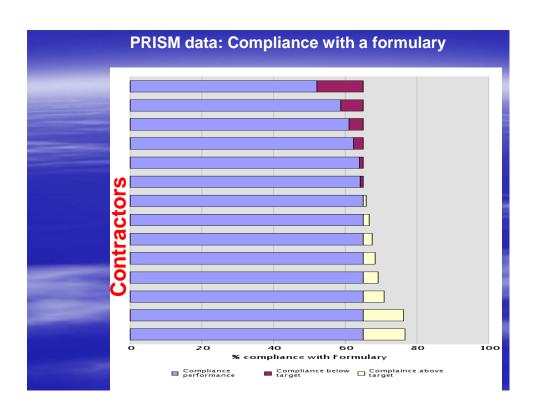
13 - SKIN



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Applications of PRISM data in GP prescribing

- Prescriber can see whether prescribing reflects policies
- Adherence to the guidelines
- To look for cost effective prescribing
- To compare with peers, other health boards and with national averages.



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APPENDIX VIII (CHAPTER 8)

Table 18.1: Univariate analysis with non-significant association of explanatory variables with the outcome measure (Note: this table extends up to two pages)

Facilitators

Scale items	Categories	Low adoption* n(%)	High adoption† n(%)	P value
Financial benefits to me (N=	Yes	5	33	0.827
490)		(13.2)	(86.8)	
	No	72	380	
		(15.9)	(84.1)	
Opportunity for enhanced	Yes	10	95	0.068
working with GPs (N=489)		(9.5)	(90.5)	
	No	67	317	
		(17.4)	(82.6)	

^{*}Represents 3 or below in the five point scale; †Represents 4 or above in the five point scale; % represent proportion within row category

Barriers

Scale items*	Categories	Low adoption n(%)	High adoption	P value
			n(%)	
Lack of satisfactory	Yes	52	308	0.252
reimbursement (N= 490)		(14.4)	(85.6)	
	No	25	105	
		(19.2)	(80.8)	
Lack of satisfactory	Yes	49	303	0.109
remuneration (N=490)		(13.9)	(86.1)	
	No	28	110	
		(20.3)	(79.7)	
Time for recording consultation	Yes	22	165	0.078
or supply (N=490)		(11.8)	(88.2)	
	No	55	248	
		(18.2)	(81.8)	
Suspected misuse/overuse of	Yes	19	105	1.000
the service by some customers		(15.3)	(84.7)	
(N=490)	No	58	308	
		(15.8)	(84.2)	
Inadequate resources of my	Yes	68	377	0.539
pharmacy (N= 490)		(15.3)	(84.7)	
	No	9	36	
		(20.0)	(80.0)	
Lack of opportunity for	Yes	66	352	1.000
enhanced working with GPs		(15.8)	(84.2)	
(N=490)	No	11	61	
		(15.3)	(84.7)	

^{*}Items reversed scored

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Demographic characteristics

Variables	Categories	Low adoption n(%)	High adoption n(%)	P value
Gender (N= 483)	Male	26	168	0.353
,		(13.4)	(86.6)	
	Female	49	240	
		(17.0)	(83.0)	
Owner (N=490)	Yes	18	67	0.174
,		(21.2)	(78.8)	
	No	59	346	
		(14.6)	(85.4)	
Manager (N= 490)	Yes	54	305	0.591
,		(15.0)	(85.0)	
	No	23	108	
		(17.6)	(82.4)	
Relief (N= 490)	Yes	2	33	0.148
,		(5.7)	(94.3)	
	No	75	380	
	- 10	(16.5)	(83.5)	
Second (N= 490)	Yes	4	12	0.295*
second (1 v 150)	100	(25.0)	(75.0)	0.250
	No	73	401	
	110	(15.4)	(84.6)	
Locum (N= 490)	Yes	2	13	1.000*
((13.3)	(86.7)	_,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
	No	75	400	
	- 10	(15.8)	(84.2)	
Non-store (N= 490)	Yes	0	1	1.000*
((0.0)	(100.0)	_,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
	No	77	412	
	110	(15.7)	(84.3)	
Pharmacist prescriber (N=	Yes	17	106	0.677
487)		(13.8)	(86.2)	
,	No	58	306	
	1,0	(15.9)	(84.1)	
Postgraduate qualification	Yes	11	71	0.692
(N= 485)		(13.4)	(86.6)	
(2. 100)	No	64	339	
	2.0	(15.9)	(84.1)	
Location (N= 437)**	Urban	20	111	0.405
		(15.3)	(84.7)	2.200
	Suburban	29	165	
	Juburban	(14.9)	(85.1)	
	D1	, ,	, ,	
	Rural	23	89	
		(20.5)	(79.5)	

^{*}Fisher's exact test; ** Locums/reliefs excluded from the analysis

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APPENDIX- X (GENERAL) (no appendix to Chapter 9 exist) Table 19.1: List of researchers' training activities

Date, Organizer, Venue	Title and brief description of training	Category of skill development
15-17 September 2009 Cochrane Qualitative Research Methods Group and University of Sheffield	Evidence Synthesis of Qualitative Research in Europe (ESQUIRE) Methods Workshop on Qualitative Evidence Synthesis	Systematic review of literature with diverse methodological applications
27 th November 2008, Writing up qualitative research, Wellcome Trust , Edinburgh.	Advanced skills on writing up qualitative research.	Technical ability, presentation of research.
24 th November 2008 NVivo course intermediate training, Robert Gordon University	Intermediate skills on application of NVivo qualitative data management software	Technical ability
28 th October 2008 IRAS application training, NHS Grampian , Aberdeen	Skills on successfully completing Integrated Research Application System	Research Ethics and Governance
8-12 September 2008 The Robert Gordon University, Aberdeen	PG Certificate module 2. Advanced courses on literature critical appraisal skills, analysing data and presenting results. The Robert Gordon University.	Technical and project management skills.
22-25 April, 2008 Social Research Association (SRA) Scotland, Edinburgh	Quantitative training courses by Social Research Association Scotland. Focussed on survey techniques. Skills around design, sampling, conduction and analysis of survey and survey results.	Technical ability
28th February- 4th March, 2008 Social Research Association (SRA) Scotland, Edinburgh	Qualitative research training course by Social Research Association Scotland: Conducting, analysing and reporting focus group and interviews data. Specialized skills around conducting focus groups and interviews, framework technique of analysis and a brief session on reporting focus group data.	Technical ability
31st January 2008 Social Research Association (SRA) Scotland, Edinburgh	Introduction to qualitative research: Designing a qualitative study. Generic training about concepts and design of qualitative research.	Project design
2 nd November, 2007 Medicine and Health Regulatory Agency (MHRA) , London	Medicine and Health Regulatory Agency (MHRA) training day for clinical pharmacologists. Training around procedures of new drug approval and reclassification of medicines. London.	Knowledge in research area.
22-26 October 2007 The Robert Gordon University, Aberdeen	PG Certificate research Methods. Basic knowledge and skills training around doing a PhD. Introduction to PhD, planning and management of project. Introduction to qualitative and quantitative methods. Research ethics and governance issues. Literature review techniques.	Critical appraisal, project management, data analysis, research governance.

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