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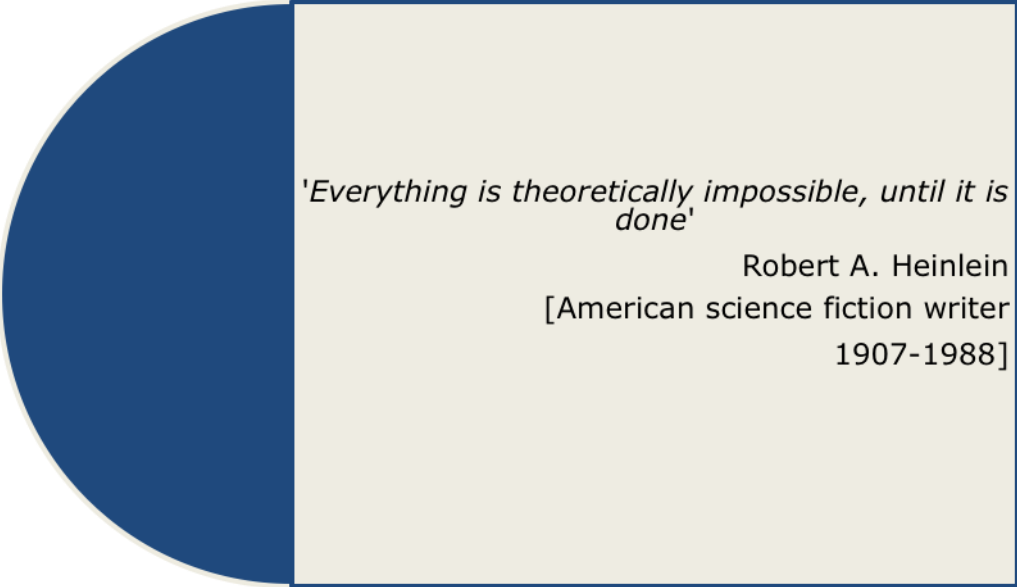
**EXPLORING STRUCTURES AND PROCESSES OF  
MEDICINES MANAGEMENT IN ELDERLY  
HOSPITALISED PATIENTS IN THE UNITED ARAB  
EMIRATES**

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[MPharm (Master of Pharmacy), PgCert (Research Methods)]

A thesis submitted in part fulfillment of the requirements of the Robert  
Gordon University for the degree of Doctor of Philosophy

**November 2015**



*'Everything is theoretically impossible, until it is  
done'*

Robert A. Heinlein  
[American science fiction writer  
1907-1988]

## **Abstract**

Given the complexity of medicines use in elderly patients, structures and processes of medicines management are key to deriving best outcomes. This research was conducted in hospitals in the United Arab Emirates (UAE) and focused on the patient journey from admission to discharge.

The overall aim was to explore the structures and processes of medicines management in elderly hospitalised patients in the UAE, conducted in three phases.

### Phase 1

Following a review of systematic reviews of aspects of medicines management (e.g. reconciliation), this phase focused on a specific, emerging tool (the Drug Burden Index (DBI)) relating to anticholinergic/sedative agents, which are problematic in the elderly. The aim was to critically appraise, synthesize and present evidence of DBI use. The review protocol was registered with the Joanna Briggs Institute and conducted according to best accepted practice. The key finding was the lack of evidence of DBI use prospectively to identify potentially inappropriate prescribing.

### Phase 2

Phase 2 employed a qualitative phenomenological design to explore health professionals' views and experiences of medicines management. Semi-structured interviews were conducted with 27 professionals and analysed using Normalization Process Theory (NPT) and the Theoretical Domains Framework (TDF). Findings revealed little evidence of coherence, cognitive participation, collective action and reflexive monitoring (NPT). TDF domains dominant were: professional role, identity; beliefs about capabilities; beliefs about consequences; environmental context, resources; and knowledge.

### Phase 3

The Delphi technique in phase 3 aimed to determine consensus around medicines management using an expert panel of policy makers, educators and lead health professionals. Phase 1 and 2 findings were used in construction of validated statements. A high level of consensus ( $\geq 70\%$  strongly agree/agree) was obtained for statements other than those for targeting medicines management (rather than all elderly admissions) and tasks linked to professions (rather than trained staff).

Overall, this research has generated original findings focused on the entire inpatient hospital journey, particularly the need to more clearly define, refine and agree on healthcare structures and processes across the entire patient journey from admission to discharge. The use of the NPT and TDF has highlighted those individual practitioners and organisational issues which require consideration.

**Keywords:** Medicines management, structures, processes, Drug Burden Index, qualitative interview, TDF, NPT, Delphi study

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## **External output**

### **Published peer reviewed papers**

1. Al Shemeili, S., Stewart, D. (2014) Use of the Drug Burden Index to identify and reduce potentially inappropriate prescribing of anticholinergic and sedative agents in elderly patients in institutionalized care: a systematic review protocol. *JBIC Database of Systematic Reviews & Implementation Reports*, 12:48-59

The following papers are under review:

1. An in-depth exploration of health professionals' views and experiences of medicines management structures, processes and outcomes in elderly, hospitalised patients in Abu Dhabi. Submitted to *International Journal of Clinical Pharmacy*
2. A Delphi study of structures and processes related to medicines management for elderly hospitalised patients in the United Arab Emirates. *European Journal of Hospital Pharmacy*

### **Peer reviewed conference abstracts**

1. Al Shemeili, S., Klein S., Strath A., Stewart, D. (2013) Identifying inappropriate anticholinergic prescribing in the elderly: a systematic review. *International Journal of Clinical Pharmacy*.  
(Poster presentation at European Society of Clinical Pharmacy Conference, Prague 2013)
2. Al Shemeili, S., Fares, S., Klein S., Strath A., Stewart, D. (2014) Exploring health professionals' views and experiences of medicines management for elderly, hospitalised patients in Abu Dhabi. *International Journal of Clinical Pharmacy*.  
(Poster presentation at European Society of Clinical Pharmacy Conference, Copenhagen 2014)



3. Al Shemeili, S., Fares, S., Klein S., Strath A., Stewart, D. (2015) Exploring health professionals' views and experiences of medicines management for elderly, hospitalised patients in Abu Dhabi.  
(Oral presentation at 20<sup>th</sup> Dubai International Pharmaceutical & Technologies Conference & Exhibition)
  
4. Al Shemeili, S., Klein S., Strath A., Stewart, D. (2015) A Delphi study to determine consensus around aspects of medicines management for elderly, hospitalised patients. *International Journal of Clinical Pharmacy*.  
(Poster presentation at European Society of Clinical Pharmacy Conference, Lisbon 2015)

## Abbreviations

ADRs	Adverse Drug Reactions
AGS	American Geriatrics Society
BCW	Behaviour Change Wheel
BNF	British National Formulary
CINAHL	Cumulative Index of Nursing and Allied Health Literature
CRD	Centre for Reviews and Dissemination
DBI	Drug Burden Index
DHA	Dubai Health Authority
HAAD	Health Authority Abu Dhabi
IPA	International Pharmaceutical Abstracts
JBI	Joanna Briggs Institute
MAI	Medicines Appropriateness Index
MEDLINE	Medical Literature Analysis and Retrieval System Online
MHRA	Medicines and Healthcare Products Regulatory Agency
MoH	Ministry of Health
MRC	Medical Research Council
NGT	Nominal Group Technique
NICE	National Institute of Health and Care Excellence
NIHR	National Institute for Health Research
NPC	National Prescribing Centre
NPT	Normalization Process Theory
PI	Principal Investigator
PICO	Population, Intervention, Comparator, Outcome
PIMs	Potentially Inappropriate Medicines
RAM	RAND/UCLA Appropriateness Method
SEHA	Abu Dhabi Health Services Company
SEMP	Scottish Centre for Evidence-based Multi-Professional Practice
SPSS	Statistical Package for the Social Sciences
START	Screening Tool to Alert Right Treatment
STOPP	Screening Tool of Older Persons Prescriptions
TDF	Theoretical Domains Framework

UAE	United Arab Emirates
UK	United Kingdom
US	United States
WHO	World Health Organization

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## **CHAPTER 1: Medicines Management in Elderly Patients**

This chapter commences with an overview of medicines management in terms of definitions and scope, while highlighting the lack of a global definition. The medicines management model to be studied in this doctoral research is presented. Attention is then paid to aspects of medicines management in the elderly, such as medicines review and medicines adherence, describing relevant, published systematic reviews. There is specific focus on tools and approaches to identify and eliminate potentially inappropriate prescribing in elderly patients. The doctoral research is then considered within the context of the United Arab Emirates (UAE). The chapter ends with defining the overall aim and the aims of the phases of the doctoral research.

### **1.1 Medicines management**

Given the multiplicity of issues relating to medicines in the elderly (which are described throughout this thesis), the structures and processes of medicines management should be defined and described clearly to optimise patient outcomes.

However, a search of several literature databases (Medline, Cumulative Index of Nursing and Allied Health Literature (CINAHL), International Pharmaceutical Abstracts (IPA) and Google Scholar) and grey literature sources (Google) highlighted the lack of a globally accepted definition of the term, 'medicines management'. There are, however, several more commonly cited definitions.

The United Kingdom (UK) Audit Commission in 2001 stated that, 'medicines management in hospitals encompasses the entire way that medicines are selected, procured, delivered, prescribed, administered and reviewed to optimise the contribution that medicines make to producing informed and desired outcomes of patient care'. (Audit Commission 2001)

In 2002, the National Prescribing Centre (NPC) in England (now part of the National Institute for Health and Care Excellence, NICE) added that medicines management 'considers the systems of processes and behaviours determining how medicines are used by patients and the [National Health Service] NHS. Medicines management has primarily been led by pharmacy teams and is the term that has been used historically in the NHS for managing people's medicines'. (National Prescribing Centre 2002) This was a comprehensive document which included details of specific objectives, and health professionals' key roles and actions. The following objectives were suggested for medicines management:

- to maintain good health,
- to improve the health status of people,
- to enable people to care for themselves,
- to improve choice and enable access to better health services and
- to reduce waste and save money.

The concept of medicines management should allow healthcare professionals and patients to 'maximise benefits from the use of medicines and reduce associated risks'. (National Prescribing Centre 2002) A wide range of practices such as prescribing, dispensing, administering and monitoring as well as promoting patient adherence to medicines are encompassed within the scope of medicines management. Key roles of healthcare professionals (particularly pharmacists and others) comprise: developing medicines related care plans to promote appropriate choice of drug therapy; monitoring outcomes of effectiveness and safety; and educating patients, families and carers to promote medicines adherence. (National Prescribing Centre 2002)

In 2004, the Medicines and Healthcare Products Regulatory Agency (MHRA) in the UK stated that 'medicine management is the clinical, cost-effective and safe use of medicines to ensure patients get the maximum benefit from the medicines they need, while at the same time minimising potential harm'. (Medicines Healthcare products and Regulatory Agency 2004)

Very recently, NICE suggested the term 'medicines optimisation' which 'requires evidence-informed decision making about medicines, involving effective patient engagement and professional collaboration to provide individualised, patient-centred approach to medicines use, within available resources'. (NICE Medicines and Prescribing Centre 2015)

Whatever the definition, medicines management in the elderly is complex, requiring clarity around healthcare structures and processes in order to achieve the best possible outcomes.

The medicines management model being studied in this thesis focuses on healthcare structures and processes throughout the patient journey while in the hospital, as depicted in Figure 1.1.

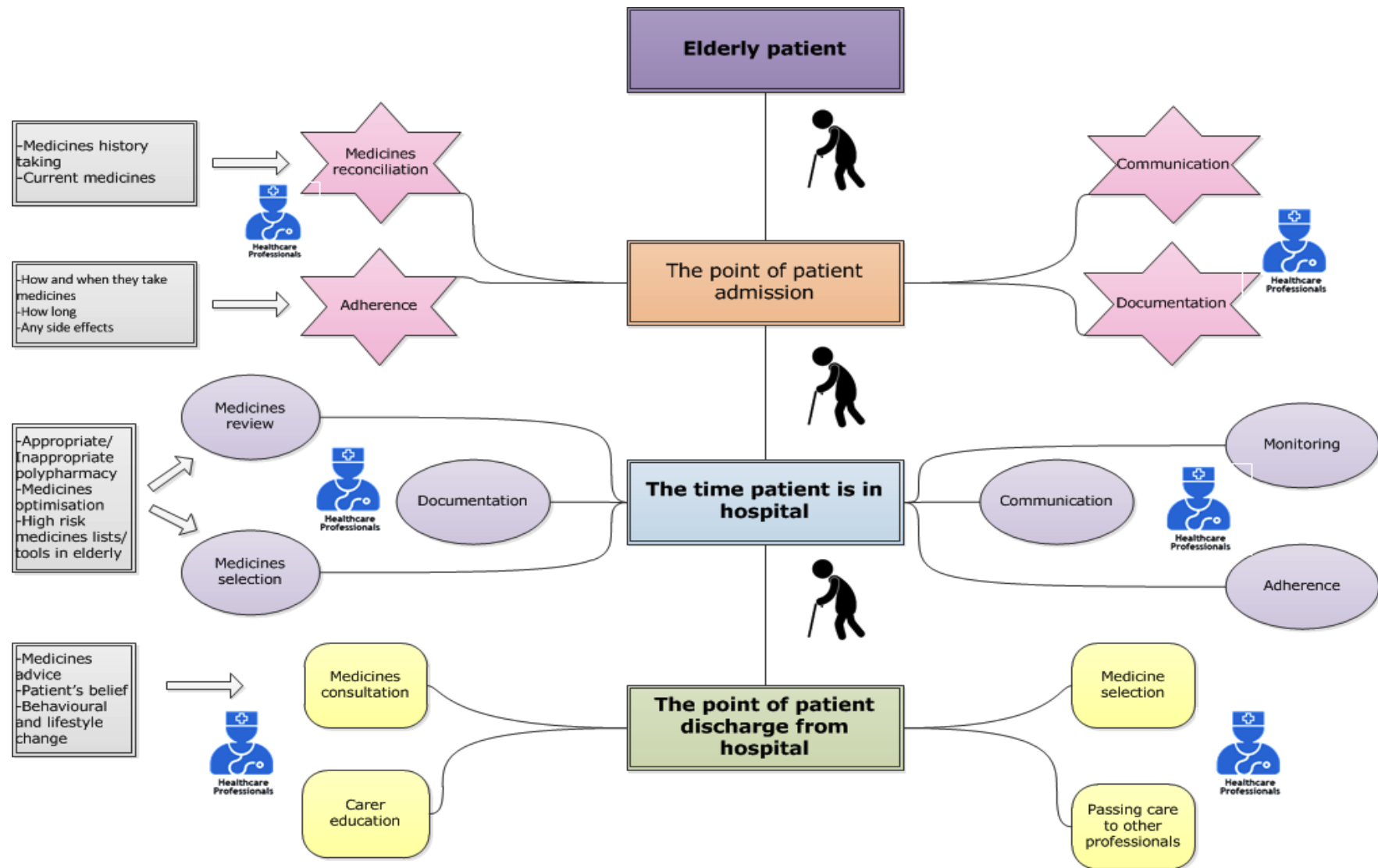


Figure 1.1: The medicines management model for patients while in hospital

## **1.2 Medicines in elderly**

This research focused on medicines management in the elderly. While the United Nations (UN) refers to those aged 60 years and over as 'older people', most developed countries have accepted the chronological age of 65 years as the definition of an 'older person'. (WHO 2015) The age of 65 years is used as a reference point for older persons as this is often the age at which persons become eligible for old-age social security benefits; Medicare in the United States of America (USA) also adopts this age as the cut-off for older people. The UN report on World Population Ageing states that the global share of older people (aged 60 years and over) increased from 9.2% in 1990 to 11.7% in 2013 and will continue to grow as a proportion of the world population, reaching 21.1% by 2050. (WHO 2015) This trend is said to have a serious impact on healthcare considerations for the elderly.

There are many issues to consider in relation to medicines and their management in this target group. These are described in relation to the components of the medicines management model described in Figure 1.1.

### **1.2.1 Physiological changes and chronic conditions**

As people age, they become more susceptible to disease and disability. The process of aging is a continuum of changes in parameters of biology, functionality, psychology and social status that vary from individual to individual. This variation depends on many factors such as genetics, age-related vulnerability, and differences in organ functioning. Chronic conditions, such as type 2 diabetes mellitus, rheumatoid arthritis, hypertension, and chronic obstructive pulmonary disease compromise the quality of life of older people. According to the USA National Council of Aging, almost all (91%) older people have at least one chronic condition, and 73% have at least two. (Lee, Cigolle and Blaum 2009)

Multimorbidity is defined by the World Health Organisation as 'the co-occurrence of two or more chronic medical conditions in one person'. (World Health Organization 2014) Epidemiological data indicate that multimorbidity increases



markedly with age, being prevalent in almost two thirds of individuals aged 80 years and over. (Barnett *et al.* 2012, Ornstein *et al.* 2013) A systematic review reported by Violan *et al.* aimed to review studies of the patterns, prevalence and determinants of multimorbidity in primary care. The search was conducted in databases (CINAHL, PsychINFO, Medline and Embase) for the period of 1961 to 2013. The review identified 5665 titles, which were reduced to 39 papers by screening of titles, abstracts, papers and critical appraisal. Synthesis of the findings highlighted that multimorbidity is associated consistently with age (odds ratio 1.26-227.46), lower socioeconomic status (odds ratio 1.20-1.91) and presence of mental health problems (odds ratio 2.90-3.00). The authors concluded that, almost regardless of study approaches and methods employed, multimorbidity is the norm in those aged 65 and older. (Violan *et al.* 2014)

A further consideration in terms of the elderly and chronic conditions is that certain conditions or syndromes, termed 'geriatric syndromes' are very common among older adults. Delirium (a form of temporary confusion) and dementia (an illness, such as Alzheimer's disease, characterized by on-going confusion and memory loss) are key examples of such syndromes. Others which are prevalent include urinary incontinence (or other bladder problems), dizziness, a tendency to falls, and deterioration in vision and hearing. (Blanco-Reina *et al.* 2014)

### 1.2.2 Pharmacokinetics, pharmacodynamics

Two basic concepts that are important considerations to pharmacotherapy in the elderly are pharmacokinetics and pharmacodynamics. Pharmacokinetics describes how medicines are absorbed, distributed, metabolized and eliminated from the body (i.e. the effect of physiological processes on drugs). Pharmacodynamics is the study of the biochemical and physiological effects of drugs (i.e. the effect of drugs on the body) which are effected through specific mechanisms of action, including therapeutic, intended effects and adverse, unwanted effects. (Hammerlein, Derendorf and Lowenthal 1998)

Age-related physiological changes influence drug absorption. These changes include increased gastric pH, decreased gastric emptying, decreased intestinal motility, and reduced splanchnic blood flow. Of the four pharmacokinetic considerations (drug distribution etc.), absorption is the least affected by age. (Kinirons and Crome 1997)

Drug distribution depends on a variety of factors including body composition, plasma protein binding and organ blood flow. The first factor, body composition, changes significantly with age. (Kinirons and Crome 1997) The elderly have lower total body water and lean muscle mass, with an increased percentage of fat tissue. (Woodhouse 1994) The significance of these changes on distribution depends on the physiochemical properties of the drug in question. For example, a fat-soluble drug taken by an elderly patient will be distributed more to the adipose tissue, reducing the amount of the drug available to the systemic circulation. (Woodhouse 1994) In contrast, a water-soluble drug taken by the same elderly patient will be more available in circulation due to decreased water composition. (Woodhouse 1994) Body composition is not the only factor that influences distribution of a drug in the body. Many drugs bind to plasma proteins circulating in the bloodstream. Acidic drugs bind primarily to albumin, which may be decreased in the elderly, especially if malnutrition or serious illness is present. Factors that influence binding and therefore drug distribution include the protein concentration, the presence of comorbid diseases and concurrent drugs, and the nutritional status of the patient. (Kinirons and Crome 1997) These factors are all relevant in the elderly.

Drug metabolism impacts how the drug in turn affects the body. Drug clearance through the liver is dependent on biotransformation through enzyme systems and hepatic blood flow. (Ritschel and Kearns 2004) Some of these enzyme systems are reduced considerably in the elderly, while others are not altered to any significant extent. The liver itself decreases in total mass with age, but its function is not impaired. Of much more importance is the decrease in hepatic blood flow with advancing age. (Ritschel and Kearns 2004) It is estimated that blood flow to the liver is reduced by as much as 45% in those over 65 years. (Woodhouse 1994) This decrease in blood flow may increase bioavailability of drugs that have a high extraction rate by the liver.

Probably the most significant change in the elderly relates to the renal elimination of drugs. Renal anatomical and functional changes are associated with aging. The kidney decreases in size, with renal tubular and vascular changes. (Ritschel and Kearns 2004) The number of glomeruli also decrease. Functional changes include a decrease in the glomerular filtration rate (GFR) and mean creatinine clearance.(Ritschel and Kearns 2004) The decrease in GFR, renal plasma flow and tubular secretion contribute to a significant decrease in elimination of renally excreted drugs, in some cases, by a factor of 50% or greater. (Ritschel and Kearns 2004) The important consideration of the changes in renal function in relation to selection of medicines, dosing, route, and monitoring required is highlighted by the number of texts which intend to support practitioners. For example the British National Formulary (BNF) guides prescribers to: only use a medicine when there is a definite indication; select a medicine with minimal or no nephrotoxicity; monitor the patient carefully for evidence of toxicity of drugs and clinical effectiveness; and use a dosage regimen recommended for renal impairment. (British National Formulary 2013)

Pharmacodynamic effects involve the positive or negative effects of drugs on the body. Pharmacodynamic effects are influenced by changes in receptor binding, the number of receptors or events that occur after binding. The consequences of these changes include increased sensitivity to a drug or a decreased response from other drugs. Receptor binding is a major factor in the occurrence of adverse reactions.(Swift 1990)

Pharmacokinetic and pharmacodynamic considerations are therefore extremely important as part of medicines management in the elderly.

### 1.2.3 Polypharmacy

Given the worldwide expansion in pharmacotherapy and an ever expanding emphasis on evidence based therapeutics, elderly patients are likely to be prescribed numerous medicines. Polypharmacy is considered to be 'one of the greatest prescribing challenges', increasing the likelihood of adverse drug reactions (ADRs), drug interactions and contributing to patient non-adherence to their medicines regimen. (Payne and Avery 2011) While traditionally polypharmacy has been classified in terms of the number of medicines (Woodward 2003, McLean and Le Couteur 2004) (usually defined as the use of five or more medicines), Patterson *et al.* suggested, as part of a Cochrane review in 2012 (later updated in 2014), that there should be a change in emphasis from inappropriate polypharmacy (prescribing of many medicines which are either inappropriate or no longer indicated) to appropriate or optimal polypharmacy (appropriate prescribing of many medicines). (Patterson *et al.* 2014)

There is a wealth of recent evidence on prevalence of polypharmacy in the elderly. UK data published in 2014 highlighted that 20.8% of patients with two clinical conditions were prescribed four to nine medicines, and 1.1% of patients ten or more medicines; in patients with six or more comorbidities, values were 47.7% and 41.7% respectively. (Payne *et al.* 2014) Similar statistics have been published for elderly residents of nursing homes in the USA.(Dwyer *et al.* 2010)

It is therefore evident that inappropriate polypharmacy is a major concern in the elderly and hence should be a focus of medicines management. Efforts are required to review medicines regimens to promote appropriate polypharmacy and indeed prevent potentially inappropriate prescribing at the point of medicines initiation. A systematic review reported by Patterson *et al.* aimed to determine which interventions, alone or in combination, were effective in improving the appropriate use of polypharmacy and reducing medication-related problems in older people. The search was conducted in databases (Database of Abstracts of Reviews of Effectiveness (DARE), Medline and Embase) for the period of 2009 to 2013. The review identified 2657 titles, which were reduced to ten papers by screening of titles, abstracts, papers and critical appraisal.

Despite its limitations, the review suggested that pharmaceutical care appears to improve prescribing for older patients receiving polypharmacy, especially when a multi-disciplinary element is included in the provision of care. The authors concluded that there is uncertainty about the elements of intervention that impact positively appropriate polypharmacy and thus further research is recommended. (Patterson *et al.* 2014)

Promoting appropriate polypharmacy at the initiation of medicines or during review of prescribed medicines is therefore a key aim of medicines management.

#### 1.2.4 Adverse drug reactions (ADR)

The World Health Organisation (WHO) in 1972 defined an ADR as 'a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function'. (World Health Organization 1972)

According to the Medicines and Healthcare Products Regulatory Agency (MHRA), an ADR is defined as 'an unwanted or harmful reaction which occurs after administration of a drug or drugs and is suspected or known to be due to the drug(s)'. (Medicines Healthcare products and Regulatory Agency 2004)

As described earlier, older people are likely to have multimorbidities and hence are likely to be prescribed a number of different medicines.

The concurrent use of multiple medicines increases the potential for ADRs and drug-drug interactions. Many studies from around the world demonstrate the correlation between increasing age and the incidence of ADRs. (Beijer and De Blaey 2002, Routledge, O'Mahony and Woodhouse 2004, Kongkaew, Noyce and Ashcroft 2008, Brahma *et al.* 2013) More than 80% of ADRs resulting in admission to hospital or occurring during stay in hospital are classified as being type A (dose-related) in nature, and thus are predictable from the known pharmacology of the drug. Such ADRs are therefore potentially avoidable, hence of relevance to medicines management. (Routledge, O'Mahony and Woodhouse

2004) In a systematic review, Wiffen *et al.* aimed to estimate the burden of ADRs in the UK. The search was conducted in databases (Medline, Embase and International Pharmaceutical Abstract). The review identified 138 titles, which were reduced to 69 papers by screening of titles, abstracts and papers. Findings of the review were that the incidence (cause of death) of ADRs in studies conducted in the UK was double that reported in the USA. (Wiffen *et al.* 2002)

The association of advanced age and vulnerability is well known. In 1991, Gurwitz and Avorn concluded that 'patient-specific physiological and functional characteristics are probably more important than any chronological measure in predicting both adverse and beneficial outcomes associated with specific drug therapies'. (Gurwitz and Avorn 1991)

Prescribing medicines with less likelihood of ADRs and monitoring regularly prescribed medicine in the elderly for the occurrence of ADRs (as well as effectiveness) is therefore a key focus of medicines management.

#### 1.2.5 Medicines review

The need for cautious prescribing of medicines in the elderly is emphasised in standard texts. For example the BNF has a specific section on prescribing for the elderly. Key issues highlighted are:

- appropriate prescribing - medicines should be reviewed regularly and medicines which are not of benefit should be stopped,
- form of medicines - patients should always be encouraged to take medicines with enough fluid,
- manifestations of ageing - for example, age related muscle weakness and difficulty in maintaining balance should not be confused with neurological disease and

- sensitivity - the nervous system of elderly patients is more sensitive to commonly used medicines, such as opioid analgesics, benzodiazepines, antipsychotics, and antiparkinsonian medicines, all of which must be used with caution. (Joint Formulary Committee and Royal Pharmaceutical Society of Great Britain 2012)

There is also a need to review regularly the medicines prescribed in the elderly (and indeed all patients) to ensure that they continue to be indicated, are effective and not resulting in ADRs. The NPC defines a 'medicines review' as a 'structured and critical examination of individual patients' medicines by a qualified healthcare provider with the objective of reaching an agreement with the patient about the continued appropriateness and effectiveness of the treatment, optimising the impact of medicines, minimising the number of medicines related problems and reducing waste'. (Room for Review 2002)

NPC describes three types of medicines review namely:

- prescription review – addresses issues related to the prescription and the medicines and may be conducted in the absence of the patient,
- concordance and compliance review – addresses issues related to the patients' medicines taking behaviours and
- clinical medicines review – addresses issues relating to the use of medicines being taken in accordance with the patients' clinical condition. (Clyne, Blenkinsopp and Seal 2008)

A guide for the UK NHS published in 2008 aimed to advise those providing and commissioning medicines reviews in a wide range of care settings. (Clyne, Blenkinsopp and Seal 2008) The medicines pathway and medicines review services are illustrated in Figure 1.2.

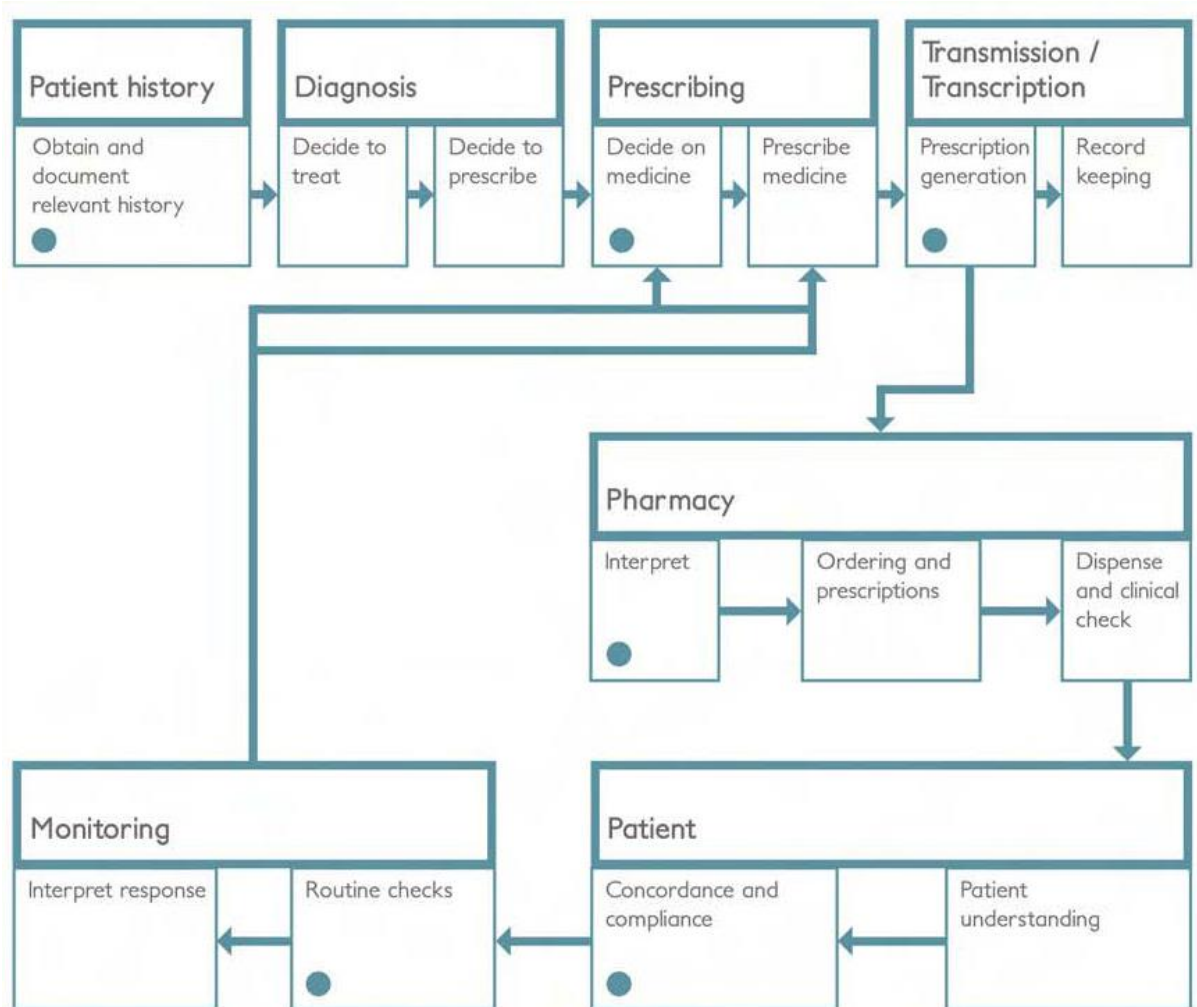


Figure 1.2: The medicines pathway and medicines review services

The authors proposed that the guide could support medicines review for safe, effective patient centred care. (Clyne, Blenkinsopp and Seal 2008, Violan *et al.* 2014) Regular, effective and efficient medicines reviews are therefore important aspects of medicines management in elderly patients.



### 1.2.6 Medicines reconciliation

A key process of medicines management for all patients (and not just the elderly) in the hospital setting is medicines reconciliation.

Medicines reconciliation has been defined by the Institute for Healthcare Improvement (an independent not-for-profit organisation based in UK) as 'the process of identifying the most accurate list of a patient's current medicines – including the name, dosage, frequency and route – and comparing them to the current list in use, recognizing any discrepancies, and documenting any changes, thus resulting in a complete list of medications, accurately communicated'.

Another definition by the Joint Commission (an independent, not-for-profit group in the US that gives voluntary accreditation to programs such as patient care, medicine safety for hospitals and other healthcare organisations) of medicines reconciliation is 'the process of comparing a patient's medicines orders to all of the medicines that the patient has been taking. This reconciliation is done to avoid medicines errors such as omissions, duplications, dosing errors, or drug interactions. It should be done at every transition of care in which new medicines are ordered or existing orders are rewritten. Transitions in care include changes in setting, service, practitioner, or level of care'. (Joint Commission 2010)

According to the Joint Commission, medicines reconciliation comprises five steps:

- developing a list of current medicines,
  - developing a list of medicines to be prescribed,
  - comparing the medicines on the two lists,
  - making clinical decisions based on the comparison and
  - communicating the new list to appropriate caregivers and to the patient.
- (Joint Commission 2010)

Across many countries, medicines discrepancies demanding reconciliation have been found at the points of patient admission and discharge, and in a range of situations, including emergency units (De Winter *et al.* 2010, Caglar *et al.* 2011, Mazer *et al.* 2011, Soler-Giner *et al.* 2011), mental health/psychiatry (Nelson *et al.* 2011, Paton *et al.* 2011), kidney dialysis (Peter 2010) and the elderly. (Gizzi *et al.* 2010, Steurbaut *et al.* 2010, Stitt, Elliott and Thompson 2011, Villanyi, Fok and Wong 2011, Pérennes *et al.* 2012)

Medicines reconciliation has been improved by a number of approaches. Various electronic reconciliation tools have been shown to be effective (Schnipper *et al.* 2009, Manzorro *et al.* 2011) and such tools have been reviewed. (Bassi, Lau and Bardal 2010) Reducing discrepancies have also been achieved by using an automated filtering process. (Hasan, Duncan, *et al.* 2008)

The use of standardised documentation has also been shown to have a positive impact, (Bédard *et al.* 2011) as has standardised list of questions. (De Winter *et al.* 2011) Standard processes for nurses to document medicines have been implemented in both home (Green, Burgul and Armstrong 2010) and hospital (Bedouch *et al.* 2012) settings.

A systematic review reported by Kwan *et al.* aimed to summarise the evidence of effectiveness of hospital-based medicines reconciliation interventions. The search was conducted in databases (Medline, EMBASE and the Cochrane Library) for the period of 1980 to 2012. The review identified 1845 titles which were reduced to 18 papers by screening of titles, abstracts, papers and critical appraisal. The review included 20 interventions (delivered largely by pharmacists, n=17; several studies had >1 intervention) at the point transitions in care. Review findings identified no clinical significance associated with the unintentional discrepancies identified. The authors concluded that medicines reconciliation alone probably does not reduce post discharge hospital utilization but it is recommended to avoid unintentional discrepancies between patients' medicines across transitions in care. (Kwan *et al.* 2013)

A further systematic review, published in the same year, by Mueller *et al.* aimed to summarize the available evidence on medicines reconciliation interventions in the hospital setting, and to identify the most effective practices. The search was conducted only in Medline for the period 1966 to 2012. The review identified 1632 titles, which were reduced to 26 controlled studies by screening of titles, abstracts, papers and critical appraisal. Findings of the review identified 15 studies of pharmacist-related interventions, 6 studies of IT interventions and 5 other interventions. These studies gave a reduction in medicines discrepancies (17 studies), potential adverse drug events (5 studies), actual adverse drug events (2 studies) and post-discharge health care utilization (2 studies). The authors concluded that the involvement of pharmacists or pharmacy staff in all medicines reconciliation related processes lead to better patient outcomes. (Mueller *et al.* 2012)

Medicines reconciliation is therefore an extremely important aspect of medicines management during transition points (admission, transfer between wards and discharge), particularly in the elderly.

#### 1.2.7 Adherence

While the UK NHS spent around £10.6billion on medicines in 2006-2007, it was estimated that up to half of all medicines prescribed for long term conditions were not taken as recommended. (Horne *et al.* 2005) Furthermore, the estimated cost of unused or unwanted medicines in the NHS is around £100million annually. (Department of Health 2008)

While there are many definitions of the term adherence, this was redefined recently as 'the process by which patients take their medicines as prescribed, composed of initiation, implementation and discontinuation'. (Vrijens *et al.* 2012) Adherence comprises three components of initiation, implementation and discontinuation as illustrated in Figure 1.3.

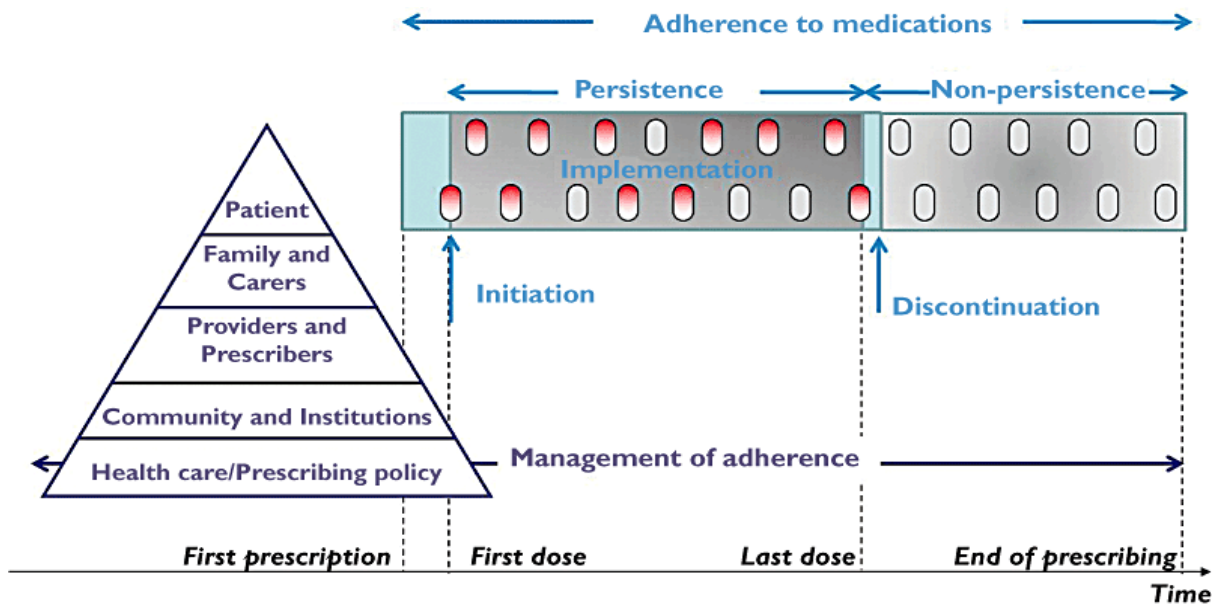


Figure 1.3: The process of adherence to medicines (light blue) and the process of management of adherence (dark blue), adapted from Vrijens *et al.* 2012)

Initiation is defined as 'the moment at which the patient takes the first dose of a prescribed medication; the implementation of the dosing regimen, being the extent to which a patient's actual dosing corresponds to the prescribed dosing regimen from initiation until the last dose taken; and discontinuation, being the end of therapy, when the next dose to be taken is omitted and no more doses are taken thereafter'. (Vrijens *et al.* 2012)

Medicines non-adherence is a major concern as only approximately 50% of patients have been estimated to adhere to their medicines (McDonald, Garg and Haynes 2002), and this percentage ranges from 47% to 100% in older adults. (Vik, Maxwell and Hogan 2004) In a recent narrative review of 51 systematic reviews covering 19 different disease categories, exclusively assessing non-adherence to chronic therapies, 771 individual factor items were identified. Factors with an unambiguous effect on adherence were further grouped (see Table 1.1) into 8 clusters of socio-economic-related factors, 6 of healthcare team- and system-related factors, 6 of condition-related factors, 6 of therapy-related factors, and 14 of patient-related factors. (Kardas, Lewek and Matyjaszczyk 2013)

Table 1.1: Summaries for all factors affecting medicines adherence (adapted from Kardas, Lewek and Matyjaszczyk 2013)

<b>Clusters</b>	<b>Domains</b>
<b>Socio-economic-related factors</b>	<ol style="list-style-type: none"> <li>1. Family support</li> <li>2. Family/Caregiver factors</li> <li>3. Social support</li> <li>4. Social stigma of disease</li> <li>5. Cost of medicines and/or disease</li> <li>6. Prescription coverage</li> <li>7. Socioeconomic status</li> <li>8. Employment status</li> </ol>
<b>Healthcare team- and system-related factors</b>	<ol style="list-style-type: none"> <li>1. Barrier to healthcare</li> <li>2. Medicines supply</li> <li>3. Prescription by specialist</li> <li>4. Information about drug administration</li> <li>5. Healthcare provider-patient communication</li> <li>6. Follow-up</li> </ol>
<b>Condition-related factors</b>	<ol style="list-style-type: none"> <li>1. Presence of symptoms</li> <li>2. Disease severity</li> <li>3. Clinical improvement</li> <li>4. Psychiatric condition</li> <li>5. Certain diagnoses/indications</li> <li>6. Duration of the disease</li> </ol>
<b>Therapy-related factors</b>	<ol style="list-style-type: none"> <li>1. Adverse effect</li> <li>2. Patient friendliness of the regimen</li> <li>3. Medicines effectiveness</li> <li>4. Duration of treatment</li> <li>5. Medicines type</li> <li>6. Well organised treatment</li> </ol>
<b>Patient-related factors</b>	<ol style="list-style-type: none"> <li>1. Age</li> <li>2. Gender</li> <li>3. Marital status</li> <li>4. Education</li> <li>5. Ethnicity</li> <li>6. Housing</li> <li>7. Cognitive function</li> <li>8. Forgetfulness and reminders</li> <li>9. Knowledge</li> <li>10. Health beliefs</li> <li>11. Psychological profile</li> <li>12. Comorbidities and patient history</li> <li>13. Alcohol or substance abuse</li> <li>14. Patient-related barriers to compliance</li> </ol>

This extensive retrospective literature review provides clear evidence that medicines non-adherence is affected by multiple determinants, many of which are modifiable and hence need to be considered as part of medicines management.

A systematic review by Haynes *et al.* aimed to review studies which assisted patients to adhere to medicines, excluding addictions. The search was conducted in databases (The Cochrane Library, MEDLINE, EMBASE, CINAHL, PsycINFO and International Pharmaceutical Abstracts) for the period 1993 to 2007. The review identified 5806 titles, which were reduced to 78 RCTs by screening of titles, abstracts, papers and critical appraisal. Findings from this review indicated that interventions (such as information, reminders, self-monitoring, reinforcement, counseling, family therapy, psychological therapy, crisis intervention, manual telephone follow-up, and supportive care) were effective on both adherence and clinical outcomes for short-term treatments, while those interventions showed less improvement on both adherence and clinical outcome for long-term treatments. The authors concluded that, improving medicines taking might have a far greater impact on clinical outcomes than an improvement in treatments. (Haynes *et al.* 2008)

A systematic review by George *et al.* identify interventions which improved adherence of community-living elderly patients prescribed at least three or more long-term medicines. The search was conducted in databases (Medline, Embase, CINAHL, PsycINFO and IPA). The review identified 1427 titles, which were reduced to eight controlled studies by screening of titles, abstracts, papers and critical appraisal. Findings from this review revealed a slight change in adherence among the intervention groups. The interventions comprised: regular scheduled patient follow-up along with a multi-compartment compliance aid; group education combined with individualised medicines cards; and medicines review by pharmacists with a focus on regimen simplification. The authors concluded that combinations of educational and behavioural strategies should be used to improve medicines adherence in the elderly. (George, Elliott and Stewart 2008)

Aiming to maximise medicines adherence in elderly patients is an important aspect of medicines management.

### 1.3 Criteria/tools to encourage optimising prescribing

Due to the factors described, the elderly are considered a high-risk population in terms of medicines selection and use. The Audit Commission in 2001 highlighted that the concepts of medicines management were particularly relevant in terms of paying prudent attention to processes of medicines choice, dosing, and monitoring for effectiveness and toxicity. (Audit Commission 2001)

A systematic review by Kaufmann *et al.* aimed to create a comprehensive and structured overview of existing tools to assess potentially inappropriate prescribing. The search was conducted in PubMed for the period 1991 to 2013. The review identified 716 titles, which were reduced to 46 papers by screening of titles, abstracts and full papers. Findings from this review identified 46 different tools to assess potentially inappropriate prescribing, showing a large variety in methodological aspects and any validation in a clinical setting. While many might serve as useful aids to improve prescribing, each tool has its limitations, strengths and weaknesses. Most were specific to the region in which they were developed. These tools were categorised as explicit, implicit or mixed tools. Implicit and explicit criteria promoting appropriate medicines selection are considered both essential and supportive tools for practitioners caring for the elderly. While implicit criteria focus on clinician interpretation and are time consuming, explicit criteria are designed to be easily and effectively interpreted. (Levy, Marcus and Christen 2010) They provide details of categories of drugs and associated prescribing indicators to enhance reliable treatment evaluation. Kaufmann *et al.* concluded that this review identified 46 assessment tools which could serve as a summary to assist readers in choosing a tool, either for research purposes or for daily practice.(Kaufmann *et al.* 2014)

Two criteria most commonly described are the 'Beers Criteria' and the 'STOPP START criteria'.

### 1.3.1 Beers Criteria

Beers Criteria were originally conceived in 1991 by Mark Beers (a geriatrician) in the USA. The criteria were developed by an expert panel of geriatric health care providers who identified medicines that should be avoided in the elderly. The main goal of the criteria was to improve care of older adults by reducing exposure to potentially inappropriate medicines (PIMs). The intended uses were to identify medicines that posed potential risk outweighing potential benefits for people  $\geq 65$  years, inform clinical decision-making concerning the prescribing of medicines for elderly and improve medicines safety and quality of care. (Beers *et al.* 1991)

The Beers Criteria were published in 1991 and consisted of two drug lists to be avoided in the elderly. The first included medicines considered inappropriate regardless of clinical condition whereas the second comprised inappropriate medicines in relation to specific medical conditions. (Beers *et al.* 1991) Beers criteria were updated in 1997 to incorporate the ambulatory elderly. The list classifies inappropriate medicines, inappropriate combinations of medicines, inappropriate (exceeded) duration of treatment, and excessive doses all with questionable efficacy or undesirable risk/benefit. (Beers 1997) Beers Criteria were updated again in 2003. (Fick *et al.* 2003) In 2011 the American Geriatrics Society (AGS) funded and undertook an update of the criteria by putting together a team of experts who used an advanced, evidence-based methodology to come up with the American Geriatrics Society (AGS) 2012 Beers criteria. (American Geriatrics Society 2012) The updated criteria aimed to incorporate new evidence related to PIMs and new medicines and conditions that were not covered in the 2003 update. The strength and quality of each PIM statement was rated on the basis of the level of evidence and strength of recommendation grading.

The AGS 2012 Beers criteria are intended for use in ambulatory or institutional settings of care of populations aged 65 and above in the United States. The



primary target audience is the practicing clinician, but researchers, pharmacy benefit managers, regulators, and policy-makers also use the criteria widely. (American Geriatrics Society 2012) The intentions of the criteria include:

- improving the selection of medicines by clinicians and patients,
- evaluating patterns of medicine use within populations,
- educating clinicians and patients on proper medicine usage and
- evaluating health-outcome, quality of care, cost, and utilization data.

A Delphi technique was employed with a 13 member interdisciplinary panel of experts in geriatric care and pharmacotherapy, with the aim of updating the 2012 AGS Beers criteria. (American Geriatrics Society 2015) Two major components incorporated into the updated AGS 2015 Beers criteria were:

- drugs for which dose adjustment was required based on kidney function and
- drug-drug interactions.

Although the Beers criteria have been the standard for documenting and identifying potentially inappropriate prescribing, several limitations have been highlighted: confinement to the USA as some indicators do not concur with guidelines in other regions/countries; and the need for regular updating. (Levy, Marcus and Christen 2010)

### 1.3.2 STOPP/START

A consensus panel of 18 experts (covering geriatric medicine and clinical pharmacology, clinical pharmacy, old age psychiatry and primary care) in Ireland and the UK defined and validated criteria the "screening tool of older persons" prescriptions (STOPP) and "screening tool to alert right treatment" (START). The criteria were developed in 2008 using a Delphi technique approach. (Gallagher *et al.* 2008) The final list of STOPP medicines comprised 65 items describing drug-drug and drug-disease interactions, therapeutic duplication, and increased risk of cognitive deterioration. START provided 22 rules related to common instances of prescribing omissions in older people.

Version 2 of STOPP/START was launched in 2015, with a 31% increase in the number of criteria compared to the original version, giving a total of 114. (O'Mahony et al. 2015)

The main goal of the STOPP/START criteria is to 'provide explicit, evidence-based rules of avoidance of commonly encountered instances of potentially inappropriate prescribing and potential prescribing omissions'. (O'Mahony et al. 2015) The aims are to: improve medicines appropriateness; prevent adverse drug events; and reduce drug costs.

A systematic review by Hill-Taylor *et al.* aimed to inform researchers, clinicians and policy makers about the quality and extent of evidence relating to the STOPP/START criteria. (Hill-Taylor *et al.* 2013) The search was conducted in databases (Cochrane Library, Database of Abstracts of Reviews of Effectiveness (DARE), PubMed, Embase, CINAHL, ISI Web of Science, IPA, Google Scholar, TRIP Database, ClinicalTrials.gov, metaRegister of Controlled Trials (mRCT), ProQuest Dissertation and Theses Database) for the period 2007 to 2012. The review identified 133 titles, which were reduced to 13 papers by screening of titles, abstracts, papers and critical appraisal. Of these 13, of which 12 were observational studies and one RCT. Due to the lack of homogeneity, a narrative analysis was carried out. Findings were that STOPP/START was more sensitive than Beers criteria, while less sensitive from tools developed in Australia. Medicines identified as potentially inappropriate were higher using STOPP/START compared to the 2002 version of Beers criteria. The authors concluded that despite the limited evidence application of STOPP/START, the criteria had been used for medicine review for community-dwelling, acute care and long-term care older patients in Europe, Asia and North America. (Hill-Taylor *et al.* 2013)

### 1.3.3 Medicines appropriateness index (MAI)

The MAI is a further tool which promoted appropriate use of medicines. It is designed to allow rating of ten explicit criteria to determine whether a given medicine is appropriate for an individual patient. The ten criteria are: an

indication for the medicines effectiveness for the patient's condition; correct dosage and directions; practical directions; drug-drug interactions; drug-disease interaction; unnecessary duplication; duration of therapy; and cost-effectiveness. Each criterion is rated on a three-point Likert scale, depending on whether the drug is 'appropriate', 'marginally appropriate', or 'inappropriate'. For each criterion a rating of 1 represents appropriate medicines use, a rating of 2 represents marginally appropriate use and a rating of 3 represents inappropriate medicines use. (Samsa *et al.* 1994, Burnett *et al.* 2009)

While the MAI was developed initially as an item-analysis tool, it was modified to derive a summated MAI score per medicines based on a weighting scheme. A weight of three is given for indication and effectiveness. A weight of two is assigned to dosage, correct directions, practical directions and drug-drug interactions. A weight of one is assigned to drug-disease interactions, expense, duplication and duration. This therefore results in a total combined score of 0 to 18 (0 meaning the drug is appropriate and 18 representing maximal inappropriateness). (Samsa *et al.* 1994, Burnett *et al.* 2009)

The MAI has several advantages for potentially inappropriate prescribing assessment: it focuses on the patient holistically, rather than on the medicine; it is comprehensive and therefore potentially sensitive to detect meaningful inappropriate prescribing or disease; it addresses multiple components of prescribing appropriateness, and can be applied to every medicines in the context of patient specific characteristics. (Burnett *et al.* 2009)

However, it has been noted that, while rather comprehensive, the MAI is time-consuming to use, and it requires a well-trained health professional. (Burnett *et al.* 2009)

#### 1.4 Anticholinergic prescribing in the elderly

There were several reasons for the specific focus on anticholinergic agents as part of medicines management in the elderly. These agents are particularly problematic in the elderly and there is limited coverage within generic potentially inappropriate prescribing scales (e.g. STOPP/START, Beers criteria).

