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Polypharmacy Management by 2030: a patient safety challenge

Polypharmacy Management by 2030: a patient safety challenge

SIMPATHY

Stimulating Innovation Management of Polypharmacy and Adherence in The Elderly

Polypharmacy Management by 2030: a patient safety challenge

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Abbreviations

ADR – Adverse drug reactions
AGREE II-GRS – Appraisal of guidelines for research and valuation II - global rating scale
EU – European Union
ICT – Information and communications technology
NPT – Normalization Process Theory
PESTEL – Political, economic, social, technological, environmental, and legal
SIMPATHY – Stimulating Innovation Management of Polypharmacy and Adherence in The Elderly
SWOT – Strengths, weaknesses, opportunities and threats
WHO – World Health Organisation

Foreword

Populations are aging, and many people over the age of 50 live with multiple long-term conditions and take multiple medications. Medication is the single most common healthcare intervention and generates the third highest cost of health expenditure. Up to 11% of all unplanned hospital admissions are attributable to medicines related harm.[a] The