(Kay *et al.* 2005, Chew *et al.* 2008, Rudolph *et al.* 2008) A systematic review by Duran, Azermai and Vender (2013) identified a list of 100 drugs (47 graded as high anticholinergic potency and 53 as low anticholinergic potency), which may be problematic in the elderly, highlighting potentially a need for more specific tools. (Durán, Azermai and Vander Stichele 2013)

There is emerging evidence the most recent scale developed to assess anticholinergic (and sedative) burden, the Drug Burden Index (DBI), may have advantages over existing scales. (Kouladjian *et al.* 2014) The development and use of this scale is the subject of the systematic review which is presented in Chapter 3.

## **1.5 Healthcare in the United Arab Emirates**

### **1.5.1 History and Demographics**

This research on medicines management was conducted in the United Arab Emirates (UAE), which comprises seven emirates: Abu Dhabi, Dubai, Ajman, Fujairah, Sharjah, Ras Al Khaimah, and Umm Al Quwain. It borders Oman in the southeast and north, and Saudi Arabia in the west and south (See Figure 1.4). Currently, these emirates have one of the highest human development indices (a composite statistic of life expectancy, education, and per capita income indicators) in Asia. The region has remained inhabited since at least 5500 B.C. The emirates saw the arrival of Islam in the seventh century A.D. During the sixteenth century, it fell under the influence of the European colonial powers, settling finally under the mastering of the British. After the end of the protectorate of the UK in December 1971, six Sheikhs formed the union by signing the Constitution of 1971, in which Ras al-Khaimah joined two months later. (Shihab 2001)



Figure 1.4: Map of the United Arab Emirates

According to the WHO in 2013, the population of the UAE is around 9,346,000. (WORLD HEALTH Organisation 2013) A recent report of the UAE National Bureau of Statistics notes that the UAE nationals account for only around 20% of the total population. (National Bureau of Statistics2014) The remainder are expatriates, predominantly from south and southeast Asia (around 60% of the UAE population), and western Europe (around 10%) While Arabic is the official language, English is spoken widely, particularly within professional settings. (WORLD HEALTH Organisation 2013)

### 1.5.2 Health Status in the UAE

Life expectancy is defined by World Bank as 'the average number of years a newborn is expected to live with current mortality patterns remaining the same'. (The World Bank Group2013) According to figures published by the World Bank in 2013, the life expectancy in the UAE is 77.13 years in 2013 compared to UK (80.96), USA (78.84) and Saudi Arabia (75.7) (See Figure 1.5). The UAE ranks highest among Arab countries in terms of life expectancy. (The World Bank Group2013)

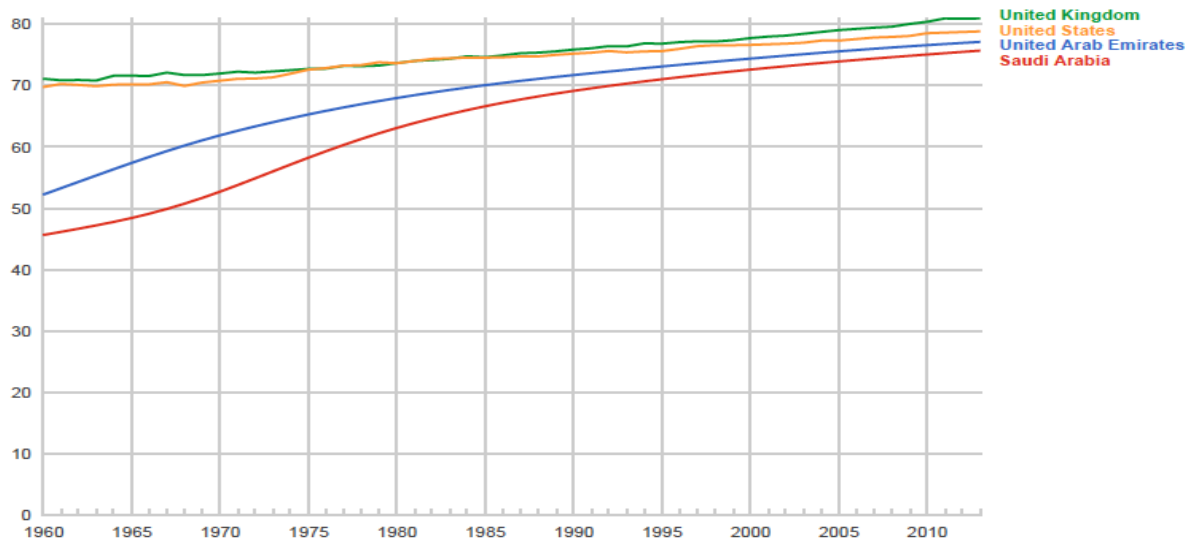


Figure 1.5: Life expectancy of the UAE compared to other countries (adapted from World Bank, 2013)

According to the UAE Ministry of Health, the percentage of Emiratis above the age of 60 years was 5.1% in 2000 and is expected to reach 11% in 2032 and 19% in 2050. (The UAE Ministry of Health. 2013) These statistics show that life expectancy has increased from around 74 years in 2000 reaching around 78 years in 2013. (The UAE Ministry of Health. 2013) This could be attributed to the improvements in the standards of living, health care facilities and management of many non-communicable diseases.

According to WHO, in 2013 ischaemic heart disease was the leading cause of death in the UAE, responsible for the death of 1,700 people. (WORLD HEALTH Organisation 2013) Table 1.2 illustrates the top ten causes of death in the UAE.

Table 1.2: The top ten causes of death in the UAE (adapted from WHO, 2013)

Number of deaths (n) 2012	Change in rank 2000-2012
Ischaemic heart disease (1700)	○
Road injury (900)	○
Stroke (700)	○
Congenital anomalies (400)	↑
Preterm birth complications (400)	↑
Diabetes mellitus (300)	↑
Self-harm (300)	↑
Lower respiratory infections (200)	○
Endocrine, blood, immune disorders (200)	↑
Interpersonal violence (200)	↑
Rank	↑ Increased      ○ No Change

### 1.5.3 Healthcare Regulation in the UAE

Public healthcare services are administered and regulated by different authorities at both the federal and local level. Figure 1.6 illustrates the principal regulatory authorities in the UAE.



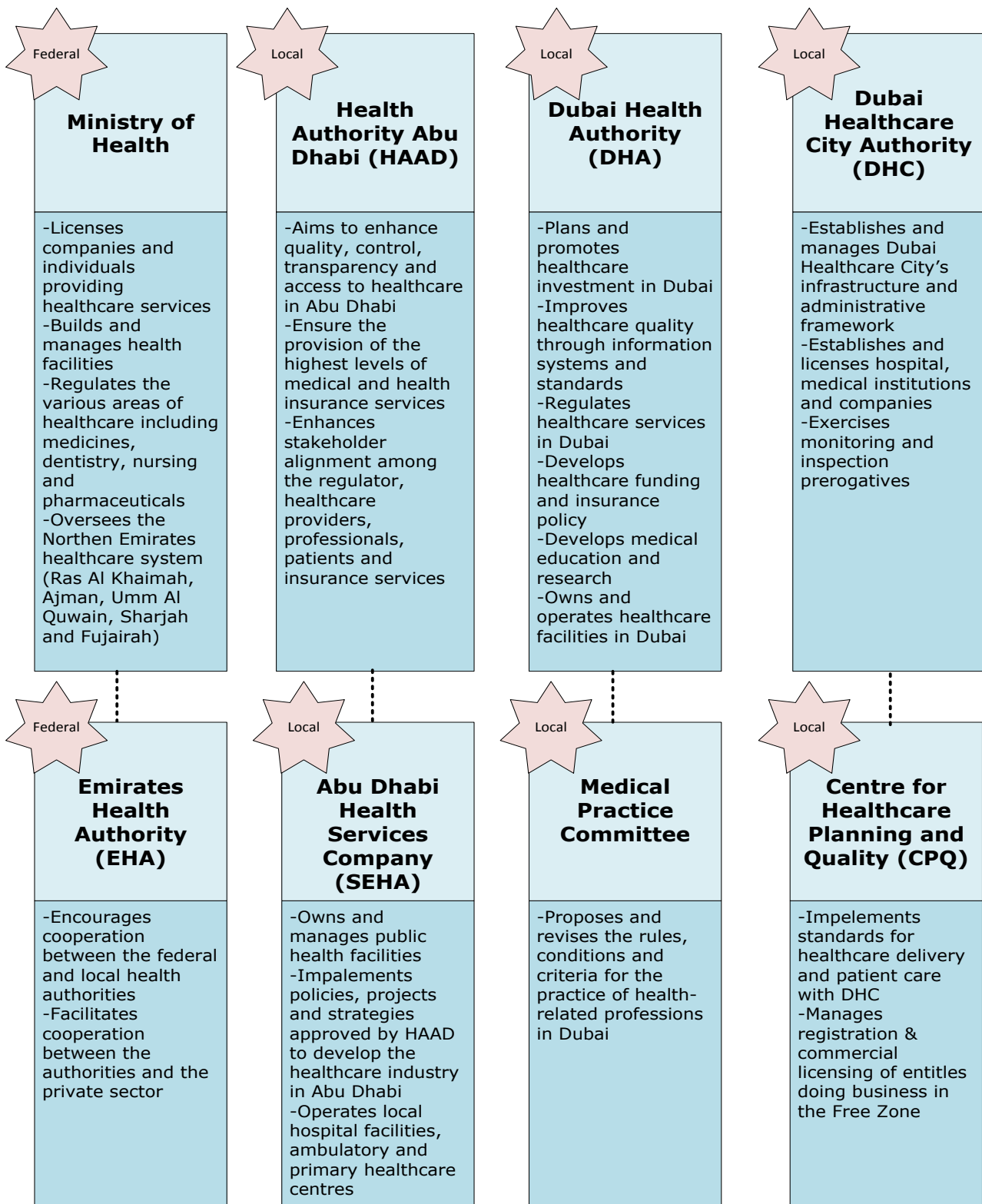


Figure 1.6: Principal Regulatory Authorities (adapted from SEHA annual report 2012)

According to a recent report of the UAE Ministry of Health, public healthcare in the UAE is planned, delivered and regulated through three geographical zones (Figure 1.7), each of which operate independently. (LATHAM & WATKINS2011) These are:

- the southern zone comprising Abu Dhabi. The Health Authority of Abu Dhabi (HAAD) is the regulatory body while the Abu Dhabi Health Service Company (SEHA ['health' in Arabic]) is manages public hospitals,
- the central zone of Dubai, under the auspices of the Dubai Health Authority (DHA) and
- the north Emirates or the northern zone under the Ministry of Health (MoH).

These three zones differ in terms of geographical and population estimates, governance systems and healthcare expenditure. Data from a 2014 national census gives Abu Dhabi the highest population at around 2.3 million. (National Bureau of Statistics2014)

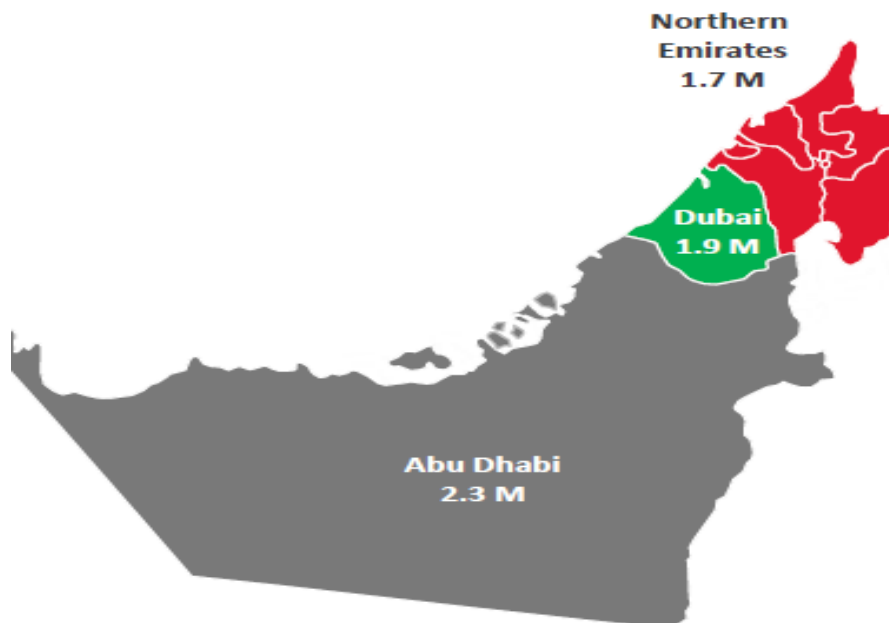


Figure 1.7: The UAE Healthcare Zones, 2014, National Bureau of Statistics (millions)

This research focuses on aspects of medicines management of elderly, hospitalised patients in the UAE. At the time of commencement of this research, there were no guidelines at country or emirate level to support medicines management and there was an absence of standard operating procedures. There was therefore the potential to generate original data to support the development of such guidelines and procedures.

### **1.6 Medical Research Council (MRC) Framework**

The development and implementation of guidelines to support medicines management of elderly, hospitalised patients in the UAE should be considered a complex intervention. Complex interventions are described by MRC framework as 'interventions that contain several interacting components'. (Craig *et al.* 2008) There are many possible dimensions of complexity. For example, it could be the range of possible outcomes, or the variability in the target population, rather than the number of elements in the intervention itself.

The key elements of the development and evaluation process are illustrated in Figure 1.8

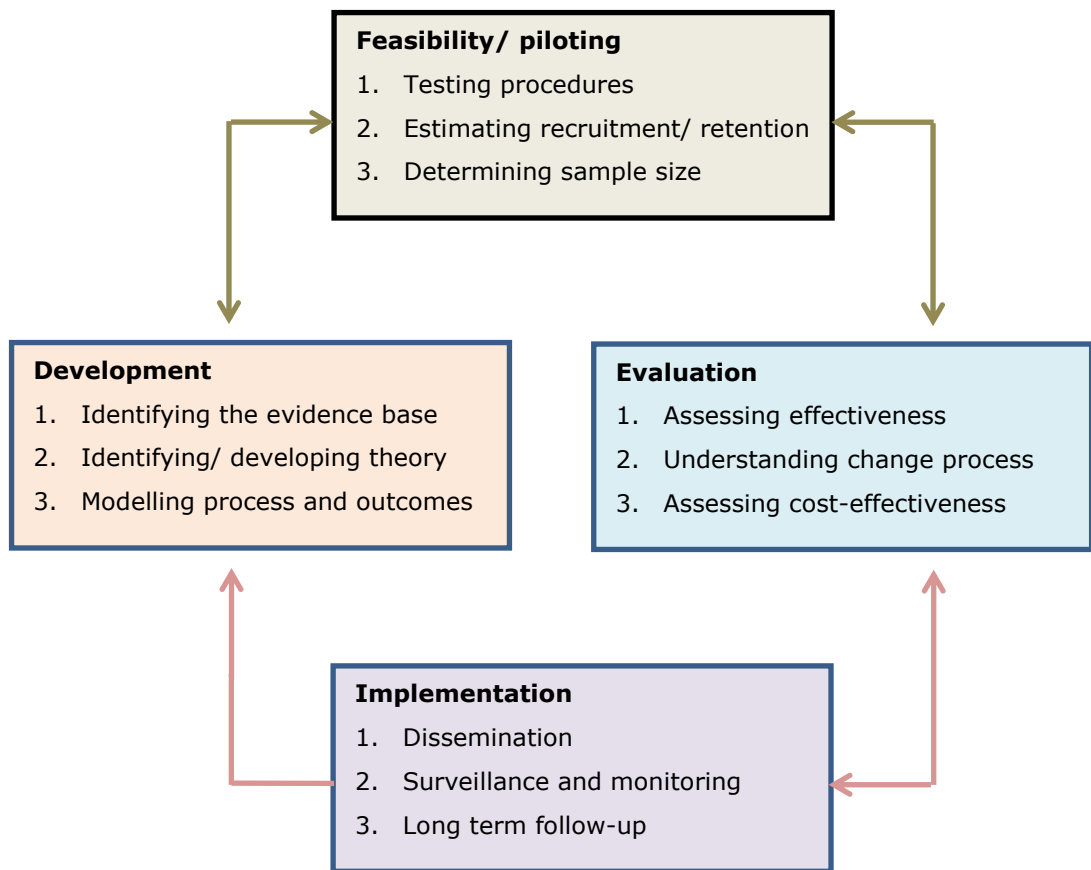


Figure 1.8: Elements of the development and evaluation process (adapted from Craig *et al.* 2008)

This doctoral research focuses on the initial stages of the development of a complex intervention. Developing interventions systematically to achieve a good practice requires consideration of the following:

- identifying the evidence base, through published systematic reviews or may necessitate conducting a systematic review,
- Identifying and applying appropriate cognitive, behavioural or organisational theory to understand better how to implement and sustain interventions, and understand better why interventions do (or do not) work and
- modelling processes and outcomes.

## **1.7 Overall study aim, review questions and objectives**

### **Research aim**

The overall aim was to explore the structures and processes of medicines management in elderly hospitalised patients in the United Arab Emirates.

This would form part of the initial phase of developing and implementing guidelines to support medicines management. The research was conducted in three phases.

#### Phase 1

The review of the literature in chapter 1 identified a wealth of evidence around aspects of medicines management in terms of medicines reconciliation, medicines adherence and potentially inappropriate prescribing.

While there are generic tools to support medicines selection and identify potentially inappropriate prescribing in the elderly, there is less evidence around specific tools which relate to anticholinergic agents. The first phase therefore was a systematic review of an emerging tool, the Drug Burden Index (DBI).

The aim of this phase was to critically appraise, synthesize and present evidence of the use of the Drug Burden Index (DBI) to identify potentially inappropriate prescribing of anticholinergic and sedative agents in elderly patients in institutionalised care.

This phase sought to answer the following review questions:

- in which specific settings and patient groups had the DBI been applied?
- what outcomes had been studied? (e.g. occurrence and incidence of adverse drug reactions, physical functioning, mental functioning, cause of admission to hospital etc.)

- had the use of DBI impacted prescribing of anticholinergic and sedative agents in elderly patients in institutionalised care? (e.g. cessation of therapy, prescribing altered to other agents, reduction in adverse drug reactions etc.)

### Phase 2

The aim of this phase of the research was to explore the views, experiences and perceptions of health professionals in Abu Dhabi in terms of the medicine management healthcare structures, processes and outcomes for elderly, hospitalised patients.

The detailed objectives were to explore health professionals' views, experiences and perceptions of the following:

- medicines related issues (e.g. drug selection, adverse drug reactions, adherence)
- current healthcare structures (e.g. personnel, resources) and processes (e.g. training, documentation, communication) of medicines management
- potential to optimise patient outcomes (e.g. clinical, economic)
- changes to structures and processes (e.g. personal, professional, organisational etc.) required to optimise patient outcomes.

### Phase 3

The aim of this phase of the research was to determine consensus in relation to strategic and operational approaches around medicines management for elderly, hospitalised patients in the UAE.

## Objectives:

The detailed primary objectives were:

- to develop and validate a series of statements in relation to the structures, processes and outcomes in relation to strategic and operational approaches around medicines management,
- to determine the levels of consensus of key stakeholders (the expert panel members) around these statements,
- to determine any additional statements derived from key stakeholder feedback and
- to determine any reasons for not achieving consensus.

The secondary objectives were:

- to determine key stakeholders' views on the potential for the findings to aid the development of policies, quality indicators and professional norms
- determine key stakeholders' views of their involvement in the consensus approach, and its potential for future healthcare developments.

By combining the findings of these three phases (Figure 1.9), original data would be generated which could potentially impact the development of guidelines of aspects of medicines management in elderly, hospitalised patients.

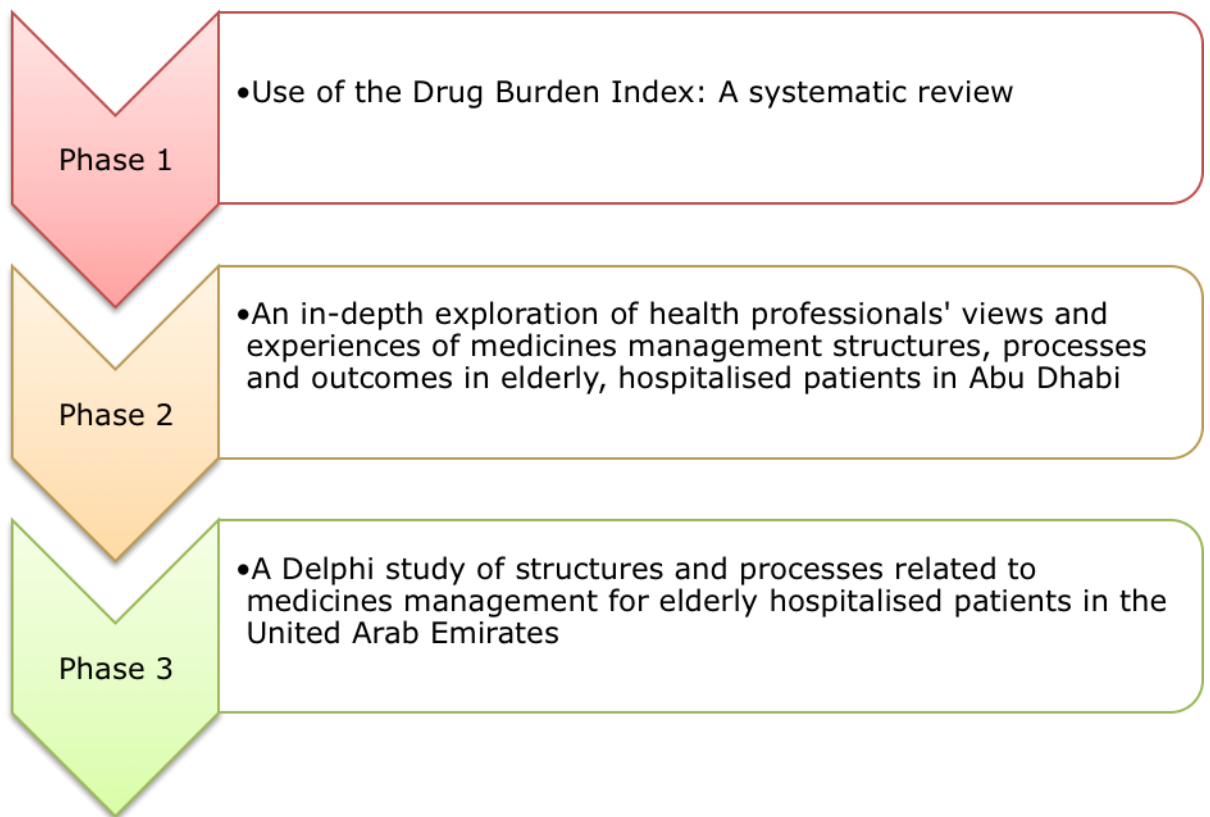


Figure 1.9: An overview of the doctoral research phases

The next chapter provides a discussion and justification for the research paradigms, methodologies, methods and underpinning theories employed throughout the research.



## CHAPTER 2: Methodology

This chapter reviews and justifies the research philosophies, methodologies and methods which underpinned the doctoral research. Specific aspects of data sampling, collection and generation, analysis, and quality assurance are discussed with justification for the chosen approaches. The following definitions are applied throughout this chapter (Bowling 2009):

- 'research' is derived from the French 'recherche', meaning 'to go about seeking',
- 'methodology' is defined as 'the systematic, theoretical analysis of the methods applied to a field of study'. This should not be confused with the research method and
- 'method' is defined as 'procedure', 'technique' or 'planned way of doing something'.

### 2.1 Theoretical perspectives: Philosophical paradigms

Johnson and Onwuegbuzie (2004), Bowling (2009) and Creswell (2013) describe that the term 'paradigm' refers to 'the progress of scientific practice based on people's philosophies and assumptions about the world and the nature of knowledge'. (Johnson and Onwuegbuzie 2004, Bowling 2009, Creswell 2013) These paradigms have three elements of

- ontology is the "reality" that researchers investigate',
- epistemology is the 'relationship between reality and the researcher' and
- methodology.

According to accepted scientific frameworks, research paradigms are classified into four as illustrated in Table 2.1.

Table 2.1: Features of Research Paradigms (adapted from Johnson and Onwuegbuzie 2004, Bowling 2009, Creswell 2013)

Paradigm	Features
Positivist	A positivist paradigm will maintain that reality is concrete and objectivity is achievable through rigorous methodologies and methods, assuming that reality is constant.
Constructivist	A constructivist paradigm will maintain that meaning does not exist in its own right but is constructed by people as they interact and engage in interpretation. Truth is said to be relative and that it is subjective to one's perspective.
Transformative	A transformative paradigm is generally applied to those marginalised in society or issues of power and social justice, discrimination and oppression.
Pragmatic	A pragmatic paradigm is not committed explicitly to any one philosophy; truth is what works at that time. Many mixed methods researchers subscribe to this paradigm.

### 2.1.2 Overall philosophical paradigm in current research

The research design must map to the research paradigms.

#### Phase 1

While the primary research considered within a systematic review could relate to either (or all) of the paradigms, depending on the review aim and questions, the DBI systematic review focused on quantitative research only and hence aligns to the positivist paradigm.

#### Phase 2

A constructivist paradigm was appropriate for phase 2, which sought to describe and understand health professionals' perspectives of aspects of medicines management structures and processes. Meaning was therefore constructed by the participants in the research.

#### Phase 3

The consensus research also maps to the positivist paradigm in that the views of the experts were quantified around a set of statements which were derived from the systematic reviews of aspects of medicines management (positivist) and phase 2 findings (constructivist).

## **2.2 Qualitative versus quantitative methodologies**

Research methodologies are described as qualitative, quantitative and mixed qualitative/quantitative approaches. Table 2.2 provides a comparison of key characteristics of qualitative and quantitative methodologies.

Table 2.2: Qualitative versus Quantitative methodologies (adapted from Johnson and Onwuegbuzie 2004, Bowling 2009, Creswell 2013)

<b>Qualitative</b>	<b>Quantitative</b>
The aim of qualitative analysis focuses on providing a complete, detailed and rich description of the research topic	The aim of quantitative research is to quantify, classify, count, construct and test statistical models in an attempt to explain what is observed
The design may be planned or emerge as the study unfolds	All aspects of the study are carefully designed before data is collected
The researcher is the data-gathering instrument	The researcher uses tools (e.g. questionnaires, equipment) to collect data
Data are in the form of words (interviews), pictures (videos) or objects (artifacts)	Data are in the form of numbers and statistics
Qualitative data are more richer, time consuming, and should not be generalized	Quantitative data are more efficient, able to test hypotheses, but may miss contextual data

The research methodologies for each of the three phases are described.

### Phase 1

The DBI systematic review in this case was quantitative research, including studies of cohort and cross-sectional survey based methodologies.

### Phase 2

Phase 2 was qualitative, employing a phenomenological design with the phenomenon being aspects of medicines management.

### Phase 3

A survey based methodology of consensus research was employed quantifying key stakeholders' levels of agreement with a series of statements derived through the previous research phases.

These quantitative and qualitative methodologies and methods are described and justified in greater detail.

## **2.3 Quantitative methodologies**

Evidence based medicine was defined by Sackett *et al.* 'the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients'. (Sackett *et al.* 1996) Within evidence based medicine and the various approaches to investigation in quantitative research, there is an accepted hierarchy of evidence that ranks the relative strengths of

evidence between different methodologies as illustrated in Figure 2.1.



Figure 2.1: Hierarchy of evidence (adopted from Markman and Callanan 1984, Greenhalgh 1997)

At the very top are systematic reviews (and meta-analyses) of well constructed randomised controlled trials. These allow pooling of data from studies which are homogenous in terms of the populations studied, settings and outcome measures. (Hunter and Schmidt 2004) Methodologies such as randomised controlled trials offer results with greater predictive power, demonstrate causal relationships between variables, and control for extraneous variables, hence are rated as providing stronger evidence. However, this methodology is not always feasible, due to issues such as: availability of resources and time; opportunities available to conduct the research; and ethical issues. Methodologies with less explanatory power can still be useful in circumstances where more rigorous approaches are not practical. (Markman and Callanan 1984, Greenhalgh 1997) Table 2.3 provides a description of the different quantitative methodologies and outlines their key advantages and disadvantages.

Table 2.3: Hierarchy of evidence in quantitative methodologies (adopted from Markman and Callanan 1984, Greenhalgh 1997)

	<b>Description</b>	<b>Advantages</b>	<b>Disadvantages</b>
<b>Systematic reviews</b>	Synthesising results from multiple studies. If homogenous, meta-analyses may be conducted.	Can detect patterns of effects rather than isolated unrepresentative results.	Sometimes produces equivocal results.
<b>Randomised controlled trials</b>	Manipulating independent variable and measuring a dependent variable. Participants randomly assigned to experimental/ control groups and performances compared.	Can make causal inferences between variables. Confounding factors can be controlled for, so that specific effects can be isolated.	Controlled conditions are not always reflective of everyday reality, so it can be difficult to generalise results. Can be resource intensive.
<b>Cohort studies</b>	A longitudinal study with a sample sharing a common characteristic, like age. Subgroups can be compared.	Efficient way to study variables over time.	Difficult to make causal inferences, as there is no true control group or random assignment.
<b>Case Control Studies</b>	Comparison between groups that are similar, except for one factor, such as presence of a disease. Used often in epidemiology.	Cheaper than randomised controlled studies.	Less evidence for causal relationships, as participants are not randomly assigned to groups.
<b>Survey based approaches (including consensus approaches)</b>	Administering questions to a group, either in writing or verbally.	Inexpensive, useful to describe characteristics of a group.	Cannot make causal inferences, although correlations may be possible.

### 2.3.1 Systematic reviews

A systematic review uses systematic, explicit methods to gather and synthesise findings from research to produce a review. (Gough, Oliver and Thomas 2012) There are three stages in producing a systematic review: retrieving and describing all relevant research; evaluating the studies; and synthesising data to develop general conclusions about the body of evidence. The robust methods used in these reviews allow for more confident use of evidence than would be possible when relying on individual studies. (Gough, Oliver and Thomas 2012)

#### 2.3.1.1 Narrative versus systematic review

Narrative reviews are commonly reported in the literature, and while these must be conducted using a systematic approach, there are key differences between a narrative review undertaken systematically and a systematic review. Narrative reviews are a more traditional approach to providing an overview of research methodologies, methods, data and findings within a field of study. They may be produced by experts using their knowledge and experience of the field to select and assess the studies, which can introduce biases into the review. Unlike a narrative review, a systematic review attempts to cover all known literature relating to a particular research question and provides its approach and methods for the reader, so that the quality of the review can be assessed. (Mulrow 1987) Table 2.4 gives a comparison between narrative and systematic reviews.



Table 2.4: Comparing narrative versus systematic reviews (adapted from Mulrow 1987, Bowling 2009, Creswell 2013)

	Narrative Review	Systematic Review
Review question	Often absent; if given is broad, exploratory	Focused
Method	Often omitted	Made explicit, with: detailed inclusion criteria; (PICO); exclusions; search strategies and sources
Quality assessment	Not a key feature	Must be robust, with specified criteria
Synthesis of research	Usually a qualitative discussion	A quantitative summary (e.g. meta-analysis or narrative synthesis)
Inferences from research	Sometimes evidence-based	Usually based on evidence
Updated with new research	Rarely	Often

### 2.3.1.2 Systematic review bodies

There are several bodies or organisations which have been established with the specific aim of supporting systematic reviews.

A Cochrane systematic review is a particular type of systematic review that specialises in the fields of medicine, healthcare and related policies. Cochrane reviews are published in the *Cochrane Database of Systematic Reviews* and are categorised as intervention, diagnostic test accuracy, methodology, qualitative or prognosis reviews. Review protocols and reports must meet certain quality standards, which include: using studies from a variety of databases; clear, predefined exclusion and inclusion criteria; and robust collection and appropriate data synthesis. Authors of reviews are also expected to update their reviews when new data becomes available to ensure they reflect the current body of evidence. (Cochrane Library 2015)

CRD reviews are produced at the University of York's Centre for Reviews and Dissemination, a research department that focuses on healthcare topics. This organisation synthesises data from a wide range of research for applications in policy development and decision-making relating to medicine, health, and well-being. (Centre for Reviews and Dissemination 2015) In other respects, CRD reviews are very similar to Cochrane reviews.

The Joanna Briggs Institute is based at the University of Adelaide in South Australia and specialises in evidence-based healthcare and related research. This organisation produces systematic reviews of healthcare practices with an interest in improving healthcare internationally. (Joanna Briggs Institute 2015)

As an extension of its global focus, the JBI has numerous collaborations with other groups and institutions around the world, including affiliates such as the Scottish Centre for Evidence-based Multi-professional Practice (SEMP 2015), based at Robert Gordon University. The SEMP's activities include training in conducting systematic reviews, reviewing research and identifying best practices in healthcare, using evidence to identify audit criteria, and assessing the impact of introducing evidence-based approaches into healthcare

organisations. (The Scottish Centre for Evidence-based Multi-professional Practice 2015) Given the link to the JBI at RGU, the doctoral student (principal investigator) undertook training with JBI; the principal supervisor is also an accredited trainer with the JBI. The systematic review conducted in phase one of the research was therefore registered with the JBI. While the systematic review of the DBI focused on quantitative research only, it should be noted that systematic reviews are also conducted for qualitative studies (or mixed methodology reviews) where appropriate, with specific qualitative approaches to data synthesis. In this case, systematic reviews can also be considered qualitative and the hierarchy of evidence does not apply.

### 2.3.2 Consensus approaches

Consensus, or 'collective agreement', involves collaboration between different key stakeholders (experts), and while it is regarded as relatively low evidence compared to randomised controlled trials, its approaches are justified in many situations. These include: where unanimity of opinion does not exist and is sought in view of a lack of scientific evidence; where there is contradictory evidence; and to develop guidelines. (Nair, Aggarwal, *et al.* 2011) This approach was employed in phase 3 to determine consensus around issues relating to medicines management.

It is worth noting that there is some debate to the classification of consensus approaches with some classifying as purely qualitative, some mixed qualitative and quantitative and some purely quantitative. (Bowling 2009, Nair, Aggarwal, *et al.* 2011, Creswell 2013) In this doctoral research, the consensus statements (see later) were derived through previous research phases and then consensus determined and quantified, hence in this research the consensus approach is more correctly described as a positivist paradigm and quantitative methodology. The specific methodology in this case was a form of survey methodology.

The three most common consensus development methods are the Delphi technique, Nominal Group Technique (NGT) and RAND/UCLA Appropriateness Method (RAM). (Bowling 2009, Nair, Aggarwal, *et al.* 2011, Creswell 2013) Each method is particularly suited for obtaining specific types of data.

In the 1960s, the Delphi Technique was originated and developed at the Research and Development (RAND) Corporation to obtain the most reliable consensus of opinion of experts on a particular area in a systematic manner. A series of well-defined questionnaires were circulated to experts based on survey and feedback. (Nair, Aggarwal, *et al.* 2011)

In the 1960s, the Nominal Group Technique (NGT) was derived from social-psychological studies of decision conferences and management sciences studies. It is mostly used in the government, social services and education and is based on a face-to-face, structured group meeting of experts led by an experienced moderator. (Nair, Aggarwal, *et al.* 2011)

In the 1980s RAND (research and development) Corporation and UCLA (University of California-Los Angeles) developed RAND-UCLA Appropriateness Method (RAM). This method is based on using current scientific evidence in conjunction with expert opinion to evaluate the overuse/underuse of medical or surgical procedures. (Nair, Aggarwal, *et al.* 2011)

Strengths and weaknesses of each of these three methods are compared in Table 2.5

Table 2.5: Strengths and weaknesses of the three consensus development methods (adapted from Bowling 2009, Nair, Aggarwal, *et al.* 2011, Creswell 2013)

Method	Strengths	Weaknesses
<b>Delphi Technique</b>	<ul style="list-style-type: none"> <li>• Large number of participants possible</li> <li>• Each participant expresses their opinion freely and impersonally</li> <li>• Limits dominance by eminent, eloquent, or highly opinionated individuals in the field</li> <li>• Less likely that the moderator of the panel may bias the group</li> <li>• Substantial amount of time to express ideas, reflect on answers, and make changes</li> <li>• Cheap, convenient, and no geographical constraints</li> <li>• Easy to understand, flexible, and can be applied to broad range of topics</li> <li>• Can be used preceding NGT meeting for initial item generation</li> </ul>	<ul style="list-style-type: none"> <li>• Generalisability of the study findings (external validity)</li> <li>• Dependent on questionnaire design</li> <li>• Vulnerability with respect to who is an “expert”</li> <li>• Obliviousness to reliability measurement and scientific validation of findings</li> <li>• Potential for bias exists in participant selection</li> <li>• Consensus panel judgments influenced by panel composition and by feedback given during the panel process</li> <li>• Coordinating large groups and several rounds can be complicated and costly</li> <li>• Delphi does not allow any personal contact between the experts</li> </ul>
<b>Nominal Group Technique</b>	<ul style="list-style-type: none"> <li>• Participants meet face-to-face</li> <li>• All participants have an opportunity to voice opinions</li> <li>• Personal contact between experts</li> <li>• Design of NGT does not allow any individual to dominate</li> <li>• Group voting can occur if desired in later rounds</li> </ul>	<ul style="list-style-type: none"> <li>• Certain members of the panel can take over discussion and drive results—experienced moderator required</li> <li>• Limited by time—only a few questions can be discussed and agreed upon</li> <li>• Economic and time costs associated with face-to-face meeting</li> <li>• Limited to providing a solution to a few problems limits its applicability to multiple scenarios</li> </ul>
<b>RAND/UCLA Appropriateness Method (RAM)</b>	<ul style="list-style-type: none"> <li>• Synthesis of published literature prior to consensus techniques incorporated</li> <li>• Allows for both confidential ratings as well as group discussion</li> <li>• Multidisciplinary panel encourage consensus from a wider group</li> <li>• Reproducibility of RAM ranges from moderate to excellent as determined by different panelists for “appropriate” and “inappropriate” care</li> <li>• Acceptable predictive validity for a recommendation supported by RCTs</li> </ul>	<ul style="list-style-type: none"> <li>• Misclassification is expected</li> <li>• Takes great deal of time from gathering of the evidence to multiple rounds of consensus</li> <li>• Face-to-face, which can add cost/time delay and lead to highly opinionated individuals in the field dominating the discussion</li> <li>• Requires third party (core panel) to construct clinical indications for an intervention and analyse/interpret the results from the expert panel meeting</li> <li>• 9-point Likert scale can be cumbersome</li> <li>• Requires voting on multiple case scenarios</li> </ul>

In this doctoral research, the Delphi technique was employed in phase 3 using an expert panel of key stakeholders in the UAE. This approach was selected over the other approaches for a number of reasons as described in Table 2.5, primarily logistics for the principal researcher (can use Internet as medium for data collection), participants (no travel, less time consuming), and cost. The Delphi technique is also characterised by anonymity of Delphi participants, with the advantage that it prevents the possibility of a group of participants dominating over others.

#### **2.4 Qualitative methodologies**

Table 2.6 provides a comparison of the five methodologies most commonly employed in the qualitative, namely narrative, phenomenology, grounded theory, ethnography and case study methodologies.

Table 2.6: Comparison of five methodologies in the qualitative (adapted from Johnson and Onwuegbuzie 2004, Bowling 2009, Creswell 2013)

<b>Dimension</b>	<b>Narrative</b>	<b>Phenomenology</b>	<b>Grounded Theory</b>	<b>Ethnography</b>	<b>Case Study</b>
Focus	Exploring the life of an individual	Understanding the essence of experiences about a phenomenon	Developing a theory grounded from data in the field	Describing and interpreting a cultural or social group	Developing an in-depth analysis of a single case or multiple cases
Main methods of data Generation	Interviews and analysis of documents	Interviews and focus groups	Interviews and focus groups	Observations and interviews with additional artefacts during extended time in the field	Multiple sources including documents, archival records, interviews, focus groups observations
Approaches to data analysis	Stories, historical content	Statements, meanings, themes, general description of the experience	Open coding, axial coding, selective coding, conditional matrix	Description, analysis, interpretation	Description, themes, assertions
Narrative Form	Detailed picture of an individual's life	Description of the "essence" of the experience	Theory or theoretical model	Description of the cultural behaviour of a group or an individual	In-depth study of a "case" or "cases"

A qualitative, phenomenological approach was employed in phase 2 of this doctoral research. This was considered most appropriate to allow generation of in-depth, rich data to describe and understand participants' experience of the phenomenon under investigation (medicines management structures and processes). There was no attempt to generate theory, hence grounded theory was rejected and existing theories (see later) applied.

#### 2.4.1 Participant observation versus Focus groups versus interview

The three most common qualitative methods are the use of participant observation, focus group discussions and in-depth interviews. (Bowling 2009, Creswell 2013) Each method is particularly suited for obtaining specific types of data. Strengths and weaknesses of each of these three methods are given in Table 2.7.



Table 2.7: Strengths and weaknesses of the three qualitative methods (adapted from Mack *et al.* 2005, Bowling 2009, Creswell 2013)

Method	Strengths	Weaknesses
<b>Participant observation</b>	<ul style="list-style-type: none"> <li>• Allows the researcher to directly see what participants actually do without having to rely on what they say they do</li> <li>• The researcher can determine what does <u>not</u> occur</li> <li>• The researcher may observe events and happenings that escape the awareness of the participants in the setting</li> <li>• May provide information on things participants would otherwise be unwilling to talk about</li> <li>• May move beyond the selective perceptions of participants</li> </ul>	<ul style="list-style-type: none"> <li>• Sampling of settings and participants may be problematic and hence limited</li> <li>• Some settings and content of interest cannot be observed</li> <li>• Collection of unimportant material may be moderately high</li> <li>• Researcher effects (e.g. personal biases and selective perception) may limit the usefulness of the data</li> <li>• Reactive effects may occur when participants know they are being observed</li> <li>• May generate vast amount of data and analysis can be time consuming</li> <li>• May place researcher at risk</li> </ul>
<b>Focus groups</b>	<ul style="list-style-type: none"> <li>• Useful for exploring ideas and concepts</li> <li>• Provides an opportunity for participants to discuss issues amongst each other</li> <li>• Researcher can assess how participants react to each other</li> <li>• Allows researcher probing.</li> <li>• Most content can be recorded</li> </ul>	<ul style="list-style-type: none"> <li>• May be difficult to find a focus group moderator with good facilitative and rapport building skills</li> <li>• Reactive and researcher effects may occur if participants feel they are being watched or studied</li> <li>• Recruitment may be difficult in certain groups, resulting in results if small, unrepresentative samples of participants</li> <li>• Data analysis can be time consuming</li> <li>• Data trustworthiness may be low</li> </ul>
<b>In-depth interviews</b>	<ul style="list-style-type: none"> <li>• Suited to discussion of views, attitudes and experiences</li> <li>• Allows probing and posing of follow-up questions by the researcher</li> <li>• Can provide in-depth information and rich textual data</li> <li>• Closed-ended interviews can provide exact information needed by researcher</li> <li>• Moderately high credibility for well constructed and tested interview protocols</li> <li>• Useful for exploration as well as confirmation</li> </ul>	<ul style="list-style-type: none"> <li>• One to one, face to face interviews can be expensive and time consuming</li> <li>• Researcher effects may occur (e.g., untrained interviewers may distort data because of personal biases and poor interviewing skills)</li> <li>• Participants may not recall important information and may lack self-awareness</li> <li>• Data analysis can be time consuming for open-ended items</li> </ul>

In-depth, face to face interviews were undertaken in phase 2. This approach was considered to be the most appropriate method of data generation to allow participants from a range of backgrounds, professions and experiences to talk about their personal views and perceptions without potentially being inhibited when openly discussing and sharing information with others. For example less experienced nurses or pharmacists may not have fully discussed issues of poor prescribing practice in the presence of high grade medical staff in a focus group setting, with implications for data trustworthiness.

#### 2.4.2 Qualitative method data collection: use of interview

The most common types of interview used in qualitative research are structured, semi-structured and unstructured. Bowling (2009) describes these and highlights similarities and differences, which are summarised in Table 2.8

Table 2.8: Features of structured, semi-structured and unstructured interviews

<b>Structured</b>	<b>Semi structured</b>	<b>Unstructured</b>
Set of questions that are asked in a standard way across all participants.	Specific topic areas and a general set of questions but the interview flows like a conversation and topics are covered as they come up.	Topic area to be explored but what gets covered is left up to the participant. An opening question might introduce the topic.
Fixed questions with fixed order.	Open questions, order can vary.	Non-directive in-depth interview.
Control lies with researcher.	Control lies with both researcher and participant.	Control lies with participant.
Data will be probably coded in advance.	Data will be probably coded and analysed after each interview (iterative development).	Data will probably be coded and analysed after interview (iterative development).
Data generation tool: questionnaire.	Data generation tool: interview schedule.	Data generation tool: interview guide.

In phase 2, a semi-structured face-to-face approach was employed. This approach allowed for collaborative (researcher and participant) designing and contributing to the content of the interviews. Core questions were offered so as to stimulate response among the respondents. Holmes (2012) noted that standardisation of at least some of the questions would increase credibility during data generation. (Holmes 2012)

#### 2.4.3 Approaches to analysis of qualitative data

Bowling (2009) highlights that qualitative research can result in large amounts of richly detailed data and that a very transparent approach to data analysis needs to be employed to avoid claims that the findings are highly subjective and open to interpretation. Bowling (2009) and Braun and Clarke (2006) suggest that qualitative data analysis should consist of identifying, coding with reference to relevant theoretical frameworks, and categorising themes. (Braun and Clarke 2006) Boyatzis (1998) defines a theme as 'a pattern in the information that at minimum describes and organises the possible observations and at maximum interprets aspects of the phenomenon'. (Boyatzis 1998) Braun and Clarke (2006) describe six phases of thematic analysis (see Table 2.9) for qualitative research.

Table 2.9: Phases of thematic analysis (adapted from Braun and Clarke 2006)

1. <b>Familiarisation</b>	Transcribing data, reading and re-reading the data, noting down initial ideas.
2. <b>Generating initial codes</b>	Coding interesting features of the data in a systematic fashion across the entire data set, collating data relevant to each code.
3. <b>Searching for themes</b>	Collating codes into potential themes, gathering all data relevant to each potential theme.
4. <b>Reviewing themes</b>	Checking if themes work in relation to the coded extracts (Level 1), and the entire data set (Level 2), generating a thematic 'map' of the analysis.
5. <b>Defining and naming themes</b>	Ongoing analysis to refine the specifics of each theme, and the overall story the analysis tells, generating clear definitions and names for each theme.
6. <b>Producing the report</b>	The final opportunity for analysis. Selection of vivid, compelling extract examples, final analysis of selected extracts, relating back of the analysis to the question and literature, producing a scholarly report of the analysis.

This approach is very similar to the Framework Approach developed by Ritchie and Spencer (2002), which is increasingly and frequently used in healthcare research where the research objectives are well defined in advance of any fieldwork. Lacey and Luff (2007) describe the Framework Approach in five phases of data analysis as illustrated in Table 2.10.

Table 2.10: Phases of Framework Approach (adapted from Lacey and Luff 2007)

1. Familiarisation	Whole or partial transcription and reading of the data.
2. Identifying a thematic framework	This is the initial coding framework which is developed both from a priori issues and from issues emerging from the familiarisation stage. This thematic framework should be developed and refined during subsequent stages.
3. Indexing	The process of applying the thematic framework to the data, using textual codes to identify specific pieces of data which correspond to differing themes.
4. Charting	Using headings from the thematic framework to create charts of data to be read easily across the whole dataset. Charts can be either "thematic" for each theme across all respondents (cases) or by "case" for each respondent across all themes.
5. Mapping and interpretation	Searching for patterns, associations, concepts, and explanations in data, aided by visual displays and plots.

This approach to coding and thematic analysis was considered more appropriate than other approaches (e.g. grounded theory) as the research objectives and theoretical frameworks were well described and there was no intention to derive new theories. (Lacey and Luff 2007) These approaches are therefore much more appropriate for phenomenological methodologies.

## **2.5 Sampling in quantitative and qualitative research**

The approaches to sampling in quantitative and qualitative research are key issues which merit further consideration. Garson (2012) describes sampling as the process of selection of a particular group of participants for a study, noting that collecting or generating data from a target population does not necessitate researching all members of that population. Oversampling has implications for study duration, resources and most importantly ethics. (Garson 2012)

Sampling techniques can be categorised as probability or non-probability techniques. Probability techniques are most commonly employed in quantitative research and use some form of randomisation to select participants. Random sampling is generally considered to produce a sample that closely reflects the larger population from which it is drawn. As a result, random sampling is regarded as the ideal approach to produce results with high internal and external reality. In contrast, non-probability sampling is commonly employed in qualitative research and uses non-random techniques to select participants. As a result, these approaches may not be representative of the broader population, but sometimes are necessary when more rigorous sampling is not practical or possible. (Black 1999) Table 2.11 illustrates comparison of different sampling techniques.



Table 2.11: Comparison of different sampling techniques

	<b>Procedure</b>	<b>Common Usage</b>	<b>Advantages</b>	<b>Disadvantages</b>
<b>Probability Sampling</b> (adapted from Morgan 2008)				
<b>Simple random</b>	Selected from population according to chance. Each member has same probability of being selected. Randomising algorithms often used to select sample.	Large, easily accessible populations.	High chance of being representative. Not much information about population required.	Can be inefficient, expensive.
<b>Systematic</b>	Similar to simple random sampling, but participants are chosen at specific intervals	Large, homogenous populations.	High chance of being representative.	Underlying patterns or non-random variations in the population can cause a sampling bias.
<b>Stratified</b>	Population is divided into homogenous subgroups, based on prior knowledge of the population, before randomly sampling from each subgroup. Each subsample is proportional to the size of its population subgroup.	Large, well-known populations.	More representative of population than simple random sampling, data can be more manageable, can control for regional differences in population size.	Requires accurate knowledge of sub-group sizes and/or proportions.
<b>Cluster</b>	Similar to stratified sampling, but a sample of subgroups is first taken, and then samples within each selected subgroup are taken. Data is grouped according to subgroups, or 'clusters'.	Very large populations with known subgroups.	Often cheaper and more efficient than other techniques.	High chance of sampling error, a systematic bias in a particular cluster can influence the impression of the larger population.

<b>Non-probability Sampling</b> (adapted from Morgan 2008)				
<b>Purposive</b>	Researcher selects participants based on their perceived relevance to study.	Small, specific populations.	Often cheap and efficient; useful for qualitative research.	Vulnerable to selection bias on the part of the researcher, therefore high risk of sampling error.
<b>Snowball</b>	Current participants recruit new participants from their acquaintances.	Small, difficult to access populations.	Low cost, easier to find otherwise hidden participants, can promote trust when investigating sensitive topics.	High chance of sampling error, potentially subject to confounding variables and participant biases.
<b>Convenience</b>	Participants selected according to availability to researcher.	Pilot studies.	Easy to recruit, efficient.	High chance of sampling error, subject to confounding variables that influence ease of access.

All sampling approaches should be undertaken with reference to the study aim, objectives and characteristics, which in turn should determine the number of participants required.

Mack *et al.* (2005), Bowling (2009) and Garson (2012) describe the two most common methods in qualitative research sampling as convenience and purposive sampling. (Mack *et al.* 2005, Bowling 2009, Garson 2012) In convenience sampling, participants are selected mainly on the basis of convenient access to the researcher and they are generally the easiest to recruit to the study and are not necessarily representative of the population.

Purposive sampling is a common strategy in qualitative research and is used when the researcher has preselected criteria considered relevant to the study. This involves filtering the selected population according to these criteria or strata which may include, for example, age, place of residence, gender, social class and profession and aim to allow researching those individuals most likely to experience, or have insights into the research topic. With purposive sampling, the number of participants is more of a target than a steadfast requirement; with sample size determined by saturation of data and is considered to be most effective when review and analysis of data is done together with the generation. (Bowling 2009, Garson 2012, Creswell 2013)

There are several variations of purposive sampling including quota and snowball sampling. Quota sampling is specific in respect to sizes and proportions of subsamples, with these subgroups chosen to reflect corresponding proportions in the population. Snowball (or chain referral) sampling is a type of purposive sampling which relies on past participants making contact with new ones through their network (e.g. relatives, friends, colleagues etc.). Snowballing is used to recruit participants who are difficult to find or not easily accessible to researchers through other sampling strategies. (Bowling 2009, Garson 2012, Creswell 2013)

In phase 2, a purposive sampling approach was employed for the face to face interviews. Sampling was undertaken purposively to explore a range of views, experiences and perceptions of medicines management in elderly, hospitalised

patients, according to the research aim. This approach was considered most likely to generate rich and complex data arising from diversity in views, experiences and perceptions, and offering further insight into factors that might not have been considered before.

In phase 3, a snowball sampling approach was employed for the Delphi technique. This is considered to be more appropriate in qualitative studies to recruit participants who are difficult to find or not easily accessible to researchers. While the Delphi study in phase 3 is described as quantitative, there was no readily list of potential participants hence snowball sampling was used.

## **2.6 Robustness and rigour in research**

Promoting validity and reliability are principal constructs to be considered in relation to the robustness of quantitative research. Validity has been defined as 'the accuracy and truth of the data being produced in terms of the concepts being investigated, the people and objects being studied and the methods of data collection and analysis being used'. (Sines *et al.* 2013) There are several aspects of validity to be considered.

Internal validity relates to the degree to which the results relate to the operationalised constructs (i.e. the cause and effect relationship). External validity is the extent to which the results can be generalised to contexts and settings outside of the study.(Black 1999)

There are specific approaches to determining internal validity:

- Content validity assesses if a tool (domains and items) covers the topic (aims and objectives) under investigation,
- Face validity assesses whether from the appearance of items, the tool measures what it claims to measure,
- Construct validity, the theoretical understanding of the item being measured and assesses how well a construct is understood and

- Criterion-related validity assesses the correlation between the tool and findings and an established standard.

In terms of the Delphi technique, attempts were made to promote the face and content validity and various theories were considered during construction of the research tool.

Reliability (consistency) refers to the likelihood that the findings from a particular study can be replicated with the same methodology, method and sample at a later time. It can also refer to the likelihood that the scores obtained on a particular measure can be repeated at a later stage. One approach to assessing the reliability of results is to replicate a study and compare the results with the original. (Black 1999)

Qualitative research is often criticised from a quantitative perspective on the basis that it is thought to lack rigour and is difficult to assess the quality of the research. (Horsburgh 2003, Shenton 2004) Essentially, by definition, qualitative research is not measurable in terms of constructs such as validity or reliability. Shenton (2004) discusses four constructs to ensure and assess trustworthiness in qualitative research, which are summarised here. (Shenton 2004)

*Credibility* is similar to internal validity in quantitative research and is an approach to ensuring that findings are an accurate reflection of a wider reality. There are numerous ways to promote credibility. Researchers can employ well-established methodologies and methods that have been used successfully in prior research. Where possible, research findings should be compared with published research and assessed for similarities or deviations. Researchers should provide detailed description of the researched phenomenon under investigation and should familiarise themselves with the population being studied. Triangulation of research data is also encouraged to promote credibility. Researchers can examine different aspects of the phenomenon by using multiple groups, organisations, or settings. Researchers should also encourage participant honesty through direct instructions, developing rapport, and giving

opportunities for withdrawing from the study. (Shenton 2004) Researchers should meet with team members frequently for debriefing sessions and peer review of all aspects of the research. Researchers can also use the participants to check the data interpretation. (Shenton 2004)

*Transferability* is similar to external validity (generalisability) and is described as the extent to which the findings can be applied to other contexts and settings. Qualitative research also tends to use small sample sizes, which can make establishing transferability difficult. Many researchers agree that a limited form of transferability is possible and advise providing detailed information so that readers can judge the applicability of the study. This detail should include: the number of organisations participating and their locations; participant inclusion and exclusion criteria; participants numbers; data generation approaches; duration and frequency of data generation sessions; and the overall duration of the data generation period. (Shenton 2004)

*Dependability* is similar to reliability, and is described as the extent to which similar findings would be generated if the study was repeated with the same methods, participants, etc. To promote dependability, detailed account should be provided of the overall research design, as well as a self-reflective examination of the effectiveness of the data-gathering process. (Shenton 2004)

*Confirmability* relates to the basis of the findings, and the extent to which they have arisen from data gathered rather than the biases and preconceived notions of the researcher. Techniques for promoting confirmability also apply to confirmability: triangulation; self-reflection; and audit trail of steps taken from the beginning to the end of the research process. (Shenton 2004)

Many of these approaches were applied in phase 2 of the research.

Bias is one issue which can affect robustness of quantitative research (validity and reliability) and rigour of qualitative research (trustworthiness). There are many different forms of bias, which are described in Table 2.12

Table 2.12: Types of bias (Adapted from Bowling 2009)

<b>Type of bias or error</b>	<b>Description</b>
<b>Acquiescence response set</b>	Participants will more frequently endorse a statement than disagree, 'yes-saying'
<b>Design bias</b>	Faulty methods, sampling and analysis
<b>Evaluation apprehension</b>	Participant anxiety may lead to giving responses which they think are expected
<b>Interviewer bias</b>	The interviewer may subconsciously, or consciously, bias by appearing to hold certain values or by asking leading questions
<b>Non-response bias</b>	Non-response reduces effective sample size. Differences between responders and non-responders reduces generalisability
<b>Recall (memory) bias</b>	Selective memories in recalling events
<b>Reporting bias</b>	Failure of the participant to reveal full information
<b>Sampling bias</b>	Non-representative selection of participants

Approaches to minimising bias are described throughout chapter 4 (section 4.2.10) and 5 (5.2.5).

## **2.6 Theoretical model and need for theory in research**

This doctoral research was conducted within a theoretical framework, which is described in detail in this section.

### 2.6.1 Definition of 'theory'

Meleis (2007) defines theory as 'an organised, coherent, and systematic articulation of a set of statements related to significant questions in a discipline that are communicated in a meaningful whole. It is a symbolic depiction of aspects of reality that are discovered or invented for describing, explaining, predicting, or prescribing responses, events, situations, conditions, or relationships. Theories have concepts that are related to the discipline's phenomena. These concepts are related to each other to form theoretical statements.' (Meleis 2011) Considering theory in research enhances robustness and rigour, and the relevance and impact of the findings. A theoretical framework assists researchers in understanding how the results they obtain fit into a larger framework. Furthermore, research informs new theories as new data can challenge our current explanatory models.

The United Kingdom Medical Research Council guidance on 'Developing and implementing complex interventions' (described in Chapter 1) highlights the role of cognitive, behavioural and organisational theoretical lenses. (Craig *et al.* 2008) This guidance describes four elements of: development; feasibility/piloting; evaluation; and implementation. Theory is a key aspect of development, '...you also need to be aware of the relevant theory, as this is more likely to result in an effective intervention, than is a purely empirical or pragmatic approach'.

### 2.6.1 Theories in current research

Theories can provide useful "lenses" to assist researchers in focusing on particular aspects of complex systems. (Reeves *et al.* 2008) The interview schedule and Delphi statements were developed with reference to two key



theories/ theoretical frameworks: Normalization Process Theory (NPT) and the Theoretical Domains Framework (TDF), as described in chapter 4 and 5.

#### 2.6.1.1 Normalization Process Theory (NPT)

NPT is a sociological, theoretical framework used to evaluate the implementation of healthcare initiatives. NPT explains ‘...the social processes through which new or modified practices of thinking, enacting and organising work are operationalised in healthcare and other institutionalised settings’. (May and Finch 2009) NPT helps to identify issues in implementation, particularly around integrating and embedding into pre-existing social and professional contexts. The model seeks to explain why some practices become normalised into practice, while others do not. NPT focuses on the contexts surrounding work, including the nature of the work, who performs the work, the manner in which the work is performed and how the work is perceived and understood. NPT analyses the individual and collective efforts of a group to accomplish particular work goals. (May *et al.* 2011) The principal mechanisms of NPT are summarised in table 2.13.

Table 2.13: Process components of NPT (adapted from May and Finch 2009)

Mechanism	Components
<b>Coherence</b>	<ul style="list-style-type: none"> <li>• Routine embedding depends on work that defines and organises practices as cognitive and behavioural ensembles</li> <li>• Embedding work is shaped by factors that promote or inhibit actors' perception of practices as meaningful</li> <li>• Production and reproduction of coherence in a practice requires actors to collectively invest meaning in it</li> </ul>
<b>Cognitive participation</b>	<ul style="list-style-type: none"> <li>• Routine embedding depends on work that defines and organises actors who are implicated in practices</li> <li>• Embedding work is shaped by factors that promote or inhibit actors' participation</li> <li>• The production and reproduction of practices requires actors to collectively invest commitment in them</li> </ul>
<b>Collective action</b>	<ul style="list-style-type: none"> <li>• Routine embedding is dependent on work that functionally defines a practice</li> <li>• Embedding work is shaped by factors that promote or inhibit actors' enacting it</li> <li>• The production and reproduction of practices require that actors collectively invest effort in them</li> </ul>
<b>Reflexive monitoring</b>	<ul style="list-style-type: none"> <li>• Routine embedding is dependent on work that defines and organises everyday understanding of a practice</li> <li>• Embedding work is shaped by factors that promote or inhibit evaluation</li> <li>• The production and reproduction practices require that actors collectively invest in understanding them</li> </ul>

NPT was applied in this doctoral research within the context of medicines management and was selected as being particularly relevant due to its use increasingly as part of implementation research. It was important to explore issues of coherence, cognitive participation, collective action and reflective monitoring from the perspectives of health professionals in phase 2 and to consider in the development of the statements in the Delphi Technique in phase 3. However, this theory focuses less on the behaviours and behavioural determinants of individuals, hence the Theoretical Domains Framework (TDF) was used alongside NPT.

#### 2.6.1.2 Theoretical Domains Framework (TDF)

TDF is not a theory but a framework derived from 33 theories of behaviour change. TDF was developed by a group of psychological theorists, health service researchers and health psychologists. (Michie *et al.* 2005) The aim of TDF is to '...simplify and integrate a plethora of behaviour change theories and make theory more accessible to, and usable by, other disciplines' hence it was considered most appropriate for this research. TDF is organised into 14 overarching domains as described in Table 2.14.

Table 2.14: Summary of refined Theoretical Domain Framework (adapted from Cane, O'Connor and Michie 2012)

Domain	Examples
Knowledge	Awareness of things (e.g. procedures) and tasks
Skills	Abilities and learnt proficiencies (e.g., interpersonal skills)
Social/Professional Role and Identity	Coherent set of personal behaviours and expressed traits in a particular setting (e.g., professional identity as a nurse)
Beliefs about Capabilities	Personal beliefs about one's own capabilities (e.g., self-confidence)
Optimism	Positive expectations for the future
Beliefs about Consequences	Expectations about all consequences, both positive and negative
Reinforcement	Influences that increase the likelihood of particular behaviours (e.g., rewards)
Intentions	Conscious decisions to perform certain behaviours
Goals	Mental representations of desirable outcomes (e.g., target-setting)
Memory, Attention and Decision Processes	The ability to retain information, focus effectively on specifics in the environment, and choose between alternatives
Environmental Context and Resources	Circumstances and aspects of the environment that influence the individual positively or negatively (e.g., climate)
Social influences	Specifically, interpersonal influences (e.g., group norms)
Emotion	Feelings and associated behaviours (e.g., fear)
Behavioural Regulation	The ability to influence one's own behaviour, (e.g., self-monitoring)

TDF has been used extensively within healthcare-related research, embedded into research methodologies ranging from RCTs to phenomenology. Fields of study have included: smoking cessation; physical activity; hand hygiene; acute low back pain; and schizophrenia. (Cane, O'Connor and Michie 2012) The rationale for including TDF as part of the study was that by identifying the behavioural determinants around aspects of medicines management, is that this would enable more effective development of interventions to alter behaviour.

## 2.7 Schematic summary of the research approaches

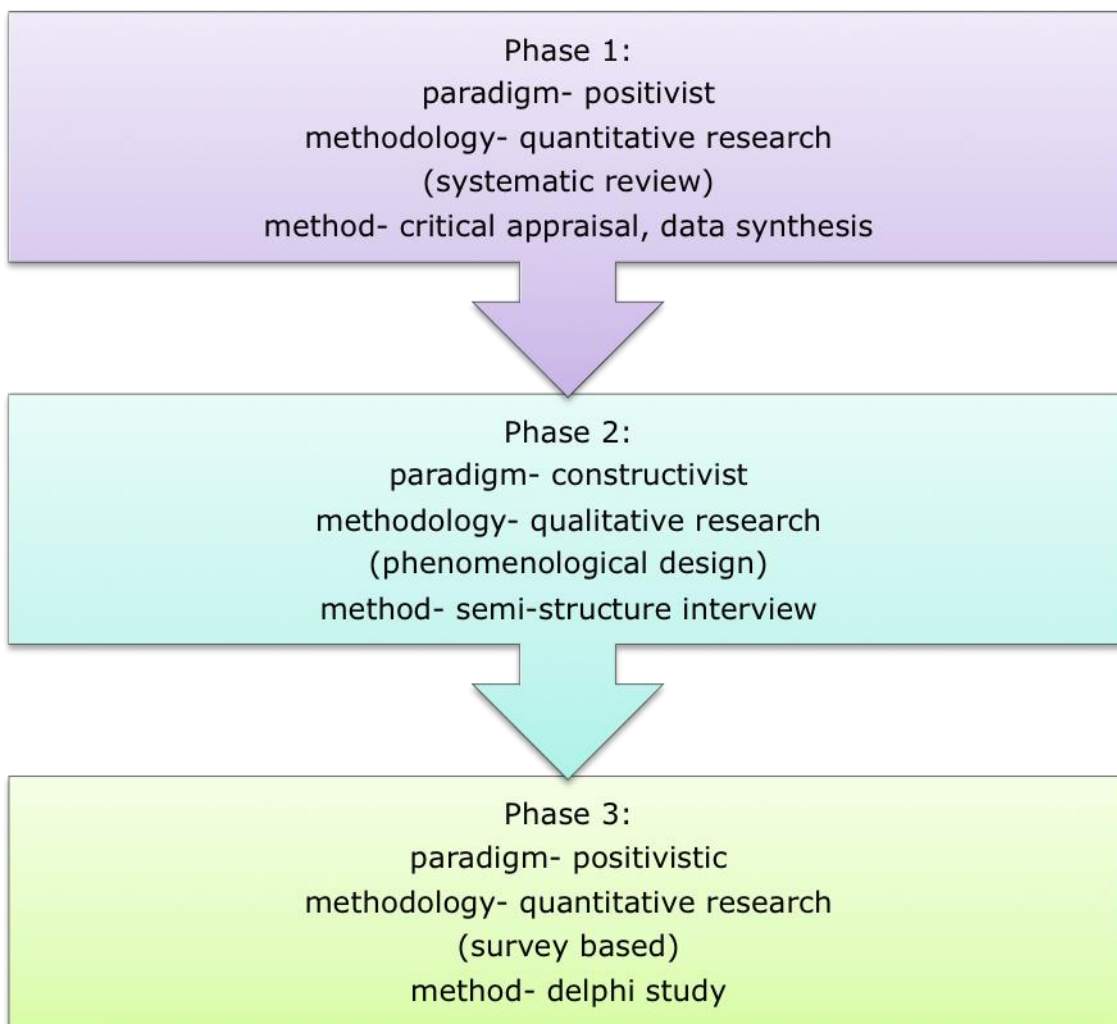


Figure 2.2: Methodological phases of current research

## **CHAPTER 3: Use of the Drug Burden Index: A systematic review**

### **3.1 Introduction to the chapter**

This chapter provides the aim, method, results and discussion of a Joanna Briggs Institute (JBI) registered systematic review of the Drug Burden Index (DBI) and consideration of its inclusion within tools for medicines management of elderly, hospitalised patients.

There were several reasons for this specific focus on anticholinergic agents as part of this doctoral medicines management research, as outlined in Chapter 1. These agents are particularly problematic in the elderly (Kay *et al.* 2005, Chew *et al.* 2008, Rudolph *et al.* 2008) and there is a notable lack of detailed coverage within generic potentially inappropriate prescribing scales (e.g. STOPP/START, Beer's criteria).

Anticholinergic agents or drugs with anticholinergic properties are widely used in the elderly, and include drugs for urinary incontinence, antidepressants and antihistamines. (Chew *et al.* 2008) Anticholinergic agents act by blocking the actions of the neurotransmitter acetylcholine. (Rudolph *et al.* 2008) Cholinergic receptors are classified into muscarinic and nicotinic, with muscarinic receptors categorised into five subtypes M1-M5; three of these subtypes play a fundamental role in cognitive function. (Kay and Granville 2005) Adverse anticholinergic effects in the elderly can be severe and debilitating, including: dry mouth and sore throat; dental caries; diplopia; glaucoma; urinary retention; tachycardia; loss of co-ordination; confusion and agitation; memory problems; incoherent speech; mental confusion; and orthostatic hypotension leading to falls. (Cilag, Abbott and Center 2001, Inouye, Schlesinger and Lydon 1999, Aizenberg *et al.* 2002)

The cumulative effect of prescribing multiple medicines that block muscarinic receptors in the cholinergic nervous system is termed the 'anticholinergic burden'. Many factors have been noted to influence the 'anticholinergic burden'

including: age-related pharmacodynamic and pharmacokinetic changes; polypharmacy (inappropriate and appropriate) drug regimens with anticholinergic effects; drug-drug interactions; exposure to certain drugs; reliability of the blood brain barrier, and co-morbid disease states, particularly dementia. (Durán, Azermai and Vander Stichele 2013) The 'anticholinergic burden' is therefore of great relevance and should be a key consideration in prescribing and monitoring of medicines in elderly, hospitalised patients.

Several scales have been developed to measure the 'anticholinergic burden'. Duran *et al.* reported a systematic review of anticholinergic risk scales in the elderly, with the aim of developing a uniform list of anticholinergic drugs, differentiating for anticholinergic properties. (Durán, Azermai and Vander Stichele 2013) Primary studies were included in the review if they provided: a finite list of anticholinergic drugs; a grading score of anticholinergic potency; and validation in a clinical setting. Studies published up to September 2012 and indexed in Medline were included. The review identified 454 articles; 422 of which were excluded during title and abstract screening and 28 during full text screening. A further three studies were identified from sources such as Google Scholar giving seven studies for data extraction. Seven different 'risk' scales were identified, with considerable variation in terms of the specific drugs included on the scales and the grading of anticholinergic potency. Synthesis of study findings gave a list of 100 drugs (47 graded as high anticholinergic potency and 53 as low anticholinergic potency). There are several key limitations to this review: there is a lack of consistency between the terms 'anticholinergic burden' and 'anticholinergic risk'; Medline was the only database searched; there was no critical appraisal step within the review; and the review did not name the different scales. To date, there have been no published studies which have employed the list synthesised in this review.

More recently, Salahudeen *et al.* reported a systematic review to compare anticholinergic burden quantified by the anticholinergic risk scales which were derived through expert opinion. (Salahudeen, Duffull and Nishtala 2015) Primary studies were included in the review if: the quantification tool was based on expert opinion; and reported the use of expert opinion quantification scale/tool to measure anticholinergic burden. The search was conducted in

Medline, Embase and PsycINFO covering the period 1984 - September 2014. Searching identified 932 studies, which was reduced to seven following title, abstract and full text screening. These seven papers reported use of: Anticholinergic Drug Scale; Anticholinergic Burden Classification; Clinician-rated Anticholinergic Score; Anticholinergic Risk Scale; Anticholinergic Cognitive Burden Scale; Anticholinergic Activity Scale; and Anticholinergic Loading Scale. The key finding was that there was no standardised tool and that the rating of anticholinergic activity for medicines between scales was inconsistent. One key limitation of this review was only including scales based on expert opinion. Additionally, there was no critical appraisal step.

A recent narrative review conducted by Kouladjian *et al.* provided an overview of the research and clinical applications of the Drug Burden Index (DBI); and its advantages and limitations, compared with other pharmacologically developed measures of high-risk prescribing (Figure 3.1). The review was based on a search of Medline and PubMed databases for articles published from January 2000. (Kouladjian *et al.* 2014) The key finding was that the DBI was a novel pharmacological evidence-based tool to measure anticholinergic and sedative agents.



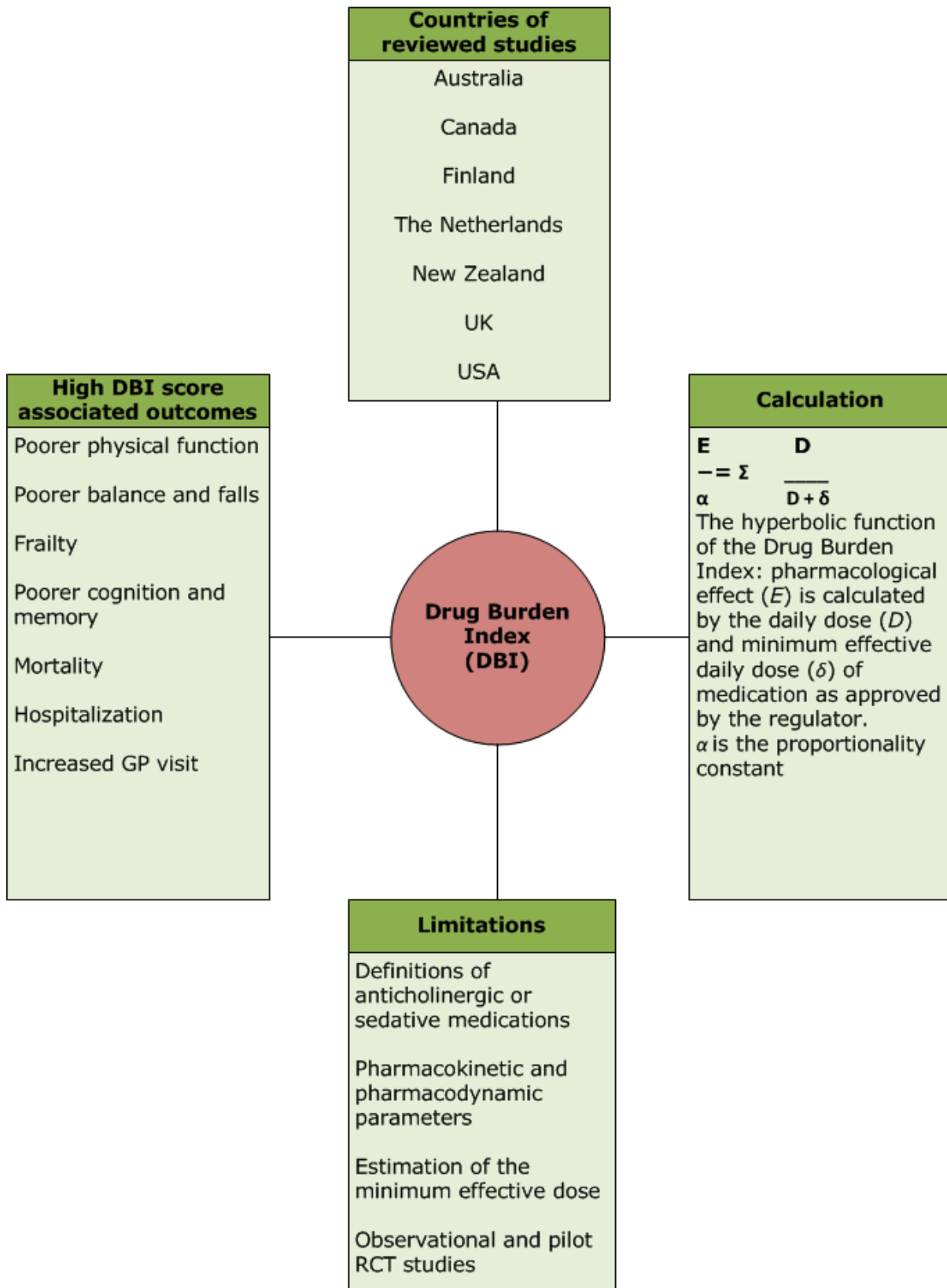


Figure 3.1: Summary of aspect of the DBI (adopted from Kouladjian *et al.* 2014)

The DBI was developed in 2007 by Hilmer *et al.* and is used to quantify the anticholinergic and sedative burden. One key advantage of DBI over other scales is that it also captures the use of sedative agents. Sedative agents can be defined as those drugs that cause physiological and mental slowing of the body. With prolonged use, sedative agents can lead to the development of symptoms of abuse, dependence and withdrawal. Examples of sedative agents are hypnotics (sleep promoting drugs), anxiolytics (anti-anxiety agents). Sedative agents enhance neurotransmitter gamma-aminobutyric acid (GABA) effects that regulate and depress the nervous system and cause reduced pain, sleepiness and reduce anxiety. (Rothberg *et al.* 2013) Adverse sedative effects in the elderly can be severe similar to adverse anticholinergic effects and lead to falls.

Anticholinergic (Nishtala *et al.* 2009) and sedative (Rothberg *et al.* 2013) agents are consistently reported as commonly prescribed medicines in elderly, and inappropriate use of these medicines is associated with adverse outcome. (Bell *et al.* 2012)

The DBI is calculated as follows:

$$\text{Drug Burden} = \frac{D}{D + \delta}$$

D is the daily dose of anticholinergic or sedative medicine, and  $\delta$  the minimum efficacious dose as approved by the Food and Drugs Administration in the United States of America (USA).

Hilmer *et al.* employed the index in a study which aimed to evaluate the association between DBI and cognitive and functional outcomes. (Hilmer *et al.* 2009) This was a cross-sectional study of community dwelling older persons participating in the Health, Ageing and Body Composition (ABC) initiative in the USA. This seminal study established that increasing DBI had a positive correlation with deterioration in functions of grip strength and gait. In addition, a unit increase in DBI was a prediction of deterioration in gait speed of 0.04 m/s.

Table 3.1 and 3.2 gives comparison of DBI with other anticholinergic burden scales.

Table 3.1: Comparison of the development and application of anticholinergic scales (by publication year) with the Drug Burden Index (adapted from Kouladjian *et al.* 2014)

	DBI (2007)	ADS (2006)	ABC (2006)	CrAS (2008)	ARS (2008)	ACB (2008)	AAS (2010)	ACL (2011)
Conceptual basis of scale Pharmacological first principles								
- Serum radioreceptor assays or SSA	✓		✓		✓	✓		
- Extensive literature reviews (including systematics review)		✓	✓		✓	✓	✓	✓
- Interdisciplinary clinician rating scales or expert opinion			✓	✓	✓	✓	✓	✓
Scoring system or calculation equations used								
- Categorical or numerical scale used		✓	✓	✓	✓	✓	✓	✓
- Pharmacological equation used	✓							
- Summation or accumulation of effect	✓	✓	✓	✓	✓	✓	✓	
- Dose consideration	✓	✓						
Medicine identification resource								
- Country-specific product information/label	✓	✓						
- Others (e.g. literature appraisals)			✓	✓	✓	✓	✓	✓
Number of anticholinergic medicines considered	Variable 128*	117	27	60	49	88	99	49

\*Number of medicines included in the DBI calculation includes sedative and anticholinergic medicines and varies according to each country's formulary at the time of the study; the number reported here is the number of anticholinergic and sedative medicines that a cohort of 2,172 older adults in the USA was exposed to (Hilmer *et al.* 2009); **Abbreviations:** SAA, serum anticholinergic activity; ADS, Anticholinergic Drug Scale; ABC, Anticholinergic Burden Classification; CrAS, Clinician-rated Anticholinergic Score; ARS, Anticholinergic Risk Scale; AAS, Anticholinergic Activity Scale; ACL, Anticholinergic Loading Scale; ACB, Anticholinergic Cognitive Burden Scale; DBI, Drug Burden Index.

Table 3.2: Comparison of aspects of sedative rating scales (by publication year) with the Drug Burden Index (adapted from Kouladjian *et al.* 2014)

	DBI (2007)	Sedative load (2003)	Sloane <i>et al.</i> (2008)	CNS drug (2009)
Conceptual basis of scale				
- Pharmacological first principles	✓		✓	✓
- Extensive literature reviews (including systematics review)		✓		
- Interdisciplinary clinician rating scales or expert opinion		✓	✓	
Scoring system or calculation equations used				
- Categorical or numerical scale used		✓	✓	✓
- Pharmacological equation used	✓	✓	✓	✓
- Summation or accumulation of effect	✓	✓	✓	✓
- Dose consideration	✓		✓	✓
Medicine identification resource				
- Anatomical Therapeutic Classification System		✓	✓	
- Iowa Drug Information System Codes				✓
- Country-specific product information/label	✓	✓	✓	
Number of sedative medicines considered	Variable128*	340	106	53

\*Number of medicines included in the DBI calculation includes sedative and anticholinergic medications and varies according to each country's formulary at the time of the study; the number reported here is the number of anticholinergic and sedative medications that a cohort of 2,172 older adults in the USA was exposed to (Hilmer *et al.* 2009); **Abbreviations:** DBI, Drug Burden Index; CNS, central nervous system.

The DBI is, therefore, a potentially powerful tool to:

- i. quantify the effects of anticholinergic and sedative agents,
- ii. to aid review of these medicines and
- iii. and to quantify the effects of interventions to reduce the DBI.

There is potential to use the DBI alongside other more generic tools or criteria which highlight potentially inappropriate prescribing, as an overall package as part of medicines management.

Since 2007, the DBI had been studied in various countries and clinical settings. A scoping search of Medline, International Pharmaceutical Abstracts (IPA), Cumulative Index of Nursing and Allied Health Literature (CINAHL), PsycArticles, and Cochrane Library identified a volume of literature focusing on the DBI. To date no systematic review had been published or protocol registered with the Joanna Briggs Institute (JBI), the Cochrane Collaboration or the Centre for Reviews and Dissemination. Since the DBI was published in 2007, the scoping search timeline was from 2007 to 2013, to identify those articles published in the English language. The PI also contacted Professor Hilmer (the corresponding author for the seminal work on the DBI) via email to confirm that she was neither conducting nor was aware of any such review.

The review focused on the use of the DBI to identify potentially inappropriate prescribing of anticholinergic and sedative agents in elderly patients in institutionalised care (e.g. hospital or care home settings). This provided an opportunity to systematically search, locate, appraise, synthesize, summarize and interpret the best available evidence using standard JBI approaches. The findings of this review would be of particular relevance to practitioners caring for elderly patients in institutionalised settings, providing quality information on any associations between DBI and health outcomes (e.g. related to adverse drug reactions), and the impact of medicines review on DBI and these outcomes.

A review protocol was developed according to best practice (Pearson, Wiechula and Lockwood 2005) and submitted for review by PI and Principal Supervisor. Following peer review, subsequent modification and further peer review, the protocol was registered with the JBI Database of Systematic Reviews & Implementation Reports and published in 2014. (Al Shemeili and Stewart 2014)

### 3.1.1 Aim and objectives

The aim of the review was to critically appraise, synthesize and present evidence of the use of the Drug Burden Index (DBI) to identify potentially inappropriate prescribing of anticholinergic and sedative agents in elderly patients in institutionalised care.

More specifically, this review sought to answer the following review questions:

1. in which specific settings and patient groups had the DBI been applied?
2. what outcomes had been studied? (e.g. occurrence and incidence of adverse drug reactions, physical functioning, mental functioning, cause of admission to hospital etc.)
3. had the use of DBI impacted prescribing of anticholinergic and sedative agents in elderly patients in institutionalised care? (e.g. cessation of therapy, prescribing altered to other agents, reduction in adverse drug reactions etc.)

## **3.2 Methods**

### 3.2.1 Inclusion criteria

The standard systematic review PICO approach was employed.

### 3.2.1.1 Types of participants

The review focused specifically on 'elderly patients' as described within the studies. If no classification was given within studies then those studies reporting on patients aged 65 years and over were included. Furthermore, the review focused on patients receiving care within either hospital or care home settings (institutionalised care). The care of these patients and hence the use of the DBI was likely to be markedly different to those home dwelling patients and hence less relevant to this doctoral research of hospitalised patients.

### 3.2.1.2 Types of intervention(s)

While the intervention was the use of the DBI, a scoping review of the literature had identified only a small number of studies where this tool was used as an intervention. Most studies used an observational design solely involving application of the tool.

### 3.2.1.3 Types of comparisons

Patients with a zero DBI score (i.e. no prescription of anticholinergic or sedative medicines) compared to DBI score; or different levels of DBI scores between sub-samples of patients. Most studies had no comparison (as described above).

### 3.2.1.4 Types of outcomes

This review considered studies that included the following outcome measures:

1. DBI scores (in observational studies).
2. impact of DBI on outcomes such as physical and mental functioning; adverse effects of anticholinergic and sedative medicines.
3. changes to therapy following application of DBI as a tool to identify potentially inappropriate prescribing.

### 3.2.1.5 Types of studies

The review considered quantitative studies relevant to the application of the DBI and hence these were observational in nature, specifically prospective and retrospective cohort studies, case control studies and analytical cross-sectional studies. While qualitative studies could elucidate practitioners' beliefs and attitudes on the use of the DBI, these were not relevant for the review questions. Furthermore, the scoping review did not identify any qualitative research on the DBI.

### 3.2.2 Search strategy

The search strategy aimed to find both published and unpublished studies. A two-step search strategy was utilized in this review.

1. 'Drug Burden Index' was a specific term and hence was the only search term employed. To ensure that all relevant papers were captured, 'Drug Burden Index' was searched in the titles, keywords, abstracts and text.
2. To ensure full coverage of all the literature, the reference lists of all papers and reports were reviewed for any previously unidentified studies.

The first paper describing the DBI was published in 2007 and hence studies published from 2007 to July 2015 in the English language were included in the review.

The databases searched were:

1. Medical Literature Analysis and Retrieval System Online (MEDLINE)  
Medline is a database provided by the United States National Library of Medicine covering basic research and clinical sciences. It contains over 14 million records (U.S. National Library of Medicine 2015)
2. International Pharmaceutical Abstracts (IPA)  
IPA is an online database produced in conjunction with the American Society of Health-System Pharmacists. It provides a comprehensive



collection of information on drug use and development from 1971 (EBSCO Health 2015)

3. Cumulative Index of Nursing and Allied Health Literature (CINAHL)  
CINAHL contains references to journals articles from hundreds of nursing journals from the UK, USA and other countries (EBSCO Health 2015)
4. PsycARTICLES  
PsycARTICLES is a database offering complete coverage of all subject areas relevant to psychological science. It includes the full text of nearly 200,000 articles, from more than 100 journals. These journals are published by the American Psychological Association, the Canadian Psychological Association and the Hogrefe Publishing Group (American Psychological Association 2015)
5. Cochrane Database of Systematic Reviews  
Archibald Cochrane (1909-88), a British epidemiologist, introduced the Cochrane Collaboration which identifies, appraises and synthesises research based evidence and presents it in an accessible format (Cochrane Library 2015)

The search for unpublished studies/grey literature was conducted in: Google Scholar (online search engine of published outputs); Science.gov (gateway to government sciences information provided by US government); Robert Wood Johnson Institute; and Dissertations Abstract International (bibliography of American and international dissertations published by University Microfilms International).

The search string was applied with results and exceptions recorded. Titles of papers returned by the search were screened independently by two reviewers, in relation to the review title, aim, research questions, and inclusion criteria, followed by abstracts and full papers. In case of uncertainty or disagreement between two reviewers a third reviewer was consulted.

### 3.2.3 Assessment of methodological quality

The papers selected for retrieval were assessed by two independent reviewers for methodological validity prior to inclusion in the review, using standardised critical appraisal instruments from the JBI Meta Analysis of Statistics Assessment and Review Instrument (JBI-MAStARI) (Appendix 3.1). Any disagreements that arose between the reviewers were resolved through discussion, or with a third reviewer.

### 3.2.4 Data collection

Quantitative data were extracted from papers included in the review using the standardised data extraction tool from JBI-MAStARI (Appendix 3.2). The data extracted included specific details of the interventions, populations, study methods and outcomes of significance to the review question and specific objectives.

### 3.2.5 Data synthesis

Due to differences in study design and the lack of homogeneity of reported data, a meta-analysis using JBI-MAStARI was considered inappropriate. A narrative synthesis approach was used to present study findings.

## **3.3 Results**

### 3.3.1 Description of studies

Seven articles (three cohort studies, three mixed cohort and cross-sectional studies and one cross-sectional study) were identified. The Transparent Reporting of Systematic Reviews and Meta-Analyses (PRISMA) flowchart is given in Figure 3.2.

A total of 44 titles were retrieved from databases (Medline, IPA, CINAHL, PsycArticles, Cochrane), of which 11 were duplicates within the same databases, leaving 33 titles to be screened by two independent reviewers. Title screening excluded 11 duplicate articles between different databases. Following

abstract screening 11 articles was excluded, as they were not addressing the review topic questions (i.e. setting of practice not institutionalised care). Following full paper screening by the PI and principal supervisor, seven articles fulfilled the inclusion criteria. No further articles were identified from review of the reference lists of these seven articles. There were therefore seven studies for critical appraisal (see Table 3.3).

Table 3.3: number of studies retrieved

Number of articles retrieved	Number selected for critical appraisal
44	7

The list of excluded articles and the reason for exclusions are presented in Appendix 3.3

In terms of study design, three of the papers considered in this review used a mixed cross-sectional design and cohort (Lowry *et al.* 2011, Best *et al.* 2013, Mangoni *et al.* 2013) although one did not clearly specify this within the methods section. (Lowry *et al.* 2011) The other studies used a cross-sectional design (Bosboom *et al.* 2012) and a cohort design. (Nishtala *et al.* 2009, Wilson *et al.* 2011, Wilson *et al.* 2012)

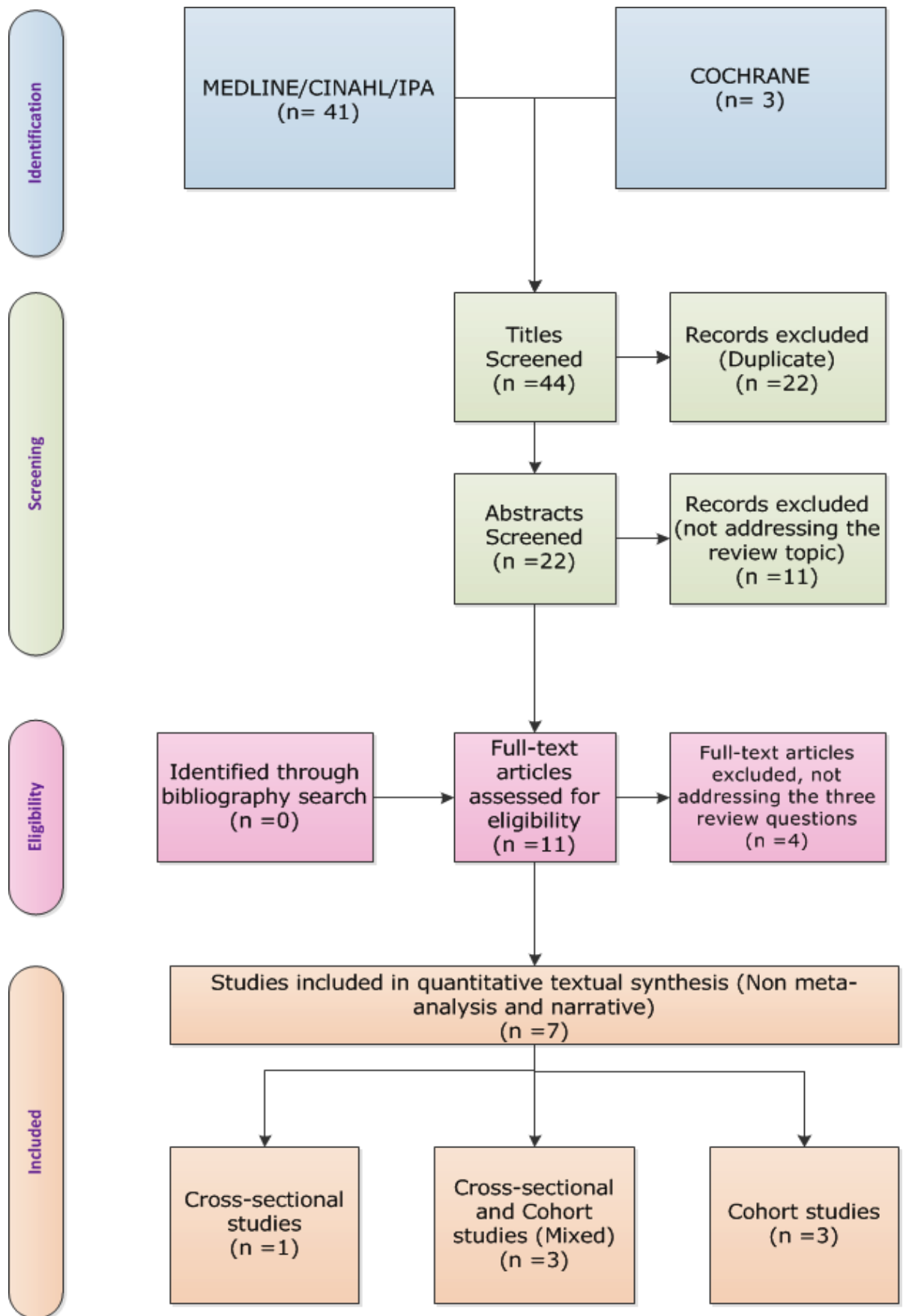


Figure 3.2: PRISMA flowchart for the search and study selection process

### 3.3.2 Methodological quality

The methodological quality of the included studies, based on using JBI-MAStARI, is reported in Table 3.4. There were only minor disagreements between the two reviewers, which were resolved through discussion.

Table 3.4: JBI-MAStARI quality assessment of reviewed studies

<b>Criteria / Author, Year</b>	<b>Nishtala <i>et al.</i> (2009)</b>	<b>Lowry <i>et al.</i> (2011)</b>	<b>Wilson <i>et al.</i> (2011)</b>	<b>Rosboom <i>et al.</i> (2012)</b>	<b>Wilson <i>et al.</i> (2012)</b>	<b>Best <i>et al.</i> (2013)</b>	<b>Mangoni <i>et al.</i> (2013)</b>
Is sample representative of patients in the population as a whole?	Y	Y	Y	U	Y	Y	U
Are the patients at a similar point in the course of their condition/illness?	Y	Y	Y	Y	Y	Y	Y
Has bias been minimised in relation to selection of cases and of controls?	Y	Y	Y	Y	Y	Y	Y
Are confounding factors identified and strategies to deal with them stated?	Y	Y	U	Y	Y	Y	Y
Are outcomes assessed using objective criteria?	Y	Y	Y	Y	Y	Y	Y
Was follow up carried out over a sufficient time period?	Y	N/A	Y	N/A	Y	N/A	N/A
Were the outcomes of people who withdrew described and included in the analysis?	Y	Y	Y	Y	Y	Y	Y
Were outcomes measured in a reliable way?	Y	Y	Y	Y	Y	Y	Y
Was appropriate statistical analysis used?	Y	Y	Y	Y	Y	Y	Y

Y, yes; N, no; U, unclear; N/A, not applicable (cross-sectional design hence no follow-up)

Table 3.5 shows the number of studies included and excluded based on the study quality assessments.

Table 3.5: MASTARI- number of studies included and excluded

Number of studies included	Number of studies excluded
7	0

It is clear from Table 3.4 that all studies were of very high quality (hence inclusion in data extraction). However, none of the studies provided any rationale to support the sample sizes. This is more relevant for the two which contained hypotheses within the study aims. The study of Rosbloom *et al.* (Bosboom *et al.* 2012) omitted any description of power while that of Best *et al.* (Best *et al.* 2013) did provide justification of sample size required at a given power of 80% to detect differences in DBI. However, it is not too clear what this difference referred to (presumably changes from admission to discharge from hospital). This estimation was based on earlier work in a different setting and should have been recalculated using the baseline data in this study, particularly as no difference was observed in the full study. It is worth noting that sample size is not considered by JBI within critical appraisal.

### 3.3.3 Data extraction and synthesis

Data extraction from these seven studies is given in Table 3.6. Due to differences in study design and the lack of homogeneity of study aims and outcomes, a meta-analysis (e.g. in relation to impact studies) using JBI-MAStARI was considered inappropriate. A narrative synthesis approach was used to present study findings.

Table 3.6: Data extraction of reviewed studies

<b>Authors, Year, Country, Setting, Design</b>	<b>Study aim(s)</b>	<b>Participants</b>	<b>Outcome measures</b>	<b>Findings</b>	<b>Authors' conclusions</b>
Nishtala <i>et al.</i> (2009) Australia 62 aged-care homes Cohort study	To evaluate whether residential medicines management recommendations made by pharmacists and their uptake by GPs impacted DBI in older people living in aged-care homes	Random sample (unclear what proportion of patients randomly sampled and if any stratification per pharmacist or per home) of 500 patients from 62 aged care homes.  Patients were ≥65 years who had received an accredited clinical pharmacist conducted Residential Medication Management Reviews (RMMR) from a single RMMR service provider	Review of each resident's case notes, which were written by the accredited pharmacists. Information gathered diagnoses, current medication, relevant pathology results, resident interview notes and consultations made with facility staff and doctors. Also recorded outcome of the pharmacist review in terms of changes to medicines. DBI calculated pre- and post-review by the	At baseline, mean number of anticholinergic and sedative medications per patient were 0.9 (0.9 SD) and 0.2 (0.4) respectively. DBI scores were significantly lower than those obtained prior to the review after uptake of recommended changes by the GP by ( $p < 0.001$ ). The median DBI exposure was reduced from 0.5 (equivalent to one minimum efficacious dose of an anticholinergic or sedative medication per resident) to 0.33 (equivalent to half a minimum efficacious dose of an anticholinergic or sedative medicine per resident). The mean decrease in DBI from pharmacist recommendations was 0.12 (95% CI 0.09, 0.14),	The study demonstrates that accredited clinical pharmacist conducted medicines reviews could reduce prescribing of sedative and anticholinergic drugs, resulting in a significant decrease in the DBI score of the study population



			researchers to determine any differences (not part of the pharmacist review)	representing a 20% decrease in mean baseline DBI for residents. When GPs implemented pharmacists' recommendations, the DBI decreased by a mean of 12% from baseline (mean decrease 0.07; 95% CI 0.05, 0.08)	
Lowry <i>et al.</i> (2011) UK Two acute geriatric units in Aberdeen, Mixed cross-sectional and cohort study	To investigate the association between the DBI score and the Barthel Index, an established scale to measure performance in basic activities of daily living, in a consecutive series of older hospitalized patients. To assess the predictive yield of the DBI score on 2 objective short-term outcomes namely, length of stay (LOS) and in-hospital mortality	The study sample consisted of a consecutive series of patients > 60 years admitted to 2 acute geriatric medicine units from February 1, 2010, to June 30, 2010. Sample size of 362	Main outcome measure, Barthel Index (performance in activities of daily living). Secondary outcomes of length of hospital stay and in-patient mortality	Median (range) DBI (total) of 0.48 (0-1), DBI anticholinergic 0 (0-0.5) and sedative 0 (0-0.5). Zero score for total (48.1%), anticholinergic (54.4%) and sedative (58.6%). The median score for the Barthel Index was 75 (range, 5-100; IQR, 60-90). Proportional odds ordinal logistic regression showed that higher DBI scores were all significantly and independently associated with being in lower Barthel Index categories after adjusting for age, sex, residency status, Charlson Comorbidity Index, dementia, total number of	Higher DBI scores on admission are strongly associated with reduced physical function and predict an increased LOS in older hospitalized patients

				<p>non-anticholinergic/sedative drugs, and hospital admission site.</p> <p>Higher DBI scores all predicted increased Length Of Stay (LOS) in univariate analysis and after adjusting for age, sex, residency status, dementia, Charlson Comorbidity Index, number of nonanticholinergic/sedative drugs, hospital site, and Barthel Index category. The DBI scores did not predict in-hospital mortality</p>	
<p>Wilson <i>et al.</i> (2011) Australia, Residential Aged Care Facilities Northern Sydney Central Coast Area Health (NSCCH) service area Cohort</p>	<p>To evaluate the association between higher DBI and fall rates in a population of older people living in RACFs</p>	<p>602 participants who were taking part in an RCT of the effect of sunlight and vitamin D on falls Individuals were eligible if they were ambulant, aged 70 and older, and likely to survive for 12 months as judged by facility staff. Exclusion</p>	<p>The main outcome measure was the number of falls recorded over the 12-month study period The main variable of interest was the DBI</p>	<p>35.2% were taking anticholinergics, 42% sedatives and 16.6% both. DBI total mean 0.60, DBI anticholinergic 0.27, DBI sedative 0.33 (with SDs) There were 998 falls during the 1-year study period; 330 residents (55%) fell one or more times in this period, and of these, 135 fell once, 69 fell twice, 35 fell three times, 30 fell four times, and 61</p>	<p>The DBI in older people living in RACFs is significantly and independently associated with falls. Intervention studies specifically designed for this population are required to determine whether cessation or reducing the dose</p>

study		<p>criteria were skin cancer within the last 3 years and taking vitamin D or calcium supplements in the last 6 months. Verbal and written consent were obtained, and in cases of cognitive impairment, consent was sought from the appropriate person as defined by legislation</p> <p>During the 1 year study period, 65 participants (10.8%) died during the observation period, and 11 (1.8%) withdrew from the study, giving the cohort a follow-up period of 574.2 person-years</p>		<p>fell five or more times. The fall rate equates to 1.74 falls per person-year, and the median time to fall was 120 days from the baseline assessment date. A statistically significant and ordered time to fall for individuals in the none, low, and high DBI categories was apparent (log rank chi square = 18.38<sub>(2)</sub> P&lt;.001). Six-month fall rates were 30%, 39% and 51% for participants in the 0, low, and high DBI categories respectively</p> <p>The multivariate analyses showed that the fall rate was greater if the individual was male, had a history of falling, was cognitively impaired, used a cane or a walker, was incontinent during the day and night, and had a low or high DBI</p>	<p>and number of anticholinergic or sedative medicines can prevent falls</p>
Rosboom <i>et al.</i> (2012) Western	Aimed to determine the association between self-	Participants were obtained from the DIRECT study dementia in	Measured QoL-AD ratings. Measured PIMs by Beers, DBI and	124 participants (56.9%) were exposed to one potentially inappropriate medicines. In terms of	The use of PHM is common and is inversely associated with the

<p>Australia</p> <p>Low-level or high-level residential aged care facilities in Perth</p> <p>Cross-sectional study</p>	<p>reported health related quality of life and the use of potentially harmful medications as defined by Beers, DBI (for this review) and polypharmacy (<math>\geq 5</math> medications) Also tested the hypothesis that Self-reported health related quality of life would be inversely associated with inappropriate prescribing as defined by Beers, DBI <math>&gt; 0</math> (for this review) and polypharmacy</p>	<p>residential care: education intervention trial) All participants in this study were the permanent residents of a low-level or high-level RACF were, aged <math>\geq 65</math> years, with a clinical diagnosis of dementia and MMSE total score of <math>\leq 24</math>. The exclusion criteria were: medically unstable or as suffering from delirium, or in the terminal stages of a co-morbid illness; or unable to participate in completion of assessment instruments in English</p> <p>The initial sample of 351 was reduced to 226 capable of self-reporting the QoL-AD instrument</p>	<p>polypharmacy</p>	<p>DBI, 178 (78.8%) were exposed to medications with DBI<math>&gt;0</math>: 82 (46.1%) anticholinergic and 96 (53.9%) sedative medicines.</p> <p>The mean QoL-AD total score by self-rating was <math>41.5 \pm 5.9</math> (range 26–58), corresponding to a mean QoL-AD % MaxSc of <math>69.2 \pm 9.9</math> (range 43.3–96.7).</p> <p>DBI<math>&gt;0</math> was associated with the self-reported QoL-AD, after adjustment for other factors. DBI<math>&gt;0</math> tripled the odds of participants being in the middle or lowest tertile of QoL ratings</p>	<p>self-reported HRQoL in PWD living in RACFs. With regard to clinical tools, the data suggests that DBI and polypharmacy may be better predictors of HRQoL than PIMs by Modified Beers criteria</p>
<p>Wilson <i>et al.</i> (2012)</p>	<p>To ascertain whether the DBI</p>	<p>602 participants who were taking</p>	<p>The main outcome measure</p>	<p>97.8% were taking medicines. Of these,</p>	<p>No significant associations</p>

<p>Australia Residential Aged Care Facilities Northern Sydney Central Coast Area Health (NSCCH) service area Cohort study</p>	<p>score is a predictor of mortality and if this association is dose related</p>	<p>part in an RCT of the effect of sunlight and vitamin D on falls. RACFs excluded individuals with a high score on the Impact Illness Severity Scale at the time of recruitment (2006-2009)</p>	<p>was mortality as recorded in nursing notes followed by review of individual subject and dates of birth (the NSW Registry of Births, Dates and Marriages)</p>	<p>41.9% were exposed to sedatives, 33.6% anticholinergic and 17.6% taking both. Mean baseline DBI in the cohort was 0.57, 0.33 sedative and 0.25 anticholinergic Significant determinants of a high DBI were female, BMI <math>\geq</math> 222, using a walking frame, taking 9 or more non-DBI prescription medicines, total number of medicines and a higher CCI (Charlson Comorbidity Index) score DBI scores were not associated with 1-year mortality data (but sample sizes may not have been adequate to identify a clinically important difference). Actually highlights this in the conclusion</p>	<p>between increasing DBI and mortality were seen</p>
<p>Best <i>et al.</i> (2013) Australia 550 bed university-teaching hospital in Sydney</p>	<p>To investigate the changes in polypharmacy and the drug burden index (DBI) occurring during hospitalisation for</p>	<p>Patients with the age of <math>\geq</math>65 years and admitted under the care of the geriatric medicine or rehabilitation teams. Consecutive</p>	<p>The reasons for admission were determined from the aged care discharge summary. The clinical case notes were also</p>	<p>The mean (<math>\pm</math>SD) age of the population was <math>84.6 \pm 7.0</math> years, 62% were female and 40% were admitted from residential aged-care facilities. On admission, DBI exposure was observed in 50% of</p>	<p>DBI was associated with an increased risk of hospital admission for delirium only. Polypharmacy was not associated with any of the</p>

Mixed cross-sectional and cohort study	older people. The secondary aim was to examine the associations of these two measures with the length of hospital stay and admission for falls or delirium	patients (n= 392) discharged from hospital between 1 January and 30 June 2011 were identified from hospital records. The final study population consisted of 329 older people discharged from hospital, with 63 patients excluded for a variety of reasons	reviewed if clarification was required Medicines at admission and discharged were extracted from medical notes All diagnoses, including delirium, were diagnosed by the attending doctor and recorded on the discharge summary or clinical notes The length of hospitalisation was recorded to the nearest whole day, from the date of admission to the date of discharge as listed on the aged care discharge summary	the cohort DBI and polypharmacy exposure decreased during hospitalisation, but only the number of medications taken decreased by a statistically significant margin (P= 0.02). Patients with a high DBI ( $\geq 1$ ) were approximately three times more likely to be admitted for delirium than those with no DBI exposure (odds ratio, 2.95; 95% confidence interval, 1.34–6.51) There was no association between increasing DBI and fall-related admissions	clinical measures
Mangoni <i>et al.</i> (2013) The Netherlands, Academic	The study aimed to assess possible associations between	The study sample consisted of patients 65 years or older admitted with hip fractures	Postoperative complications, hospital length of stay, and 3-month and 1-year	No significant associations were observed between the number of anticholinergic drugs, ADSSs (including the	The main results of this study showed poor associations between ADSSs (including DBI)

<p>Medical Centre, Amsterdam Mixed cross-sectional and cohort study</p>	<p>anticholinergic drug scoring systems (ADSS) and serum anticholinergic activity (SAA) and their capacities to predict all-cause mortality in older hospitalized patients Drug Burden Index (DBI) was one of the four ADSS, specifically focusing on the anticholinergic element</p>	<p>and scheduled for surgery between May 2005 and November 2008 The sample comprised those patient eligible (following application of exclusion criteria) and those not consenting. From an initial 313 patients, 71 were included in the study</p>	<p>all-cause mortality Serum anticholinergic activity determined and in terms of DBI, the anticholinergic element score derived</p>	<p>anticholinergic element of the DMI), and SAA In univariate analysis, SAA was higher in patients with preadmission cognitive impairment (<math>4.3 \pm 3.9</math> versus <math>2.4 \pm 2.1</math> pmol/mL, <math>p = 0.009</math>) and in-hospital delirium (median 4.0 versus 2.1 pmol/mL, <math>p = 0.02</math>) SAA was positively associated with age and Katz Activities of Daily Living score and negatively associated with the number of non-anticholinergic medicines In multivariate linear regression preadmission cognitive impairment (<math>\beta = 2.12 \pm 0.71</math>, <math>p = 0.004</math>) and the number of non-anticholinergic drugs (<math>\beta = 0.29 \pm 0.13</math>, <math>p = 0.03</math>) were independently associated with SAA</p>	<p>and SAA in older hospitalized patients awaiting hip surgery This suggests that factors other than anticholinergic drug prescribing might influence the in vitro measurement of SAA in addition to the known inherent limitations of the technique Further studies are required to confirm these findings in different and larger patient groups and to also assess the relative impact of the SAA versus ADSSs on adverse medical and psychiatric outcomes in older patients</p>
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In relation to the review questions:

- i) in which specific settings and patient groups had the DBI been applied?

The studies were based largely in Australia (Nishtala *et al.* 2009, Wilson *et al.* 2011, Bosboom *et al.* 2012, Wilson *et al.* 2012, Best *et al.* 2013), the Netherlands (Mangoni *et al.* 2013), and the United Kingdom. (Lowry *et al.* 2011) They were conducted in either aged care facilities (Nishtala *et al.* 2009, Wilson *et al.* 2011, Bosboom *et al.* 2012, Wilson *et al.* 2012) or geriatric medicine units of hospitals. (Lowry *et al.* 2011, Best *et al.* 2013, Mangoni *et al.* 2013)

There were slightly varied patient inclusion criteria, with most (Wilson *et al.* 2011, Bosboom *et al.* 2012, Wilson *et al.* 2012, Best *et al.* 2013, Mangoni *et al.* 2013) including those older than 65 years, one (Lowry *et al.* 2011) older than 60 years while one study was more general, randomly selecting participants of various ages in residential aged care facilities. (Nishtala *et al.* 2009) Sample sizes varied from 226 (Bosboom *et al.* 2012) to 602. (Wilson *et al.* 2011, Wilson *et al.* 2012)

The following sources of information (largely medical notes and less commonly via patient interview) were used to gather medicines information:

- the use of two investigators to review each patients' medical notes (but not clear if they both reviewed each patient and worked independently) (Nishtala *et al.* 2009, Lowry *et al.* 2011, Wilson *et al.* 2011, Wilson *et al.* 2012),
- from clinical records by trained research assistants and face to face interviews (Bosboom *et al.* 2012),



- from medical notes, patient medicines admission data (Best *et al.* 2013) and
- from medical notes at 3 and 12 months post surgery (Mangoni *et al.* 2013).

In terms of computing for the DBI, almost all the studies provided a clear and detailed approach to their derivation.

- The DBI was calculated using formula ( $DBI = \sum D/\delta + D$ ) where D represented the total daily dose of sedative or anticholinergic medication, and  $\delta$  was the minimum efficacious daily dose according to the Food and Drugs Administration in the USA (Nishtala *et al.* 2009),
- the DBI was calculated using formula ( $DBI = \sum D/\delta + D$ ) where D represented the total daily dose of sedative or anticholinergic medication, and  $\delta$  was the minimum efficacious daily dose according to the British National Formulary (Lowry *et al.* 2011, Mangoni *et al.* 2013),
- the DBI was calculated using formula ( $DBI = \sum D/\delta + D$ ) where D represented the total daily dose of sedative or anticholinergic medication, and  $\delta$  was the minimum efficacious daily dose according to Australian approved product information (Wilson *et al.* 2011, Wilson *et al.* 2012, Best *et al.* 2013) and
- one study (Bosboom *et al.* 2012) did not provide this level of detail.

While these studies provided information on the source of the minimum efficacious dose, it is clear that the source varied and hence there is potential for lack of consistency if different doses are listed in the different sources. One further potential issue may be the lack of detail regarding the classification and identification of medicines as 'anticholinergic' and/or 'sedative'.

In general, there was a lack of detailed information on who calculated the DBI and whether or not there was any reliability check on the calculation. Furthermore, in cohort studies which involved following patients over a period of time, it appeared that the DBI was calculated only at one point in time, which may not have reflected any changes in medicines. An example would be Wilson *et al.* 2011 (Wilson *et al.* 2011), DBI was calculated only once (at baseline) and medicines may have changed at follow-up.

There were inconsistent approaches to the presentation of DBI scores ranging from: percentage of patients with zero scores (total, anticholinergic and sedative) (Wilson *et al.* 2011, Wilson *et al.* 2012, Best *et al.* 2013); percentage of patients with scores > 0 (total, anticholinergic and sedative) (Bosboom *et al.* 2012); mean scores (with standard deviations) (Mangoni *et al.* 2013); and median scores. (Lowry *et al.* 2011) While some of the studies presented DBI scores as continuous data, others categorised patients as high and low DBI scores. It was not always evident what was meant by 'higher' etc. Again, this diversity of approaches reduces the potential of being able to combine different study measures.

ii) what outcomes had been studied?

The aims of all studies were very different and this was reflected in a wide diversity of outcome measures, including falls, quality of life etc. As described earlier, this meant that a meta-analysis was not appropriate.

Lowry *et al.* used the Barthel Index as the main outcome measure. This is an established scale, which measures a person's performance in activities of daily living. The secondary outcome measure was the length of the patient's stay in the hospital and in-patient morbidity. (Lowry *et al.* 2011) DBI was treated as a continuous variable in this study. Higher DBI scores (total, anticholinergic and sedative) were found to be significantly and independently associated with lower Barthel categories (after adjusting for variables such as age, sex etc.) hence lower score for activities of daily living. Similarly, higher DBI scores were all found to predict increased length of stay, after adjustment but not in-patient

mortality. One limitation is the lack of clarity over the interpretation of 'higher' DBI scores within the paper.

Wilson *et al.* calculated DBI at baseline and recorded falls over a 12 month period as the outcome measure. (Wilson *et al.* 2011) A number of covariates (e.g. comorbidities, medical history, sociodemographic information) were considered. In this study, DBI was treated as a categorical variable (0, <1, ≥1), with high DBI (≥1) being significantly and independently associated with falls.

Rosboom *et al.* used a different categorisation for DBI and classified patients taking at least one anticholinergic agent or one sedative agent as DBI (i.e. >0 DBI). They also identified potentially inappropriate prescribing using the modified Beer's criteria. The outcome measure was the quality of life Alzheimer's disease questionnaire. They found that 78.8% of patients had a DBI >0 and that 54.9% had one or more potentially inappropriate medicines (according to the modified Beer's). While the use of potentially inappropriate medicines was not associated with the quality of life scores (after adjustment for covariates), the DBI score was. (Bosboom *et al.* 2012)

In a further study, Wilson *et al.* categorised DBI scores as 0 (none), 0-1 (low) and ≥1 (high) and measured mortality data as the outcome. DBI scores were presented as mean scores (with standard deviations). While there was no association between DBI and mortality, the authors did conclude that the sample size was most likely underpowered. (Wilson *et al.* 2012)

Best *et al.* used the length of stay and admission for falls or delirium as outcome measures related to DBI scores. Additionally, they investigated the changes in DBI during hospital stay. DBI scores were categorised as low (<1) and high (≥1) and also presented as both mean and median values. While the DBI scores reduced during stay, this did not reach statistical significance. After adjustment for covariates, those with high DBI scores were three times more likely to be admitted for delirium than those with no DBI exposure. No data were provided in relation to DBI scores and falls. (Best *et al.* 2013)

As part of a large study, Mangoni *et al.* calculated the anticholinergic component of the DBI scale and presented as median and range. The outcome measures were postoperative complications, hospital length of stay, and all-cause mortality. (Mangoni *et al.* 2013) No independent of postoperative complications or increased length of stay were identified. However, many factors, including the DBI anticholinergic score were significantly associated with one year mortality.

iii) had the use of DBI impacted prescribing of anticholinergic and sedative agents in elderly patients in institutionalised care?

Nishtala *et al.* examined the impact of clinical pharmacist medicines review on DBI scores. The DBI scores were calculated retrospectively at baseline (prior to review), after the review and after uptake of recommendations by physicians. DBI scores were presented as median (and interquartile ranges). The median scores decreased significantly after pharmacist review, with the pharmacist recommending medicines that lowered the patients' DBI by an average of 20%. (Nishtala *et al.* 2009)

### **3.4 Discussion**

The aim of this review was to critically appraise, synthesize and present evidence of the use of the Drug Burden Index (DBI) to identify potentially inappropriate prescribing of anticholinergic and sedative agents in elderly patients in institutionalised care.

#### **3.4.1 Key findings**

One key finding of this systematic review is that there is a lack of studies which have focused on any aspect of the use of the DBI in institutionalised care, with only seven studies (three cohort studies, three mixed cohort and cross-sectional studies and one cross-sectional study) identified. These studies had only been conducted in three countries (Australia, the Netherlands, the UK), mostly

Australia (n=5). While the studies were generally of high quality, there was a lack of sample size justification, particularly for those with research hypotheses and this may impact the conclusions. Furthermore, there was a lack of detail on the sources of information used to categorise medicines as anticholinergic and/or sedative. DBI scores were presented in many different ways, both continuous and categorical. DBI scores (or categories) were found to be associated with an array of outcomes, including activities of daily living, length of hospital stay, falls and quality of life. None of the studies used the DBI prospectively as a tool to identify the need to alter potentially inappropriate prescribing; one used it retrospectively to check if the pharmacists' interventions, as part of a medicines review service, had resulted in decreased DBI scores, and identified statistically significant reductions in scores.

#### 3.4.2 Study strengths and limitations

A key strength of this systematic review is that it was conducted using the JBI approach, with the review protocol being peer reviewed through JBI and published (Al Shemeili and Stewart 2014) prior to the review being conducted. This highlights that there was a need for the review and a gap in the literature. The JBI focuses on supporting reviews which will provide evidence based information on effectiveness, meaningfulness, appropriateness, and feasibility of healthcare interventions. Best practice was followed in conducting the review in that two independent reviewers completed the templates for quality assessment and data extraction and indeed the review cannot proceed on the JBI software until there is complete agreement.

However, there are several limitations to this review and hence the findings should be interpreted with caution. As described, the data extraction and synthesis is derived from only seven studies and hence there is a need for further investigation into the predictive ability of the DBI in hospitalised older people. Also the heterogeneity of study methods and outcome measures eliminated the possibility of meta-analysis, hence reducing the strength of evidence on the use of the DBI to identify potentially inappropriate prescribing of anticholinergic and sedative agents in elderly patients in institutionalised care.

The DBI has only been studied in three countries and hence there is limited information on its use on a global scale. This is particularly relevant to this doctoral research which is based in the UAE. Different cultural issues of prescribing and medicines use more generally may limit the generalisability of the findings.

Due to the lack of qualitative studies identified in the scoping search, the review was restricted solely to quantitative studies. There is a clear research gap of in-depth studies on health professionals' perspectives of the use, utility and value of the DBI in practice.

### 3.4.3 Interpretation of findings

Chapter 1 presented the evidence base, derived from systematic reviews, of various elements of the medicines management model. While there is evidence to support the use of generic tools to support the identification of potentially inappropriate prescribing in the elderly, there is less specific guidance around anticholinergic and sedative agents. The DBI has potential, hence this systematic review was conducted to explore its use in institutionalised care, and as a predictive tool.

Only one study used the DBI in the context of medicines management and this study used it retrospectively after the pharmacist recommendations to measure the impact on DBI scores. (Nishtala *et al.* 2009) There is a need to research the DBI to support intervention in terms of medicines appropriateness. Such studies should have a prospective RCT design (the highest level of evidence) with one group of practitioners using the DBI to guide prescribing compared to a control group of normal practice. Studies such as these would require prospective calculation of sample size to determine a clinically important difference in prescribing at a minimum power of 80%.

In using the DBI, there is a need to standardise the sources of information in two regards. The medicines patients are taking at the point of admission to

hospital should be determined using the principles of medicines reconciliation (as described in Chapter 1) and have consideration of patient adherence. (Greenwald *et al.* 2010, Mueller *et al.* 2012) Furthermore, there should also be emphasis on 'as required' medicines as these are excluded from the DBI calculation. However, many medicines such as opiate analgesics have significant sedative effects. (Rothberg *et al.* 2013) In relation to the calculation of the DBI, there are several issues to consider. A standard information source should be used for the efficacious dose rather than the varied sources used in the studies in this review. A standard approach is required for drugs which have different doses for different indications. There is also a need to standardise the sources for determining whether or not a medicine is classified as anticholinergic or sedative. As described earlier, Duran *et al.* reported a systematic review of anticholinergic risk scales in the elderly, with the aim of developing a uniform list of anticholinergic drugs, differentiating for anticholinergic properties. (Durán, Azermai and Vander Stichele 2013) Such an approach could be useful in relation to the DBI. There is also a need to standardise the reporting of DBI scores as either categorical or continuous outcomes.

Faure *et al.* reported a cohort study, conducted in France, to assess exposure of anticholinergic and sedative medicines in elderly patients. (Faure *et al.* 2013) Given the issues around global comparison of DBI score (indications and dosages varying from one country to another),  $\delta$  (the minimum efficacious dose as approved by the Food and Drugs Administration in the USA) was redefined. In order to allow appropriate comparison of DBI across countries, a calculation was proposed using a common  $\delta$  to represent the defined daily dose (DDD), the assumed average maintenance daily dose for the most common indication, in accordance with the World Health Organization (WHO). This study calculated DBI and DBI-WHO for 337 individuals aged 85 and over admitted to three geriatric hospitals. The results suggested that DBI-WHO and DBI were correlated on admission (correlation coefficient ( $r$ ) = 0.96,  $P < 0.001$ ) and on discharge ( $r = 0.97$ ,  $P < 0.001$ ). The authors concluded that it may be more appropriate to use DDD to calculate DBI-WHO which might lead to a quality indicator in medicines management.

One advantage of the DBI (or DBI-WHO) is that it provides a total score for the anticholinergic and sedative burdens as well as the separate components and hence may be useful as part of medicines management. This is particularly important given the adverse profiles of these agents and hence the outcomes of higher DBI scores found in this systematic review have been linked to these agents. (Durán, Azermai and Vander Stichele 2013) The seven studies focused on different outcome measures related to the prescribing of anticholinergic and sedative medicines and hence DBI scores. While this may be strength in providing more complete information, it reduced the potential for meta-analysis and hence actually weakens the evidence base.

#### 3.4.4 Conclusion

This systematic review has identified that there is a limited literature base on the use of the DBI in elderly, hospitalised patients. However, there appears to be a link between higher DBI scores and several outcomes around the risk of functional impairment. There is a need for research studies which employ the DBI as a tool to guide interventions to promote appropriate prescribing and for studies which explore practitioners' awareness and perspectives of DBI.

#### 3.4.5 Implications for further research phase

This is the first systematic review of the use of DBI and complements the evidence base for other medicines management related tools and processes outlined in Chapter 1. Given the reservations highlighted, the DBI may have a place in medicines management alongside more generic tools which promote rationalisation of potentially inappropriate prescribing and promote appropriate prescribing in the elderly. These aspects will be considered as part of a set of tools in the next phases of this doctoral research into medicines management.



## **CHAPTER 4: Qualitative interviews with health professionals in Abu Dhabi**

### **4.1 Introduction to the chapter**

This chapter provides a detailed description of qualitative interpretative phenomenological interviews with samples of health professionals (doctors, nurses and pharmacists) in a hospital practice in Abu Dhabi. The research aims and objectives are provided followed by a description of the method, findings, discussion, conclusion and summary.

This research phase focused on medicines management healthcare structures, processes and outcomes. A conceptual model and framework for health services and quality of care was proposed by Donabedian in 1990, describing the elements of structures, processes and outcomes as follows:

- structures, which are the characteristics of the care delivery setting and includes attributes of material resources (e.g. facilities, equipment, and financing), human resources (e.g. the number of qualified personnel) and the organisational structure (e.g. healthcare staff, methods of peer review, methods of reimbursement);
- processes, which detail what is actually carried out as part of giving and receiving care (e.g. practitioner's activities in making a diagnosis, recommending or implementing treatment, or other interactions with the patients);
- outcomes, which attempt to describe the patients' resultant status of health. Improvements in patients' knowledge and understanding, and changes in patients' behaviours and levels of satisfaction may also be included under a broad definition of outcome. (Donabedian 1990)

Donabedian (1990) described this framework to facilitate assessing the quality of care by providing a structure for examining in detail the elements of structures, processes and outcomes. This framework, which is shown in Figure 4.1, is considered to be flexible enough to apply to many situations.



Figure 4.1: the relationship between the three related concepts of structures, processes and outcomes. (Donabedian A.1980)

Donabedian's model is a linear framework which has been criticised for being an over simplification, omitting key factors such as individual patient characteristics and environmental features that may significantly impact assessment of quality of care. Coyle and Battles proposed a modified framework which considers antecedents in addition to structural and care process variables impacting the resultant outcome of care. (Coyle and Battles 1999)

Antecedents are described as those factors that affect the structures, processes and outcomes and are thought to have the greatest impact on resultant outcomes. These comprise the environmental context of an individual, an individual's characteristics (e.g. genetics, socio-demographics, health habits, beliefs attitudes, preferences) and environmental factors (e.g. social, cultural, political, personal, physical).

The research in this chapter describes medicines management healthcare related structures, processes and outcomes in relation to the patient journey or flow from the point of admission to hospital to the point of discharge back to the patient's home or other care setting. The terminology of Donabedian is

employed, while also considering the expanded list of variables of Coyle and Battles.

Modern hospitals and health services are organisationally complex entities, employing several thousand staff working in professional, functional and geographical groups. Each of these groups has an internal, usually hierarchical structure, and traditionally orientates its work by the views held within its dominant professional or organizational membership. Patients, however, move horizontally across healthcare settings, primary care based medical practices and hospitals. Their journeys take them from unit to unit, receiving care from different groups as they go. (NHS Institute 2012) A recent report from the UK Health Foundation on improving the patient journey or patient flow defined and described the term 'flow' as,

*'the progressive movement of people, equipment and information through a sequence of processes. In healthcare, the term generally denotes the flow of patients between staff, departments and organisations along a pathway of care'.* (The Health Foundation 2013)

In addition, flow is about the how, where, when and who of care provision, and not about the what of clinical care decisions. Flow is described in terms of

- how services are accessed,
- when and where assessment and treatment are available and
- who it is provided by.

Increasing efficiency (i.e. improving quality and reducing costs) has traditionally been the responsibility of different functions (and executives) across healthcare organisations. It is understood increasingly that these are inextricably linked. (NHS Institute 2012) Improving structures, processes and outcomes of care is a shared agenda; the full benefit is only achieved if a co-ordinated patient pathway approach is taken across all departments.

In terms of medicines management, there is a need to understand the structures, processes and outcomes throughout the patient journey or flow. These structures, processes and outcomes will also be considered in relation to aspects previously described in this thesis, specifically: medicines review, medicines reconciliation, medicines adherence and potentially inappropriate prescribing.

#### 4.1.1 Aim and objectives

The aim of this phase of the research was to explore the views, experiences and perceptions of health professionals in Abu Dhabi in terms of the medicine management healthcare structures, processes and outcomes for elderly, hospitalised patients.

The detailed objectives were to explore health professionals' views, experiences and perceptions of the following:

- i. medicines related issues (e.g. selection, adverse drug reactions, adherence),
- ii. current healthcare structures (e.g. personnel, resources) and processes (e.g. training, documentation, communication) of medicines management,
- iii. potential to optimise patient outcomes (e.g. clinical, economic) and
- iv. changes to structures and processes (e.g. personal, professional, organisational etc.) required to optimise patient outcomes.

## **4.2 Methods**

### 4.2.1 Research Design

A qualitative interpretative phenomenological methodology of in-depth semi-structured, face-to-face interviews with samples of those health professionals most involved in medicines management was employed. This was considered most appropriate in terms of the research aim to provide in-depth, rich information around views, experiences and perceptions of medicines management. As described in chapter 2, interpretative phenomenology seeks to generate rich description and understanding of the phenomenon of medicines management in elderly, hospitalised patients.

Qualitative research and the use of open-ended, in-depth, probing questioning gave the participants the opportunity to respond in their own words, rather than forcing them to choose from the fixed responses of quantitative approaches.

Face to face interviews of health professionals in Abu Dhabi were undertaken for this research. This was considered to be the most appropriate method of data generation to allow participants from a range of backgrounds, professions and experiences to talk about their personal views and perceptions without potentially being inhibited when openly discussing and sharing information with others. For example, less experienced nurses or pharmacists might not discuss fully issues of poor prescribing practice in the presence of high-grade medical staff in a focus group setting, with implications for data trustworthiness.

### 4.2.2 Setting

This research was conducted within Abu Dhabi, which is one of the seven Emirates. Abu Dhabi was selected for this research phase for several reasons as follows:

- i. Abu Dhabi is largest in terms of geographical size and population numbers, has the highest rate of healthcare expenditure and more

established governance systems than the other zones. (National Bureau of Statistics 2010),

ii. sampling of health professionals within this zone provided a range of views, experiences and perspectives which were likely to be transferable to the other zones and

iii. for logistical reasons of resources and time which would have been incurred in travelling to other zones.

Conducting the research within Abu Dhabi was likely to generate research findings which could be transferred to the other six Emirates within the UAE, and potentially the Middle East and beyond.

Eighteen public hospitals and institutions in Abu Dhabi (shown in Figure 4.2) had been authorised by HAAD to conduct research studies on human subjects. (SEHA annual report 2012)



Figure 4.2: Map of Abu Dhabi, highlighting the location of all 18 hospitals

Table 4.1: The hospitals and institutions in Abu Dhabi authorised to conduct human research (adapted from SEHA annual report 2012)

	
<p><b>1- Sheikh Khalifa Medical City</b> SKMC's staff numbers more than 4183. It has total capacity of roughly 764 beds.</p>	<p><b>2- Corniche Hospital</b> Corniche is the UAE's leading referral hospital for obstetric and neo-natal care. It has a professional staff of about 1,200.</p>
	
<p><b>3- Ambulatory Healthcare Services</b> AHS operates 62 ambulatory and primary healthcare clinics. The four AHS subsidiaries are Ambulatory Care Centres (ACCs), Disease Prevention &amp; Screening Centres (DPSCs), School Health Services (SHS) and Mobile Clinic Solutions (MCS).</p>	<p><b>4- Abu Dhabi Blood Bank</b> Abu Dhabi Blood Bank is the major donor centre and blood bank in Abu Dhabi. It is part of the Transfusion Medicine Services Division of the Department of Laboratory Medicine at Sheikh Khalifa Medical City (SKMC).</p>
	
<p><b>5- Mafraq Hospital</b> Mafraq Hospital has a bed capacity for roughly 451 beds</p>	<p><b>6- Mafraq Dialysis Centre</b> Mafraq Dialysis Centre is a state-of-the-art dialysis clinic</p>

and a professional staff of almost 2000.

situated in Mafraq.



**7- Al Rahba Hospital**

Al Rahba is a 114-bed hospital with a professional staff of about 845.



**8- Al Ain Hospital**

Al Ain hospital is a 412-bed hospital. It has a professional staff of 2000.



**9- Tawam Hospital**

Tawam Hospital has 461 beds and a professional staff that numbers over 3400.



**10- Al Wagan Hospital**

Al Wagan Hospital is a primary care and critical access hospital with two wards, ambulatory treatment clinics, general dentistry facilities, and a critical access emergency department.



**11- Al Sila Hospital**

Sila Hospital is a 36-bed facility with a total staff of 16 doctors, 40 nurses, 17 allied health, and 15 administrative personnel.



**12- Dalma Hospital**

Dalma Hospital provide emergency services as well as specialised medical care in the fields of Internal Medicine, Paediatrics, Obstetrics and Gynaecology, General Surgery and Dialysis.





### 13- Ghiathy Hospital

Ghiathy Hospital is a 30-bed facility with a team of 22 doctors, two surgeons, 48 nurses, and 20 technicians and paramedics.



### 14- Marfa Hospital

Marfa Hospital is a 28-bed rural community secondary hospital with a professional staff of 20 physicians and surgeons, 49 nurses, and 26 technicians and paramedics.



### 15- Madinat Zayed Hospital

Madinat Zayed is a 155-bed secondary hospital. It is well equipped and provides all basic and specialized medical services.



### 16- Liwa Hospital

Liwa Hospital provides emergency services as well as outpatient services in the fields of General Medicine, Paediatrics and Mother and Child Health.



### 17- Zayed Military Hospital

Zayed Hospital is a 365-bed tertiary care hospital. It provides medical services to the families of the UAE Armed Forces with a professional staff of about 2000.



### 18- Imperial College London Diabetes Centre

Imperial College Diabetes Centre is a one-stop, state-of-the-art, outpatient facility that specialises in diabetes treatment, research, training and public health awareness.

The sampling frame comprised these 18 hospitals. The following sample inclusion criteria were applied:

- i. hospitals within Abu Dhabi city centre, for reasons of logistics considering distance to travel for interviews.
- ii. hospitals with more than 250 beds, to provide a sample of health professionals most likely to have a range of views, experiences and perceptions.

Six hospitals met these criteria, one of which was excluded as it cared for obstetric and neonatal patients thus interviewing these staff would not have provided data useful to the research aims and objectives.

The research was conducted in five major hospitals in Abu Dhabi which were:

- i. Sheikh Khalifa Medical City (SKMC)
- ii. Al Ain Hospital
- iii. Tawam Hospital
- iv. Mafreq Hospital
- v. Zayed Military Hospital

The five study hospitals provided care for 85% of the Abu Dhabi population. (SEHA annual report 2012)

#### 4.2.3 Research governance

The research was reviewed and approved by the following:

- i. the ethical review panel of the School of Pharmacy and Life Sciences at Robert Gordon University (see Appendix 4.1)

- a. a detailed research protocol was prepared and reviewed by team research members.
- b. the protocol was submitted to the ethical review panel and approval received four weeks later.

All five hospitals had independent ethical review processes, documentation, requirements and committees. Approval was sought and obtained from:

- i. Ethics and Research Committee in Al Mafraq Hospital (see Appendix 4.2)
  - a. the completed ethical application form for Mafreq Hospital and the ethical approval letter from the School of Pharmacy and Life Sciences at RGU were submitted online to the Ethics and Research Committee at Al Mafreq Hospital.
- ii. Al Ain Hospital Ethics Committee (see Appendix 4.3)
  - a. the completed ethical application form for Al Ain Hospital and the ethical approval letter from the School of Pharmacy and Life Sciences at RGU were submitted online to Ethics Committee at Al Ain Hospital.
- iii. Institutional Review Board/Research Ethics Committee in SKMC (see Appendix 4.4)
  - a. the completed ethical application form of SKMC and the ethical approval letter from the School of Pharmacy and Life Sciences at RGU were submitted online to Institutional Review Board/Research Ethics Committee (IRB/REC) at SKMC.
- iv. Al Ain Medical District Human Research Ethics Committee in Tawam Hospital (see Appendix 4.5)
  - a. the completed ethical application form of Tawam Hospital and the ethical approval letter from the School of Pharmacy and Life Sciences at RGU were submitted online to Ethic & Research Committee at Tawam Hospital.

- v. Ethic and Research Committee in Zayed Hospital (see Appendix 4.6)
  - a. the completed ethical application form of Zayed Hospital and the ethical approval letter from the School of Pharmacy and Life Sciences at RGU were submitted online to Ethics Committee at Zayed Hospital.
  - b. in addition, the researcher had to present for a face-to-face interview with the ethical committee at Zayed Hospital. The interview focused on research method, participants' recruitment and data generation.

All approvals were in place prior to sampling and recruiting any research participants. Throughout the research, all study materials were stored in accordance with the Standard Operating Procedures of the School of Pharmacy and Life Sciences and the governance policies of Robert Gordon University. Signed, informed consent was obtained from all participants.

#### 4.2.4 Participant inclusion and exclusion criteria

The inclusion criteria were those health professionals mainly involved in medicines management (i.e. doctors, nurses and pharmacists) and also working in hospitals in the public sector within Abu Dhabi. Those working in specialties not caring for elderly patients (e.g. maternity and paediatrics) were excluded.

#### 4.2.5 Participant sampling

This total sampling frame of the five hospitals was estimated to be around 1,000 health professionals. This estimation was based on the experience of the researcher, who had five years' experience working as a hospital clinical pharmacist in Abu Dhabi, and one of the supervisors who was a leading hospital consultant physician with many years of experience in Abu Dhabi. The hospitals were unable to give the likely numbers of professionals meeting the inclusion criteria.

Sampling was undertaken purposively to explore a range of views, experiences and perceptions of medicines management in elderly, hospitalised patients.

Several authors describe purposive sampling (also referred to as judgmental, selective or subjective sampling) as a non-probability sampling technique. (Mack *et al.* 2005), (Bowling 2009) and (Garson 2012) This approach was selected over other forms of sampling described in chapter 2 for several reasons: it was most appropriate for the research aim and qualitative design; it was most likely to generate rich and complex data arising from diversity in views, experiences and perceptions; and offer further insight into factors that might not have been considered. Francis *et al.* (2010) describe that purposive sampling conducted using pre-specified 'stratification' factors will lead to heterogeneity in the sample. The 'stratification' factors used in this study were: profession, years of experience, training and countries of practice. These were considered by the research team to be key variables in forming views, experiences and perceptions, although it was acknowledged that there could be other non-identified factors.

#### 4.2.6 Participant recruitment

As information around these sampling criteria was not easily available, a two staged process of sampling and recruitment took place. The process of participant recruitment, including ethical approval in the UAE, is given in Figure 4.3.

##### Stage 1

All doctors, nurses and pharmacists working in the five study hospitals were emailed. As part of the ethical approval, it was agreed that the human resources department of each hospital would send the invitation email. The text for the email was drafted and agreed by the research team (see Appendix 4.7). The email also contained the following:

- i. a link to the participant information leaflet (see Appendix 4.8) which was developed according to the guidance for National Health Service (NHS) ethical committee submissions in the UK. (National Research Ethics Service 2011)

- ii. a short online sampling questionnaire (see Appendix 4.9). The questionnaire contained items on profession, years of experience, education and training, and countries of practice.
- iii. instructions for those working with elderly patients (i.e. those over the age of 60 years) to express their interest in participation in the research interviews by completing and submitting the questionnaire electronically.

The questionnaire was developed in Survey Monkey.

### Stage 2

Responses to the questionnaire were collated and used to purposively select participants. Those selected were contacted by email to arrange a convenient location, date and time of interview.

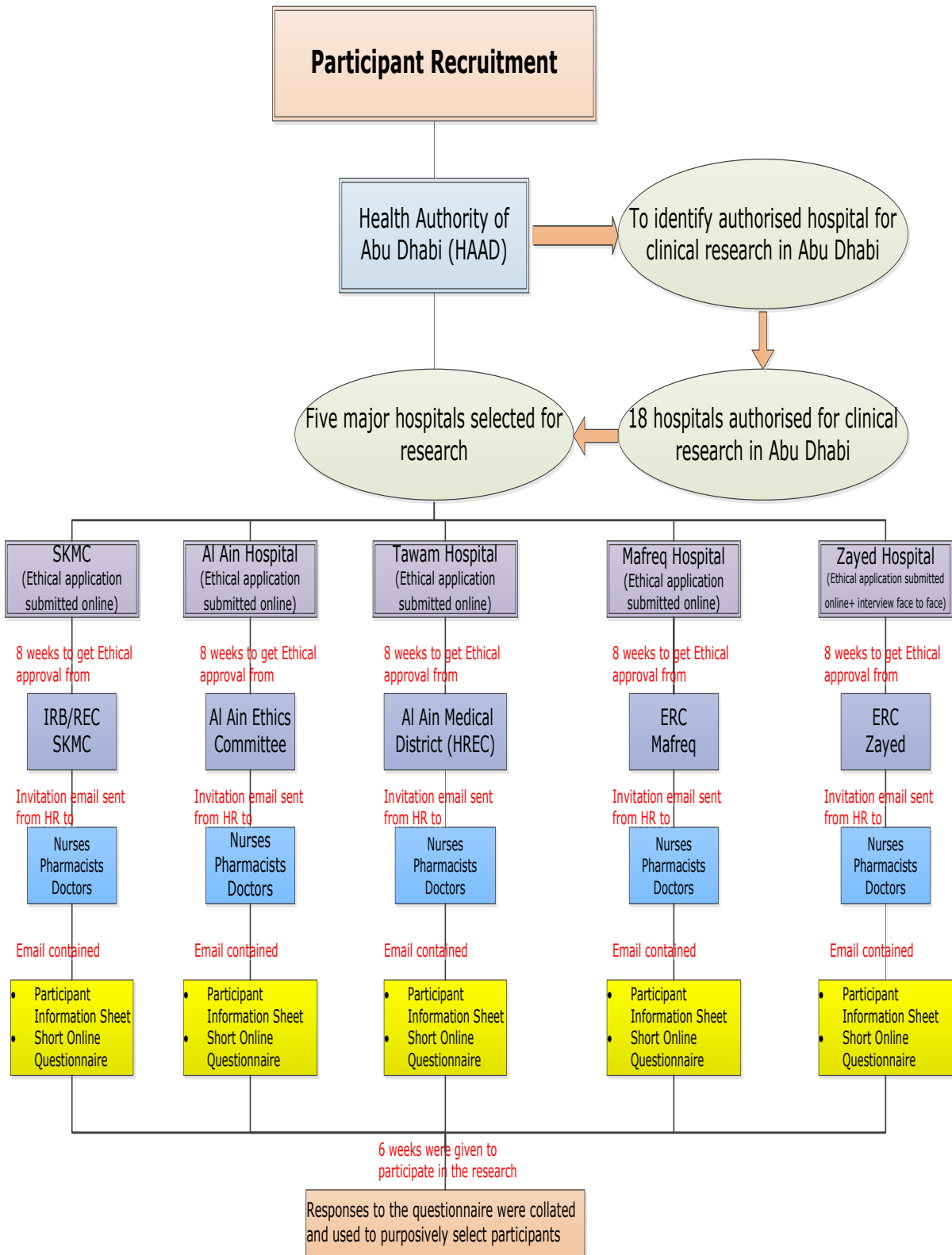


Figure 4.3: the process of ethical approval and participant recruitment

#### 4.2.7 Sample size

Marshall (1996) states quite simply that, 'an adequate sample size for qualitative research is one that appropriately answers the research question', noting that the quality of data generated is more important than either the number of participants or volume of data. He later comments that, 'in practice, the number of required subjects usually becomes obvious as the study progresses, as new categories, themes or explanations stop emerging from the data (data saturation)'.

Glaser and Strauss (1967) describe the concept of data saturation as the point in data generation when no new additional data are found that develop aspects of a conceptual category. Guest, Bunce and Johnson (2006) claim that saturation has 'become the gold standard by which diversity samples are determined in health science research'.

Francis *et al.* (2010) more recently suggest an alternative approach for determining the point of data saturation. Their approach is described in terms of four principles, illustrated as follows:

- i. initial analysis sample - the researchers should first specify a priori the sample size at which the first round of analysis will be complete.
- ii. stopping criterion - Francis *et al.* (2010) describe that 'the researchers should specify a priori how many more interviews will be conducted, without new shared themes or ideas emerging, before the research team can conclude that the data saturation has been achieved'.
- iii. independent coders - the initial analysis sample should be reviewed independently by a member of the research team to promote rigour.
- iv. the data saturation methods and findings should be reported so that the readers can evaluate the evidence (credibility).



The approach described by Francis *et al.* was adopted in this study, with an initial analysis sample size of 15 (5 each for doctors, nurses and pharmacists). The stopping criterion was tested after each of two consecutive interviews. As the study included three different professions, each profession had two consecutive interviews until no additional themes or viewpoints emerged, as depicted in Figure 4.4. Two independent researchers coded the interviews and made comparisons before confirming that data saturation had been achieved.

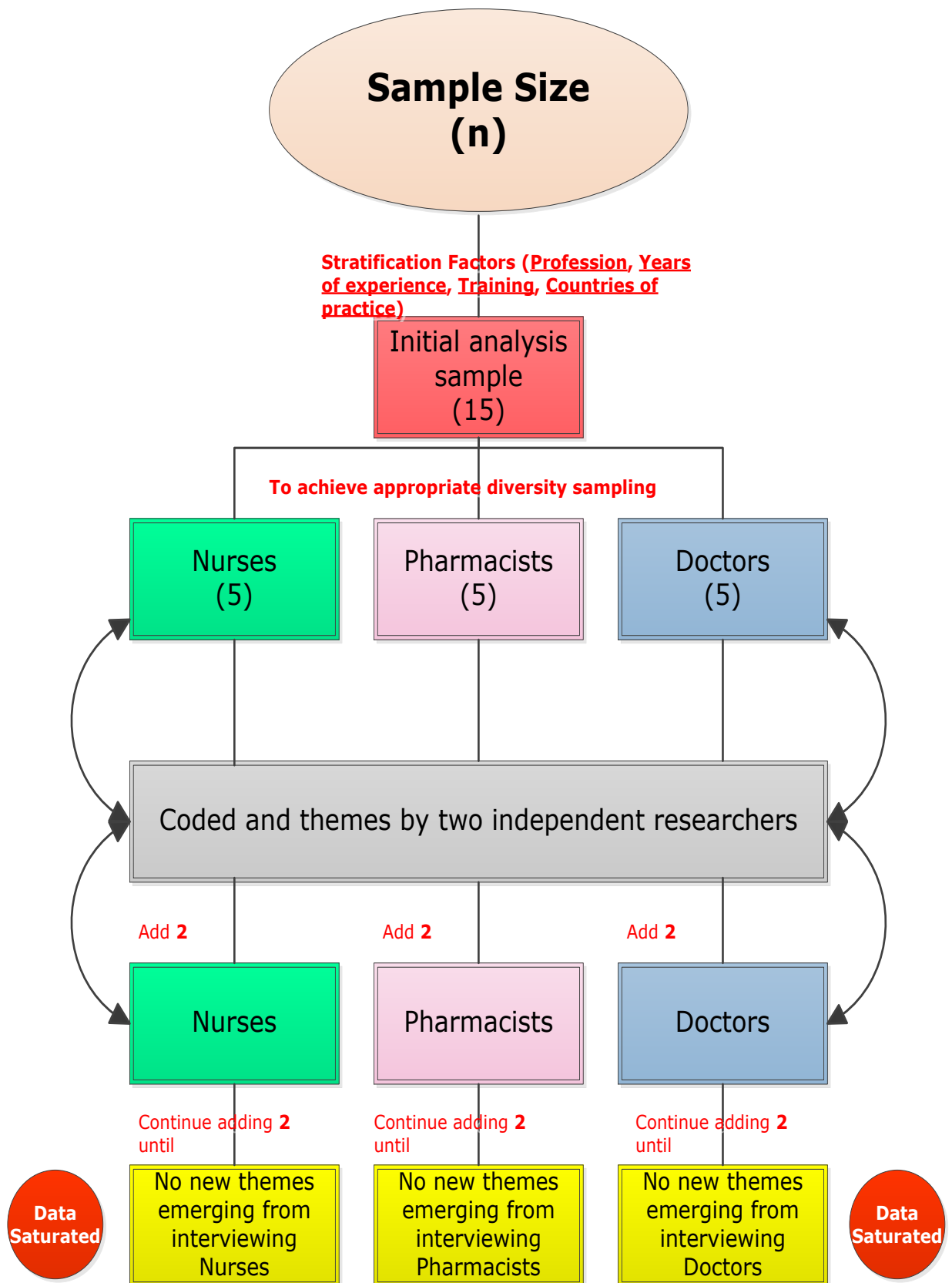


Figure 4.4: process of sampling and data saturation

#### 4.2.8 Data generation

The interviews were arranged at the convenience of the participants, with informed consent (see Appendix 4.10) obtained prior to the interview commencing. The interviews were audio-recorded using a digital voice recorder (Olympus-WS811).

A semi-structured face-to-face approach was employed to allow for collaborative (researcher and participant) contribution to the content of the interviews. The interview schedule was developed with reference to two key theories/theoretical frameworks: NPT and TDF, as described in chapter 2.

May and Finch (2009) highlight the importance of theory in research, noting the relevance of NPT to healthcare research, 'material practices become routinely embedded in social contexts as the results of people working, individually or collectively, to implement them'. This happens through the four mechanisms of the NPT, which are coherence (what is the work?), cognitive participation (who does the work?), collective action (how does the work get done?) and reflexive monitoring (how is the work understood?).

As described in Chapter 2, the TDF summarises key elements of 33 theories with determinants of behaviour or practice clustered into 14 domains. Those domains most relevant (professional role and identity, beliefs about capabilities, beliefs about consequences, goal, knowledge and environmental context and resources, see Table 4.2) were used to guide construction of the interview schedule, which was organised around structures, processes and outcomes throughout the patient journey. While the emphasis was placed on these six domains during the interview, the interviewees were also invited to add any other relevant information.

The interview schedule was reviewed by members of the research team, which included a leading international pharmacy practice educationalist, a psychologist, a pharmacist with strategic development experience, and a leading medical consultant from the UAE. The interview schedule was then piloted with two academics at RGU with significant hospital clinical pharmacy

experience, following which minor modifications were made to question sequencing and wording (credibility). The final interview schedule is given in Appendix 4.11.

Table 4.2 illustrates the mapping of selected items of the interview schedule to the theories i.e. NPT and TDF.

Table 4.2: Mapping of selected items of the interview schedule to the theories (NPT and TDF)

<b>Normalization Process Theory</b>	
Mechanism	Key content of interview schedule items
<b>Coherence</b> Defines and organises the components in an implementation process	Perceptions of the overall goals of the different processes involved in the medicines management model
<b>Cognitive participation</b> Work that defines and organises the actors involved in an implementation process	Which profession is responsible for and undertakes specific processes (e.g. medicines history taking) in relation to medicines management
<b>Collective action</b> Work that defines and organises the enacting of an implementation process	What detailed tasks are actually carried out in delivering any process (e.g. medicines history taking)
<b>Reflexive monitoring</b> Defines and organizes assessment of the outcomes of an implementation process	How effectiveness each task is monitored; any changes made of processes
<b>Theoretical Domains Framework</b>	
Domain	Key content of interview schedule items
<b>Professional role &amp; identity</b>	Descriptions of the current roles of different health professionals throughout the medicines management processes
<b>Beliefs about capabilities</b>	Views on how well they carried out these processes
<b>Beliefs about consequences</b>	Perceptions of the resultant effect of performing processes

<b>Goals</b>	Perceptions of why a process is delivered
<b>Environmental context and resources</b>	What structures are employed (e.g. documentation etc.) and in which setting
<b>Knowledge</b>	Knowledge of SOPs, tools (e.g. DBI, Beers and STOPP/START)

#### 4.2.9 Data Analysis

Oliver, Serovich and Mason (2005) describe the differences between the two most commonly used transcribing techniques: naturalised (verbatim) in which every utterance is transcribed in as much detail as possible; and denaturalised, in which idiosyncratic elements of speech (for example stutters, pauses and nonverbal speech and involuntary vocalisations) are removed. Each interview was transcribed verbatim (ie naturalised) as soon as possible following the interview to allow further refining of the interview schedule and consideration of saturation, and hence the need for further interviews to be determined. The first three interview transcripts were reviewed independently by a member of the research team to ensure reliability of the transcription process. Each interviewee was allocated a code to avoid the need to include interviewee names on the transcript. A separate log was maintained linking codes to interviewees.

Bowling (2009) highlights that qualitative research can result in large amounts of richly detailed data and that a very transparent approach to data analysis needs to be employed to avoid claims that the findings are highly subjective and open to interpretation. Braun and Clarke (2006) suggest that qualitative data analysis should consist of identifying, coding with reference to relevant theoretical frameworks, and categorising themes. Boyatzis (1998) defines a theme as 'a pattern in the information that at minimum describes and organises the possible observations and at maximum interprets aspects of the phenomenon'.

Different processes for thematic analysis were described in detail in Chapter 2 and are outlined briefly. Braun and Clarke (2006) describe six phases of thematic analysis (see Table 4.3) for qualitative research.

Table 4.3: Phases of thematic analysis (adapted from Braun and Clarke, 2006)

1. <b>Familiarisation</b>	Transcribing data, reading and re-reading the data, noting down initial ideas.
2. <b>Generating initial codes</b>	Coding interesting features of the data in a systematic fashion across the entire data set, collating data relevant to each code.
3. <b>Searching for themes</b>	Collating codes into potential themes, gathering all data relevant to each potential theme.
4. <b>Reviewing themes</b>	Checking if themes work in relation to the coded extracts (Level 1), and the entire data set (Level 2), generating a thematic 'map' of the analysis.
5. <b>Defining and naming themes</b>	Ongoing analysis to refine the specifics of each theme, and the overall story the analysis tells, generating clear definitions and names for each theme.
6. <b>Producing the report</b>	The final opportunity for analysis. Selection of vivid, compelling extract examples, final analysis of selected extracts, relating back of the analysis to the question and literature, producing a scholarly report of the analysis.



This approach is very similar to the Framework Approach developed by Ritchie and Spencer (2002), which is increasingly and frequently used in healthcare research where the research objectives are well defined in advance of any fieldwork. Lacey and Luff (2007) describe the Framework Approach in five phases of data analysis (see Table 4.4)

Table 4.4: Phases of Framework Approach (adapted from Lacey and Luff, 2007)

<b>1. Familiarisation</b>	Whole or partial transcription and reading of the data.
<b>2. Identifying a thematic framework</b>	This is the initial coding framework which is developed both from a priori issues and from issues emerging from the familiarisation stage. This thematic framework should be developed and refined during subsequent stages.
<b>3. Indexing</b>	The process of applying the thematic framework to the data, using textual codes to identify specific pieces of data which correspond to differing themes.
<b>4. Charting</b>	Using headings from the thematic framework to create charts of data to be read easily across the whole dataset. Charts can be either "thematic" for each theme across all respondents (cases) or by "case" for each respondent across all themes.
<b>5. Mapping and interpretation</b>	Searching for patterns, associations, concepts, and explanations in data, aided by visual displays and plots.

This approach to coding and thematic analysis was considered more appropriate than other approaches (e.g. grounded theory) as the research objectives and theoretical frameworks were well described and there was no intention to derive new theories. (Lacey and Luff 2007)

The development of the coding framework and thematic analysis was also undertaken independently by another member of the research team, findings compared and discussed to reach consensus. NVivo software 10.0 was used as an aid to data management. The process of data generation and analysis is given in Figure 4.5.

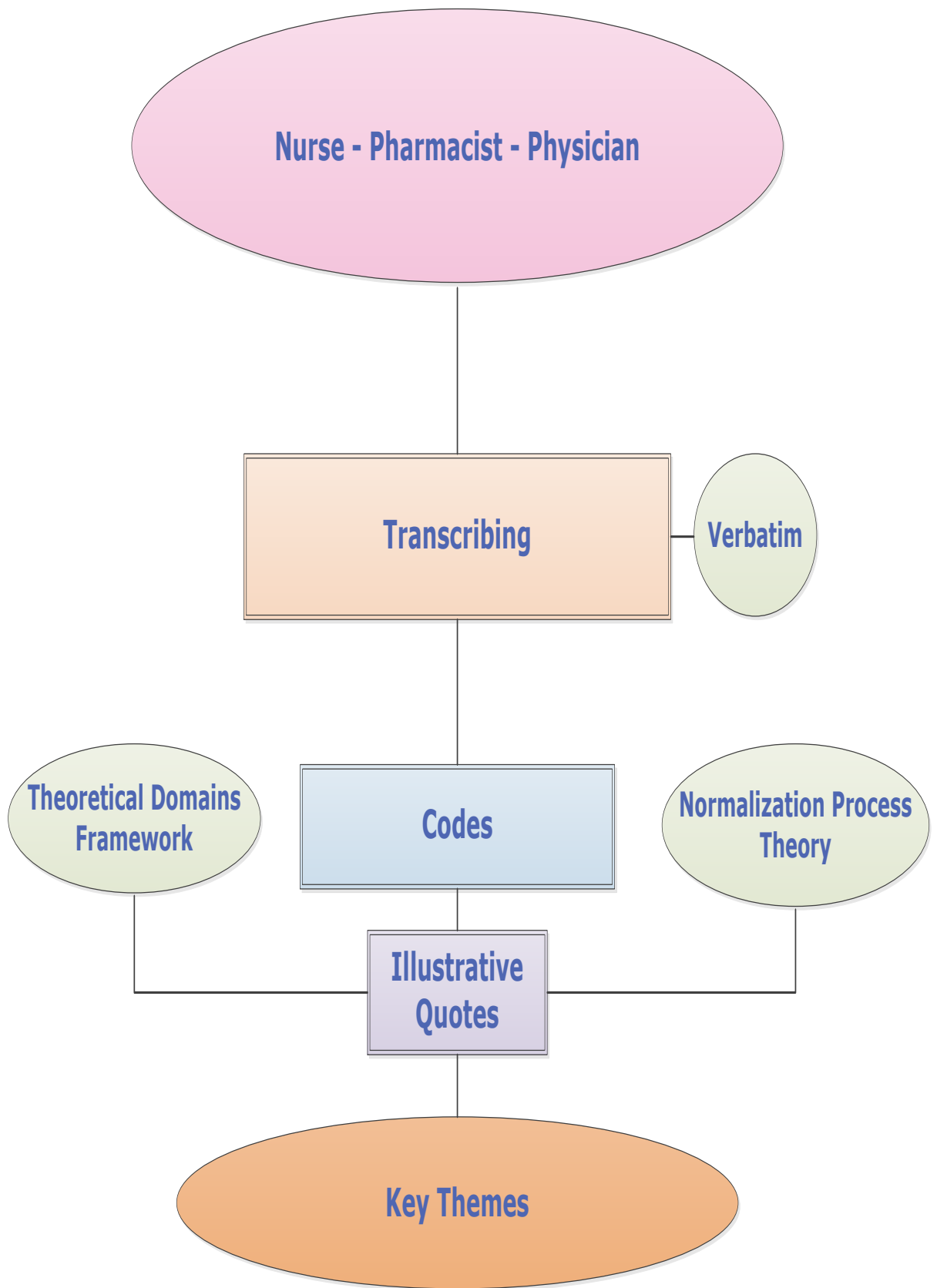


Figure 4.5: Processes of data generation and analysis

#### 4.2.10 Promoting research quality

A number of steps were taken throughout to enhance the rigour of the research. Establishing the validity (accuracy or truth) and reliability (consistency) of findings in qualitative research is thought to be more problematic than in quantitative research. While Bowling (2009) and Gerrish and Lacey (2010) describe methods to enhance validity and reliability, others argue that these concepts are more appropriate to quantitative research and that in qualitative research, the concept of trustworthiness may be more appropriate.

Guba describes trustworthiness as four separate elements of credibility, transferability, dependability and confirmability, as described in chapter 2. The following measures were adopted to enhance trustworthiness (Guba 1981):

- i. the researcher was trained in qualitative interviewing and data analysis (credibility, aiming to reduce design and interviewer bias)
- ii. the researcher position and stance (as a pharmacist in UAE interested in medicines management) were clearly described (credibility, aiming to reduce interviewer bias)
- iii. members of the research team brought additional perspectives, particularly non-pharmacy and psychology (credibility, aiming to reduce interviewer bias)
- iv. a clearly described sampling strategy was described (credibility, aiming to reduce sampling bias)
- v. the draft interview schedule was grounded in theory and reviewed (credibility, aiming to reduce design bias)
- vi. the interview schedule developed iteratively (credibility)
- vii. all participants were clearly characterised and described in the results (credibility, aiming to reduce reporting bias)

- viii. participants were given the opportunity to review and comment on the transcripts (member checking) (credibility, aiming to reduce reporting bias)
  
- ix. the coding framework and thematic analysis were independently reviewed by a member of the supervisory team (credibility, aiming to reduce design bias)

## **4.3 Results**

### 4.3.1 Sampling questionnaire

Eighty-three completed sampling questionnaires were received in response to the emails being sent by the human resources department in each of the five hospitals. The total number of emails sent in each hospital could not be obtained (despite repeated requests) and hence the overall response rate is unknown. The respondents were 33 doctors, 31 nurses and 19 pharmacists. Table 4.5 gives the summarised questionnaire data and Table 4.6 the demographics of the individuals (n=32) agreeing to be interviewed.

Table 4.5: Summarised sampling questionnaire data (N=83)

<b>Questionnaire Item</b>	<b>Response categories</b>	<b>% (n)</b>
<b>Managing elderly in day-to-day work</b>	Yes	83% (69)
	No	14% (12)
		Missing (2)
<b>Years of practice</b>	5 years or less	21% (18)
	6-10 years	25% (21)
	11-15 years	13% (11)
	16-20 years	10% (9)
	21-25 years	15% (13)
	26-30 years	6% (5)
	31-35 years	3% (3)
	More than 35 years	2% (2)
	Missing (1)	
<b>Countries in which practised as a health professional</b>	UAE only	38% (32)
	UAE and other	59% (49)
		Missing (2)
<b>Agree to take part in interview</b>	Agree	38% (32)
	Not Agree	55% (46)
		Missing (5)

Table 4.6: Demographic data and codes of those agreeing to be interviewed (N=32)

A-N1 Nurse 11-15 years Philippine	T-N1 Nurse 6-10 years UAE	Z-N1 Nurse 16-20 years India	Z-N2 Nurse 6-10 years Europe	M-N1 Nurse 16-20 years UAE
M-N2 Nurse 6-10 years UAE	K-N1 Nurse 11-15 years Egypt	K-N2 Nurse 5 years or less Libya	A-D1 Neurologist 21-25 years UK	A-D2 ICU doctor 6-10 years India
Z-D1 Internist 26-30 years USA	Z-D2 Internist 16-20 years USA	K-D1 GP 5 years or less UAE	K-D2 Cardiologist More than 35 India	K-D3 Cardiologist 6-10 years Pakistan
M-D1 Internist 26-30 years Egypt	M-D2 ICU 6-10 years Egypt	A-P1 Pharmacist 6-10 years Egypt	A-P2 Pharmacist 16-20 years UK	A-P3 Pharmacist 5 years or less UAE
A-P4 Pharmacist 5 years or less UAE	T-P1 Pharmacist 6-10 years USA	T-P2 Pharmacist 16-20 years UK	T-P3 Pharmacist 5 years or less UAE	Z-P1 Pharmacist 21-25 years Egypt
Z-P2 Pharmacist 5 years or less USA	Z-P3 Pharmacist 6- 10 years India	M-P1 Pharmacist 16-20 years Sudan	M-P2 Pharmacist 21-25 years USA	K-P1 Pharmacist 11-15 years Oman
K-P2 Pharmacist 16-20 years Pakistan	K-P3 Pharmacist 6-10 years UAE			

N, nurse; P, pharmacist; D, doctor.



Saturation of themes was deemed to occur after interviewing 7 nurses, 13 pharmacists and 7 physicians. Figure 4.6 illustrates the process of purposively sampling interviewees, interview setting and determining data saturation.

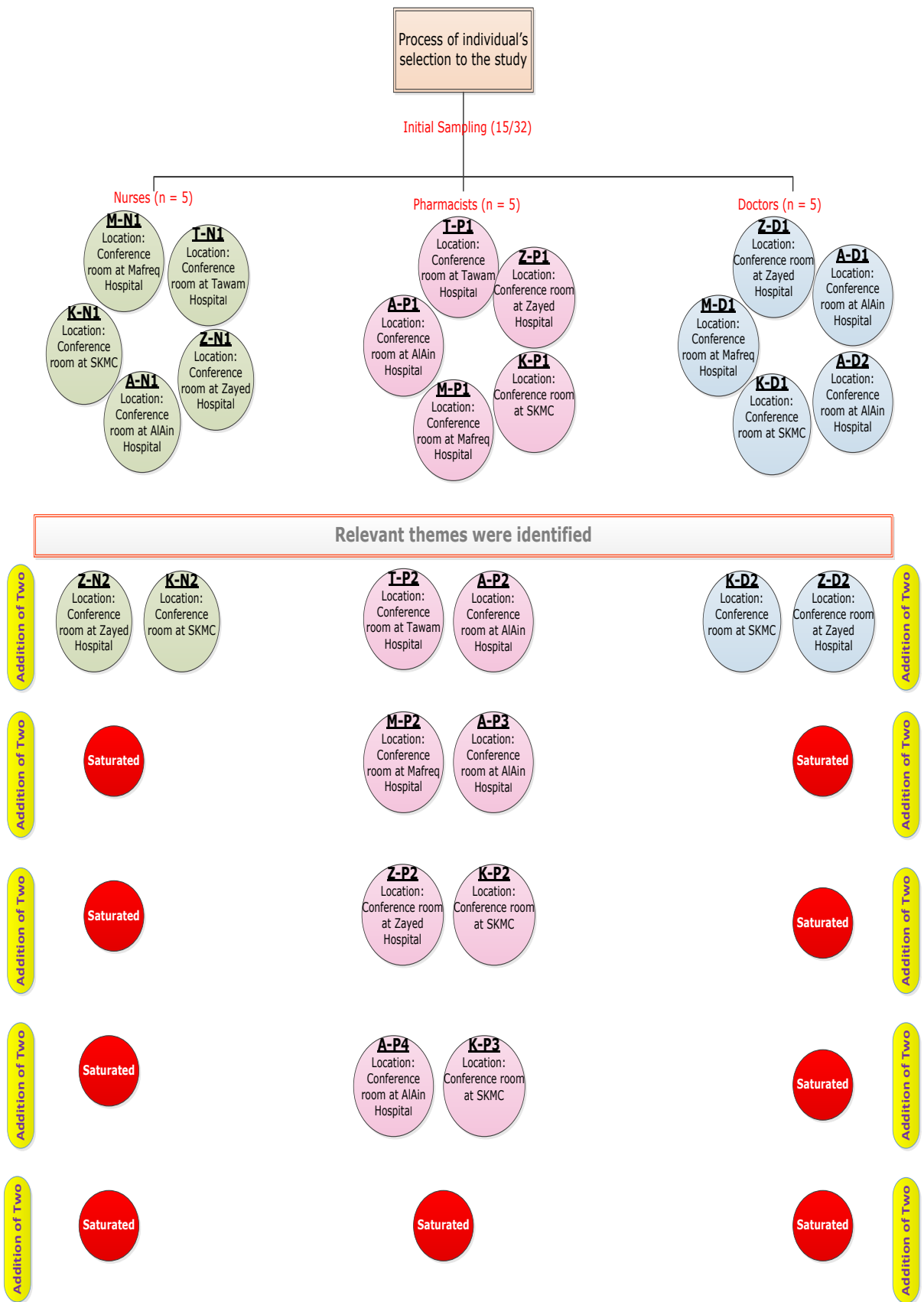


Figure 4.6: Processes of sampling and saturation

#### 4.3.2 The key themes emerged from the qualitative interviews

This section provides a detailed description of each of the key themes and subthemes from the perspectives of the different professionals, namely the doctors, pharmacists and the nurses.

##### **Theme 1 - Need for appropriate polypharmacy in elderly patients with multimorbidities**

One key theme which emerged during data analysis was the need for appropriate polypharmacy ('prescribing of many medicines which are suitable') in this patient group. During discussion, one pharmacist noted the lack of a clear definition for polypharmacy,

*"Polypharmacy does not have a clear definition..... "*

(Pharmacist Z1, Clinical)

While respondents appeared to hold diverse views on aspects of medicines management in relation to the goal of achieving appropriate polypharmacy in elderly patients, they were largely aware of the association between multimorbidities and polypharmacy (appropriate or inappropriate).

##### **Subtheme 1 – Consequences of polypharmacy**

Among the many consequences of polypharmacy highlighted by doctors, nurses and pharmacists were issues of drug interactions, adverse effects and poor adherence,

*"This is again a big issue of elderly patients. They have polypharmacy - they have a lot of medications. Sometimes the family does not know the medications. Multiple medications for same disease or different disease that will make it difficult for the patient and the family. Compliance will go down usually. Drug-drug interaction will be high. Side effects will be high"*

(Doctor M1, Internist)

*"..... but at least with multiple co-morbidities and to treat side effects of the major treatment plans we have to give a cascade of medications like*

*if we give aspirin we have to give PPI, and if the PPI causes some sort of constipation or diarrhoea we have to treat the constipation or diarrhoea with a third medication, and it is a chain reaction"*

(Pharmacist Z1, Clinical)

*"We have a lot of these patients who especially having multiple medical problems. Somehow it is a problem, because some medication we should not give it together"*

(Nurse M1)

### **Subtheme 2 - Responsibilities for managing polypharmacy**

Some doctors were of the opinion that they dealt with the management and control of their specialist condition only, and while this may have involved an element of polypharmacy in the use of several medicines, they considered polypharmacy to be the responsibility of others. As one neurologist described,

*"In my practice, when epilepsy is not controlled I use polypharmacy to kill the seizures; we try to stick to the baseline neurologic condition. Polypharmacy, usually it is the internist or general medicine doctors who figure that out"*

(Doctor A1, Neurologist)

This individual distinguished between the appropriate use of several anti-epileptics within his specialised field of practice and general polypharmacy (whether appropriate or inappropriate) to be the domain of others.

Several doctors noted the need for specialist and multidisciplinary input.

*"..... If you have a lot of these issues and you have a problem we need to involve our clinical pharmacist with these kind of problems especially for multiple, polypharmacy."*

(Doctor A2, ICU)

*"As physicians, we should know what the drug-drug interactions are as a safety feature, and then we have clinical pharmacists who come in, make recommendations"*

(Doctor Z1, Internist)

*"most of the time these elderly patients have multiple comorbidities. So their management actually requires multidisciplinary approach by various teams"*

(Doctor A2, ICU)

Many of the pharmacists also considered that they had a clinical role in these patients,

*"I will say this is a group of patients who really deserve to have an extra effort to optimise their medications"*

(Pharmacist K1, Clinical)

*"I take care especially the elderly patients with polypharmacy. I review their medication profiles, their labs, their vital signs, and I keep the high-risk patient at follow-up on daily basis"*

(Pharmacist K2, Clinical)

*"I am seeing the elderly and paediatric are the same. We need to carefully look after them and to optimise their drug use."*

(Pharmacist A2, Clinical)

However, some also commented that the clinical service currently provided was not always sufficient,

*"It's not like optimising. It is hard to reach the optimum goal, but at least we are working on it and trying to improve it, see where the gaps are and trying to fill it"*

(Pharmacist K3, Clinical)

The current clinical pharmacy service was focused on targeting specific medical conditions and drug groups,

*"As much as we can we optimise it, but it is not up to the required standards. Like if the patient is facing osteoporosis we are trying to deal with it. If the patient has some GERD or other symptoms we are dealing with it. We are trying to avoid using sedating agents or anticholinergic agents as much as we can, but generally speaking it is not up to the required standard"*

(Pharmacist Z2, Clinical)

Some doctors suggested that a multidisciplinary team approach was needed to adequately manage polypharmacy and that should be led by a geriatrician,

*"I emphasize more on multidisciplinary approach. Well, it should be more coordinated with direct involvement by the geriatrician. We have certain issues regarding this multidisciplinary approach. If different specialties have to be involved in dealing with the patient, we have a little bit of difficulty in coordinating them"*

(Doctor A2, ICU)

*"I think if we just keep getting that reinforcement and constant education from the geriatrician saying don't do this, don't do that, it will become habit and will give knee-jerk reaction that we don't have to keep doing this"*

(Doctor Z1, Internist)

None of the nurses interviewed described any role in promoting appropriate polypharmacy.

### **Subtheme 3 - Need for a systematic approach to a full medicines review**

Several doctors and pharmacists discussed the need for a systematic approach to a full medicines review in elderly patients.

*"These kind of patients they need analysis, meaning you need to analyse their problem like system by system, problem by problem. You don't take them in general like any healthy personal, because they have a lot of interactions....."*

(Doctor A2, ICU)

A similar approach was described by one of the clinical pharmacists,

*"I always first try to understand that what we are treating and how we are treating and is there any alternative or easier any solution for this regimen to be simplified. So usually I review the medications and I focus on the what alternative, whether are extended release or modified*

*release or is there any therapeutic substitution, which is equivalent and safe"*

(Pharmacist K2, Clinical)

In undertaking the review, the need to discontinue as many medicines as possible was highlighted, particularly in the context of patient safety,

*"We try to avoid unnecessary medications, like lot of patients take B complex, which has got no significant role to play, so we just cut down those unnecessary medications"*

(Doctor K1, GP)

*".....at least eliminate whatever is not important for the patient and put what is important and not cause any harm to the patient"*

(Pharmacist K3, Inpatient)

Another approach was the use of fixed dose combinations in order to reduce the number of medicines and improve adherence. As one of the doctors stated,

*"Polypharmacy is one of the common term these days because the patient comes with multiple illnesses, multiple ailments, and he is having hypercholesterolemia, he is having coronary artery disease, he is having hypertension, so he ends up taking about four or five medications. If he is on two or three antihypertensive medications, we have a got a combination of two or three in one pill, so we try to give one pill with the three-in-one, which reduced three tablets to one tablet".*

(Doctor K1, GP)

*"The patient will not take his medicines after seeing this, you know number of medicines. So sometimes, I say, "sir, doctor, why don't you just go for this polypill""*

(Nurse Z1)

Some senior doctors were of the view that after specialist care in hospital, elderly patients with multimorbidities required regular input from a health professional to provide more general care,

*"Get some geriatrician after our primary care as a cardiologist or as acute problem has been resolved, the patient should be followed up with someone more close, more free, and more frequent"*

(Doctor K2, Cardiologist)

#### **Subtheme 4 - Contribution of healthcare structures and processes to inappropriate polypharmacy**

Several aspects of the structures and processes of the healthcare system in the UAE were discussed by doctors, nurses and pharmacists. They considered the system to be contributing to inappropriate polypharmacy. These included: individual patients being treated by multiple prescribers, sometimes for the same indication; poor documentation; and a lack of inter- and intra-professional communication. These aspects were highlighted by a junior doctor,

*"..... they shift from one doctor to another and nobody explains to them. You know, some of the medications have the generic name and different trade names and they keep using both, they do not know about it..... I look at the medication compared to the system we have in the chart. The problem, many times there is no documentation about the medication"*

(Doctor Z2, Internist)

*"I think, physicians when they prescribe they are not checking each other which the doctor prescribed and he will just come and prescribe and go"*

(Pharmacist M2, Clinical)

*"If the patient comes like, goes to the facilities under SEHA, then we can follow it through Cerner, our program, but he went to private sectors, so in this case we will ask him and take the information from the patients or caregiver or family member and this happens through the nurse mainly."*

(Pharmacist K3, Clinical)

*"Sometimes when we are talking with the patient and sometimes they will bring their medication. They have two bags of medication which — almost the same generic name but different brand name"*

(Nurse A1)



## **Theme 2 – Need for systematic approach to medicines history taking**

All interviewed highlighted the need to obtain an accurate, up to date, list of medicines being taken at the point of admission to hospital.

### **Subtheme 1 – Sources of information**

Interviewees described one particular issue of obtaining information from elderly patients who could be confused and the need to use as many sources of information as possible including family members and carers. While this was described in the context of all patient admissions, the issues of multimorbidities and polypharmacy in the elderly highlighted the need for a systematic approach.

*"We have something called medication reconciliation in the hospital in which we have the patient medications like home medications. We usually ask them to bring their medications so that anything not available in the patient charts so that we enter those medications that are taken from even from outside from retail pharmacies, from other hospitals"*

(Pharmacist T1, Clinical)

*"I try to gather whatever from the online record or record whatever, but still I will ask the family to bring it. Because this is very important to know what the patient is on, what to continue, what to hold, and later on after discharge ... This is again a big issue of elderly patients. They have polypharmacy - they have a lot of medications. Sometimes the family does not know the medications"*

(Doctor M1, Internist)

*"I look at the admission note from the primary, you know from the internal resident, see what medications they are and they call me as consultant of the patient, I go through that and I usually go to the patient room and ask them. Patients' especially elder ones they are hard-headed. They do not listen. They go from one doctor to another and they keep sometimes taking the same medications on different names"*

(Doctor Z2, Internist)

*"We are asking them to bring from home all of their medications and we are checking all of the medications and we are asking them "do you have any issues with such medications, "are you taking this regularly?" "What is your routine?", "what is the time you are taking?"*

(Nurse K1)

Some noted issues of elderly patients when being able to provide full and accurate medicines history,

*"If the patient came to our hospital confused or disoriented, we always check who sit or taking care of the patient at home. So we ask the caregiver about the patient in term of his medication, his physical status, also his eating and drinking status."*

(Nurse T1)

During discussion, the pharmacists described in detail the new Hospital Information System (HIS) that linked all SEHA hospitals and clinic in Abu Dhabi. SEHA chose Cerner as its Health Information Technology supplier because of Cerner's flexible platform and ability to support large-scale implementations such as ensuring medication safety, reducing medical errors and improving access to information.

*"The good thing about this new system that it covers all the governmental hospitals in Abu Dhabi. So you can know what is the drug history of our patient who has been admitted in another hospital"*

(Pharmacist K1, Clinical)

One limitation of the system was not linked to private sectors,

*"If the patient comes like, goes to the facilities under SEHA, then we can follow it through Cerner, our program, but he went to private sectors, so in this case we will ask him and take the information from the patients or caregiver or family member and this happens through the nurse mainly."*

(Pharmacist K3, Clinical)

Some of the pharmacists noted that it was not always clear who was responsible for medicines history taking and reconciliation,

*"Before admission, we have no relation with the patient, but upon admission if we receive calls to come to reconcile patients' medications, we go immediate to the point of admission and we reconcile the patient's medications"*

(Pharmacist Z2, Clinical)

On admission, one nurse pointed out that patient medicine's history always taken by an ER doctor, noting that this was not always clear who did it.

*"Actually, we are all secondary for this one because most of this were always taken by the doctor .. as per their decision of what were going to do with the patient .. "what their problem?" or "their medication" or "previous medication or allergies""*

(Nurse A1)

Another nurse pointed out that the use of pharmacist for medicines history taking and reconciliation was not consistent,

*"documentation ... first patient admitted in ER then we inform the doctor and then the doctor will document all medication history. But all the documentation happened after the admission and sometimes we asked for help from clinical pharmacist"*

(Nurse T1)

### **Theme 3 – Need to improve communication and documentation**

Generally, doctors, nurses and pharmacists all highlighted the need for more effective and efficient multidisciplinary team working around aspects of medicines management when caring for elderly patients with multimorbidities. They described particular issues relating to poor intra and interdisciplinary communication or documentation.

#### **Subtheme 1 - Lack of communication**

Several doctors stressed the need to improve communication at all levels,

*"We have certain issues in communication which will be resolved by multidisciplinary approach. For example if different specialties have to be involved in dealing with same patient, we have a little bit difficulty in coordinating them"*

(Doctor A2, ICU)

One doctor used the whole team (i.e. doctor, pharmacists and nurses) on the same patient to minimise poor communication, noting that this approach was not used by all.

*"Sometimes, there is gap. It is different from doctor to doctor. I try usually to have the whole team on the same patient"*

(Doctor M1, Internist)

Pharmacists also noted issues related to the processes of communicating with doctors. As described by one respondent, different modes of communication had been tried and none were particularly met their expectations,

*"We are trying verbal communication, also electronic communications, sometimes we will put notes on patient's profile, so the physician can look at it, but the communication in general is, we are not meeting our expectations with communication. Physicians they don't have specific time to be available for us as a pharmacy. We are trying to reach them, but sometimes they are busy with other patients "*

(Pharmacist K3, Inpatient)

*"I cannot say it is a perfect practice. Communication is also difficult between healthcare professionals especially during the peak time or during the rush time we have a very difficult way to communicate with each other even in the same location. "*

(Pharmacist Z2, Clinical)

While nurses also described issues of communication, these did not appear to be as marked as those described by the doctors and pharmacists. They however felt that their communication with the pharmacists was only occasional.

*"It is not that an issue, you know. Because there is a policy control everything at the end. But still the lack of communication is there"*

(Nurse M1)

Communication at ward level with the pharmacists was noted to be infrequent,

*"We are dealing most of the time with doctors. When it comes to the pharmacists, really we are not dealing with them, except if there is something that really needs to be adhered we will call the pharmacy"*

(Nurse K1)

Electronic based information was also noted to be problematic, as described by one doctor,

*"Because the communication nowadays is computer-based, meaning that I see the patient, I read the note, and I think the other doctor will read my note and exclude the information from the note, but this usually does not happen"*

(Doctor K1, GP)

Pharmacists viewed the same electronic system more favourably, considering the Hospital Information System (HIS) to be an effective tool in enhancing communication,

*"The HIS is a very good tool for communication. Whenever there is something that needs to be communicated, the emails are a second tool to use, the system gives us the privilege you can address these notes to the MRP (most responsible physician), so it goes to him as an email or as a note to alert him that there is something to be considered"*

(Pharmacist K1, Clinical)

## **Subtheme 2 - Lack of documentation**

There were mixed views on the quality and extent of documentation of medicines and medicines related in patient records.

Generally the doctors and pharmacists expressed reservations, with some doctors repeating the work of others,

*"It will be medical residents who do it. But I go over it again. You know you have to."*

(Doctor Z1, Internist)

*"I look at the medication compared to the system we have in the chart. The problem, many times there is no documentation about the*

*medication. Most people write documentation. Some don't write it. Some write incoherent handwriting"*

(Doctor Z2, Internist)

While most of the pharmacists described a systematic approach to review of patients' medicines and documentation of issues,

*"I go through their medication charts and the labs, and vital signs and if there is some feedback, I always give the feedback in verbal and in addition I give my medication review also in the patient chart documentation."*

(Pharmacist K2, Clinical)

Several admitted that they did not always record any identified issues,

*"be honest, sometimes I forget to document like, I forget to document on daily basis, so sometimes there are something that I forget to document, but I try to do my best to document like every intervention I do."*

(Pharmacist T1, Clinical)

There appeared to be a more defined process if there is an ADR for specific medicines as described by some,

*"Number of adverse reaction or number of admission due to adverse reaction of drug is extremely low. Any adverse reaction to medications we have a protocol to inform to the pharmacy as well as document in the literature, patient's file, and also inform to the nurse and nursing-in-charge for that patient is probably having sensitivity or adverse reaction with particular medication."*

(Doctor K2, Cardiologist)

*"We will have it in our system under adverse reaction, under medication. There is certain part under allergy and there is adverse reaction, and we need to document that"*

(Nurse K1)

*"Regarding adverse drug reactions, if there was a suspicion that this may have been because of a drug, we have an adverse drug reaction policy and clear documentation"*

(Pharmacist T1, Clinical)

#### **Theme 4 – Need to improve patients' adherence to medicines**

The issues of non-adherence of elderly patients were discussed at length. Many viewed this as a key issue in the care of elderly patients.

##### **Subtheme 1 – Non-adherence as a consequence of multimorbidities and polypharmacy**

Several shared similar views of the links between multimorbidities, polypharmacy and adherence,

*"The poor adherence is more frequent compared to overdosing or extra doses taken and the poor adherence I think, the polypharmacy is number one factor for this "*

(Pharmacist K1, Clinical)

*"We try to reduce their medication because you know if the elder patients see lots of medication he /she will refuse to take it"*

(Nurse K1)

*"Especially with long-term medications like anti-hypertensive, anti-diabetes, and bronchodilators, we usually get patients for non-adherence to their medication regimen. "*

(Doctor A2, ICU)

##### **Subtheme 2 – patients' lack of knowledge**

Doctors, nurses and pharmacists described many issues related to difficulties in patients' knowledge which led to non-adherence.

These issues included the lack of knowledge of the need to continue long term therapy,

*"Many patients who have been given medication, after about few months they feel comfortable and normally they think why do I am taking this*

*medication. So they start reducing their own and sometimes they stop also. Once we crosscheck, patient says nobody told me that this medication I have to take lifelong"*

(Doctor K1, GP)

*"Some people do not comply.... they stop the medication without the knowledge of the doctor, so their blood pressure shoots up, so they come to hospital and get admitted"*

(Doctor M1, Internist)

One pharmacist described elderly patients taking more medicine than prescribed to gain increased effect,

*"I think this patient is too worried that he has taken everything that he can, not understanding that he has taken the same thing or some patients think oh, if one tablet will make my blood pressure lower, oh, if I take two it is going to be lowered more. I think it is mostly education part in understanding fully what the medicine is, how to take the medicine, and what is important about taking medicine"*

(Pharmacist Z1, Clinical)

One described issue of concerns over adverse drug reactions,

*".... elderly patients say the medicine makes their body more prone to get sick and the other thing is lack of education may be and then lack of family support"*

(Nurse Z1)

### **Subtheme 3 – Need for patient/carer/family counselling**

While all interviewees were able to describe at length the need for and importance of counselling elderly patients and their carers/family, it appeared that this tended to take place at the point of discharge from hospital.

A range of professionals were involved as described by one pharmacist,

*"First of all, it is the responsibilities for the doctor to tell the patient that he is upon discharge and he will tell him what kind of medications he will take. On our part as pharmacists, we do the patient counselling and when*



*we dispense medications, give the patient counselling, and also document this that we educated the patient about his medications. We try to educate the caregiver, educate family members. We try to target many caregivers, not only on the caregiver himself, also the family members, sometimes anyone who is involved or near to the patient."*

(Pharmacist K3, Inpatient)

In some instances, the input of pharmacist was targeted at patients prescribed high risk medicines,

*"There is a program for counselling the patient on select drugs, which have been identified as either high-alert high-risk medications. So I am involved in the education of the patients regarding high-alert medications like warfarin and some other drugs."*

(Pharmacist M1, Clinical)

*"Any patient who has been on warfarin in the hospital will have to be counselled by clinical pharmacist"*

(Pharmacist K1, Clinical)

This approach was also described by nurses,

*"There are some medications some pharmacists will come and explain to the patient about it. Certain medications like vancomycin or inhalers and all of these will be educated by the pharmacists."*

(Nurse M1)

One doctor described the importance of counselling family/carer, particularly if the patient was cognitively impaired,

*"if they are cognitive impaired, we don't usually counsel on them, we counsel in the caregiver/family ... we inform family about the medication and why they have to be on this medication and how long they have to take it"*

(Doctor A1, Neurologist)

None of the interviewees described the need to educate and counsel patients at several points during stay, nor the need to focus on aspects other than impacting knowledge.

## **Theme 5 - Need for guidelines and policies to support medicines selection**

Several doctors and pharmacists raised aspects such as a standardised approach of policies and guidance to support medicines selection in this population of patients.

### **Subtheme 1 - Awareness of and adherence to guidelines and policies**

There were diverse views on organisational and clinician approaches to medicines selection. Two pharmacists gave detailed accounts of the organisational level approaches in their hospitals, comprising Pharmacy and Therapeutic Committees which aimed to provide recommendations on preferred medicines to medical staff. While not specifically relating to medicines for elderly, hospitalised patients, it was evident that this was a generic approach for all patients.

*"Physicians in our hospital they cannot prescribe whatever they want to prescribe. We have here what is called 'pharmacy & therapeutic committee', generates a list for our hospital and this pharmacy and therapeutic committee is a multidisciplinary team constitutes from all the departments dealing with the drug."*

(Pharmacist A2, Clinical)

*"each hospital has its own PTC [Pharmacy and Therapeutics Committee] and then at SEHA level we have the PTC that controls all other PTCs, they are controlling the formulary we have, so that, like the physicians have only those options and now they are in the process of applying the order sets, so I think order sets will also help in limiting the choices."*

(Pharmacist T1, Clinical)

This pharmacist, however, noted that the process of medicines selection was less controlled at the individual doctor level,

*"Most of our physicians are basically free to prescribe whatever they want"*

(Pharmacist T1, Clinical)

One doctor expressed his frustration in the lack of freedom to prescribe any medicine,

*"The problem is a lot of times we do not get the drugs that we want. If I give them this antibiotic and they have to jump through a lot of hoops to get the medication, are they really going to end up getting it? No. It is going to go back to the noncompliance"*

(Doctor Z1, Internist)

There was also a notable lack of use of guidelines and policies to support medicines choice and that selection was normally at the discretion of the doctor, but acknowledging that specific clinical guidelines may be referred to,

*"It is like physician discretion rather than based on any guideline, but we rely on like international guidelines such as for epilepsy, American Heart Association in Stroke and then we have other guidelines for so many other things"*

(Doctor A1, Neurologist)

Some doctors were of the view that there was a need for the development and implementation of guidelines for elderly patients,

*"Elderly – we try to establish guidelines. I think we are a little bit behind. We should do even better. There are some policies in the hospital where we follow, but I think we should do better, definitely"*

(Doctor M1, Internist)

*"There should be more strict policies for elderly patients. So you have to be familiar with those medications and side effects and drug-drug interaction. So I think if somebody is really focused on this will hopefully prevent some side effects or some other issues. So it will be very helpful if it is available."*

(Doctor Z1, Internist)

When asked specifically about their awareness and use of any lists of drugs potentially inappropriate in the elderly or drugs commonly omitted in the elderly, only one pharmacist was aware of Beers Criteria and admitted not using routinely,

*"Yes, sometimes. Yeah. It is not always the case, but sometimes I use this list and first I got through the idea of this list in 2011 when I was doing research from my pharmacotherapy, so I found this article in annual of pharmacotherapy, the Beers Criteria, and I shared with other colleagues for some patients it is useful and helpful."*

(Pharmacist K2, Clinical)

The general response from the other pharmacists and all doctors on their awareness was, "No, no I am not". Notably, none of the nurses gave detailed responses in relation to questions on medicines selection.

### **Theme 6 - Need for an educated and trained multidisciplinary team**

Another key theme which emerged during data analysis was the need for a focused education and training programme for health professionals to optimise all aspect of medicines management.

#### **Subtheme 1 - Need for specialised education and training**

Doctors, nurses and pharmacists strongly proposed that there was an inherent need for specialised education and training in medicines management for elderly patients, highlighting several issues including medicines selection.

As several doctors stated that they need specific training on elderly medication.

*"You need to have training, because like paediatrics, geriatric population needs specific involvement. Even the pharmacokinetics is different like the paediatrics."*

(Doctor A2, ICU)

*"Absolutely we need this. We need specialised training, we need courses, and we need a lot of issues"*

(Doctor K1, GP)

*"That will be very helpful. Because in this elderly, there are specific medications where you use, which you do not use it in young"*

(Doctor M1, Internist)

*"Their doses are different and we cannot give someone adult the same dose like young or whatever. They have different way of approaching things and drug interaction in the elderly is a little bit different"*

(Doctor Z2, Internist)

Pharmacists were of the view that they needed specialised training to improve their skills,

*"I don't have any specific skills and every time I have to search a lot for specific medications whether it can be given or not or what will be outcome, what will be the administration of medication especially to these patients ..... it would be up to having some specialised training or... I personally believe that now is the era of the specialised treatment, so the treatment should be optimised..."*

(Pharmacist K1, Clinical)

*"If we have someone who is with specialised cares and practices these patients get the outcome in a better way, then it will reduce the burden on the society"*

(Pharmacist K2, Clinical)

*"I would encourage that especially for UAE where we have like, I guess, a huge number and large population of elderly people. So to keep this valued population, we need to have like someone specialised in this."*

(Pharmacist K3, Inpatient)

*"This population needs, I think, they need a lot of adjustments like medication adjustment.. I think that is why there should be someone who is specialised who monitor those patients and who know how to do adjustments or how to adjust the patient's medication"*

(Pharmacist T1, Clinical)

Nurses' also shared these views,

*"If there is training, it is really, you know we can improve our knowledge. I mean, if anything is lacking, you know, we could understand "*

(Nurse Z2)

*"It is better you have to have a special geriatric nurse for geriatric patients. It is better."*

(Nurse K1)

Table 4.7 provides a summary of the themes and subthemes. These are mapped to TDF domains (Table 4.8) and NPT mechanisms (Table 4.9).

Table 4.7: A summary of key themes and subthemes

Key Themes	Subthemes
<p><b><u>Theme 1</u></b>  <b>Need for appropriate polypharmacy in elderly patients with multimorbidities</b></p>	<p><u>Subtheme 1</u> - Consequences of polypharmacy  <u>Subtheme 2</u> - Responsibilities for managing polypharmacy  <u>Subtheme 3</u> - Need for a systematic approach to a full medicines review  <u>Subtheme 4</u> - Contribution of healthcare structures and processes to inappropriate polypharmacy</p>
<p><b><u>Theme 2</u></b>  <b>Need for systematic approach to medicines history taking</b></p>	<p><u>Subtheme 1</u> - Sources of information</p>
<p><b><u>Theme 3</u></b>  <b>Need to improve communication and documentation</b></p>	<p><u>Subtheme 1</u> - Lack of communication  <u>Subtheme 2</u> - Lack of documentation</p>
<p><b><u>Theme 4</u></b>  <b>Need to improve patients' adherence to medicines</b></p>	<p><u>Subtheme 1</u> - Non-adherence as a consequence of multimorbidities and polypharmacy  <u>Subtheme 2</u> - patients' lack of knowledge  <u>Subtheme 3</u> - Need for patient/carer/family counselling</p>
<p><b><u>Theme 5</u></b>  <b>Need for guidelines and policies to support medicines selection</b></p>	<p><u>Subtheme 1</u> - Awareness of and adherence to guidelines and policies</p>
<p><b><u>Theme 6</u></b>  <b>Need for an educated and trained multidisciplinary team</b></p>	<p><u>Subtheme 1</u> - Need for specialised education and training</p>

Table 4.8: Themes and subthemes mapped to TDF domains

Theoretical Domains Framework	
Domain	Themes & Subthemes
<p><b>Professional role &amp; identity</b> (Coherent set of behaviours and displayed personal qualities of an individual in a social or work setting)</p>	<p>Several subthemes mapped to the domain of professional role and identity. Most notably, interviewees expressed diverse views around roles and responsibilities in managing polypharmacy from those doctors who viewed that their remit was solely around managing the conditions within the specialist field of practice to those more concerned with polypharmacy (<u>theme 1, subtheme 2</u>). Other similar themes were around less clearly defined roles and responsibilities in medicines history taking (<u>theme 2, subtheme 1</u>), patient/carer/family counselling (<u>theme 4, subtheme 3</u>), medicines selection (<u>theme 5, subtheme 1</u>) and optimising medicine management for elderly patients (<u>theme 6, subtheme 1</u>).</p>
<p><b>Beliefs about capabilities</b> (Acceptance of the truth, reality, or validity about an ability, talent, or facility that a person can put into constructive use)</p>	<p>While not explicitly discussing beliefs about their individual capabilities regarding the different aspects of medicines management, the interviewees emphasised the need for specialised education and training in medicines management for elderly patients, highlighting particularly the complexities of medicines selection (<u>theme 6, subtheme 1</u>).</p>
<p><b>Beliefs about consequences</b> (Acceptance of the truth, reality, or validity about the outcomes of a behaviour in a given situation)</p>	<p>Several respondents highlighted the consequences of polypharmacy in terms of drug interactions, the occurrence of adverse effects and poor patient medicines adherence (<u>theme 1, subtheme 1</u>). Awareness of these consequences appeared to influence behaviours of some interviewees in relation to their practices of conducting full medicines reviews in elderly patients (<u>theme 1, subtheme 3</u>).</p>



	<p>Several interviewees described that the consequences of their experiences of cognitive impairment and confusion in elderly patients resulted in them using several sources of information (including family members and carers) to ensure as complete a medicines history as possible (<u>theme 2, subtheme 1</u>)</p> <p>All interviews demonstrated their awareness of the heightened issue of non-adherence in elderly patients due to inappropriate polypharmacy (<u>theme 4, subtheme 1</u>), patients' lack of medicines knowledge (<u>theme 4, subtheme 2</u>) all of which impacted their behaviours relating to medicines counselling (<u>theme 4, subtheme 3</u>).</p>
<p><b>Environmental context and resources</b> (Circumstances of a person's situation or environment that discourages or encourages the development of skills and abilities, independence, social competence, and adaptive behavior)</p>	<p>Several themes and subthemes mapped to domain of environmental context and resources and how these affected behaviours of individuals. Many interviewees commented on the issue of individual patients being treated by multiple prescribers, sometimes for the same indication, and the problem of poor documentation (<u>theme 3, subtheme 2</u>); and a general lack of inter- and intra-professional communication (<u>theme 3, subtheme 1</u>). As a result doctors, nurses and pharmacists considered the healthcare system to be contributing to inappropriate polypharmacy (<u>theme 1, subtheme 4</u>).</p> <p>Several doctors and pharmacists were of the view that more standardised approach to the development and use of policies and guidance to support medicines selection would be of benefit (<u>theme 5, subtheme 1</u>).</p>
<p><b>Knowledge</b> (An awareness of the existence of something)</p>	<p>Interviewees expressed diverse views around their awareness of polypharmacy and its association with interactions, adverse drug reactions, and impacting patient medicines adherence (<u>theme 1, subtheme 1</u>).</p>

	<p>While some interviewees were aware of the existence of international guidelines to support their prescribing in the elderly, there was a major gap in knowledge specific tools such as Beers, STOPP/START to aid appropriate prescribing and identify potentially inappropriate prescribing in the in elderly (<u>theme 5, subtheme 1</u>).</p>
<p><b>Goals</b> (Mental representations of outcomes that an individual wants to achieve)</p>	<p>Several of the themes and subthemes map to the domain of goals, particularly around the need for appropriate polypharmacy (<u>theme 1</u>), need for a systematic approach to medicines history taking (<u>theme 2</u>) and need to improve patient adherence (<u>theme 4</u>).</p>

Table 4.9: Themes and subthemes mapped to the four mechanisms of NPT

Normalization Process Theory	
Mechanism	Themes & Subthemes
<p><b>Coherence</b></p> <p>Defines and organises the components of a practice</p>	<p>While respondents appeared to be aware of the different processes in relation to medicines management in elderly hospitalised patients (i.e. medicines history taking, reconciliation, medicines selection, counselling etc.), there appeared to be less coherence around actually defining these processes and demonstrating consistent, shared beliefs in a structured manner. For example, all were aware of the consequences of polypharmacy (<u>theme 1, subtheme 1</u>) but there were varied responses to defining appropriate polypharmacy (<u>theme 1, subtheme 2</u>). Also there were varied responses in terms of the approach to a full medicines review (<u>theme 1, subtheme 3</u>). There was more coherence around the goals of patient counselling in relation to medicines adherence (<u>theme 4, subtheme 3</u>).</p>
<p><b>Cognitive participation</b></p> <p>Defined and organises the people implicated in a complex intervention and brings a practice into practice, organising ways that people join and support a practice</p>	<p>There were diverse views around task allocation in relation to the different elements on medicines management in elderly hospitalised patients. Specific responsibilities and roles around managing polypharmacy were unclear (<u>theme 1, subtheme 2</u>), as were those relating to conducting medicines reviews (<u>theme 1, subtheme 3</u>). For example, on occasions pharmacists were involved in processes of medicines reconciliation, but this did not appear to be a clearly allocated task (<u>theme 2</u>).</p> <p>It appeared that doctors, nurses and pharmacists were all involved in patient medicines counselling with no clearly defined remit assigned to each profession (<u>theme 4, subtheme 3</u>)</p> <p>However, all interviewees were aware of the need to undertake education and training in relation to medicines management in elderly hospitalised patients (<u>theme 6, subtheme 1</u>)</p>
<p><b>Collective action</b></p>	<p>This mechanism related to the actual work or skills involved in delivering the tasks relating</p>

<p>Defines and organising the enacting of a practice through skill set and task allocation, and performance with accountability and interconnected work</p>	<p>to medicines management.</p> <p>The actual approach to medicines review varied amongst doctors in different specialties and between different professions such as pharmacists and nurses (<u>theme 1, subtheme 3</u>). All those involved in medicines history taking described the use of multiple sources in an attempt to gather as much information as possible (<u>theme 2, subtheme 1</u>). Interviewees were aware of the suboptimal inter and intraprofessional communication (<u>theme 3, subtheme 1</u>) and documentation (theme 3, subtheme 2).</p> <p>All discussed the need to counsel the family and carers in addition to (and sometimes instead of) the patient (<u>theme 4, subtheme 3</u>). There were diverse descriptions of the use of policies and guidelines in relation to medicines selection (<u>theme 5, subtheme 1</u>).</p>
<p><b>Reflexive monitoring</b> Defines and organises assessment of the outcomes of a practice in terms of effects, communal and individual appraisal</p>	<p>There was very little description or discussion of how the patient outcomes of the processes of medicines management were assessed, either at individual patient or population levels. However, many expressed the need of a multidisciplinary team approach for better medicines review (<u>theme 1, subtheme 3</u>) and for specialised education and to optimise patient outcomes (<u>theme 6, subtheme 1</u>).</p>

## 4.4 Discussion

This section provides an overview of the key findings in relation to the aims and objectives, consideration of the study strengths and weaknesses, discussion and interpretation of the findings in relation to the published literature, reflection on research progress and how these findings impacted the next phase of the research.

### 4.4.1 Key findings

The aim of this phase of the research was to explore the views, experiences and perceptions of health professionals in Abu Dhabi in terms of the medicine management healthcare structures, processes and outcomes for elderly, hospitalised patients.

Analysis of the data from 27 qualitative, face to face interviews with doctors, nurses and pharmacists in Abu Dhabi identified key themes around their views, experiences and perceptions of aspects of medicine management. The key themes were around the need for: appropriate polypharmacy in elderly patients with multimorbidities; a systematic approach to medicines history taking; improved communication and documentation; improved patients' adherence to medicines; guidelines and policies to support medicines selection; and an educated and trained multidisciplinary team.

Further analysis mapped these themes to two theoretical frameworks. The TDF was used in relation to domains of determinants of behaviour at the individual practitioner level. The domains which were most dominant were: professional role and identity; beliefs about capabilities; beliefs about consequences; environmental context and resources; knowledge; and goals. NPT was used at the organisational level with little evidence of coherence, cognitive participation, collective action and reflexive monitoring. There is clearly overlap between these two theories in that individual behaviours and behavioural determinants will influence the organisational activities.

For example,

- coherence may be influenced by goals, knowledge and beliefs about consequences,
- cognitive participation may be influenced by professional role and identity,
- collective action may be influenced by knowledge, beliefs about capabilities and professional role and identity and
- reflexive monitoring may be influenced by beliefs about consequences.

#### 4.4.2 Study strengths and limitations

Prior to discussing and interpreting the findings, there is a need to reflect on the strengths and limitations of the study.

There are a number of strengths to this study. To date, while several studies have used a qualitative approach to research aspects of medicines management (e.g. medicines selection and prescribing) there is an absence of published qualitative studies relating to the full spectrum of medicines management activities as described in this thesis. (Horne *et al.*, 2001; Chong *et al.*, 2012; Cullinan *et al.*, 2014) This study has therefore generated novel knowledge and understanding in this area.

Throughout this qualitative study, attention was paid to aspects of research trustworthiness. As described earlier (section 4.2.10) consideration was given to credibility, transferability and dependability: members of the research team brought medicine and psychology perspectives in addition to the pharmacy perspective; the sampling strategy was described clearly; the draft interview schedule was grounded in theory and reviewed by three expert team members; the interview schedule was developed iteratively; and the coding framework and thematic analysis were independently reviewed by a member of the supervisory team.

In addition, the approach to sample size and determination the point of saturation were guided using that described by Francis *et al.* (2010). Data

saturation was considered to be achieved after 27 interviews (seven doctors, seven nurses and 13 pharmacists). However, while data saturation was obtained for the overall sample, it may have not been achieved for the individual professions. If the interviews had continued to the point of saturation in each profession, it is likely that the number of pharmacists would have exceeded the doctors and nurses. This may reflect the diverse roles of pharmacists and the evolving nature of ward based clinical pharmacy in the UAE. There are several other limitations to this study and hence the findings should be interpreted with caution. Given their number of steps and processes involved in obtaining ethical and management approvals in the UAE, the research was limited to five major hospitals and all of these were from the public sector. Although qualitative findings do not seek to be generalizable, the research was conducted within Abu Dhabi city only and hence the research findings may not be transferrable to other hospitals in Abu Dhabi (particularly those from the private sector), the other six Emirates within the UAE, the Middle East and beyond.

There were several issues around sampling. The total number of doctors, nurses and pharmacists with direct patient contact in the five hospitals was an estimate due to the unavailability of the numbers of professionals meeting the inclusion criteria. This estimation was based on the experience of the researcher and a leading hospital consultant physician with many years of experience in Abu Dhabi. Furthermore as the email invitation was sent from the human resources departments in each hospital, the number of professionals receiving the email was unknown.

While the response rate to the sampling survey could not be calculated, the total number of responses was very low, and it may have been that those most interested in the research topic responded, introducing a response bias and affecting the credibility and transferability of the qualitative findings. A systematic review of the literature on maximising response rates to online surveys reported by Fan and Yan (2010) highlighted several key factors which could have yielded a higher response. The most notable of these would have been to have made contacted each member of the sample prior to sending the recruitment email. While this may have increased the response, it was not

feasible in this study as the research team had no contact with the sample. More pharmacists than doctors or nurses responded to the survey; this response may have been due to their awareness that the main researcher was a pharmacist and had been a colleague of some. Furthermore, not all survey respondents were willing to participate in the interviews. This may have been due to a number of factors including: the time commitment for the interview; the recoding of the interview; or their perceptions of being identified in any study report. Again, these issues may have had implications for data trustworthiness.

While combining two theories may have brought benefits in terms of providing findings relevant at both individual and organisation levels, this may have complicated both undertaking the interviews and data analysis, and also impacted the duration of the interviews. Notably, the emphasis was placed on selected TDF domains and while interviewees were encouraged to add any other relevant comments, the lack of attention placed on domains such as 'social influences' may have impacted the findings.

#### 4.4.3 Interpretation of findings

This section is informed by a comprehensive literature search of Medline, CINAHL, and International Pharmaceutical Abstracts (see Appendix 4.12 for search strategy) of qualitative research in relation to structure and processes of medicines management from the health professional perspective. Five relevant studies were identified which are described in Table 4.10.



Table 4.10: Data extraction for five relevant qualitative studies

Reference	Specified Aim/objective	Setting (country, institution)	Design	Participants	Outcome measures	Key Findings	Conclusion
(Horne <i>et al.</i> 2001)	To elicit the views and experiences of GPs and hospital doctors about existing arrangements for shared care applied to the prescribing of specialist medicines.	South Thames region (UK).	Qualitative study based on semi-structured interviews.	GP sample comprised 39 males and nine females.  The sample of hospital doctors comprised 12 consultants and one senior registrar.	The interviews focused on how far experiences with shared care compared to the arrangements currently in place for prescribing specialist medicines; identified barriers and facilitators of effective shared care.	The themes centred around issues of clinical responsibility, 'cost-shifting', availability of medicines, GP satisfaction, and the nature of the prescribing relationship	GPs appeared dissatisfied with arrangements for prescribing specialist medicines, while hospital doctors were generally satisfied.
(Skoglund, Segesten and Björkelund 2007)	To describe GPs' thoughts on prescribing and evidence-based knowledge concerning drug therapy.	South eastern part of Vastra Gotaland (Sweden).	Audio recorded focus group interviews transcribed verbatim.	A total of 16 GPs out of 178 from the south eastern part of the region strategically chosen to represent urban and rural, male and female, long and short GP experience.	The outcome measure was focused on GPs' thoughts on prescribing and on evidence-based knowledge concerning drug therapy.	The categories were: benefits, time and space, and expert knowledge The benefit was a merge of positive elements, all aspects of the GPs' tasks Time and space were limitations for GPs' tasks. EBM as a constituent of expert knowledge should be more customer adjusted to be able to be used in practice.	GPs' thoughts on evidence based medicine and prescribing medication were highly related to reflecting on benefit and results. The interviews indicated that prompt and pragmatic benefit is important.
(Chong, Aslani and Chen 2013)	To explore the perspectives of health care	Australian health care setting,	Individual semi-structured	31 health care providers: 4	The outcome measure was focused on	Participants acknowledged medication non-	Participants were able to identify issues and

	providers on antidepressant medication non-adherence in clinical practice	within the state of New South Wales	interviews were conducted with a purposive sample of 31 health care providers	psychiatrists, 4 GPs, 11 pharmacists, 7 mental health nurse, 5 social workers	medication adherence issues in depression and participants' strategies in addressing them.	adherence to be a complex problem in depression, and attributed this problem to patient, medication and environmental-specific issues. Five approaches in addressing non-adherence were reported: patient education, building partnerships with patients, pharmacological management, developing behavioural skills and building supportive networks. Challenges to the management of non-adherence were lack of time and skills, assessment of medication adherence, transition period immediately post-discharge and conflicts in views between providers.	strategies in addressing antidepressant non-adherence; however, barriers were also identified that could impact on providers' ability to address this issue effectively.
(Vogelsmeier <i>et al.</i> 2013)	To illuminate interprofessional factors that complicate effective and efficient medication reconciliation and to report clinicians' perceptions of medication reconciliation as	Three Veterans Administration hospitals (United States).	Qualitative study using focus groups of physicians, nurses and pharmacists.	Three focus groups were conducted at each of three veterans administration hospitals. Participants were 13 physicians, 19 nurses and	The outcome measure was focused on specific discussions about medication reconciliation.	Two primary thematic questions emerged from the discussion about medication reconciliation: what does medication reconciliation really mean?; and who is actually responsible for the process? Participants from each	Translating the intent of medication reconciliation into effective practice requires acknowledgment of the involved professionals' diverse perspectives on

	related to adverse drug events. s			16 pharmacists.		profession had differing perspectives about the purpose and processes of medication reconciliation.	the independent, joint, and overlapping functions of medication management as well as recognizing the limitations of technology.
(Cullinan <i>et al.</i> 2014)	Aims of this study were; using the TDF, (1) explore hospital doctors' perceptions as to why PIP occurs, (2) identify the barriers to addressing the issues identified, thus identifying potential targets for intervention and (3) to use the behaviour change wheel to determine which intervention types would be best suited.	Four Hospital: two public hospitals, owned and funded by the Health Service Executive and voluntary hospitals, run by voluntary/private boards (Ireland)	Semi-structured interviews based on the Theoretical Domains Framework (TDF), a tool used to apply behaviour change theories, were conducted with 22 hospital doctors.	A total of 22 hospital doctors, representative of doctors prescribing for older people in the hospital setting and represented doctors working in both geriatrics and in general medicine.	Content analysis was conducted to identify domains of the TDF that could be targeted to improve prescribing for older people.	Content analysis identified 5 of the 12 domains in the TDF as relevant; (1) environmental context and resources, (2) knowledge, (3) skills, (4) social influences and (5) memory/attention and decision processes. Using the behaviour change wheel, the types of interventions deemed suitable were those based on training and environmental restructuring.	This study showed that doctors felt there was insufficient emphasis on geriatric pharmacotherapy in their undergraduate/postgraduate training. An intervention providing supplementary training, with particular emphasis on decision processes and dealing with social influences would be justified

The study of adherence to antidepressants reported by Chong, Aslani and Chen focused on one specific therapeutic category and is therefore less relevant to the research presented in this thesis. (Chong, Aslani and Chen, 2013) The remaining four studies focused on more general elements of medicines management structures and processes.

The key finding of Vogelsmeier *et al.*, in a study of health professionals in the US, that there is a need for more efficient deployment of staff in medicines reconciliation is in line with the findings of this research. (Vogelsmeier *et al.*, 2013) This relates specifically to the themes of need for a systematic approach to medicines history taking and the need to improve communication and documentation, aligning to TDF behavioural determinant of professional role and identity, and NPT mechanism of cognitive participation. Skoglund, Segesten and Bjorkelund, in a focus group study of 16 GPs in Sweden, indicated that the practice of evidence based medicine in relation to prescribing was more pragmatic, considering individual patient benefit. (Skoglund, Segesten and Bjorkelund, 2007) These findings relate to the themes of the need for appropriate polypharmacy in elderly patients with multimorbidities and the need for guidelines and policies to support medicines selection. The findings also align to the TDF behavioural determinant of beliefs about consequences (of applying evidence based practice) and goals.

Cullinan *et al.*, in studying employing qualitative interviews with 22 hospital doctors in Ireland, highlighted the lack of emphasis on geriatric clinical pharmacotherapy in their undergraduate course and the need to consider social influences on prescribing decision making. These findings relate to the theme around the need for an educated and trained multidisciplinary team. These align to the TDF behavioural determinants of knowledge and beliefs about capabilities (Cullinan *et al.*, 2014). It should be noted that while social influences did not emerge as a key determinant in this doctoral research, this may have been due to the limitation attention to this domain in the interview schedule.

In an earlier study, Horne *et al.* interviewed 39 GPs and 12 hospital doctors in the UK on their experiences with shared care. While the hospital doctors were generally satisfied, the GPs were clearly dissatisfied with the arrangements

relating to more specialised medicines. No reasons were provided to explain the lack of satisfaction. (Horne *et al.*, 2001) These findings relate to the themes of need to improve communication and documentation, and the need for guidelines and policies to support medicines selection. These may relate to the TDF behavioural determinants of knowledge, beliefs about capabilities and environmental context and resources. In terms of NPT, they may relate to the mechanisms of coherence in terms of a lack of shared beliefs and collective action.

The key finding of this phase of the doctoral research is that there was a diversity of approach in respect of all the processes in relation to medicines management, as defined in this project: medicines reconciliation and history taking at the point of admission to hospital; medicines selection during the inpatient stay; constant review of medication; planning for counselling to promote medicines adherence; and communication of information at the point of discharge from hospital. There were also issues in relation to the structures around policies, guidelines and systems of documentation. There appears to be a need for a more systematic approach to medicines management in elderly, hospitalised patients, which will require further consideration of these structures and processes. This key finding is directly related to the aim of this phase of the study.

The detailed thematic analysis aligned to NPT highlighted a lack of coherence around medicines management among the elderly patients in Abu Dhabi. There appeared to be an absence of shared belief around the aims of medicines management, defining appropriate polypharmacy (or indeed polypharmacy itself) and the approaches taken to enabling appropriate polypharmacy. However, there was clear knowledge around the implications and consequences of inappropriate polypharmacy, particularly around the potential for increased incidence and severity of adverse drug reactions, drug interactions, complicating adherence. In terms of the other mechanisms of NPT, there was little evidence of cognitive participation (defining the professions) and collective action (task allocation) with no clear allocation of the processes of medicines reconciliation, history taking and counselling. While medicines selection was more clearly the remit of the physicians, there was confusion relating to multiple prescribers

(particularly in primary care) prescribing for the same indication, and responsibility for medicines review within the hospital setting. There is clearly a need for considering task allocation with clearly defined roles and responsibilities, all of which will also require improved standards for documentation and inter and intra-professional communication. All of these issues could be captured within agreed SOPs. There is then a need to promote reflexive monitoring to evaluate the outcomes of the processes which will require agreeing clear service aims and objectives, all of which must centre on optimising patient outcomes.

Two studies have applied NPT to analyse data relating to the management of heart failure. Gallacher *et al.* interviewed 47 patients with chronic heart failure managed in UK primary care settings. They identified that the NPT mechanisms of coherence, cognitive participation and cognitive action aided their understanding of the patient perspective of developing an understanding of treatments, interacting with others to organize care, attending appointments, taking medications, enacting lifestyle measures, and appraising treatments. They concluded that NPT could be used as a framework in developing interventions at the individual practitioner and organisational levels to enhance the patient experience. (Guthrie *et al.* 2012) Lowrie *et al.* conducted focus groups with pharmacists and semi-structured interviews with individual patients in the UK to explore and portray in detail, the perspectives of patients receiving and pharmacists delivering an enhanced performance community pharmacy heart failure service. They used NPT to allow understanding of the patient perspective in terms of: coherence, learning about heart failure and its consequences, cognitive participation, engaging with others; collective action, methods for managing symptoms and treatments; and reflexive monitoring, changing routine. While the discussion elaborates the benefits of NPT, there is little emphasis on the multidisciplinary care team. (Lowrie *et al.* 2014)

These two studies differ from the current research by focusing on the patient perspective, which may be more relevant in the primary care setting.

There is a consensus in the literature that behaviour change is key to increasing the uptake of evidence into healthcare practice. (Francis, O'Connor and Curran 2012) This has also been endorsed in the Medical Research Council framework

for evaluating complex interventions, as described in chapter 1.(Craig *et al.* 2008) Francis, O'Connor and Curran (2012) highlight that designing behaviour-change interventions first requires problem analysis, which would ideally be informed by theory. The NPT mechanisms and the TDF behavioural determinants have provided a theoretical approach to identifying the behaviour determinants in relation to medicines management. The TDF is particularly useful in this study to identify the individual practitioner behaviours to change. Michie, van Stralen and West developed the Behaviour Change Wheel (BCW) to aid characterising and designing behaviour change interventions ((Michie, van Stralen and West 2011). This behaviour change wheel can be used to link behavioural determinants to specific interventions. The BCW is similar to the TDF in that it was developed from 19 frameworks of behaviour change. It consists of three layers.

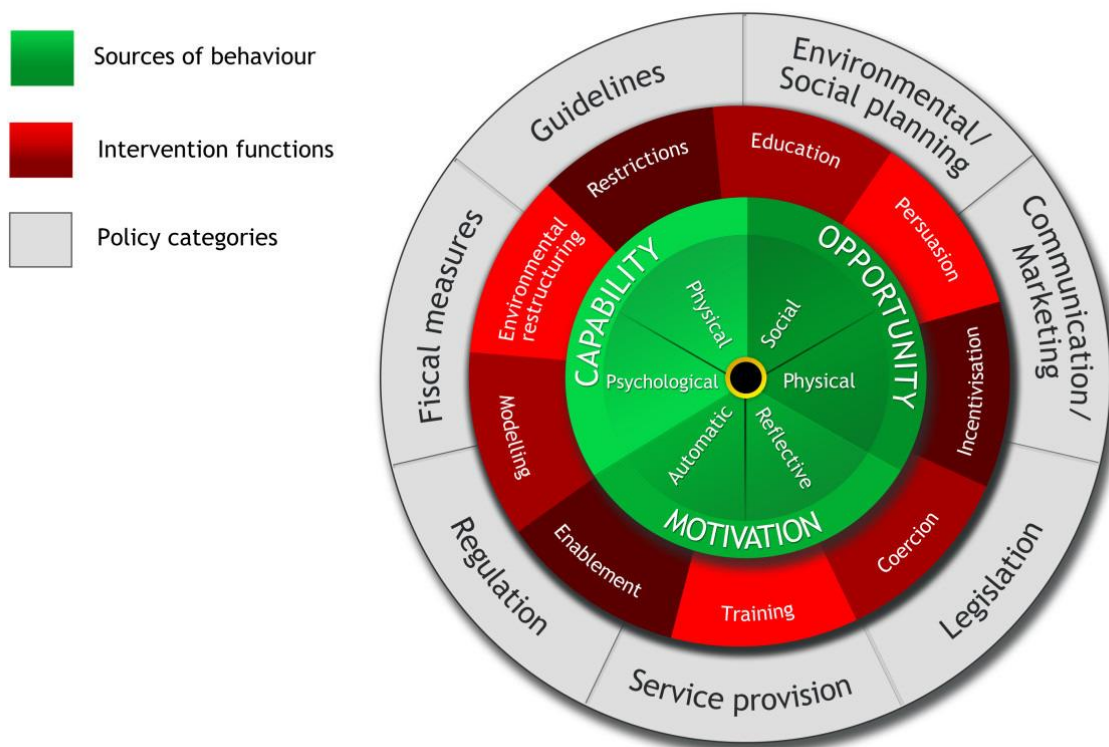


Figure 4.7: The BCW (adapted from Michie, van Stralen and West, 2011)

The hub describes the behaviours using the COM-B ('capability', 'opportunity', 'motivation' and 'behaviour') model, which is similar to the TDF behavioural determinants. Surrounding the hub is a layer of nine intervention functions to choose from based on the particular COM-B analysis. The outer layer, the rim of

the wheel, identifies seven policy categories that can support the delivery of these intervention functions. The potential use of the BCW in developing interventions relating to medicines management is discussed in more detail in chapter 6.

Selection of medicines is complex in elderly patients. Interviewees in this study (particularly the physicians and pharmacists) described the need for clinical, evidence based therapeutic and pharmacological guidelines to support medicines selection and review. While there is a vast volume of international clinical guidelines, the failure of these to account for patients with multimorbidities has been highlighted. Guthrie *et al.*, in an editorial article, highlighted that, 'clinical guidelines almost entirely focus on single conditions' and that 'guidelines could be made more useful for people with multimorbidity if they were delivered in a format that brought together relevant recommendations for different chronic conditions and identified synergies, cautions, and outright contradictions'. (Guthrie *et al.* 2012) They suggest that it may be possible to improve morbidity through the use of technology to link the most appropriate medicines with each patient's specific circumstances. In a later paper, Hughes, McMurdo and Guthrie further explored the challenges of applying UK clinical guidelines to those with multimorbidities. (Hughes, McMurdo and Guthrie 2013) They considered the extent to which National Institute of Health and Clinical Excellence (NICE) guidelines dealt with patient comorbidities, patient centred care and if patients complied with their treatment recommendations. They reviewed five NICE clinical guidelines (type-2 diabetes mellitus, secondary prevention for people with myocardial infarction, osteoarthritis, chronic obstructive pulmonary disease and depression), and noted the extent to which the guidelines accounted for patient comorbidity, patient centred care and patient compliance. They noted that, 'comorbidity and patient adherence were inconsistently accounted for in the guidelines, ranging from extensive discussion to none at all'. There is therefore a clear need to further consider patients with multimorbidities in the development of clinical guidelines.

Chapter 1 outlines the issue of potentially inappropriate prescribing in the elderly, describing a systematic review of criteria to aid the identification of



potentially inappropriate prescribing. (Hill Taylor *et al.* 2013) Notably, none of the interviewees in this study reported any awareness of criteria such as Beers and STOPP/START, and none reported using such criteria in their daily practice. Furthermore, none were aware of tools such as the Drug Burden Index to determine anticholinergic burden. This is an area which requires further attention and research. There are no published papers which report the use of such criteria within the Middle East. While it may be necessary to review these criteria for their appropriateness to Middle Eastern practice and culture, these provide a useful starting point.

Several of the key themes which emerged during this research are related to the systematic reviews which were described in chapter 1.

In a recent systematic review of the literature on interventions (alone or in combination) to improve the appropriate use of polypharmacy for older people, Patterson *et al.* highlighted the lack of clarity around the impact of interventions to improve appropriate polypharmacy, such as pharmaceutical care, on health outcomes despite the impact relating to reducing potentially inappropriate prescribing. (Patterson *et al.* 2014) The findings of this research demonstrate the lack of clarity of professional roles and goals around medicines review in the elderly hence it is even less likely positive outcomes in relation to health status can be realised.

One further finding of this research is the expressed need to improve patients' adherence to their medicines. The review of systematic reviews in the field of medicines adherence described in chapter 1 Kardas, Lewek and Matyjaszczyk (2013) and a recent systematic review of 109 RCTs published since 2007 Nieuwlaat *et al.* (2014) highlight that the vast majority of the primary literature is of poor quality (high potential for bias, few studies of clinical outcomes) and that improving adherence is complex and may be multifactorial. There may be merit in employing tools such as the TDF and BCW in the development of tailored interventions. The findings of this research impact the remainder of the doctoral research. Areas of further research outwith the doctoral research are described in chapter 6.

#### 4.4.4 Conclusion

This phase of the research has generated novel knowledge and understanding in medicines management activities. Doctors, nurses and pharmacists in Abu Dhabi are quite aware of the issues in different processes in relation to medicines management in elderly hospitalised patients (i.e. medicines history taking, reconciliation, medicines selection, counselling etc.). It appears the causes are at individual level (e.g. education, training, defined roles) and organisational level (e.g. developing policies and guidelines). This study has identified key areas for targeting of intervention studies in the future, changes that need implementation and the need for specialised training and education.

#### 4.4.5 Implications for further research phase

The findings of

- i. Narrative overview of systematic reviews on medicines reconciliation, medicines adherence and potentially inappropriate prescribing (chapter 1)
- ii. JBI systematic review of the use of the DBI (chapter 3)
- iii. Qualitative interviews to explore the views, experiences and perceptions of health professionals in Abu Dhabi in terms of healthcare structures, processes and outcomes relating to medicine management for elderly, hospitalised patients (chapter 4)

were used in the development of consensus statements employed in the next phase of the research, specifically in relation to the structures and processes for medicines management in elderly, hospitalised patients in the UAE.

## **Chapter 5: The Delphi study**

### **5.1 Introduction to the chapter**

The concept of medicines management should allow healthcare professionals and patients to maximise benefits from the use of medicines and reduce associated risks. (National Prescribing Centre 2002) In Chapter 1, a medicines management model for the patient journey in secondary care was proposed encompassing

- medicines history taking/ medicines reconciliation
- selection and prescribing of medicines
- monitoring medicines
- counselling and information provision

Chapter 1 provided a narrative overview of systematic reviews on medicines reconciliation, medicines adherence and potentially inappropriate prescribing.

In the first phase of doctoral research, a systematic review was undertaken using the Joanna Briggs Institute (JBI) approach. The aim of the review was to critically appraise, synthesise and present evidence of guidelines and tools to manage the risk of adverse effects of anticholinergic agents (as exemplars of high-risk medicines) in elderly patients.

The second research phase focused on medicines management related healthcare structures, processes and outcomes in Abu Dhabi.

In this final phase of the doctoral research, a consensus based approach was adopted which involved identifying and recruiting key stakeholders (who were the expert panel members) in relation to medicines management in elderly patients to explore levels of consensus around statements derived from the previous research phases.

Essentially, consensus methods utilize a group of experts in a particular field to gather evidence and insight into a research topic. (Fink *et al.* 1984, Falzarano and Zipp 2013) These approaches are particularly suited to the development of professional norms and areas of practice where published evidence is lacking. In these situations, there will undoubtedly be potential for diverse personal and subjective opinions that need to be considered. Consensus methods attempt to systematically and objectively gather, organise and synthesise this diversity in an attempt to provide a single consensus. Consensus development is the process through which the members of the group attempt to reach agreement towards this single group opinion. Although in many cases agreement summarising a single perspective is not achieved, data will be gathered identifying the central tendency of expert opinion.

#### 5.1.1 Aim and objectives

The aim of this phase of the research was to determine consensus in relation to strategic and operational approaches around medicines management for elderly, hospitalised patients in the UAE.

The primary objectives were:

1. to develop and validate a series of statements in relation to the structures, processes and outcomes in relation to strategic and operational approaches around medicines management
2. to determine the levels of consensus of key stakeholders (the expert panel members) around these statements

3. to determine any additional statements derived from key stakeholder feedback
4. to determine any reasons for not achieving consensus

The secondary objectives were

5. to determine key stakeholder views on the potential for the findings to aid the development of policies, quality indicators and professional norms
6. determine participant's views of their involvement in the consensus approach, and its potential for future healthcare developments.

## **5.2 Methods**

### 5.2.1 Research Design

A quantitative, positivistic approach was employed in this phase of the study.

A Delphi technique, using an expert panel of key stakeholders in the UAE, was employed. This was selected over the other consensus approaches for a number of reasons, as described in chapter 2. These were primarily logistical considerations for the researchers (using Internet as medium for data collection) and participants (no travel, less time consuming) and cost.

### 5.2.2 Setting

This research was conducted within Abu Dhabi, which is the largest city in the UAE in terms of geographical size and population numbers, has the highest rate of healthcare expenditure and more established governance systems than the other zones (National Bureau of Statistics 2010).

Stakeholders in this research represented:

- all 18 public hospitals in Abu Dhabi which had been authorized by Health Authority of Abu Dhabi (HAAD) to conduct research on human subjects
- HAAD
- Al Ain Medical University

### 5.2.3 Research Governance

The research was reviewed and approved by:

- i. the ethical review panel of the School of Pharmacy and Life Sciences at Robert Gordon University. (see Appendix 5.1)
  - a. a detailed research protocol was prepared and reviewed by team research members.
  - b. the protocol was submitted to the ethical review panel and approval received four weeks later.

All approvals were in place prior to sampling and recruiting any research participants. Throughout the research, all study materials were stored in accordance with the Standard Operating Procedures of the School of Pharmacy and Life Sciences and the governance policies of Robert Gordon University. Signed, informed consent was obtained from all participants.

### 5.2.4 Delphi statements

The statements for the Delphi survey instrument were developed from three sources: review of narrative and systematic literature reviews related to medicines management (Chapter 1); systematic review of the Drug Burden Index (Chapter 2); and analysis of data generated from the in-depth interviews (Chapter 3). A series of initial statements was developed during several meetings of the PI and the research supervisors, as given in Table 5.1. The statements were organised into the key elements of the medicines management model:

1. Guidelines for medicines management in elderly hospitalised patients
2. Medicines reconciliation
3. Medicines review
4. Medicines adherence
5. Medicines counselling
6. Health professional training
7. Evaluation research

Two theoretical frameworks were applied in the design of the Delphi statements in this study. Normalization Process Theory was applied in terms of coherence (definitions of key elements of medicines management), cognitive participation (task allocation of the responsibilities of health professionals), collective action (the actual work or skills involved in delivering the tasks relating to medicines management) and reflexive monitoring (specialised education and training services). The Theoretical Domain Framework and the associated Behaviour Change Wheel were applied in terms of changing behaviour via training, SOPs, documentation and research. Draft statements were discussed revised iteratively at several meetings of the research team.

The statements were tested for face and content validity by a panel of seven experts in Scotland and the UAE on aspects of medicines management, healthcare processes, behaviour change and research, identified from the professional networks of members of the supervisory team. These individuals were emailed the statements with instructions to comment on the clarity and appropriateness of the statements prior to using it in the UAE. This was considered necessary for several reasons: to assess the feasibility of the Delphi statements; to assess whether the Delphi statements were realistic and workable (Van Teijlingen *et al.* 2001). Responses are provided in Table 5.1.

Table 5.1: Verbatim responses to the face and content validation of Delphi statements

	Expert Group Comments							
Professional Title	Director (psychologist), Aberdeen Centre for Trauma Research	Professor of Community Pharmacy Practice	Academic, Researcher	Academic, School of Nursing and Midwifery	Professor and Director of Pharmacy, NHS Education for Scotland	Lead Pharmacist Diabetes and Advanced Pharmacist Clinical Research	Head of Emergency Department in Zayed Hospital	PI Action
Statements								
Background	What is meant by "medicine-related issues"							medicines related issues (e.g. drug selection, adverse drug reactions, adherence)
1. General Statements	Clear						Clear and appropriate	
1.1 The following definition of medicines management should be adopted in the UAE - 'the clinical, cost effective and safe use of medicines to ensure patients get the maximum benefit from the medicines they need, while at the same time minimizing potential harm'			Clear and appropriate		I would rate 'safe' before 'cost effective' in the statement			Reworded
1.2 Elderly patients with multi-morbidities are at particular risk of medicines related issues			Clear and appropriate			'multi-morbidities' - change to multiple co-morbidities		
1.3 Medicines management should be a focus of every elderly patient admitted to hospital, irrespective of the reason for admission or presenting complaint			Reads as though it's the elderly patient's focus rather than healthcare professionals. Perhaps 'a focus in the care of'? Otherwise clear and			Change to 'should be a focus for' rather than 'of'		Reworded



			appropriate					
1.4 Medicines management should be a focus of every elderly patient admitted to hospital, irrespective of the admitting ward or speciality			Reads as though it's the elderly patient's focus rather than healthcare professionals. Perhaps 'a focus in the care of'? Otherwise clear and appropriate			Change to 'should be a focus for' rather than 'of'		Reworded
1.5 Medicines management should be a focus of every elderly patient admitted to hospital, irrespective of the duration of stay in hospital			Reads as though it's the elderly patient's focus rather than healthcare professionals. Perhaps 'a focus in the care of'? Otherwise clear and appropriate			Change to 'should be a focus for' rather than 'of'		Reworded
1.6 Medicines management should only be a focus for those elderly patients admitted to hospital with a medicines related issue			Reads as though it's the elderly patient's focus rather than healthcare professionals. Perhaps 'a focus in the care of'? Otherwise clear and appropriate		Should the word <b>ONLY</b> be in bold type?			Reworded
1.7 Medicines management is the responsibility of all members of the healthcare team, specifically nurses,			Clear and appropriate	Two different things going on in this	Should it mention Prescribers?	It should either be all the		Reworded

pharmacists and physicians.				statement, one general, one specific. Better to separate out into two.		healthcare team or specifically nurses, pharmacist and physicians – not both.		
1.8 All health professionals (specifically nurses, pharmacists, physicians) should be competent in medicines management			Clear and appropriate but would use commas rather than brackets as per previous statement	As above, this doesn't make sense to me.	Define competent?	It should either be all the healthcare team or specifically nurses, pharmacist and physicians – not both.		Reworded
1.9 Single disease state evidence based recommendations should be applied with caution in elderly patients with multi-morbidities			Clear and appropriate		Single state disease – does not read well – rewords?	'multi-morbidities' – change to multiple co-morbidities		Reworded
<b>2. Guidelines for Medicines Management in Elderly Hospitalised Patients</b>	Clear						Clear and appropriate	
2.1 There is a need to develop guidelines for medicines management in elderly hospitalised patients in the UAE			Clear and appropriate					
2.2 A guideline development group should be established, under the auspices of Health Authority of Abu Dhabi (HAAD) <sup>1</sup> , with representation of experts in medicines in the elderly			Clear and appropriate			'representati on of experts' change to 'from'		"of" changed to "from"
2.3 The guidelines should have a focus on medicines reconciliation at the point of admitting elderly patients to hospital			Clear and appropriate		Also at Discharge??			Reworded
2.4 The guidelines should have a focus on the prescribing of medicines in the elderly			Clear and appropriate					
2.5 The guidelines should have a focus on the monitoring of medicines			Clear and appropriate					

in the elderly								
2.6 The guidelines should have a focus on managing inappropriate polypharmacy (the prescribing of too many medicines which are inappropriate or no longer indicated) in elderly patients with multi-morbidities			Appropriate but would be easier to read if reworded so that the definition is at the end. Also, using 'inappropriate' in both the term and its definition is unusual.					Reworded
2.7 The guidelines should have a focus on reviewing all medicines in elderly patients with multi-morbidities to promote appropriate polypharmacy (prescribing of many drugs but which are appropriate)			Clear and appropriate but, again, would it be possible to avoid using 'appropriate' in both the term and its definition?		Define appropriate polypharmacy?	Change drugs to medicines		Reworded
2.8 The guidelines should highlight high risk/potentially inappropriate medicines in the elderly			Clear and appropriate but would use a comma rather than '/'		There are two questions on one statement here?			Split into two statements
2.9 Consideration should be given to adapting for the UAE context defined lists of high risk/potentially inappropriate medicines in the elderly <sup>2</sup> , such as: i) Beers Criteria (potentially inappropriate medicines use in older adults) ii) STOPP Criteria (screening tool of potentially inappropriate prescribing) iii) IPET- Improving Prescribing in the Elderly Tool (commonly encountered drug-disease			Appropriate but would use a comma rather than '/' and also move 'for the UAE context' to after 'elderly <sup>2</sup> ' but before the comma.		Too lengthy??			Reworded

interactions, mostly focusing on cardiovascular and psychotropic drugs)								
2.10 Consideration should be given to adapting for the UAE context defined list of commonly omitted medicines in the elderly <sup>2</sup> , such as: i) START Criteria (screening tool to alert physicians to right treatment)			Appropriate but would move 'for the UAE context' to after 'elderly' but before the comma, also add 'a' before 'defined' and 'the' before 'right'.					Moved to 2.13
2.11 The guidelines should have a focus on identifying and managing adverse drug reactions in the elderly			Clear and appropriate					Moved to 2.12
2.12 Anticholinergic and sedative agents are problematic in the elderly			Clear and appropriate		Too bold a statement – define more of the drugs?			Deleted
2.13 Consideration should be given to using the Drug Burden Index <sup>3</sup> as a tool to quantify exposure to anticholinergic and sedative agents in the elderly			Clear and appropriate					Moved to 2.11
2.14 Consideration should be given to adopting validated measures of adherence <sup>4</sup> , such as: i) Morisky scale ii) Medication adherence questionnaire iii) Self-Efficacy for Appropriate Medication Use Scale			For consistency add 'for the UAE context' after 'adherence <sup>4</sup> '. I'm not familiar with all of these but think the full name (and correct spelling) of the Morisky			Morisky		Morisky

			Medication Adherence Scale (MMAS-8) should be listed, identify item ii more clearly and add acronym for SEAMS					
2.15 The guidelines should have a focus on adherence (or non-adherence) to medicines			Clear and appropriate					
2.16 Consideration should be given to adopting in the UAE evidence based approaches to guideline implementation			Appropriate but clearer if 'in the UAE' is moved to the end of the statement					Reworded
<b>3. Medicines Reconciliation</b>	Clear						Clear and appropriate	
3.1 The following definition of 'medicines reconciliation' should be adopted in the UAE - 'the process of identifying the most accurate list of a patient's current medicines – including the name, dosage, frequency and route – and comparing them to the current list in use, recognising and discrepancies, and documenting any changes, thus resulting in a complete list of medications, accurately communicated'			Clear and appropriate but would delete the quotes around medicines reconciliation and correct typo 'any discrepancies'. Should this be referenced?					the quotes around medicines review was deleted
3.2 Medicines reconciliation should be determined at the point of admitting all elderly patients to hospital			Clear and appropriate		And also at Discharge??			Reworded
3.3 Determination of medicines reconciliation can be undertaken by any health professional (nurse, pharmacist, physician)			If it is 'any health professional' shouldn't be followed by a	Not sure about use of the word "determination" in these		Take out examples.		Reworded

			restricted list	statements. Does it mean "deciding about" or "doing it themselves"? Could it be omitted?				
3.4 Determination of medicines reconciliation can be undertaken by any nurse			Clear and appropriate					
3.5 Determination of medicines reconciliation can be undertaken by any pharmacist			Clear and appropriate					
3.6 Determination of medicines reconciliation can be undertaken by any physician			Clear and appropriate					
3.7 Determination of medicines reconciliation should only be undertaken by a health professional trained in that role			Clear and appropriate					
3.8 Determination of medicines reconciliation in an elderly patient with dementia or other cognitive impairment requires specialist input			Clear and appropriate					
3.9 Any medicines related issues resulting from determination of medicines reconciliation should be recorded in the shared medical records			Clear and appropriate					
3.10 There is a need for a standard operating procedure to guide the determination of medicines reconciliation in elderly patients			Clear and appropriate					
3.11 There is a need to develop standardised documentation to record determination of medicines reconciliation in elderly patients			Clear and appropriate		Any electronic records??			
<b>4. Medicines Review</b>	Clear						Clear and appropriate	
4.1 The following definition of 'medicines review' should be adopted in the UAE - 'a structured, critical examination of the complete list of a patient's medicines with the			Clear and appropriate but would delete the quotes					the quotes around medicines review was deleted

objective of reaching an agreement with the patient about treatment, optimising the impact of medicines, minimising the number of medication-related problems and reducing waste'			around medicines review. Should this be referenced?					
4.2 All elderly patients with multi-morbidities should have a full medicines review during stay in hospital to promote appropriate polypharmacy			Clear and appropriate but add 'their' before 'stay'					'their' before 'stay'
4.3 Only elderly patients admitted with a medicines related issue should have a full medicines review during stay in hospital to promote appropriate polypharmacy			Clear and appropriate but add 'their' before 'stay'					'their' before 'stay'
4.4 A full medicines review can be undertaken by any health professional (nurse, pharmacist, physician)			If it is 'any health professional' shouldn't be followed by a restricted list			Removes examples.		Reworded
4.5 A full medicines review can be undertaken by any nurse			Clear and appropriate					
4.6 A full medicines review can be undertaken by any pharmacist			Clear and appropriate					
4.7 A full medicines review can be undertaken by any physician			Clear and appropriate					
4.8 A full medicines review should only be undertaken by a health professional trained in that role			Clear and appropriate					
4.9 A full medicines review in an elderly patient with dementia or other cognitive impairment requires specialist input			Clear and appropriate					
4.10 Any medicines related issues resulting from a full medicines review should be recorded in the shared medical records			Clear and appropriate					
4.11 There is a need for a standard operating procedure to guide the conduct of a full medicines review in elderly patients			Clear and appropriate					
4.12 There is a need to develop standardised documentation to			Clear and appropriate		To include any			

record a full medicines review in elderly patients					electronic prescribing?			
4.13 A multi-disciplinary ward team (specifically nurses, pharmacists and physicians) should review the medicines prescribed to elderly patients on a regular basis during stay in hospital			Clear and appropriate but add 'their' before 'stay'		Define regular?			'their' before 'stay'
4.14 All medicines prescribed to elderly patients during stay in hospital should be reviewed prior to discharge			Clear and appropriate but add 'their' before 'stay'					'their' before 'stay'
4.15 The standard operating procedure should include providing information to health professionals (family doctor, nurse, pharmacist) working in primary care informing them of the nature of any changes made to medicines during stay and any follow-up required			Clear and appropriate					
<b>5. Medicines Adherence</b>	Clear						Clear and appropriate	
5.1 The following definition of 'medicines adherence' should be adopted in the UAE - 'the extent to which patients take medications as prescribed by their health care providers'			Clear and appropriate but would delete the quotes around medicines adherence. Should this be referenced?					the quotes around medicines adherence was deleted
5.2 Adherence (or non-adherence) to all medicines should be determined at the point of admitting all elderly patients to hospital			Clear and appropriate		And also at discharge?			
5.3 Determination of adherence (or non-adherence) can be undertaken by any health professional (nurse, pharmacist, physician)			If it is 'any health professional' shouldn't be followed by a restricted list		Would "finding out about" be better than "determination"?	Removes examples.		Reworded
5.4 Determination of adherence (or			Clear and					



non-adherence) can be undertaken by any nurse			appropriate					
5.5 Determination of adherence (or non-adherence) can be undertaken by any pharmacist			Clear and appropriate					
5.6 Determination of adherence (or non-adherence) can be undertaken by any physician			Clear and appropriate					
5.7 Determination of adherence (or non-adherence) should only be undertaken by a health professional trained in that role			Clear and appropriate					
5.8 Determination of adherence (or non-adherence) in an elderly patient with dementia or other cognitive impairment requires specialist input			Clear and appropriate					
5.9 Any medicines related issues resulting from determination of adherence should be recorded in the shared medical records			Clear and appropriate					
5.10 There is a need for a standard operating procedure to guide the determination of adherence (or non-adherence) in elderly patients			Clear and appropriate					
5.11 There is a need to develop standardised documentation to record determination of adherence (or non-adherence) in elderly patients			Clear and appropriate					
<b>6. Medicines Counselling</b>	Clear							
6.1 The following definition of 'medicines counselling' should be adopted in the UAE - 'provision of advice and instruction by a health care professional to patients regarding the use of their medicines'			Clear and appropriate but would delete the quotes around medicines counselling. Should this be referenced?	A very strange definition indeed. Counselling first involves listening. This seems a totally health professional dominated agenda. What about the idea of concordance?	Regarding the APPROPRIATE use of their medicines?			Reworded

6.2 All elderly patients should be counselled on their medicines prior to discharge			Clear and appropriate		Needs to take more account of therapeutic partnerships with the prescriber and the patient and the healthcare professionals ?			
6.3 Only elderly patients identified as non-adherent/ potentially non-adherent should be targeted for counselling on their medicines prior to discharge			Clear and appropriate					
6.4 Only elderly patients commenced new medicines or having a change in medicines should be targeted for counselling on their medicines prior to discharge			Appropriate but should it be 'commenced <b>on</b> ' or perhaps 'started on'?					
6.5 Medicines counselling can be undertaken by any health professional (nurse, pharmacist, physician)			If it is 'any health professional' shouldn't be followed by a restricted list			Removes examples.		Reworded
6.6 Medicines counselling can be undertaken by any nurse			Clear and appropriate					
6.7 Medicines counselling can be undertaken by any pharmacist			Clear and appropriate					
6.8 Medicines counselling can be undertaken by any physician			Clear and appropriate					
6.9 Medicines counselling should only be undertaken by a health professional trained in that role			Clear and appropriate					
6.10 Medicines counselling in an elderly patient with dementia or other cognitive impairment requires specialist input			Clear and appropriate					
6.11 Medicines counselling should			Think if you		To use where			"where

always involve the elderly patient's family/carers/friends where possible			say 'always' should delete 'where possible'		appropriate instead of where possible?			appropriate" instead of "where possible"
6.12 Counselling should focus on elderly patients' beliefs, intentions, and values relating to medicines to encourage behavioural and lifestyle changes			Clear and appropriate but delete comma after 'intentions'	Probably the most important of all your statements as far as I am concerned, but why is there an assumption that there is something wrong that they need to change? Why can't you have a statement that just pledges that pharmacists will listen to what is important in people's lives that influences what medicines they take, how and why? Until you do that I don't think you will ever understand why so many people don't behave as health professionals				

				think they should.				
6.13 There is a need for a standard operating procedure to guide medicines counselling in elderly patients			Clear and appropriate					
6.14 The standard operating procedure should include providing information to health professionals (family doctor, nurse, pharmacist) working in primary care informing them of the nature of any counselling provided prior to discharge and any follow-up support required			Clear and appropriate					
6.15 There is a need to develop standardised documentation to record counselling in elderly patients			Clear and appropriate					
6.16 There is potential to include medicines counselling programmes or group sessions as part of out-patient care			Clear and appropriate		Not clear – needs to be reworded?			Deleted
<b>7. Health Professional Training</b>	Clear							
7.1 All health professionals working with medicines in the elderly should receive regular, ongoing training relating to medicines management			Clear and appropriate					
7.2 Training should focus on patient involvement in decision making			Clear and appropriate					
7.3 Training should focus on aspects of cultural diversity			Clear and appropriate					
<b>8. Evaluation Research</b>								
8.1 Consideration should be given to developing a research programme to evaluate the implementation of the guidelines			Clear and appropriate but add 'in the UAE'		These Guidelines?			These guidelines
8.2 Evaluation should consider the perspectives of all stakeholders, including patients			Clear and appropriate					

#### 5.2.4.1 Rating of statements

Each Delphi statement was rated on the following six point rating scale:

- 1. Strongly disagree**
- 2. Disagree**
- 3. Somewhat disagree**
- 4. Somewhat agree**
- 5. Agree**
- 6. Strongly agree**

This Likert Scale had no central or neutral point so that the expert had to rate whether he/she was in agreement or disagreement.

#### 5.2.4.2 Determining consensus

There is no individual approach consistently used for determining the point of consensus in Delphi studies, and most use either subjective criteria or descriptive statistics. In a review paper, Heiko (2012) describes a number of different approaches, which are summarised in Table 5.2. (adapted from Heiko 2012).

Table 5.2: Approaches to consensus measurement (adapted from Heiko 2012)

<b><u>Measurements of consensus</u></b>	<b><u>Criteria</u></b>
<b>Stipulated number of rounds</b>	<i>"Research indicated that three iterations are typically sufficient to identify points of consensus...Thus, three rounds were used in this study."</i> (Fan and Cheng 2006)
<b>Subjective analysis</b>	<i>"Overall, it was felt that a third round of the study would not add to the understanding provided by the first two rounds and thus the study was concluded."</i> (MacCarthy and Atthirawong 2003)
<b>Certain level of agreement</b>	<i>"Consensus was achieved on an item if at least 60% of the respondents were in agreement and the composite score fell in the "agree" or "disagree" range." (on a 5 point Likert scale)</i> (Seagle and Iverson 2001)
<b>APMO Cut-off Rate (average percent of majority opinions)</b>	APMO is based on the sum up of the majority (defined as a percentage above 50%) of agreements and disagreements divided by the total number of opinions expressed. (Cottam, Roe and Challacombe 2004) calculate an APMO Cut-off Rate of 69.7%, thus, questions having an agreement level below this rate have not reached consensus and are included in the next round.
<b>Mode, mean/median ratings and rankings, standard deviation</b>	<i>"In our case, mode was used as an enumeration of respondents who had given 75% or more probability for a particular event to happen. If this value was above 50% of the total respondents, then consensus was assumed."</i> (Chakravarti et al. 1998)
<b>Interquartile range (IQR)</b>	<i>"Consensus was obtained, if the IQR was 1 or below on a 7-point Likert scale"</i> (De Vet et al. 2005)
<b>Coefficient of variation</b>	<i>"A consistent decrease of the coefficients of variation between the first and the second round indicated an increase in consensus (greater movement toward the mean)." (Buck et al. 1993)</i>
<b>Post-group consensus</b>	<i>"Post-group consensus concerns the extent to which individuals – after the Delphi process has been completed – individually agree with the final group aggregate, their own final round estimates, or the estimates of other panelists."</i> (Rowe and Wright 1999)

The three most widely approaches are: subjective analysis by the researchers; average percent of majority opinions cut-off rate; and certain level of agreement.

The approach used in this study was 'certain level of agreement'. While Powell (2003) highlights that there is no set standard for the level of agreement, Heiko (2012) notes that a cut off point of 70% agreement is commonly employed.

In this study, consensus to an individual statement was deemed to have been achieved if 70% or more experts agreed or strongly agreed.

#### 5.2.4.3 Panel of experts

In any Delphi study, the careful selection of participants as 'expert panel members' is an essential step to providing high quality, robust and valid data. Hanley *et al.* (2004) define three types of panelists: the stakeholders, the experts and the facilitators. Elwyn *et al.* (2006) describe four types: decision aid developers and researchers, policy makers, health practitioners and patients. Delbecq, Van de Ven, Andrew H and Gustafson (1975) describe in detail three roles of panellists which should be represented as

1. top management decision makers who will utilize the outcomes of the Delphi study
2. professional staff together with their support team
3. the experts to the Delphi questionnaire whose judgments are being sought

#### Defining an 'expert'

A dictionary definition of an 'expert' is, 'a person who is very knowledgeable about or skilful in a particular area'. (Soanes 2003) Several papers on the use

of the Delphi technique have described characteristics which experts should possess as being knowledge, experience and ability to influence policy (Cantrill, Sibbald and Buetow 1996, Crisp *et al.* 1999, Keeney, Hasson and McKenna 2001, Mead and Moseley 2001, Kennedy 2004). Mead and Moseley (2001) state that experts can be defined in many ways, for example their public acknowledgement or position in a hierarchy or as recommended by other participants in a study. Crisp *et al.* (1999) suggest that the use of the word 'expert' can be changed to 'informed advocates', as it is more appropriate. A critical review of the Delphi technique by Keeney, Hasson and McKenna (2001) quote a variety of definitions of 'expert' including 'informed individual', 'specialist in the field' or 'someone who has knowledge about a specific subject'.

## 1. Knowledge

There are several approaches to identifying knowledge, such as possessing professional qualifications or being registered with professional bodies or statutory regulators. Several authors use the term 'professional qualification' within their definition of 'expertise' (Williams and Webb 1994, Hardy *et al.* 2004)

Keeney, Hasson and McKenna (2001) however, comment that using knowledge alone to define and identify 'experts' may be limited, suggesting that knowledge does not necessarily equate to expertise. Knowledge can be verified in ways other than a professional qualification, for example, possessing a higher degree in a specific area may increase the credibility of an expert.

## 2. Experience

A predetermined level of experience may reflect a certain level of expertise and while this may be connected with a professional qualification (knowledge), the two are not necessarily interlinked (Jeffery, Ann Ley, Ian Bennun, Stuart McLaren, David 2000, Hardy *et al.* 2004).

Again, caution is required as Hardy *et al.* (2004) suggest that it is weak to



consider an individual to be an expert by a certain number of years of experience and that consideration still needs to be given to whether the individual will possess the required knowledge, attitude and skills.

### 3. Policy influence

Several articles recommend the need to consider those holding positions at strategic and operational levels within key organisations (Graham, Regehr and Wright 2003, Kennedy 2004)

#### Homogenous or heterogeneous

Many researchers Mead and Moseley (2001), Mullen (2003), Powell (2003), Hardy *et al.* (2004) have all recommended the need for heterogeneity of experts, including those from diverse settings, in an attempt to increase the validity of the findings. Mead and Moseley (2001) suggest that study findings must be meaningful if heterogeneous experts agree.

#### Number of experts

There is no clear guidance on the number of panel experts. Delbecq, Van de Ven, Andrew H and Gustafson (1975) recommend that the study population be as small as possible, giving reasons of convenience for follow-up. Several papers on the use of the Delphi technique have described the most reliable samples for Delphi should be small (<20 experts). (Jeffery, Ann Ley, Ian Bennun, Stuart McLaren, David 2000, Phillips 2000, Mullen 2003)

In this study, careful attention was paid to the selection and number of expert panel members. (Sumsion 1998) notes that '... there is no ready answer and it becomes the responsibility of each researcher to choose the most appropriate group of experts and defend that choice.'

#### 5.2.4.4 Recruitment of experts

The key stakeholders in Abu Dhabi in this study were identified as potential experts and constituted the sampling frame

- senior doctors working within the geriatric speciality, or those with ten years or more experience in managing elderly patients
- Director or Managers of a hospital department of pharmacy
- Directors or Managers of a hospital department of nursing
- chief health professionals (doctors, nurses, pharmacists) holding strategic positions within HAAD
- chief policy makers working either in hospitals or HAAD
- chief social workers working either in hospitals or HAAD
- Senior educators or researchers in Al Ain Medical School working in fields relating to medicines management

This sampling frame was estimated to be around 75 health professionals and 25 other professionals.

INVOLVE (Hanley *et al.* 2004) is a UK national advisory group, funded by the National Institute for Health Research (NIHR), that encourages and supports active public involvement in NHS, public health, and social care. INVOLVE defines users as “the public,” or “people who use services”.

While best practice in the UK would be to include expert patients, the position in the UAE is very different in terms of patient involvement. Expert patient programmes had not yet been established, and the patient’s voice is commonly provided from the perspective of healthcare professionals or social workers. Patients were therefore not being included as expert panel members for this study.

The process of the recruitment of the experts is illustrated in Figure 5.1. This involved face to face meetings with key individuals and organisations at distant sites in Abu Dhabi.

Informed consent (Appendix 5.2) was obtained from each expert by email once they had accepted the invitation to participate in the Delphi method.

At the time of study commencement, each expert was sent an email with a link to the online survey tool which had been formatted using SNAP 10 (See Appendix 5.3). This is an integrated software package used to design surveys for either printing or for publishing on the web. Data generated from online surveys using SNAP can be transferred directly into SPSS® for data analysis (Directorate of Information technology, University of Aberdeen, 2007).

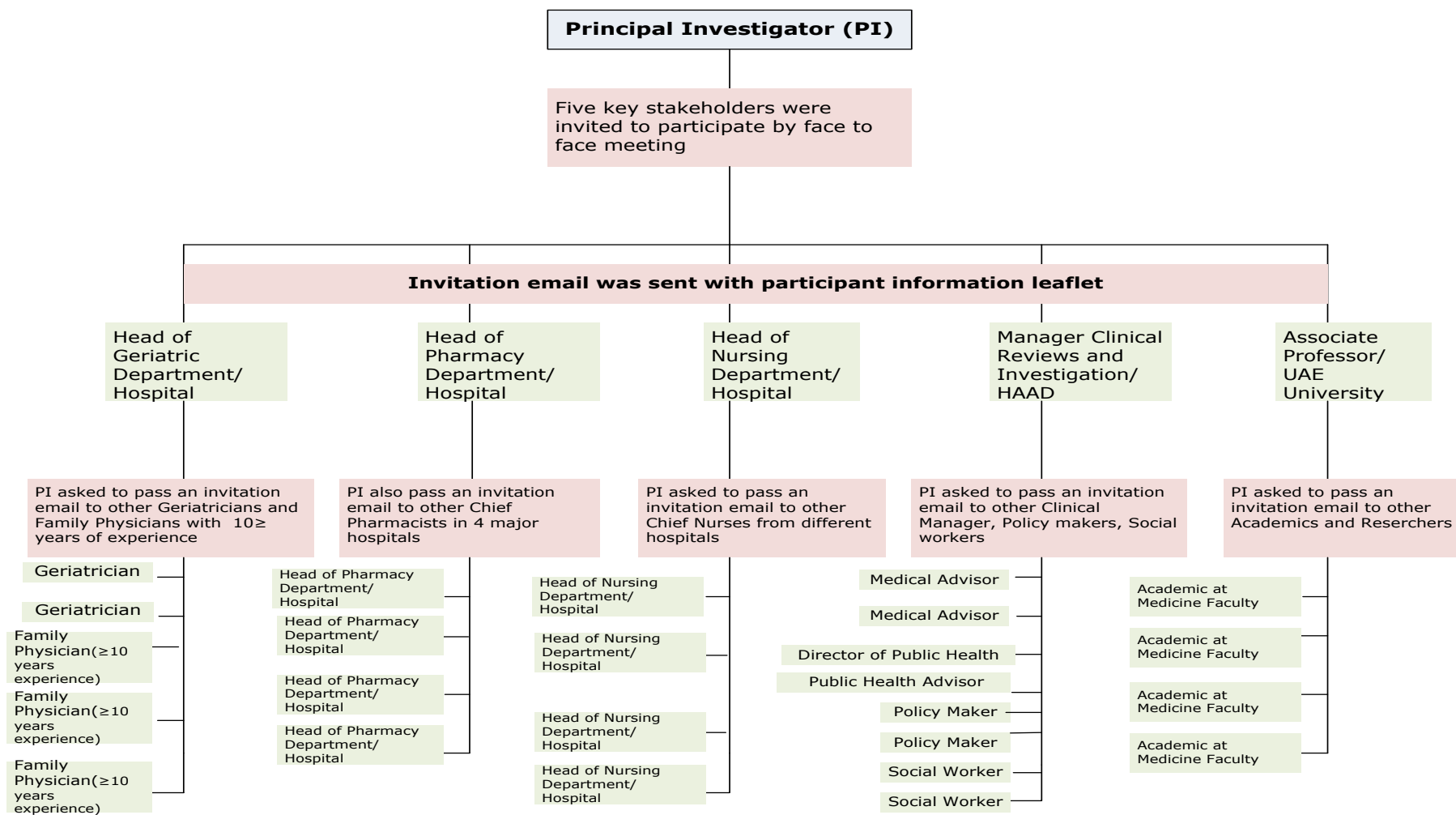


Figure 5.1: the process of expert panel member recruitment (n=30)

#### 5.2.4.5 Delphi round 1

The round 1 survey was structured into eight sections covering key elements of the medicines management, each with several statements. Experts were requested to rate their levels of agreement or disagreement with each statement on a 6-point Likert scale (strongly disagree, disagree, somewhat disagree, somewhat agree, agree, strongly agree). A comments box was included for each statements, allowing experts to comment, justify their responses and propose new statements. A three week deadline was given for completion and return of round 1.

##### 5.2.4.5.1 Analysis of round 1 responses

Descriptive statistics (frequencies and percentages) were used to analyse responses. Content analysis was undertaken for textual responses to identify any key emerging themes.

Following analysis, each expert was provided with the summary responses for each statement and the verbatim experts' comments for each statement. Comments from the research team were also provided.

#### 5.2.4.6 Delphi round 2

In addition to providing round 1 responses (see later), the second round provided an opportunity to gathering experts' views and experiences of the Delphi approach and its potential uses in the UAE and beyond (the secondary research objectives).

A separate survey tool was developed, consisting of a series of statement to be rated using a semantic differential scale. Verhagen, van Den Hooff and Meents (2015) stated that this scale requires 'careful consideration of the research context in terms of whether the selected bipolar scales fit the concept being

judged (i.e. concept delineation) and the subject group being used (i.e., population specification)'. Semantic differential scales had been used to measure the meaning of concepts in related areas of I information systems planning (Doherty, Marples and Suhaimi 1999), information technology (Bhattacharjee and Premkumar 2004), website performance (Huang 2005), information systems satisfaction (Xue, Liang and Wu 2011) and perceived enjoyment (Luo, Chea and Chen 2011). The scale was devised using opposite-meaning statements at each pole relating to Delphi participants' views of their involvement in the consensus study (see table 5.4). The statements were reviewed at meetings of the research supervisory team. A three week deadline was given to panellists for completion of round 2.

#### 5.2.4.6.1 Analysis of round 2

Descriptive analysis was used to analyse all responses. Median and interquartile range (IQR) were calculated to describe the mid point and range of scores (Agresti 2013).

#### 5.2.5 Promoting quality in research: validity and reliability

Steps were taken to enhance the robustness in terms of the validity and reliability of the research at all stages, as described in chapter 2.

- the draft statements of Delphi method was reviewed by academics and practitioners independent of the research team
- heterogeneous members were invited to the study which included those from diverse settings (Mead and Moseley 2001)
- a clearly described sampling strategy was described
- all participants were given the opportunity to review and comment on the statements
- analysis was independently reviewed by the supervisory team

## **5.3 Results**

### 5.3.1 Panel of experts

Out of the original 30 experts invited to participate, 26 consented: three geriatricians, two family physicians, five directors of pharmacy departments, three directors of nursing departments, five senior academics and eight key HAAD professionals (three key medical officers, one director of public health, two policy makers and two social workers). The panel composition is summarised in Table 5.3

Table 5.3: Composition of the panel of experts (n= 26)

<b>Panel of experts</b>	<b>Male</b>	<b>Female</b>	<b>Total</b>
<b><u>Academics</u></b>			
• Physician	1	1	2
• Pharmacist	2	1	3
• Nurse	0	0	0
<b><u>Health Professionals</u></b>			
(working in hospitals)			
• Physician	3	2	5
• Pharmacist	4	1	5
• Nurse	0	3	3
<b><u>Health Professionals and other Professionals</u></b>			
(working in HAAD)			
• Physician	1	1	2
• Pharmacist	1	0	1
• Nurse	0	0	0
• Others	2	3	5
<b>Total</b>	<b>14</b>	<b>12</b>	<b>26</b>



### 5.3.2 Round 1 Delphi technique

This section provides the levels of consensus of experts around each statement, separated into eight different sections. Verbatim comments are given for each statement; content analysis was not undertaken due to the relatively low number of comments. Given the anonymous nature of the Delphi, the responses and comments could not be attributed to an individual expert.

#### 5.3.2.1 General Statements

1. The following definition of medicines management should be adopted in the UAE - 'the clinical, safe and cost effective use of medicines to ensure patients get the maximum benefit from the medicines they need, while at the same time minimizing potential harm'

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
4	-	-	-	6	16

Consensus reached (84%)

Verbatim comments:

- a general method is in place but not for above 60 years
- it covers all the requirements
- should be adopted because most of the time the availability, selection and more specifically administration of medicines to elderly affect outcome significantly

2. Elderly patients with multi-morbidities are at particular risk of medicines related issues

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
2	-	-	-	7	17

### Consensus reached (92%)

Verbatim comments:

- drug interactions are high in elderly because of polypharmacy, and altered pharmacodynamics in the elderly
- patients with dementia, A-fibrillation, Heart failure are usually candidate for polypharmacy and hence increased risk of medicine related issues

3. Medicines management should be a focus in the care of every elderly patient admitted to hospital, irrespective of the reason for admission or presenting complaint

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
2	-	-	1	7	16

### Consensus reached (92%)

Verbatim comments:

- medication reconciliation and review of patient medications for any actual and potential side effects should be given high priority in causing mental status changes, electrolyte imbalance and renal functions deterioration

4. Medicines management should be a focus in the care of every elderly patient admitted to hospital, irrespective of the admitting ward or speciality

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
2	-	-	-	8	16

Consensus reached (92%)

5. Medicines management should be a focus in the care of elderly patient admitted to hospital, irrespective of the duration of stay in hospital

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
2	-	-	3	7	14

Consensus reached (92%)

Verbatim comments:

- but those should be categorise to high risk elderly patients

6. Medicines management should only be a focus in the care of elderly patients admitted to hospital with a medicines related issue

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
10	5	-	2	5	4

Consensus **not** reached (34%)

Verbatim comments:

- medication review and management should be applied to every elderly admitted to the hospital regardless the diagnosis
- should focus on elderly in the primary healthcare first

7. Medicines management is the responsibility of all nurses, pharmacists and physicians

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
1	-	-	3	3	19

Consensus reached (84%)

8. All nurses, pharmacists, physicians should be competent in medicines management

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
1	-	-	1	9	15

Consensus reached (92%)

Verbatim comments:
- team work...but not entering the fields of expertise and interfering
- should be competent in elderly management

9. Evidence based recommendations which focus on single disease states should be applied with caution in elderly patients with multi-morbidities

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
1	-	-	1	8	16

Consensus reached (92%)

In summary:

Section 1: consensus achieved for eight statements.

Consensus not achieved for statement 1.6, that medicines management is a focus for those with medicines related issues BUT reached consensus on 1.3, that it is a focus for every elderly patient.

### 5.3.2.2 Guidelines for Medicines Management in Elderly Hospitalised Patients

1. There is a need to develop guidelines for medicines management in elderly hospitalised patients in the UAE

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
2	-	-	1	7	16

Consensus reached (88%)

Verbatim comments:

- currently no guidelines
- medication errors can arise from lack of such guidelines or not applying the existing ones
- but not leave patient untreated because of guideline

2. A guideline development group should be established, under the auspices of Health Authority of Abu Dhabi (HAAD), with representation from experts in medicines in the elderly

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
2	-	1	1	9	13

Consensus reached (84%)

Verbatim comments:

- include: MOH / Dubai health authority
- i agree with this plan, but I am not sure if HAAD is the only regulatory authority

3. The guidelines should have a focus on medicines reconciliation at the point of admitting and discharging elderly patients to hospital

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
2	-	-	1	8	15

Consensus reached (88%)

4. The guidelines should have a focus on the prescribing of medicines in the elderly

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
2	-	-	-	11	13

Consensus reached (92%)

5. The guidelines should have a focus on the monitoring of medicines in the elderly

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
1	-	-	-	10	15

Consensus reached (96%)

6. The guidelines should have a focus on managing inappropriate polypharmacy in elderly patients with multi-morbidities. (Inappropriate polypharmacy is

defined as 'the prescribing of too many medicines which are unsuitable or no longer indicated')

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
1	1	-	-	10	14

Consensus reached (92%)

Verbatim comments:

- check interactions and find suitable solutions always
- we noticed many geriatric patients taking more than 15 medications

7. The guidelines should have a focus on reviewing all medicines in elderly patients with multi-morbidities to promote appropriate polypharmacy (Appropriate polypharmacy is 'prescribing of many medicines but which are suitable')

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
-	-	-	-	9	17

Consensus reached (100%)

8. The guidelines should highlight high risk medicines in the elderly

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
1	-	-	-	7	18

Consensus reached (96%)

Verbatim comments:

- especially with medications with narrow therapeutic index and anti-cholinergic properties as they are troublesome

9. The guidelines should highlight potentially inappropriate medicines in the elderly

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
1	1	-	1	6	16

Consensus reached (84%)

10. Consideration should be given to adapting defined lists of high risk or potentially inappropriate medicines in the elderly,<sup>2</sup> for the UAE context, such as:

- Beers Criteria (potentially inappropriate medicines use in older adults)
- STOPP Criteria (screening tool of potentially inappropriate prescribing)
- IPET- Improving Prescribing in the Elderly Tool (commonly encountered drug-disease interactions, mostly focusing on cardiovascular and psychotropic drugs)

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
1	-	1	-	12	12

Consensus reached (92%)

Verbatim comments:

- I have no experience of validity of those criteria!

11. Consideration should be given to using the Drug Burden Index as a tool to quantify exposure to anticholinergic and sedative agents in the elderly



Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
1	-	-	2	12	11

Consensus reached (88%)

Verbatim comments:

- not sure of the impact

12.The guidelines should have a focus on identifying and managing adverse drug reactions in the elderly

Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
1	-	1	1	9	14

Consensus reached (88%)

13.Consideration should be given to adapting defined list of commonly omitted medicines in the elderly, for the UAE context, such as:

- START Criteria (screening tool to alert physicians to right treatment)

Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
1	1	-	4	7	13

Consensus reached (76%)

14.Consideration should be given to adopting validated measures of adherence, such as:

- Morisky scale
- Medication adherence questionnaire
- Self-Efficacy for Appropriate Medication Use Scale

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
-	1	-	4	7	14

Consensus reached (80%)

Verbatim comments:
- adherence is a major issue in the UAE not only for the elderly
- I am not familiar with these scales

15.The guidelines should have a focus on adherence (or non-adherence) to medicines

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
1	1	-	3	10	11

Consensus reached (80%)

16.Consideration should be given to adopting evidence based approaches to guideline implementation in the UAE

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
-	-	-	2	10	14

Consensus reached (92%)

In summary:

Section 2: consensus achieved for all statements.

### 5.3.2.3 Medicines Reconciliation

1. The following definition of medicines reconciliation should be adopted in the UAE - 'the process of identifying the most accurate list of a patient's current medicines – including the name, dosage, frequency and route – and comparing them to the current list in use, recognizing and discrepancies, and documenting any changes, thus resulting in a complete list of medications, accurately communicated'

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
1	-	-	2	11	12

Consensus reached (88%)

Verbatim comments:

- the max dose of medications for elderly - the starting dose
- we find few patients are taking medications from same Pharmacological group as brand names are different. So medication reconciliation is particularly important

2. Medicines reconciliation should be determined at the point of admission to and discharge from hospital

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
1	-	-	-	9	16

Consensus reached (96%)

Verbatim comments:

- also between services if the patient has been transferred from one department to another

3. Determination of medicines reconciliation can be undertaken by any nurse, pharmacist, physician

Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
1	5	4	7	5	4

Consensus **not** reached (34%)

<p>Verbatim comments:</p> <ul style="list-style-type: none"> <li>- not the nurse - it might be difficult for them to know the drug names</li> <li>- Physician and Pharmacist should only be involved</li> <li>- all together not separately</li> <li>- nurses are not prescribers in this country</li> <li>- guided by policy and medication reconciliation verified by the Clinical Pharmacist</li> </ul>
--

4. Determination of medicines reconciliation can be undertaken by any nurse

Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
5	6	6	5	2	2

Consensus **not** reached (15%)

<p>Verbatim comments:</p> <ul style="list-style-type: none"> <li>- as long as this is guided by policy</li> </ul>
---

5. Determination of medicines reconciliation can be undertaken by any pharmacist

Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
1	3	3	7	6	6

Consensus **not** reached (46%)

6. Determination of medicines reconciliation can be undertaken by any physician

Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
1	3	3	4	8	7

Consensus **not** reached (57%)

7. Determination of medicines reconciliation should only be undertaken by a health professional trained in that role

Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
-	2	3	2	9	10

Consensus reached (73%)

8. Determination of medicines reconciliation in an elderly patient with dementia or other cognitive impairment requires specialist input

Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
-	1	-	1	12	12

Consensus reached (92%)

9. Any medicines related issues resulting from determination of medicines reconciliation should be recorded in the shared medical records

Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
-	-	-	2	9	15

Consensus reached (92%)

10. There is a need for a standard operating procedure to guide the determination of medicines reconciliation in elderly patients

Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
1	-	1	-	9	15

Consensus reached (92%)

11. There is a need to develop standardised documentation to record determination of medicines reconciliation in elderly patients

Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
-	2	-	-	7	17

Consensus reached (92%)

In summary:

Section 3: consensus achieved for seven statements.

Consensus not achieved for statements 3.3, 3.4, 3.5 and 3.6, that determination of medicines reconciliation can be undertaken by any nurse or any pharmacist or any physician BUT reached consensus on 3.7, that it should only be undertaken by a health professional trained in that role.

#### 5.3.2.4 Medicines Review

- The following definition of medicines review should be adopted in the UAE - 'a structured, critical examination of the complete list of a patient's medicines with the objective of reaching an agreement with the patient about treatment, optimising the impact of medicines, minimising the number of medication-related problems and reducing waste'

Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
-	-	1	1	16	8

Consensus reached (92%)

2. All elderly patients with multi-morbidities should have a full medicines review during their stay in hospital to promote appropriate polypharmacy

Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
-	1	-	2	8	15

Consensus reached (88%)

3. Only elderly patients admitted with a medicines related issue should have a full medicines review during their stay in hospital to promote appropriate polypharmacy

Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
6	5	5	2	6	2

Consensus **not** reached (30%)

4. A full medicines review can be undertaken by any nurse, pharmacist, physician

Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
3	8	5	1	6	3

Consensus **not** reached (34%)

5. A full medicines review can be undertaken by any nurse

Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
10	3	10	-	3	-

Consensus **not** reached (11%)

6. A full medicines review can be undertaken by any pharmacist

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
2	5	2	5	4	8

Consensus **not** reached (46%)

Verbatim comments: - In elderly, you need expert clinical pharmacist
---

7. A full medicines review can be undertaken by any physician

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
2	3	3	4	9	5

Consensus **not** reached (54%)

8. A full medicines review should only be undertaken by a health professional trained in that role

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
2	1	1	3	7	12

Consensus reached (73%)

9. A full medicines review in an elderly patient with dementia or other cognitive impairment requires specialist input

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
1	1	1	-	9	14

Consensus reached (88%)



10. Any medicines related issues resulting from a full medicines review should be recorded in the shared medical records

Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
-	1	1	-	8	16

Consensus reached (92%)

Verbatim comments:

- should be discussed during multidisciplinary meeting for the patients

11. There is a need for a standard operating procedure to guide the conduct of a full medicines review in elderly patients

Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
-	-	1	-	10	15

Consensus reached (96%)

12. There is a need to develop standardised documentation to record a full medicines review in elderly patients

Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
-	-	1	1	8	16

Consensus reached (92%)

13. A multi-disciplinary ward team (specifically nurses, pharmacists and physicians) should review the medicines prescribed to elderly patients on a regular basis during their stay in hospital

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
-	-	1	3	6	16

Consensus reached (84%)

14.All medicines prescribed to elderly patients during stay in hospital should be reviewed prior to their discharge

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
-	-	1	-	9	16

Consensus reached (96%)

15.The standard operating procedure should include providing information to health professionals (family doctor, nurse, pharmacist) working in primary care informing them of the nature of any changes made to medicines during stay and any follow-up required

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
-	-	1	-	9	16

Consensus reached (96%)

Verbatim comments:

- this is mostly not applied and lead to repetition of the problem

In summary:

Section 4: consensus achieved for 10 statements.

Consensus not achieved for statement 4.3, that only elderly patients admitted with a medicines related issue should have a full medicines review BUT reached consensus on 4.2, that all elderly patients with multi-morbidities should have a full medicines review.

Consensus not achieved for statements 4.4, 4.5, 4.6 and 4.7, that a full medicines review can be undertaken by any nurse or any pharmacist or any physician BUT reached consensus on 4.8, that It should only be undertaken by a health professional trained in that role.

#### 5.3.2.5 Medicines Adherence

1. The following definition of medicines adherence should be adopted in the UAE - 'the extent to which patients take medicines as prescribed by their health care providers'

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
1	-	-	1	13	11

Consensus reached (92%)

2. Adherence (or non-adherence) to all medicines should be determined at the point of admitting all elderly patients to hospital

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
2	1	-	4	9	10

Consensus reached (73%)

Verbatim comments:

- during each visit to the clinic
- may not be possible to determine this on admission
- 

3. Determination of adherence (or non-adherence) can be undertaken by any nurse, pharmacist, physician

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
1	4	3	8	6	4

Consensus **not** reached (38%)

Verbatim comments:

- pharmacist is the best to do it

4. Determination of adherence (or non-adherence) can be undertaken by any nurse

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
3	5	1	10	6	1

Consensus **not** reached (27%)

5. Determination of adherence (or non-adherence) can be undertaken by any pharmacist

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
1	2	2	5	9	7

Consensus **not** reached (62%)

6. Determination of adherence (or non-adherence) can be undertaken by any physician

Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
2	2	1	5	11	5

Consensus **not** reached (62%)

7. Determination of adherence (or non-adherence) should only be undertaken by a health professional trained in that role

Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
2	1	1	1	14	7

Consensus reached (80%)

8. Determination of adherence (or non-adherence) in an elderly patient with dementia or other cognitive impairment requires specialist input

Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
1	-	2	3	9	11

Consensus reached (76%)

9. Any medicines related issues resulting from determination of adherence should be recorded in the shared medical records

Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
-	-	1	-	11	14

Consensus reached (96%)

10. There is a need for a standard operating procedure to guide the determination of adherence (or non-adherence) in elderly patients

Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
1	-	3	1	6	15

Consensus reached (80%)

11. There is a need to develop standardised documentation to record determination of adherence (or non-adherence) in elderly patients

Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
1	-	2	-	7	16

Consensus reached (88%)

In summary:

Section 5: consensus achieved for seven statements.

Consensus not achieved for statements 5.3, 5.4, 5.5 and 5.6, that determination of adherence can be undertaken by any nurse or any pharmacist or any physician BUT reached consensus on 5.7, that It should only be undertaken by a health professional trained in that role.

### 5.3.2.6 Medicines Counselling

1. The following definition of medicines counselling should be adopted in the UAE - 'provision of advice and instruction by a health care professional to patients regarding the appropriate use of their medicines'

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
1	-	1	1	8	15

Consensus reached (88%)

2. All elderly patients should be counselled on their medicines prior to discharge

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
-	-	1	-	8	17

Consensus reached (96%)

3. Only elderly patients identified as non-adherent/ potentially non-adherent should be targeted for counselling on their medicines prior to discharge

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
4	7	4	1	5	5

Consensus **not** reached (38%)

Verbatim comments:

- every single patient of any age or case must have counselling prior to discharge

4. Only elderly patients commenced new medicines or having a change in medicines should be targeted for counselling on their medicines prior to discharge

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
5	8	2	2	8	1

Consensus **not** reached (34%)

Verbatim comments:

- all elderly should be targeted
- all patient and sometimes reinforcement needed
- medication counselling should be done on regular basis

5. Medicines counselling can be undertaken by any nurse, pharmacist, physician

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
5	6	4	4	5	2

Consensus **not** reached (26%)

6. Medicines counselling can be undertaken by any nurse

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
6	8	7	3	1	1

Consensus **not** reached (7%)

7. Medicines counselling can be undertaken by any pharmacist

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
2	2	2	5	6	9

Consensus **not** reached (57%)

8. Medicines counselling can be undertaken by any physician



<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
2	6	1	5	8	4

Consensus **not** reached (46%)

9. Medicines counselling should only be undertaken by a health professional trained in that role

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
2	1	1	3	9	10

Consensus reached (73%)

Verbatim comments:

- only pharmacist who is an expert in that field

10. Medicines counselling in an elderly patient with dementia or other cognitive impairment requires specialist input

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
-	-	1	2	11	12

Consensus reached (88%)

11. Medicines counselling should always involve the elderly patient's family/carers/friends where appropriate

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
1	-	1	1	7	16

Consensus reached (88%)

12. Counselling should focus on elderly patients' beliefs, intentions and values relating to medicines to encourage behavioural and lifestyle changes

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
1	-	1	3	9	12

Consensus reached (80%)

Verbatim comments: - not applicable here
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13. There is a need for a standard operating procedure to guide medicines counselling in elderly patients

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
1	-	2	1	6	16

Consensus reached (84%)

14. The standard operating procedure should include providing information to health professionals (family doctor, nurse, pharmacist) working in primary care informing them of the nature of any counselling provided prior to discharge and any follow-up support required

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
-	-	-	1	10	15

Consensus reached (96%)

15. There is a need to develop standardised documentation to record counselling in elderly patients

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
1	-	-	1	9	15

Consensus reached (92%)

In summary:

Section 6: consensus achieved for nine statements.

Consensus not achieved for statement 6.3 and 6.4, that only elderly patients identified as non-adherent/ potentially non-adherent or commenced new medicines should be targeted for counselling on their medicines prior to discharge BUT reached consensus on 6.2, that all elderly patients should be counselled on their medicines prior to discharge.

Consensus not achieved for statements 6.5, 6.6, 6.7 and 6.8, that medicines counselling can be undertaken by any nurse or any pharmacist or any physician BUT reached consensus on 6.9, that It should only be undertaken by a health professional trained in that role.

#### 5.3.2.7 Health Professional Training

1. All health professionals working with medicines in the elderly should receive regular, ongoing training relating to medicines management

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
1	-	1	-	7	17

Consensus reached (92%)

2. Training should focus on patient involvement in decision making

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
1	-	1	2	9	13

Consensus reached (84%)

3. Training should focus on aspects of cultural diversity

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
1	-	2	-	10	13

Consensus reached (88%)

In summary:

Section 7: consensus achieved for all statements.

5.3.2.8 Evaluation Research

1. Consideration should be given to developing a research program to evaluate the implementation of the these guidelines in the UAE

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
1	-	-	1	10	14

Consensus reached (92%)

2. Evaluation should consider the perspectives of all stakeholders, including patients

<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Somewhat Disagree</b>	<b>Somewhat Agree</b>	<b>Agree</b>	<b>Strongly Agree</b>
1	-	-	-	10	15

Consensus reached (96%)

In summary:

Section 8: consensus achieved for all statements.

### 5.3.3 Round 2 Delphi technique

During round 2, experts were provided with the detailed results of round 1, highlighting most of statements achieving consensus agreement ( $\geq 70\%$ ). While 20 statements did not reach consensus, the decision was taken to not repeat a further round attempting to gain consensus for these 20. It was considered that the responses to those statements achieving consensus themselves explained those not achieving consensus. For example, while consensus was achieved that all elderly patients should be a focus for medicines management, it was not achieved for only targeted patients.

The second round therefore focused on the secondary research objectives, gathering expert' views and experiences of the Delphi approach and its potential uses in the UAE and beyond.

Out of the original 30 key stakeholders invited to participate, the response rate was 83% (n=25). Eighty-four percent (n=21) of panellists were not aware of consensus research methods and only 8% (n=2) had prior experience of being involved in a consensus study. Table 5.4 gives detailed responses.

Table 5.4: Delphi participants' views of their involvement in the consensus study (n=25)

Statements	Anchor 1 %(n)	2 %(n)	3 %(n)	4 %(n)	Anchor 5 %(n)	Statements	Median (M) & IQR
The information provided was sufficient to complete the tasks	68 (17)	16 (4)	8 (2)	4 (1)	4 (1)	The information provided was insufficient to complete the tasks	M = 1 IQR = 1
I had sufficient knowledge and understanding of the subject to participate	32 (8)	52 (13)	8 (2)	4 (1)	4 (1)	I had insufficient knowledge and understanding of the subject to participate	M = 2 IQR = 1
Completing the survey was time consuming	0	12 (3)	60 (15)	16 (4)	12 (3)	Completing the survey was not time consuming	M = 3 IQR = 1
The survey was easy to complete	12 (3)	64 (16)	12 (3)	8 (2)	4 (1)	The survey was difficult to complete	M = 2 IQR = 0.5
Statements were not at all threatening	68 (17)	8 (2)	12 (3)	0	12 (3)	Statements were extremely threatening	M = 1 IQR = 1.5
I gained new knowledge from completing the survey	20 (5)	52 (13)	12 (3)	12 (3)	4 (1)	I did not gain new knowledge from completing the survey	M = 2 IQR = 1
I was under no pressure to agree with the other panel members	68 (17)	16 (4)	4 (1)	4 (1)	8 (2)	I felt under great pressure to agree with the other panel members	M = 1 IQR = 1
The Delphi was a very useful approach to obtaining consensus	36 (9)	48 (12)	8 (2)	0	8 (2)	The Delphi was not very useful approach to obtaining consensus	M = 2 IQR = 1
The Delphi process met my expectations	48 (12)	28 (7)	16 (4)	4 (1)	4 (1)	The Delphi process did not meet my expectations	M = 2 IQR = 1.5
Using the Delphi approach in developing medicines management guidelines was effective	24 (6)	60 (15)	8 (2)	4 (1)	4 (1)	Using the Delphi approach in developing medicines management guidelines was not effective	M = 2 IQR = 0.5
Using the Delphi approach promoted multidisciplinary working	40 (10)	44 (11)	12 (3)	4 (1)	0	Using the Delphi approach did not promote multidisciplinary working	M = 2 IQR = 1
I will consider adopting the Delphi approach to future practice developments	28 (7)	52 (13)	8 (2)	12 (3)	0	I will not consider adopting the Delphi approach to future practice developments	M = 2 IQR = 1

## 5.4 Discussion

### 5.4.1 Key findings

The aim of this phase of the research was to determine consensus in relation to strategic and operational approaches around medicines management for elderly hospitalised patients.

A high level of expert participation was achieved with consensus agreement for almost all statements on structures and processes of medicines management at round one. Twenty statements did not reach consensus and the reasons for not undertaking a further round as follows

#### Statement 6 (section 1):

Only 34% of the panellists voiced an agreement, stated that 'medicines management should only be a focus in the care of elderly patients admitted to hospital with a medicines related issue.' In contrast, there was 84% agreement regarding the statement that 'medicines management should be a focus in the care of every elderly patient admitted to hospital, irrespective of the reason for admission or presenting complaint'.

#### Statements 3, 4, 5 and 6 (section 3):

Consensus was not achieved on the matter of the specific professionals who should undertake medicines reconciliation. However, consensus was achieved (73%) for that 'medicines reconciliation should only be undertaken by a health professional trained in that role'.

#### Statements 3, 4, 5, 6 and 7 (section 4):

Consensus was achieved on all elderly patients with multi-morbidities should have a full medicines review hence not for only those with a medicines related issue. Continuing the trend from previous section, there was no agreement over which specific professionals should undertake medicines reviews but consensus that this could be undertaken by those trained for that role. This was also

observed in relation to determining medicines adherence (statements 3, 4, 5 and 6 (section 5)) and counselling (statements 3, 4, 5, 6, 7 and 8 (section 6)).

The second round involved gathering experts' views and experiences of the Delphi approach. Panellists responded positively to all aspects of the process (other than the time commitment) and the potential for Delphi to be employed in future studies and professional development.

#### 5.4.2 Study strengths and limitations

There are a number of strengths to this study. The current study provided quantitative information regarding aspects of the structures and processes of medicines management of elderly hospitalised patients. The statements for Delphi survey instrument were developed from three sources: review of narrative and systematic literature reviews related to medicines management (Chapter 1); systematic review of the Drug Burden Index (Chapter 3); and analysis of data generated from the in-depth interviews (Chapter 4). It was also grounded in theory with NPT being applied as a theoretical lens in terms of coherence (definitions of key elements of medicines management), cognitive participation (task allocation of the responsibilities of health professionals), collective action (the actual work or skills involved in delivering the tasks relating to medicines management) and reflexive monitoring (specialised education and training services). The TDF and BCW were also lenses applied in terms of changing behaviour via training, SOPs, documentation and research. In addition, these statements were tested for face and content validity by a panel of seven experts on medicines management and related areas in Scotland and the UAE.

The expert panel members came from diverse settings of different healthcare professionals and other key professions. This increases the likelihood of having generated valid responses, addressing all the key elements of medicines management for elderly, hospitalised patients in the UAE.



The different expertise and professions among panel members allowed for more generalisable (externally valid) research findings. The importance of heterogeneity in healthcare decision-making has been highlighted recently by Kanoute, Faye and Bourgeois (2014) and is clearly a feature of NPT. Indeed, when several different professions are represented in a decision-making team, the Delphi method may be the most effective tool for reaching a decision which is suggested by Elwyn *et al.* (2006).

This study produced a high response rate of 87% which meant that the likelihood of response bias is low and the data are therefore more likely to be internally valid and generalisable.

Throughout this Delphi study, attention was paid to aspects of the robustness of research. Validity and reliability are found to decrease in Delphi studies due to subject or situation bias. (Kastein *et al.* 1993) In this study, validity was supported and maximised by selecting expert panel members, the use of multiple iterations, a structured response analysis, statistical consensus and a feedback loop to expert panel members. Delphi studies are considered reliable if the same results can be obtained from similar panellists under similar contexts and conditions. (Kastein *et al.* 1993)

The research design attempted to avoid issues around sampling bias but the exact sampling frame was difficult to access and therefore unknown (roles and numbers). However the Delphi sample size does not depend on statistical power; it depends on group dynamics for arriving at consensus among experts. (Delbecq, Van de Ven, Andrew H and Gustafson 1975)

However, there are study limitations and hence the findings should be interpreted with caution. There was a 'snowballing' element to the sampling process where certain individuals were requested to pass study invites to others. While instructions were given on the criteria of the individuals to be invited, the actual approach to identifying and selecting these individuals was outwith the control of the PI and hence largely unknown. In Delphi studies, snowballing is used to recruit participants who are difficult to find or not easily

accessible to researchers through other sampling strategies. A study by Cohen and Arieli (2011) describes that snowball sampling contradicts many conventional assumptions of statistical sampling, though it does hold several advantages in allowing access to certain segments of the population that may not be otherwise easily accessed.

Another limitation is that the cut off value for determining consensus of agreement was rather arbitrary with no set of standard, although this is one of the most widely used approaches. (Powell 2003 and Heiko 2012) It was not possible to identify individual respondents and hence there could be unidentified skewing of the findings. For example, while 84% of experts agreed with the proposed definition of medicines management, four experts strongly disagreed. It is possible that these four may all be from the same profession, which could reduce the validity of the conclusion and generalisability of the data. It is notable that for almost all those statements where consensus was achieved, one or more experts strongly disagreed but provided little comment to justify their responses. Future studies could build in a process to identify individual experts but this may reduce the participation and hence response rate.

Another limitation is that there were no expert patients included in this study, for reasons described previously.

Moreover, though the study was unique in its focus on a Middle Eastern area (UAE), its generalisability may be questionable due to cultural and conceptual differences. (Lages, Pfajfar and Shoham 2015) Nair, Aggarwal, *et al.* (2011) state that one of the weaknesses of Delphi study is generalisability of the study findings hence while these findings have been generated for Abu Dhabi, they may not be applicable to the entire emirate, the UAE, the Middle East and beyond. While this is a limitation, the funding for the research was provided by the UAE Embassy to provide data relevant to that country. However, experts without the UAE were involved in statement validation, which may increase generalisability.

### 5.4.3 Interpretation of findings

The responses to the statements are in line with the concept of clinical governance, defined as 'a system through which organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish'. (Sally and Donaldson 1998) A policy manual issued by HAAD (2012) indicated the purpose of clinical governance, which is to ensure, as far as possible, the provision of safe, effective, ethical and high quality healthcare in the Emirate of Abu Dhabi. Responses highlight the need for trained staff to deliver high quality service supported by standard operating procedures and clearly documented audit trails.

This remainder of this section is informed by a comprehensive literature search of Medline, CINAHL, and International Pharmaceutical Abstracts (see Appendix 5.4 for search strategy) of consensus method research in relation to strategic and operational approaches around medicines management for elderly patients, from the health professional perspective. Four relevant studies were identified which are described in Table 5.5.

The four studies focused on general elements of medicines management structures and processes.

Table 5.5: Data extraction for four relevant consensus studies

Reference	Specified Aim/objective	Setting (country, institution)	Design	Participants	Outcome measures	Key Findings	Conclusion
(Esmaily <i>et al.</i> 2008)	To obtain experts' consensus about appropriate educational outcomes of rational prescribing for general physicians in CME and developing curricular contents for this education.	Tabriz (Iran)	A two-round Delphi consensus process to identify the outcome-based educational indicators regarding rational prescribing for general physicians in primary care	21 stakeholders: 7 experienced GPs, 4 CME decision makers, 3 pharmacists, 3 pharmacologists and 4 medical specialists	Potential outcome for rational prescribing identified from a range of sources.	21 learning outcomes were identified through a modified Delphi process. The indicators were used by the panels of experts and six educational topics were determined for the CME programme and the curricular content of each was defined. The topics were 1) Principles of prescription writing, 2) Adverse drug reactions, 3) Drug interactions, 4) Injections, 5) Antibiotic therapy, and 6) Anti-inflammatory agents therapy.	Consensus on learning outcomes was achieved and an educational guideline was designed. Before suggesting widespread use in the country the educational package should be tested in the CME context.
(Greenwald <i>et al.</i> 2010)	To identify barriers to meaningful implementation of medication reconciliation and developing a feasible plan toward its effective implementation in the hospital setting	Chicago (US)	Consensus method by invitation-only meeting held on the Northwestern Medical Campus in Chicago	Stakeholders representing professional, clinical, health care quality, consumer, regulatory, and accreditation organizations	The outcome measure was four key relevant domains: (1) how to measure success in medication reconciliation, (2) key elements of successful strategies, (3) leveraging partnerships outside the hospital setting to support medication reconciliation, and 4) the roles of the patient and family/caregivers and health literacy	The participants identified 10 key areas requiring further attention in order to move medication reconciliation toward this focus: 1. There is need for a uniformly acceptable and accepted definition of what constitutes a medication and what processes are encompassed by reconciliation. 2. The varying roles of the multidisciplinary participants in the reconciliation process must be clearly defined. 3. Measures of the reconciliation processes must be clinically meaningful (that is, of defined benefit to the patient) and derived through consultation with stakeholder groups. 4. While a comprehensive	Medication reconciliation is complex and made more complicated by the disjointed nature of the American health care system. Addressing these 10 points with an overarching goal of focusing on patient safety rather than only accreditation should result in improvements in medication reconciliation and the health of patients

						<p>reconciliation system is needed across the continuum of care, a phased approach to implementation, allowing it to start slowly and be tailored to local organizational structures and workflows, will increase the chances of successful organizational uptake.</p> <p>5. Developing mechanisms for prospectively and proactively identifying patients at risk for medication-related adverse events and failed reconciliation is needed</p> <p>6. Given the diversity in medication reconciliation practices, research aimed at identifying effective processes is important and should be funded with national resources.</p> <p>7. Strategies for medication reconciliation-both successes and key lessons learned from unsuccessful efforts-should be widely disseminated.</p> <p>8. A personal health record that is integrated and easily transferable between sites of care is needed.</p> <p>9. Partnerships between health care organizations and community-based organizations create opportunities to reinforce medication safety principles outside the traditional clinician- patient relationship.</p> <p>10. Aligning health care payment structures with medication safety goals is critical to ensure allocation of adequate resources to design and implement effective medication reconciliation</p>	
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						processes.	
(Clyne, White and McLachlan 2012)	To develop practical consensus-based policy solutions to address medicines non-adherence for Europe	Europe	A four-round Delphi study was conducted	The Delphi Expert Panel comprised 50 participants from 14 countries and was representative of: patient/carers organisations; healthcare providers and professionals; commissioners and policy makers; academics; and industry representatives experience	Participants were invited to respond to open questions about the causes, consequences and solutions to medicines non-adherence	43 separate policy solutions to medication non-adherence were agreed by the Panel. 25 policy solutions were prioritised based on composite scores for importance, and operational and political feasibility. Prioritised policy solutions focused on interventions for patients, training for healthcare professionals, and actions to support partnership between patients and healthcare professionals. Few solutions concerned actions by governments, healthcare commissioners, or interventions at the system level	Consensus about practical actions necessary to address non-adherence to medicines has been developed for Europe. These actions are also applicable to other regions. Prioritised policy solutions for medicines non-adherence offer a benefit to policymakers and healthcare providers seeking to address this multifaceted, complex problem
(O'Mahony <i>et al.</i> 2015)	Aims of this study: screening tool of older people's prescriptions (STOPP) and screening tool to alert to right treatment (START) criteria were first published in 2008. Due to an expanding therapeutics evidence base, updating of the criteria was required	European countries	Delphi consensus methodology	Nineteen experts from 13 European countries reviewed a new draft of STOPP & START criteria including proposed new criteria	To propose additional criteria they considered important to include in the revised STOPP & START criteria and to highlight any criteria from the 2008 list they considered less important or lacking an evidence base.	The expert panel agreed a final list of 114 criteria after two Delphi validation rounds, i.e. 80 STOPP criteria and 34 START criteria. This represents an overall 31% increase in STOPP/START criteria compared with version 1	STOPP/START version 2 criteria have been expanded and updated for the purpose of minimizing inappropriate prescribing in older people. These criteria are based on an up-to-date literature review and consensus validation among a European panel of experts

Esmaily *et al.*, in a two round Delphi study of 21 stakeholders in Iran, highlighted 21 learning outcomes to achieve an educational approach regarding rational prescribing for general physicians in primary care (Esmaily *et al.* 2008). These findings relate to the seventh section which comprised three statements regarding health professional training.

Greenwald *et al.*, in employing consensus methods with key stakeholders in Chicago, highlighted 10 key areas requiring attention to improve medicines reconciliation and the health of patients (Greenwald *et al.* 2010). These findings relate to 11 statements regarding medicines reconciliation in this doctoral research.

Clyne, White and McLachlan in a four round Delphi study of 50 participants from 14 European countries, indicated that the causes, consequences and solutions to medicines non-adherence (Clyne, White and McLachlan 2012). These findings relate to the fifth set of statements consisted of 11 statements relating to medicines adherence.

A Delphi study of 19 experts from 13 European countries conducted by (O'Mahony *et al.* 2015) generated an updated criteria for the purpose of minimizing potentially inappropriate prescribing in older people. While the STOPP/START criteria have been used widely in Europe to aid the identification of potentially inappropriate prescribing no studies have focused on the Middle East. (Hill-Taylor *et al.* 2013) In this doctoral research, 92% of the panellists agreed that 'consideration should be given to adapting defined lists of high risk or potentially inappropriate medicines in the elderly, for the UAE context such as STOPP/START'.

Chapter 1 outlines the issue of potentially inappropriate prescribing in the elderly, describing a systematic review of criteria to aid the identification of potentially inappropriate prescribing. (Hill-Taylor *et al.* 2013) Notably, 92% agreement was reached among the experts around adopting lists of high risk or potentially inappropriate medicines in the elderly such as Beers and STOPP/START. Furthermore, 88% consensus reached to consider using the Drug Burden Index to determine anticholinergic burden. This is an area which

requires further attention and research. Notably there are no published papers which report the use of such criteria within the Middle East. While it may be necessary to review these criteria for their appropriateness to Middle Eastern practice (medicines available, commonly used etc.) and culture, these provide a useful starting point.

In a recent systematic review of the literature on interventions (alone or in combination) to improve appropriate polypharmacy for older people, Patterson *et al.* highlighted the lack of clarity around the impact of interventions to improve appropriate polypharmacy, such as pharmaceutical care, on health outcomes despite the impact relating to reducing potentially inappropriate prescribing. (Patterson *et al.* 2014) The findings of this research demonstrate complete agreement (100%) that medicines management guidelines should focus on reviewing all medicines in elderly patients with multi-morbidities to promote appropriate polypharmacy.

A very recent systematic review of 26 studies (10 RCTs, 3 non-RCTs and 13 pre-post design) of the determinants of medicines reconciliation identified three possible interventions to reduce risk of medicines discrepancies. (Mueller *et al.* 2012) Notably, 88% agreement was achieved to adopting this definition of medicines reconciliation in the UAE 'the process of identifying the most accurate list of a patient's current medicines – including the name, dosage, frequency and route – and comparing them to the current list in use, recognizing and discrepancies, and documenting any changes, thus resulting in a complete list of medications, accurately communicated'. Also consensus was reached (73%) for the statement authorising a 'health professional trained in that role' to undertake medicines reconciliation.

One further finding of this research is the very high level of agreement to adopting the following definition of medicines adherence in the UAE, 'the extent to which patients take medications as prescribed by their health care providers'. Furthermore, 80% consensus was reached that determination of adherence should be undertaken by a health professional trained in that role and 80% agreed to develop a standardised operating procedure to guide the determination of adherence (or non-adherence) in elderly patients. The review



of systematic reviews in the field of medicines adherence described in chapter 1 (Kardas, Lewek and Matyjaszczyk 2013) and a recent systematic review of 109 RCTs published since 2007 Nieuwlaat *et al.* (2014) highlight that the vast majority of the primary literature is of poor quality (high potential for bias, few studies of clinical outcomes) and that improving adherence is complex and may be multifactorial.

Experts' responses to round two are encouraging in terms of the future use of consensus approaches within the UAE for both development of policy and practice, and research. To date, few published studies from the Middle East have reported the use of consensus approaches. Consensus research, involving a group of tobacco cessation experts in Africa and the Middle East who participated in a series of four meetings held in Cairo, Cape Town, and Dubai in to develop a draft guideline tailored to their region. (Ali *et al.* 2012) A multidisciplinary expert panel critically reviewed available evidence to provide consensus recommendations for the management of invasive *Candida* infections in the Middle East. (Alothman *et al.* 2014) This doctoral research therefore extends the available literature on the of consensus approaches in the Middle East.

#### 5.4.4 Conclusion

The current study sought to determine the consensus of experts in regards to various aspects of medicines management for elderly hospitalised patients. The results of the Delphi study have identified very high levels of agreement around structures and processes of medicines management for elderly, hospitalised patients and will form the basis for further work. Grounding the research in theoretical frameworks of NPT and TDF offer a unique insight into aspects of medicines management and will form the basis for further discussion and research.

#### 5.4.5 Summary

This phase of the research has resulted in a set of statements around medicines management in guidelines, medicines reconciliation, medicines review, medicines adherence, medicines counselling, health professional training and

evaluation research where consensus has been achieved by a panel of experts in the UAE.

The following chapter will consider the all findings of the doctoral research, their implications and potential impact.

## **CHAPTER 6: Discussion**

This chapter commences with restating the overall aim of the doctoral research, the aim of each phase and the key findings. The originality of the research is highlighted and there is further interpretation of the results. The chapter ends with further work related to the on development, implementation and sustainability of the guidelines to impact practice, patient care and outcomes.

### **6.1 Overall aim and aim of each phase**

The overall aim of the doctoral research was to explore the structures and processes of medicines management in elderly hospitalised patients in the UAE.

This would form part of the initial phase of developing and implementing guidelines to support medicines management. The research was conducted in three phases, each of which was sequential, and building on the findings of the previous phases.

#### Phase 1

The review of the literature in chapter 1 identified a wealth of evidence around aspects of medicines management in terms of medicines reconciliation, medicines adherence and potentially inappropriate prescribing. Generic tools and criteria to support medicines selection and identify potentially inappropriate prescribing in the elderly were described in terms of their development and use, noting the lack of evidence around specific tools which relate to anticholinergic agents.

The aim of this phase was to critically appraise, synthesize and present evidence of the use of the Drug Burden Index (DBI) to identify potentially inappropriate prescribing of anticholinergic and sedative agents in elderly patients, focusing on institutionalised care (in line with the doctoral research setting).

## Phase 2

The aim of this phase of the research was to explore the views, experiences and perceptions of health professionals in Abu Dhabi in terms of the medicine management healthcare structures, processes and outcomes for elderly, hospitalised patients.

## Phase 3

The aim of the final phase of the research was to determine consensus in relation to strategic and operational approaches around medicines management for elderly, hospitalised patients in the UAE.

## **6.2 Key findings**

Chapter 1 provided a narrative overview of systematic reviews on medicines reconciliation, medicines adherence and potentially inappropriate prescribing.

One key finding of phase 1 (systematic review) was that there was a lack of studies which had focused on any aspect of the use of the DBI in institutionalised care, with only seven studies (three cohort studies, three mixed cohort and cross-sectional studies and one cross-sectional study) identified. DBI scores (or categories) were found to be associated with an array of outcomes, including activities of daily living, length of hospital stay, falls and quality of life. None of the studies used the DBI prospectively as a tool to identify the need to alter potentially inappropriate prescribing; one used it retrospectively to check if the pharmacists' interventions, as part of a medicines review service, had resulted in decreased DBI scores, and identified statistically significant reductions in scores.

The key findings of phase 2 (qualitative exploration of structures, processes and outcomes around medicines management for elderly, hospitalised patients) highlighted health professionals' perceptions of the need for: appropriate polypharmacy in elderly patients with multimorbidities; a systematic approach to medicines history taking; improved communication and documentation; improved patients' adherence to medicines; guidelines and policies to support medicines selection; and an educated and trained multidisciplinary team. These

findings were underpinned by two theoretical frameworks. The TDF was used in relation to domains of determinants of behaviour at the individual practitioner level. The domains which were most dominant were: professional role and identity; beliefs about capabilities; beliefs about consequences; environmental context and resources; knowledge; and goals. NPT was used at the organisational level with little evidence of coherence, cognitive participation, collective action and reflexive monitoring.

Key findings of phase 3 demonstrated the achievement of a high level of consensus ( $\geq 70\%$  strongly agree/agree) from expert panel members for most statements relating to the structures and processes of medicines management for elderly hospitalised patients.

Expert panel members did not support targeting medicines management processes to those with medicines related issues but to all elderly patients. They did not support which professions (nursing, pharmacy, physician) were most suited to roles (e.g. medicines reconciliation, review etc.) but were in high agreement that those delivering the roles should be trained.

Strengths and weaknesses of each phase were discussed in the individual chapters; one key strength is that each phase was designed to build on the methodologies, methods and findings of the previous phase(s).

### **6.3 Originality of the research**

This doctoral research is a novel and original contribution to knowledge in several regards. Firstly, it focuses on the structures and processes (as defined by Donabedian 1990) of medicines management across the entire patient journey (from admission to hospital to the point of discharge back to the patient's home or other care setting). Figure 6.1 illustrates how the findings of each phase relate to each other, in terms of the medicines management model proposed in Figure 1.1

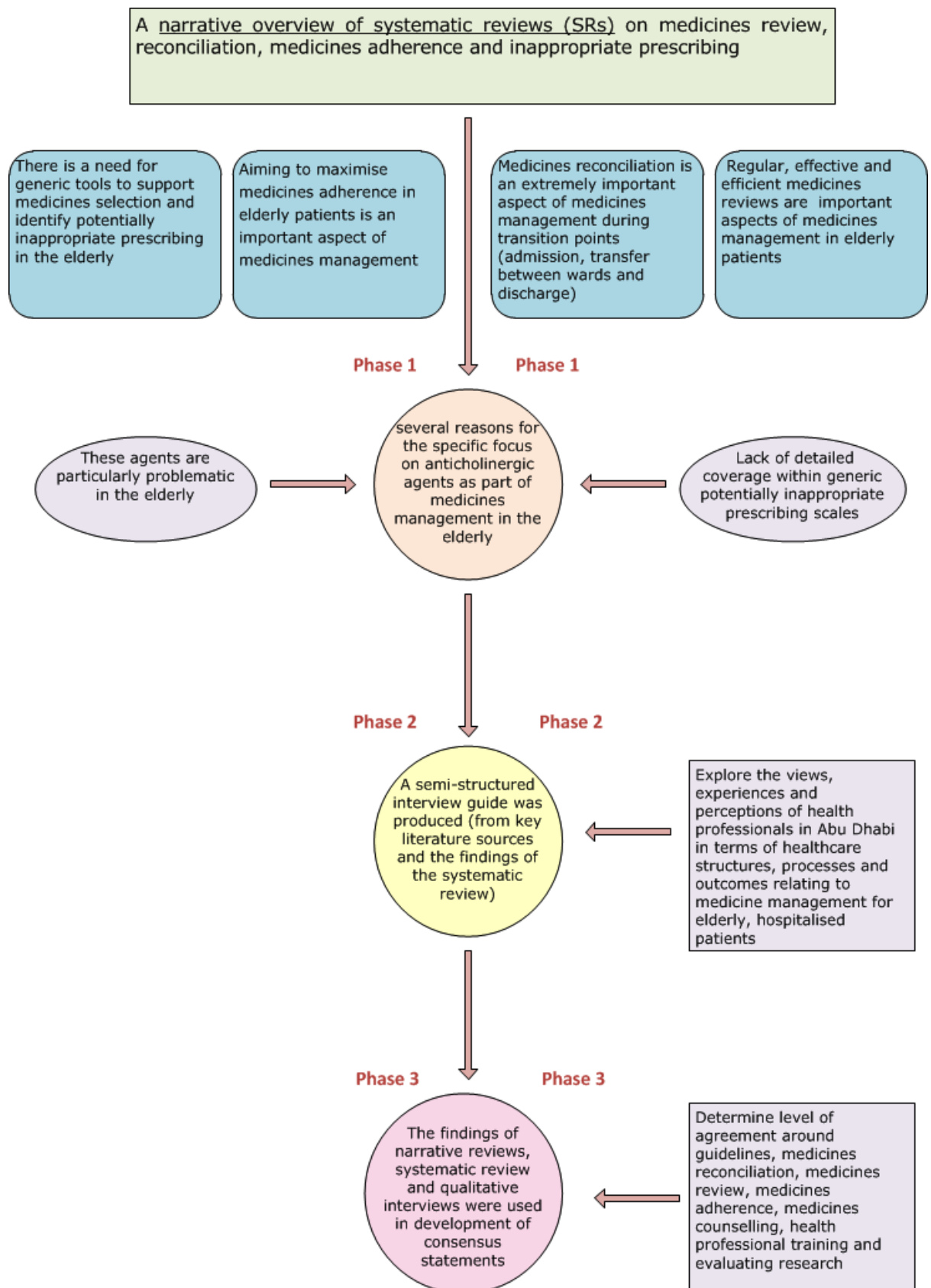


Figure 6.1: An illustration of the overall research findings

Secondly, there is extensive application of behavioural and organisational theory underpinning the research conducted in phases 2 and 3. Thirdly, there is a paucity of published research in the UAE (and the Middle East more generally) which used consensus based approaches. Findings have been presented at several international conferences and via peer reviewed publications, with further dissemination planned.

The findings of the Delphi study identified very high levels of agreement around structures and processes of medicines management for elderly, hospitalised patients. This work will form the basis for further research focusing on developing the guidelines to support medicines management of elderly, hospitalised patients, followed by pilot testing and with evaluation from the perspectives of health professionals, managers, leaders and patients, prior to full scale implementation.

While this research has focused on elderly, hospitalised patients where issues of medicines management may be more complex, the findings are relevant to the care of all patients.

#### **6.4 Development, Implementation, Evaluation of guidelines**

Guidelines have been a feature of clinical practice for decades. The practice guidelines are defined as 'systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances'. These guidelines 'should identify recommendations for appropriate and cost effective management of clinical conditions or the appropriate use of clinical procedures with principal aim of promoting good performance'. (Field and Lohr 1990)

There are many steps in developing guidelines, summarised in table 6.1.

Table 6.1: Summary steps in the guideline development process (adapted from Kish and Infectious Diseases Society of America 2001)

<b>Step</b>	<b>Description</b>	<b>Recommended time to completion</b>
1	Selection of panel	2-4 weeks
2	Introductory meeting of panel members (via conference call or in person, as determined by the panel chair); if the guideline so lends itself, the chair could divide and distribute the assignments among individual panel members; steps 3-5 can done at the same time	1-2 months
3	Determine the scope of the guideline	Concurrent with step 2
4	Determine the target audience and the target population	Concurrent with step 2
5	Determine how the evidence will be selected (e.g., by means of a MEDLINE search); review the plan with the chair of the Practice Guidelines Committee	Concurrent with step 2
6	Select and review the evidence to be used in writing the guideline (this step should be divided among panel members); set a date for completion	2-3 months
7	Grade the evidence and determine what will be used and what will be discarded	Concurrent with step 6
8	Write the guideline, including an executive summary; if algorithms are used, be sure that they are presented in the proper format; tables and graphs, which are useful for guideline readers, should be provided	3 months
9	Submit the guideline for outside review	Within 9-10 months of the start of the project
10	Modify the guideline on the basis of the outside review	1-2 months
11	Submit the guideline to Infectious Diseases Society of America (IDSA) Practice Guidelines Committee for review and publication	Preferably within 12 months of the start of the project
12	Review and update the guideline as appropriate	Every 2 years



Findings of this research relate to:

- Step 1-4, the Delphi panel of experts and the statements reaching consensus
- Steps 5-8, based on the findings of the systematic reviews presented in chapter 1, the DBI systematic review, the interviews and the Delphi.

While developing guidelines is an extremely important step, many have noted that great attention must be given to guideline implementation, and there is a wealth of evidence to support implementation. A literature search of identified many systematic reviews relating to guideline implementation. (Davis and Taylor-Vaisey 1997, Grimshaw *et al.* 2004, Kawamoto *et al.* 2005, Francke *et al.* 2008, Hakkennes and Dodd 2008) Three of these focus specifically on health care and are described in the data extraction table (Table 6.2).

Table 6.2: Data extraction from systematic reviews relating to guideline implementation

Authors/year published	Review aim	Databases/years	Hits	Number of papers reviewed	Findings
(Davis and Taylor-Vaisey 1997)	To recommend effective strategies for implementing clinical practice guidelines	Medline 1990-1996	Not specified	Not specified	<p>Findings from the review stated that the variables affecting the adoption of guidelines include:</p> <ul style="list-style-type: none"> <li>• qualities of the guidelines</li> <li>• characteristics of the health care professional</li> <li>• characteristics of the practice setting</li> <li>• incentives</li> <li>• regulation and patient factors</li> </ul> <p>Specific strategies fell into 2 categories:</p> <ul style="list-style-type: none"> <li>• primary strategies involving mailing or publication of the actual guidelines</li> <li>• secondary interventional strategies to reinforce the guidelines</li> </ul> <p>The interventions were shown to be:</p> <ul style="list-style-type: none"> <li>• weak (didactic, traditional continuing medical education and mailings)</li> <li>• moderately effective (audit and feedback, especially concurrent, targeted to specific providers and delivered by peers or opinion leaders)</li> <li>• relatively strong (reminder systems, academic detailing and multiple interventions)</li> </ul>
(Francke <i>et al.</i> 2008)	To gain a better understanding of which factors affect the implementation of guidelines, and to provide insight into the "state-of-the-art" regarding research within this field	<p>PubMed (2006)</p> <p>CINAHL (2006)</p> <p>Cochrane Library (2006)</p> <p>Embase (2006)</p> <p>NIVEL catalogues (2006)</p>	1359	12	<p>Findings from the review were that effective strategies often have multiple components and that the use of one single strategy, such as reminders only or an educational intervention, is less effective.</p> <p>Various factors could influence the implementation such as:</p> <ul style="list-style-type: none"> <li>• characteristics of the guidelines themselves; e.g. guidelines that are easy to understand, can easily be tried out, and do not require specific resources, have a greater chance of implementation</li> <li>• characteristics of professionals – e.g. awareness of the existence of the guideline and familiarity with its content</li> <li>• patient characteristics appear to exert influence- for</li> </ul>

					<p>instance, co-morbidity reduces the chance that guidelines are followed</p> <ul style="list-style-type: none"> <li>environmental characteristics may influence guideline implementation; e.g. a lack of support from peers or superiors, as well as insufficient staff and time, appear to be the main impediments</li> </ul> <p>The authors concluded that future research comparing combinations of implementation strategies versus single strategies was needed</p>
(Hakkennes and Dodd 2008)	To evaluate the effects of the introduction of clinical guidelines for allied health professionals, and to estimate the effectiveness of the guideline dissemination and implementation strategies used	<p>Medline (1966-2006)</p> <p>CINHAL (1988-2006)</p> <p>Embase (1988-2006)</p> <p>PsychINFO (1985-2006)</p> <p>AMED (1985- 2006)</p> <p>Cochrane Controlled Trials Register (2006)</p> <p>DARE (2006)</p>	4569	14	<p>Of the 14 included studies, intervention categories were 7 on distribution of educational material, 5 on educational meetings, 3 on reminders, 3 on guideline care, 2 on educational outreach visit and one each for audit and feedback, local opinion leaders, revision of professional roles and provider incentive. Also findings from 14 studies stated that 6 used a single intervention strategy, 7 used a multifaceted implementation strategy and one study compared both single and multifaceted strategies. The review showed that multifaceted interventions were no more effective than single intervention strategies and effects of the same strategy varied across trials. Authors concluded that implementing clinical guidelines required first to identify specific barriers to change using theoretical frameworks of behaviour change and after that apply strategies that deal with these barriers</p>

There is some overlap to the findings of these three systematic reviews. Guidelines are may be more likely to be effective if educational strategies (interventions that aim to influence targeted professionals' attitudes, awareness and understanding of guidelines) implementation strategies (interventions that aim to translate knowledge into changes in practice) are considered.

## **6.5 Use of theory**

The development and implementation of guidelines to support medicines management of elderly, hospitalised patients in the UAE is considered a complex intervention. Complex interventions are described by MRC framework (as discussed in Chapter 1) as 'interventions that contain several interacting components'.(Craig *et al.* 2008)

Hakkennes and Dodd (2008) (see table 6.2) concluded in their systematic review that 'When implementing clinical guidelines it is important to first identify specific barriers to change using theoretical frameworks of behaviour change and then develop strategies that deal with these barriers'. (Hakkennes and Dodd 2008)

There is a consensus in the literature that behaviour change is key to increasing the uptake of evidence into healthcare practice (Francis, O'Connor and Curran 2012) and this is reiterated within the MRC guidelines. (Craig *et al.* 2008) Implementing behaviour-change interventions commences with problem analysis, which would ideally be informed by theory. The NPT (May and Finch 2009) mechanisms and the TDF (Michie *et al.* 2005) behavioural determinants utilised in this study have provided a theoretical approach to identifying the determinants in relation to medicines management, specific to the UAE, which require consideration and attention. It should be noted, however, that these were studied using a qualitative approach and hence are not necessarily transferable to all health professionals in the UAE.

NPT was used at the organisational level with findings related to the four mechanisms of coherence, cognitive participation, collective action and reflexive monitoring.

The following is a brief description of the initial conceptualisation of how the four mechanisms of NPT might apply to the implementation of medicines management for elderly hospitalised patients.

- coherence: one key element of coherence is a shared understanding of the overall aim of medicines management, its structures, processes and intended outcomes. If the processes of the medicines management model (e.g. medicines reconciliation) are to be 'normalized', there needs to be effective engagement throughout the organisation from policy makers, managers, leaders and health professionals.
- cognitive participation: the organisational division of staff is a key element of cognitive participation and relates to who (i.e. the structures) performs the specific tasks (i.e. the processes). For medicines management processes to be normalized in the organisation there would need to be clear task allocation and definition of responsibilities. For example, it needs to be very clear who is responsible for medicines reconciliation, and in what circumstances. While there is insufficient evidence to support allocating this task to a specific health profession, it is clear from the Delphi that the main consideration is training and competence. Consideration also needs to be given to the number and types of staff available at any given time. It could be that this is a task undertaken by trained, competent nurses and that patients are referred to pharmacists in situations (clearly defined) where more extensive expertise in areas of medicines is required.
- collective action: is a construct that relates to specific task definition (the actual process) of the different elements on the medicines management model. These medicines management processes could become normalized if the specific tasks are clearly defined. Using the medicines reconciliation example, there should be standard operating procedures which clearly outline how the task will be performed, documented and communicated to the relevant members of the healthcare team. This is in line with the findings of the Delphi around the need for standard

operating procedures, consistent documentation and channels of communication.

- reflexive monitoring: is a construct which describes or discusses of how the patient outcomes of the processes of medicines management are assessed. The approaches to reflexive monitoring should be clearly defined, communicated and agreed (coherence) by all. Furthermore, these should be normalized within daily practice so that data are routinely gathered, analysed and used to inform that practice.

Consideration of the structures and processes of medicines management relating to these mechanisms should result in more effective and efficient use of health professionals, resulting in enhanced care and patient outcomes.

The doctoral research used two theoretical frameworks as underpinning. The TDF was used in relation to domains of determinants of behaviour at the individual practitioner level. Paying attention to these determinants at level of the practitioners, in combination with the NPT organisational focus, should result in more effective and efficient guideline implementation. The use of the Behaviour Change Wheel to identify these change strategies has been discussed in Chapter 4. The following is a consideration of the TDF determinants might apply to the implementation of guidelines for medicines management.

- Professional role and identity: very much in line with NPT cognitive participation, for guidelines to be implemented effectively clearly defined roles and responsibilities in the different processes of medicines management are required. Throughout the implementation, attention should be paid to encouraging, supporting and mentoring health professionals.
- beliefs about consequences: health professionals need to have shared beliefs (coherence) around the consequences of the specific elements of the medicines management model. Intervention is required at the individual practitioner levels to highlight the need for processes. For example, in terms of determining medicines adherence at the point of

admission to hospital, if practitioners are not fully aware of the benefits of undertaking this assessment and how it can contribute to decision making around diagnosis, medicines selection, support following discharge, need for family and carer involvement etc. then they are less likely to perform the task to the best of their abilities and hence be less likely to realise the implications of any findings. As above, support involving persuasive communication could assist in implementation.

- beliefs about capabilities: similarly, practitioners who are fully educated and trained should be supported so that they are confident in the processes being undertaken.
- knowledge: this is fundamental and interviewees expressed clearly their lack of knowledge around tools to support medicines selection and identifying potentially inappropriate prescribing in the elderly.
- goals: again, aligned to coherence, all health professionals need to be aware of, understand and engage with the overall goals of medicines management and the goals of the specific processes. Education, training, support, persuasion and agreed guidelines could all assist in implementation.
- environmental context and resources: the actual guidelines themselves should be a key resource to improving medicines management. Lack of time to deliver care may be alleviated through clearly defined roles, responsibilities and tasks (i.e. cognitive participation and collective action) avoiding duplication of tasks.

## **6.6 Future work**

Further work now must focus on development, implementation and sustainability of the guidelines to impact practice, patient care and outcomes. The work involved should not be underestimated and while changing behaviours at the organisational or individual level is complex and difficult.

The following outlines key, prioritised research questions which emerge from the doctoral research.

#### 6.6.1 Exploring the impact of medicines management guidelines implementation from health professionals' perspectives

##### Research Question:

What are the health professionals' perspectives of the impact of the implementation of medicines management guidelines on healthcare structures and processes and outcomes?

##### Research philosophy:

This study will adopt a pragmatic approach, both quantifying and exploring the impact of the implementation of medicines management guidelines.

##### Methodology and method:

A mixed methodology (an explanatory sequential approach) combining cross-sectional survey and phenomenology, perhaps with focus groups or interviews, will be employed to determine the impact in terms of healthcare structures and processes and outcomes. The quantitative element will take the form of a questionnaire using stratified sampling across the UAE to determine their self-reported perspectives. Questionnaire items will be developed from the findings of this research, with aspects of TDF and NPT. Following analysis of questionnaire data, qualitative interviews or focus groups of purposive samples would explore and triangulate the findings of the cross-sectional survey.

##### Outcome measures:

Quantitative measures would include their perceptions of:

- coherence,
- goals and intentions,
- task allocation,
- involvement in processes,
- professional role and identity and
- beliefs of consequences



Qualitative measures would focus on their experiences of and behaviours relating to the implementation and sustainability of the guidelines.

6.6.2 The impact of medicines management guidelines implementation on elements of medicines management. For example this could be related to the determination of medicines adherence at the point of admission to hospital.

Research Question:

What is the impact of medicines management guidelines implementation on medicines adherence determination at the point of admission?

This study would be based on the guideline part which relates to medicines adherence and any SOPs contained within the guideline.

Research philosophy:

This study would adopt a positivist approach in which it quantifies medicines adherence determination at the point of admission.

Methodology and method:

The SOP would identify which profession should conduct medicines adherence determination, the tools to be employed and how the results of the process would be documented.

Outcome measures:

The key outcome measures would include:

- adherence scores, measured using the Arabic translation of the Morisky questionnaire (Nguyen, Caze and Cottrell 2013),
- the proportions fully adherence, poorly adherent etc. and
- actions documented in relation to the scores and actions.

## **6.7 Impact of research**

Research Councils UK (RCUK is 'committed to research excellence with impact') defines research impact as 'the demonstrable contribution that excellent research makes to society and the economy through fostering global economic

performance, increasing effectiveness of public services and policy and enhancing quality of life, health and creative output'. (Hughes *et al.* 2013)

RCUK suggests that research impact is considered in terms of its:

- academic impact,
- economic impact and
- societal impact.

This has been used as a template to consider the doctoral research impact, which is summarised in Figure 6.2.

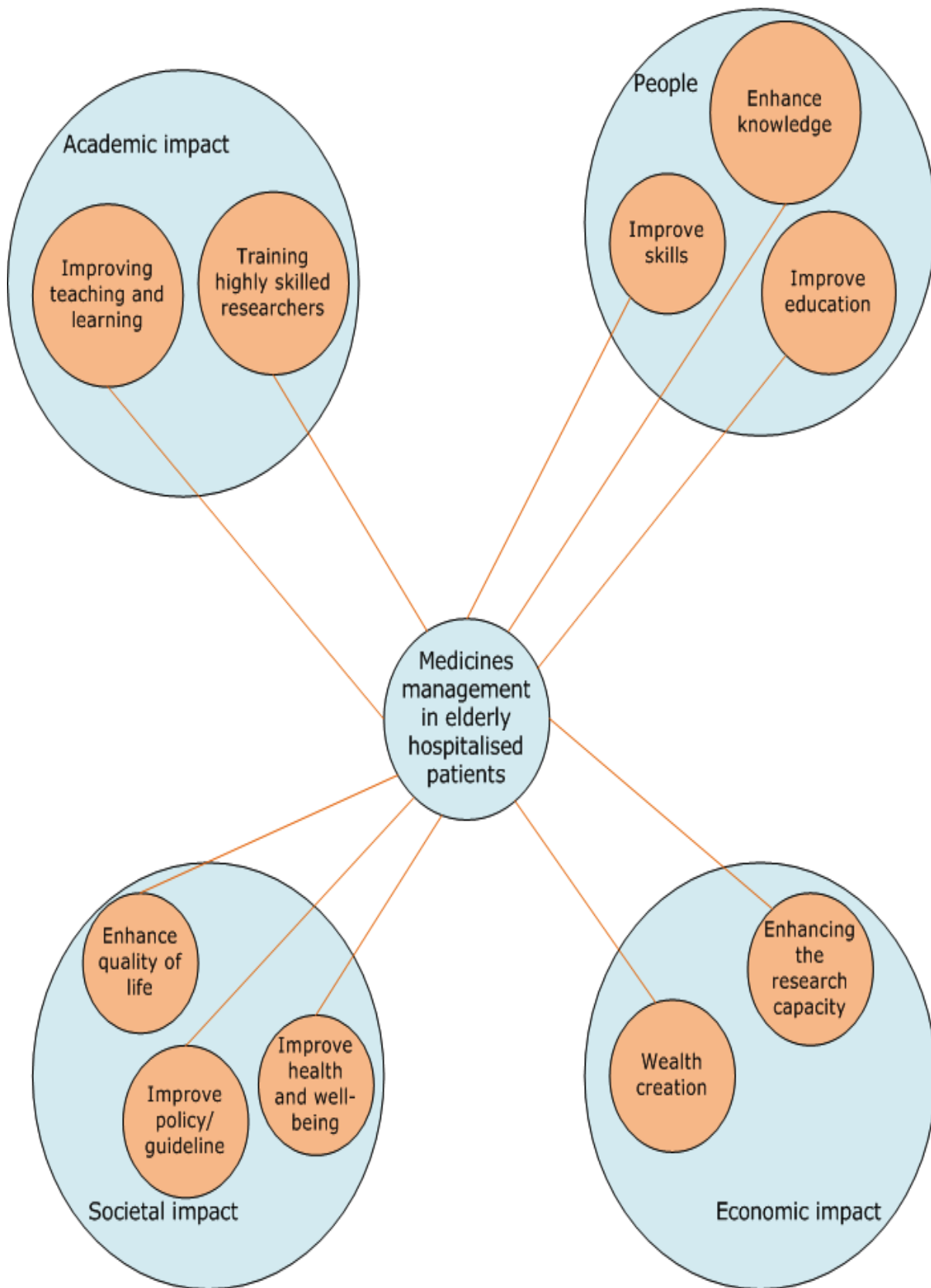


Figure 6.2: Doctoral research impact

This doctoral research has impacted:

- the principal researcher in terms of the overall training in a range of health services related research paradigms, methodologies and methods
- the research team, specifically around the use of the TDF and NPT in research
- the participants in the research, particularly those involved in the Delphi study
- practitioners in the UAE in terms of collecting, generating original data and presenting and publishing that data may also impact a wider audience
- the likelihood of the development and implementation of medicines management guidelines for elderly, hospitalised patients in the UAE which in turn should impact the structures, processes and outcomes.

The 'pathway to impact' outlined by RCUK is given in Figure 6.3. In terms of this doctoral research, the pathway is:

- presentation of findings at international conferences
- publication in peer reviewed journals
- feedback of research findings to participants

Further feedback is planned within the UAE and specifically the hospitals in which the research was conducted.

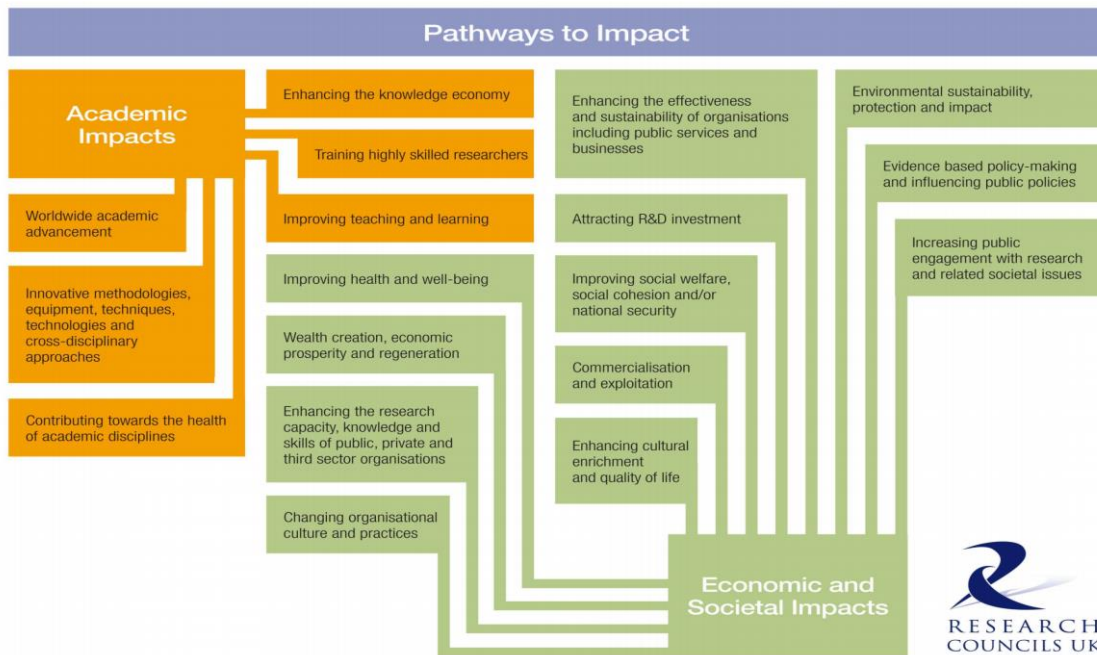


Figure 6.3: Pathways to Impact (adapted from Hughes *et al.* 2013)

## 6.8 Conclusion

This doctoral research has generated original findings which contribute to knowledge. While the DBI is an emerging tool to quantify anticholinergic and sedative burden, there is a limited literature base on its use in elderly, hospitalised patients. The potential link between higher DBI scores and several outcomes around the risk of functional impairment requires further research, as does its role alongside explicit tools of potentially inappropriate prescribing.

There is a lack of published studies which research the entire process of medicines management in patients while in the hospital. The primary research conducted is therefore highly original and has identified a clear need and consensus agreement for well defined approaches to medicines management in elderly, hospitalised patients in the UAE. In particular, this research has identified the need to more clearly define, refine and agree on healthcare structures and processes across the entire patient journey from admission to the point of discharge. The findings of the consensus study will contribute to the future development and implementation of guidelines within the UAE. The use of the NPT and TDF has highlighted those individual practitioners and organisational issues which require consideration through interventions such as

policy development, education and training, health professional engagement, support and mentoring. These findings have the potential to impact greatly on healthcare practice and patient care. While the research was conducted within the UAE, there is potential for wider impact and this will be facilitated by ongoing dissemination of the research.

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## Appendix 3.1: the JBI Meta Analysis of Statistics Assessment and Review Instrument (JBI-MAStARI)

### JBI Critical Appraisal Checklist for Randomised Control / Pseudo-randomised Trial

Reviewer ..... Date .....

Author ..... Year ..... Record Number .....

	Yes	No	Unclear	Not Applicable
1. Was the assignment to treatment groups truly random?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Were participants blinded to treatment allocation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Was allocation to treatment groups concealed from the allocator?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Were the outcomes of people who withdrew described and included in the analysis?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Were those assessing outcomes blind to the treatment allocation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Were the control and treatment groups comparable at entry?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Were groups treated identically other than for the named interventions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Were outcomes measured in the same way for all groups?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Were outcomes measured in a reliable way?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Was appropriate statistical analysis used?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Overall appraisal:    Include                   Exclude                   Seek further info.

Comments (Including reason for exclusion)

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## JBI Critical Appraisal Checklist for Descriptive / Case Series

Reviewer ..... Date .....

Author ..... Year ..... Record Number .....

	Yes	No	Unclear	Not Applicable
1. Was study based on a random or pseudo-random sample?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Were the criteria for inclusion in the sample clearly defined?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Were confounding factors identified and strategies to deal with them stated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Were outcomes assessed using objective criteria?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. If comparisons are being made, was there sufficient descriptions of the groups?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Was follow up carried out over a sufficient time period?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Were the outcomes of people who withdrew described and included in the analysis?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Were outcomes measured in a reliable way?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Was appropriate statistical analysis used?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Overall appraisal:      Include                   Exclude                   Seek further info

Comments (Including reason for exclusion)

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### Appendix 3.2: JBI-MAStARI data extraction instrument

**JBI Data Extraction Form for  
Experimental / Observational Studies**

Reviewer ..... Date .....

Author ..... Year .....

Journal ..... Record Number .....

**Study Method**

RCT                       Quasi-RCT                       Longitudinal   
Retrospective                       Observational                       Other

**Participants**

Setting \_\_\_\_\_

Population \_\_\_\_\_

**Sample size**

Group A \_\_\_\_\_ Group B \_\_\_\_\_

**Interventions**

Intervention A \_\_\_\_\_

Intervention B \_\_\_\_\_

Authors Conclusions:  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Reviewers Conclusions:  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Study results**

**Dichotomous data**

<b>Outcome</b>	<b>Intervention ( ) number / total number</b>	<b>Intervention ( ) number / total number</b>

**Continuous data**

<b>Outcome</b>	<b>Intervention ( ) number / total number</b>	<b>Intervention ( ) number / total number</b>

### Appendix 3.3: The list of excluded articles and the reason for exclusions

I searched Medline, IPA, CINAHL, PsycArticles using "Drug Burden Index" resulted in Title screening for 41 articles. The system automatically reduced to 32 articles following review of duplicates.

From abstract screening (32 articles) were reduced to (18 articles). The reason for excluding (14 articles) = 11 (Duplicate), 1 (Narrative Study), 1 (Comparison study), 1 (Construction study).

Table 1: illustrate all studies in search strategies (Database: Medline, IPA, CINAHL, PsycArticles)

Date of search: 29 August 2013

Key word search: (Drug Burden Index) ALL TEXT, Limit (English Language and Time line 2007 to 2013)

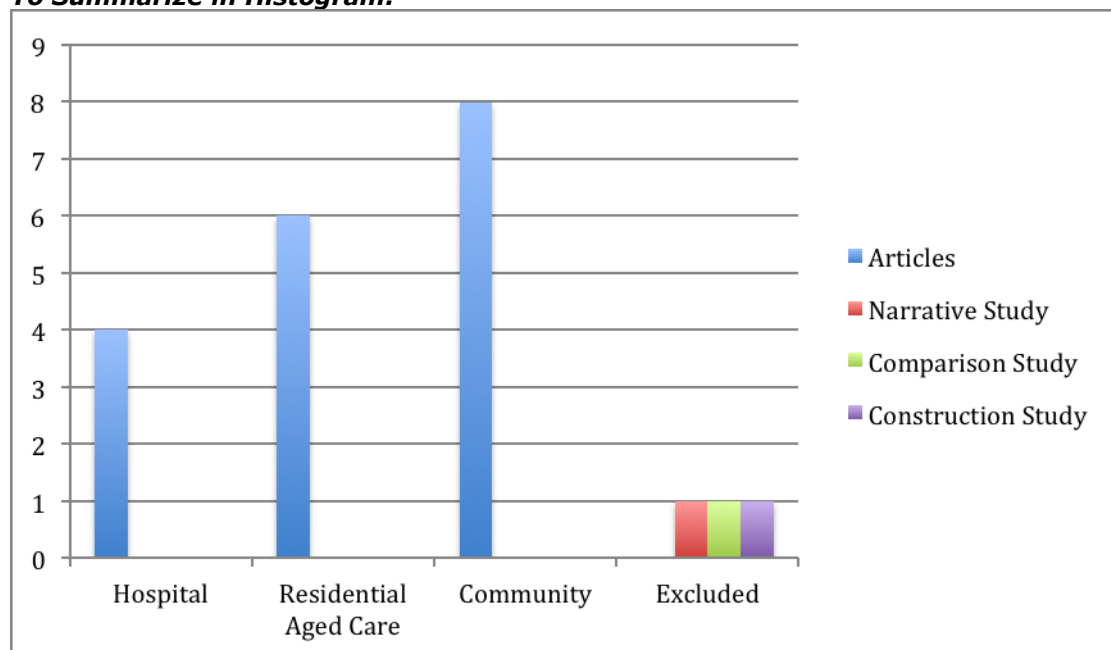
<b>Title</b>	<b>Setting</b>	<b>Describe the Use of DBI</b>	<b>Describe the Construction of DBI</b>
1. A standard international version of the drug burden index for cross-national comparison of the functional burden of medications in older people	Hospital	No (Excluded)	Yes
2. Drug burden index, physical function, and adverse outcomes in older hospitalized patients.	Hospital	Yes	No
3. Drug Burden Index and hospitalization among community-dwelling older people.	Community	Yes	No
4. Drug Burden Index associated with function in community-dwelling older people in Finland: a cross-sectional study.	Community	Yes	No
5. Effects of drug burden index on cognitive function in older men.	Community	Yes	No
6. Associations between drug burden index and mortality in older people in residential aged care facilities.	Residential aged care	Yes	No
7. Drug Burden Index and physical function in older Australian men.	Community	Yes	No
8. Associations between drug burden index and falls in older people in residential aged care.	Residential Aged Care	Yes	No
9. A drug burden index to define the functional burden of medications in older people.	Community	Yes	No
10. Drug Burden Index and Beers Criteria: Impact on Functional	Self Care Retirement Village	Yes	No

Outcomes in Older People Living in Self-Care Retirement Villages.			
11. A pilot randomized clinical trial utilizing the drug burden index to reduce exposure to anticholinergic and sedative medications in older people.	Self care Retirement Village	Yes	No
12. Drug Burden Index and potentially inappropriate medications in community-dwelling older people: the impact of Home Medicines Review.	Community	Yes	No
13. Drug burden index score and functional decline in older people.	Community	Yes	No
14. Associations between drug burden index and physical function in older people in residential aged care facilities.	Residential Aged Care	Yes	No
15. Impact of residential medication management reviews on drug burden index in aged-care homes: a retrospective analysis.	Hospital	Yes	No
16. Measures of Anticholinergic Drug Exposure, Serum Anticholinergic Activity, and All-cause Postdischarge Mortality in Older Hospitalized Patients With Hip Fractures.	Hospital	Yes	Yes
17. High risk prescribing in older adults: prevalence, clinical and economic implications and potential for intervention at the population level.	Hospital	Yes	Yes
18. A comparison of four methods to quantify the cumulative effect of taking multiple drugs with sedative properties.	Comparison Study	No	No
19. Medication use and functional status decline in older adults: a narrative review.	Narrative Review	Yes	No



20. Use of Potentially Harmful Medications and Health-Related Quality of Life among People with Dementia Living in Residential Aged Care Facilities.	Residential Aged Care	Yes	No
21. High-risk prescribing and incidence of frailty among older community-dwelling men.	Community	Yes	No

**To Summarize in Histogram:**



**Appendix 4.1: The ethical review panel of the School of Pharmacy and Life Sciences at Robert Gordon University- Phase 2**

**ROBERT GORDON UNIVERSITY  
SCHOOL OF PHARMACY AND LIFE SCIENCES  
ETHICAL APPROVAL FORM FOR UNDERGRADUATE, TAUGHT MSc, PhD AND EXTERNAL PROJECTS**

**SECTION 1 – to be completed**

<b>Research Student Name</b>	Saeed Al Shemeili
<b>Study Coordinator</b>	Professor Derek Stewart
<b>Research Project Title</b>	Exploring medicines management in elderly, hospitalized patients in the United Arab Emirates: health professionals' views, experiences and perceptions of associated healthcare structures, processes and outcomes

**SECTION 2 – to be completed by the School Research Ethics Committee**

Date submitted to panel: 2013

<b>Indicate Yes or No to each question and comment as appropriate.</b>	<b>Panel member 1</b>	<b>Panel member 2</b>	<b>Panel member 3</b>	<b>Student Response</b>
Is the research question clear?	Partially – doesn't fully tie to research – could do with some rethinking and mapping to method.	Partially – agree with PM1's comments	Yes	
Is the project scientifically robust?	yes	yes	Yes	
Are the procedures for obtaining informed consent clear and appropriate? If an audit does the student have approved access to information?	yes	yes	yes	
Is the extent of participant involvement clear?	yes	yes	yes	

Are the recruitment procedures ethical and appropriate?	yes	yes	yes	
Are the inclusion and exclusion criteria relevant and appropriate?	yes	yes	yes	
Is the extent and type of participant involvement ethical? (consider issues of unnecessary invasiveness, exposure, undue stress, anxiety and concern, inappropriate time commitments)	yes	yes	yes	
Are there clear procedures for ensuring compliance with the Data Protection Act?	yes	yes	yes	

Please check the boxes below with your decision	Panel member 1	Panel member 2	Panel member 3
<b>1. Approved – submit to LREC / MREC as appropriate and provide copy of approval letter to supervisor OR provide supervisor with evidence that submission not necessary</b>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
<b>2. NOT Approved – MINOR ISSUES approval subject to submitting a response, to ethics review panel via supervisor, addressing minor issues outlined above</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>3. NOT approved – MAJOR ISSUES serious issues of concern to be addressed and whole proposal to be resubmitted via supervisor for further ethical review.</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>4. NOT approved – UNETHICAL the study is unethical and a re-submission will not be considered.</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Comments:</b>			

SECTION 3 - OVERALL ETHICAL DECISION to be completed by Chair of School Research Ethics Committee

- 1. Approved – submit to LREC / MREC as appropriate and provide copy of approval letter to supervisor OR provide supervisor with evidence that submission to LREC / MREC not necessary**
- 2. NOT Approved – MINOR ISSUES: subject to submitting a response, to ethics review panel via supervisor, addressing minor issues outlined above**
- 3. NOT approved – MAJOR ISSUES: there are serious issues of concern to be addressed and whole proposal to be resubmitted via supervisor for further ethics panel review.**
- 4. NOT approved – UNETHICAL: the study is completely unethical and a re-submission will not be considered.**

Signed (on behalf of the School Research Ethics Committee) Dr Lesley Diack

Date: 9<sup>th</sup> July 2013

Membership: Dr Stuart Cruickshank, Dr Lesley Diack (Chair), Dr Marie Goua, Dr Graeme Kay, Dr Morag McFadyen, Mrs Katie Maclure, Dr Stephen Macmanus, Dr Colin Thompson, Dr Anita Weidmann, Dr Wendy Wrieden.

## Appendix 4.2: Ethics and Research Committee in Al Mafraq Hospital

### مستشفى المفرق Mafraq Hospital

22<sup>nd</sup> December 2013

**Principal Investigator:**

Saeed Al Shemeili  
PhD Student  
School of Pharmacy and Life Sciences  
Robert Gordon University

**Study Title:**

**Exploring medicines management in elderly, hospitalized patients in the United Arab Emirates: health professionals' views, experiences and perceptions of associated healthcare structures, processes and outcomes.**

Dear Mr. Saeed,

On behalf of *Ethics & Research Committee*, please be informed that your proposal was reviewed and approved as there are no ethical concerns of the project.

Regards,



**Mustafa Al-Maini, MD, FRCP C Msc**  
Chair of Ethics & Research Committee  
Deputy Medical Director  
Chief of Rheumatology, Allergy and Clinical Immunology Division

## Appendix 4.3: Al Ain Hospital Ethics Committee



### AAH Ethics Committee

TO: Mr. Saeed Al Shemeli  
Graduate Student  
*Robert Gordon University*

CC: AAH Ethics Committee

Date: 22<sup>nd</sup> October 2013

RE: **Proposed Research Study: Exploring medicines management in elderly, hospitalized patients in the United Arab Emirates: Health Professionals' views, experiences and perceptions of associated healthcare structures, processes and outcomes**

Ref: AAH/EC10-13-004

Dear Mr. Shemeli:

On behalf of the Ethics Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form and supporting documentation.

The favorable opinion is given provided that you comply as per the context set out in your research study.

You are hereby advised to commence your research study at Al Ain Hospital. In keeping with our policy, the AAH Ethics Committee is kindly requesting that please report any ethical concerns/considerations that may arise during the course of your research, in a timely manner. The Committee is wishing you a success for this project.

Yours sincerely,

  
Dr. Mouza A. Al Kuwaiti  
Acting Chief Medical Officer  
Chair, AAH Ethics Committee  
*Al Ain Hospital*



## Appendix 4.4: Institutional Review Board/Research Ethics Committee in SKMC



managed by  
  
Cleveland  
Clinic

Institutional Review Board  
Research Ethics Committee

### APPROVAL LETTER

12 September 2013

**Saeed Al Shemali**  
PhD Student  
Robert Gordon University  
Aberdeen, United Kingdom

<b>Ethics Approval Reference No:</b> <i>Please quote this ref # in all correspondence</i>	<b>REC-12.09.2013 [RS-275]</b>
<b>Research Title:</b>	<b>Exploring medicines management in elderly, hospitalized patients in the United Arab Emirates: health professionals' views, experiences and perceptions of associated healthcare structures, processes and outcomes</b>

Dear Sir,

Thank you for submitting the above-titled research proposal seeking approval from Institutional Review Board/Research Ethics Committee (IRB/REC).

Submitted proposal and its related documents were reviewed. As part of a submission towards a Doctor of Philosophy qualification from Robert Gordon University and ethically approved from your university in UK, this project poses no ethical issues and the committee approved to carry out this project in SKMC as designed with the approval and guidance from the Human Resources Department designated staff as agreed upon.

Kindly note that approval is given on the understanding that the researcher complies on the applicable guidelines and regulations governing the conduct of clinical trials<sup>1</sup> particularly as to the following:

- *Any amendments or significant change which occurs in connection with this study and/or which may alter its ethical consideration, premature suspension or termination of the study must be reported immediately to the Research Ethics Committee Office.*
- *IRB has an authority to suspend or terminate approval of this research study if not being conducted in accordance with the IRB's requirements or has been associated with unexpected serious harm to subjects.*

<sup>1</sup> <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>



## Appendix 4.5: Al Ain Medical District Human Research Ethics Committee in Tawam Hospital



6<sup>th</sup> August 2013

**Saeed Al Shemeili**  
**Graduate Student**  
**Robert Gordon University**

Dear Mr. Saeed:

**Re: Al Ain Medical District Human Research Ethics Committee - Protocol No. 13/75 - Exploring medicines management in elderly, hospitalized patients in the United Arab Emirates: health professionals' views, experiences and perceptions of associated healthcare structures, processes and outcomes.**

Thank you very much for submitting your application to the Ethics Committee.

Your submitted documents were reviewed by the committee and I am pleased to provide you ethical approval of your project.

May I reiterate, should there be any ethical concern arising from the study in due course the Committee should be informed.

Annual reports plus a terminal report are necessary and the Committee would appreciate receiving copies of abstracts and publications should they arise.

I wish to take this opportunity to wish you success with this important study.

This Ethics Committee is an approved organization of Federal Wide Assurance (FWA) and compliant with ICH/GCP standards.

**Note: This was expediting process done for student research and any extensions of the objects of the study will need a new application.**

With kind regards,

Yours sincerely,

**Dr. Fawaz Torab**

Chair, Al Ain Medical District Human Research Ethics Committee

## Appendix 4.6: Ethic and Research Committee in Zayed Hospital

MEDICAL SERVICES CORP



### NOTIFICATION OF APPROVAL OF A PROPOSED RESEARCH STUDY

Date: 23/1/2014

To: Dr Saeed Al Shemeli

study titled: Exploring medicine management in elderly, hospitalized patients in UAE: health professionals view, experience & perception of associated health care structure, process & outcome.

Study reference number : 2014.04.

**The Committee has given a favorable ethical opinion for the above project based on the application form, protocol and supporting documentation that comply with the conditions and principles established by (ICH GCP) according to HAAD regulations**

Yours Sincerely

Dr Asma Ali Al Nuaimi  
Ethical Committee Chair

Dr. Sherine Naser .  
Ethical committee co chair

#### Appendix 4.7: Email Invitation- Phase 2

Dear Colleagues,

I am a hospital pharmacist from Abu Dhabi who is studying for a PhD at Robert Gordon University (RGU) in Scotland. My research focuses on medicines management in elderly hospitalized patients in Abu Dhabi. I am keen to obtain the views and experiences of health professionals such as you in respect of this key aspect of healthcare delivery and support.

The study has been approved by RGU and HAAD. It is being conducted under the supervision of Professors Derek Stewart, Susan Klein and Alison Strath in Aberdeen and Dr Saleh Fares (Consultant, Emergency Department, Zayed Military Hospital) in Abu Dhabi.

I would be grateful if you could click on the following link or cut and paste the entire URL into your browser to get information about the study:

[al](https://www.surveymonkey.com/s/HospitalProfession)

If you are willing to take part, please complete the short questionnaire, and I will be in touch with you to conduct the next stage of this research.

Yours faithfully

Saeed Al Shemeili

00971505526562

[0303462@rgu.ac.uk](mailto:0303462@rgu.ac.uk)

## **Appendix 4.8: Participant information leaflet-Phase 2**

## **PARTICIPANT INFORMATION**

### **Research Team**

Robert Gordon University (RGU): Saeed Al Shemeli  
Professor Derek Stewart  
Professor Susan Klein  
Professor Alison Strath

United Arab Emirates (UAE): Dr Saleh Fares

### **Title of Project**

Exploring medicines management in elderly, hospitalized patients in the United Arab Emirates (UAE): health professionals' views, experiences and perceptions of associated healthcare structures and processes.

You are being invited to take part in a research study. Before you decide if you wish to take part, it is important for you to understand why the research is being undertaken and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish.

Ask me if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

### **What is the purpose of the study?**

The aim of the research is to explore the views, experiences and perceptions of doctors, nurses and pharmacists in the UAE relating to medicines management for the elderly, hospitalized patients. While there is no standardized, universally accepted definition of 'medicines management', this basically refers to 'getting the best from medicines'.

### **Study aim**

This research aims to explore the role of the health professional in medicines management for the elderly, hospitalized patients in the United Arab Emirates. It also takes into consideration the views of health professionals, their experiences and perceptions of healthcare structures and processes.

A researcher (Saeed Al Shemeili) from the UAE and former employee at Zayed hospital will carry out the study. I am currently studying at Robert Gordon University and this work will form part of a submission towards a Doctor of Philosophy qualification from Robert Gordon University.

### **Why have I been chosen?**

You have been chosen because you are a doctor, nurse or pharmacist working in hospital practice in the UAE. You therefore have experience of medicines related issues and belong to one of the health professional groups involved with medicines management in elderly, hospitalized patients and you are familiar with the current healthcare structure and process in the UAE.

### **Do I have to take part?**

No. It is up to you to decide whether or not to take part. If you do, you will be given this information sheet to keep and be asked to sign an informed consent form. 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 any way your employment with Health Authority of Abu Dhabi (HAAD).

### **What will happen to me if I take part?**

If you interested, you should complete the short questionnaire. You may then be invited to take part in an interview of approximately 30 to 45 minutes with the researcher at either a private room in the hospital or your office, whichever is more convenient. You will be asked to provide your views and experiences relating to medicines management in elderly hospitalized patients. The interview will be audio

recorded with your permission. The recording will be transcribed into a qualitative data software system to aid analysis. You will be provided with a transcript of the audio recording if requested and allowed to make any required amendments to the transcript.

Any information provided during the interview will be anonymous and confidential. Your name will not appear on the transcript or any report of the research. This information may be used anonymously in any publication or presentation of the study results.

### **What do I have to do?**

If you decide to take part in the study, you will be asked to sign an informed consent form and to take part in the interview as described above.

### **What are the possible benefits of taking part?**

There are no direct benefits to you by taking part in the study.

There may be benefits to the organisation in term of learning from your views and experiences of medicines management for elderly.

### **What if there is a problem?**

Any complaint about the way you have been dealt with during the study will be addressed. If you have any complaints or would like further information about the study please contact:

Professor Derek Stewart  
School of Pharmacy & Life Sciences  
Robert Gordon University  
Aberdeen  
AB10 7QJ  
Scotland  
+44 (0)1224 262432  
d.stewart@rgu.ac.uk

**Will my taking part in the study be kept confidential?**

Yes. All the information about your participation in this study will be kept confidential. Any data relating to your participation will be stored securely at all times and can only be accessed by the researcher.

**You will be given a copy of the information sheet and a signed consent form to keep.**

Thank you for taking time to read the information sheet and for considering taking part in this study.



**Appendix 4.9: Online sampling questionnaire**

**ONLINE QUESTIONNAIRE**

1. Your profession is

- Doctor                       Nurse                       Pharmacist

2. Your main place of work is

- Government services/ Public sector                       Private Sector

3. You manage elderly patients (60 years or older) in your day to day work

- Yes                       No

4. You have been practising in your profession for

- 5 years or less                       6-10 years                       11-15 years  
 16-20 years                       21-25 years                       26-30 years  
 31-35 years                       >35 years

5. You completed your undergraduate training in

- UAE                       Other, please specify\_\_\_\_\_

6. You have also practised as a health professional in countries other than UAE

- No                       Yes, please specify country\_\_\_\_\_

7. Are you willing to take part in the interview, as described in the participant information leaflet?

- Yes                       No

If yes, please give the following details so that you can be contacted to arrange the interview

Name \_\_\_\_\_  
Email \_\_\_\_\_

**Appendix 4.10: Interview participant consent form**

**CONSENT FORM**

Title of Project

Exploring medicines management in elderly, hospitalized patients in the United Arab Emirates (UAE): health professionals' views, experiences and perceptions of associated healthcare structures and processes.

**Researcher**

Saeed Al Shemeili  
PhD Student  
Robert Gordon University  
UK  
E-mail: 0303462@rgu.ac.uk

Participant Study Number.....

**Please INITIAL  
box**

I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions.

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving reason.

I agree to take part in the above study.

I agree to the interview being audio recorded.

I agree to the use of anonymised quotes in publications.

\_\_\_\_\_  
Name of Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Name of Researcher

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

**Appendix 4.11: Draft semi-structured interview schedule**

**SEMI-STRUCTURED INTERVIEW SCHEDULE**

Title of Project  
Exploring medicines management in elderly, hospitalized patients in the United Arab Emirates (UAE): health professionals’ views, experiences and perceptions of associated healthcare structures and processes.

Participant Number	Date / /	Start time :
--------------------	-------------	-----------------

**Introduction**

Hello, thanks for agreeing to be interviewed for this project. Please, can I check you have read the participant information sheet?  
If not, here is a copy to read before we begin.

The main purpose of this interview is to find out your views, experiences and perceptions of medicines management for elderly, hospitalised patients in the United Arab Emirates (UAE).

Your participation is voluntary and you may withdraw at any point.  
If you do not want to answer a specific question, then please let me know.  
There are no right or wrong answers and I am interested in your personal opinions.

Your identity will remain strictly confidential and it will not be possible to identify individuals from the study results.

The interview should take approximately 30 to 45 minutes. Are you ok to go ahead?

<p><b>IF NO:</b> That’s okay. When would be more convenient?</p> <p>Thanks I’ll see you on day/date/time at .....location. Bye.</p>	<p>Write the new day/date/time here and in the diary chart:</p>
---	---

**IF YES continue:** That’s great, thank you.

## Housekeeping

As you are aware from the information sheet and consent form, this conversation is being audio recorded but I would emphasise that it is confidential.

Please do not use names of patients or hospital staff during this interview. It is ok to refer to "a patient", "another doctor", " a nurse", "a pharmacist" etc

Are you still OK with that?

<b>IF NO:</b> That's fine. I'll need a bit more time to write down notes as we go through the sections and I may ask you to repeat some answers so I don't miss anything.	<b>Reminders</b> <ul style="list-style-type: none"><li>• Take time to write detailed notes</li><li>• If in doubt, ask the interviewee for clarification before you move on to the next section</li></ul>
--	--

If you decide after the interview you no longer wish to be a part of the research, please let me know. The contact details are on the information sheet.

Do you have any questions before we begin?

**Technical problem? Keep calm!** Explain, apologise and rearrange interview day/date/time

Can I start off by asking if you have had any specific training around medicines in the elderly?

- can you please describe the training, where you received it, when, duration etc.
- what did you think of the training?
- would you recommend it to others?

I am interested in issues/problems/difficulties relating to medicines in elderly patients and how you handle these.

**Note answers here for backup and reference**

What issues do you routinely encounter in your day to day practice?

How do you handle these?

Why in that way?



I am now going to ask you about different stages of the patient journey or patient stay while in hospital. **I am really interested in your routine day to day practice and care given to every patient**

These first questions are about how you are routinely involved at the point of patient admission to hospital

Are you routinely involved with patients and medicines that were taking before they admitted to hospital

What do you do in relation to

- Finding out medicines patients take,
- Finding out how and when they take them,
- Finding out how long,
- Finding out any side effects they are having,
- Finding out issues related to poor adherence

Do you have sufficient time and resources to do this for every patient or do you target certain patient.

- If target, how do decide which patient

How and where do you document your actions?

Do you share this information with other health professionals?

- Probe on how etc.

Why do you do what you do?

- Probe around learnt from others, experience etc

Do you think that it works well?

- Probe around how do you know, measure that it works well etc

Why does it work well or not work well?

**Note answers here for backup and reference**

<p>Now moving from the point of admission to in-patient stay in hospital.</p>	
<p>Are you routinely involved with patients and medicines prescribed in hospital</p> <p>What do you do in relation to</p> <ul style="list-style-type: none"> <li>• Probe around issues relating to medicine choice,</li> <li>• ADRs,</li> <li>• interactions,</li> <li>• continuous review and monitoring</li> </ul> <p>Do you do this for every patient or do you target certain patient</p> <ul style="list-style-type: none"> <li>• If target, how do decide which patient</li> </ul> <p>How and where do you document your actions?</p> <p>Do you share this information with other health professionals?</p> <ul style="list-style-type: none"> <li>• Probe on how etc.</li> </ul> <p>Why do you do what you do?</p> <ul style="list-style-type: none"> <li>• Probe around learnt from others, experience etc</li> </ul> <p>Do you think that it works well?</p> <ul style="list-style-type: none"> <li>• Probe around how do you know, measure that it works well etc</li> </ul> <p>Why does it work well or not work well?</p>	<p><b>Note answers here for backup and reference</b></p>

Now moving to the point of patient discharge from hospital.

**Note answers here for backup and reference**

Are you routinely involved with patients and medicines as they discharged from the hospital

What do you do in relation to

- Probe around issues relating to review of medicines, medicine choice etc
- Probe around patient/carer education
- Probe around passing care to other professionals

Do you do this for every patient or do you target certain patient.

- If target, how do decide which patient

How and where do you document your actions?

Do you share this information with other health professionals?

- Probe on how etc.

Why do you do what you do?

- Probe around learnt from others, experience etc

Do you think that it works well?

- Probe around how do you know, measure that it works well etc

Why does it work well or not work well?

Now some more general questions.

<p>In your experience are ADRs a common cause of admission for elderly patients? Or during stay?</p> <ul style="list-style-type: none"> <li>• Probe for examples, reasons</li> </ul> <p>In your experience are there issues related to poor adherence to medicine regimens? And educating patients and carers</p> <ul style="list-style-type: none"> <li>• Probe for examples, reasons</li> </ul> <p>In your experience are there issues around prescribing/drug selection?</p> <ul style="list-style-type: none"> <li>• Probe for examples, reasons</li> </ul> <p>Do you use any guidelines or policies to help you in drug selection?</p> <p>Are you aware of any list of high risk medicines in the elderly</p> <ul style="list-style-type: none"> <li>• STOPP/START,</li> <li>• BEERS,</li> <li>• Medication Appropriateness Index (MAI)</li> <li>• DBI</li> <li>• Probe how heard, what are their opinions?</li> </ul> <p>Have you heard of the term 'polypharmacy'? What does it mean to you? Are there implications for your practice?</p> <p>What is your experience around issues of communication between health professionals related to medicines in the elderly?</p> <p>Can you tell me about the main influences on your practice around medicines in the elderly</p> <ul style="list-style-type: none"> <li>• Probe on the role of peers and significant others, personal experiences, professional experiences, their profession, the organisation</li> </ul> <p>Do you think there is any need for specialist education and training around medicines in the elderly?</p> <ul style="list-style-type: none"> <li>• Probe on what, how</li> </ul> <p>Do we think that we optimise medicines management of elderly patients?</p> <ul style="list-style-type: none"> <li>• Probe on how can we do it better - prescribing/drug selection/appropriate polypharmacy – you, profession, organisation</li> </ul>	<p><b>Note answers here for backup and reference</b></p>
--	--

**4. Is there anything else you would like to add on medicines and elderly patients?** Note answers here for backup and reference

<p>Is there anything that prevents us better optimising their medicines?</p> <ul style="list-style-type: none"> <li>• Probe them, peers, organisation etc</li> <li>• Resources and time</li> </ul> <p>Do you think that there would be any barriers to change?</p> <p>What would help with change?</p>	<p>Note answers here for backup and reference</p>
<p>How ready are you for any change?</p> <ul style="list-style-type: none"> <li>• Probe on reasons for response, factors influencing readiness, do you like change</li> </ul> <p>Lastly, do you think that patients are satisfied and that they think we optimise their medicines?</p> <ul style="list-style-type: none"> <li>• Probe on why and how</li> </ul>	

Well that's all of my questions. You've been very helpful and I appreciate you taking the time to speak to me. If you think of anything else you would like to add, please get in touch. If you would like to see a copy of the transcript from the interview, please let me know and I will arrange for this to be supplied to you. Thank you very much.

**Transcript  
Y/N**

**Interview  
concluded at:  
:**

## Appendix 4.12: Search Strategy - Phase 2

**Database:** MEDLINE, CINAHL, INTERNATIONAL PHARMACEUTICAL ABSTRACTS

**Date of search:** 24 Jan 2015

Key words Search: **TEXT**, Limit (English Language and Time line 2000 to 2015)

	<b>Medicines</b>	<b>Hits</b>
1	medic*	5,354,648
2	drug*	2,907,261
3	pharmaceutical*	373,247
<b>A</b>	1 or 2 or 3	6,925,758
	<b>Management</b>	<b>Hits</b>
4	prescrib*	200,833
5	management*	1,517,507
6	process*	2,689,679
7	activit*	2,889,399
8	adherence*	145,129
9	counselling	50,668
10	reconcil*	24,639
11	train*	712,882
<b>B</b>	4 or 5 or 6 or 7 or 8 or 9 or 10 or 11	6,813,783
	<b>Qualitative</b>	<b>Hits</b>
<b>C</b>	Qualitative	260,122
<b>Final search</b>	A and B and C	81,668
	Abstract- A and B and C	0
	Title- A and B and C	0



## Appendix 5.1: The ethical review panel of the School of Pharmacy- Phase 3



### School of Pharmacy and Life Sciences Research Ethics Committee

**COMPLETED**

**26 November 2013**

Determination of the United Arab Emirates stakeholder consensus in relation to strategic and operational approaches around medicines management in the elderly.

Dear Saeed

We have reviewed your ethics application (Title above) and it has been approved with a few small changes as listed below:

- Joanna Brings to Joanna Briggs
- Take out purposive before snowball
- Put your address at end of Information leaflet not in middle and not your supervisor

However once these changes are made the panel recommends that it is of sufficient standard for you to proceed.

If there are any questions please do not hesitate to get in touch.

Regards

A handwritten signature in black ink that reads 'Lesley Diack'.

Dr Lesley Diack  
Chair of the School Ethics Review Panel

## **Appendix 5.2: Participant consent form- Delphi Study**

**CONSENT FORM**

**Title of Project**

Determination of the United Arab Emirates stakeholder consensus in relation to strategic and operational approaches around medicines management in the elderly.

**Researcher**

Saeed Al Shemeili  
PhD Student  
Robert Gordon University  
UK  
E-mail: 0303462@rgu.ac.uk

Participant Study Number.....

**Please INITIAL  
box**

I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions.

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving reason.

I agree to take part in the above study.

I agree to the use of anonymised quotes in publications.

\_\_\_\_\_  
Name of Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Name of Researcher

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

## Appendix 5.3: SNAP 10- Online survey tool

J15

Exploring Medication Management in UAE (Round 2)

### INSTITUTE FOR HEALTH & WELLBEING RESEARCH: GRADUATE SCHOOL



#### 1. General Statements

- 1.1** The following definition of medicines management should be adopted in the UAE - 'the clinical, safe and cost effective use of medicines to ensure patients get the maximum benefit from the medicines they need, while at the same time minimizing potential harm'.  
**Consensus reached: 84%**
- 1.2** Elderly patients with multi-morbidities<sup>1</sup> are at particular risk of medicines related issues  
**Consensus reached: 92%**
- 1.3** Medicines management should be a focus in the care of every elderly patient admitted to hospital, irrespective of the reason for admission or presenting complaint  
**Consensus reached: 84%**
- 1.4** Medicines management should be a focus in the care of every elderly patient admitted to hospital, irrespective of the admitting ward or speciality  
**Consensus reached: 92%**
- 1.5** Medicines management should be a focus in the care of elderly patient admitted to hospital, irrespective of the duration of stay in hospital  
**Consensus reached: 80%**

- 1.6** Medicines management should only be a focus in the care of elderly patients admitted to hospital with a medicines related issue  
**Consensus not reached: 34%**
- 1.7** Medicines management is the responsibility of all nurses, pharmacists and physicians  
**Consensus reached: 84%**
- 1.8** All nurses, pharmacists, physicians should be competent in medicines management  
**Consensus reached: 92%**
- 1.9** Evidence based recommendations which focus on single disease states should be applied with caution in elderly patients with multi-morbidities  
**Consensus reached: 92%**

**Section 1: consensus achieved for eight statements.**

Consensus not achieved for statement 1.6, that medicines management is a focus for those with medicines related issues BUT reached consensus on 1.3, that it is a focus for every elderly patient.

Enter any comments below:



### Appendix 5.4: Search strategy - Phase 3

**Database:** MEDLINE, CINAHL, INTERNATIONAL PHARMACEUTICAL ABSTRACTS

**Date of search:** 12 April 2015

Key words Search: **Title**, Limit (English Language and Time line 2000 to 2015)

	<b>Medicines</b>	<b>Hits</b>
1	medic*	586,816
2	drug*	413,590
3	pharmaceutical*	38,835
<b>A</b>	1 or 2 or 3	1,023,463
	<b>Management</b>	<b>Hits</b>
4	prescrib*	23,186
5	management*	369,493
6	process*	196,210
7	activit*	586,490
8	adherence*	26,429
9	counselling	5,910
10	reconcil*	2,688
11	train*	130,165
<b>B</b>	4 or 5 or 6 or 7 or 8 or 9 or 10 or 11	1,326,528
	<b>Delphi</b>	<b>Hits</b>
12	Delphi	2,143
13	Consensus	19,040
<b>C</b>	12 or 13	20,846
<b>Final search</b>	A and B and C	194
	A and B and Delphi	21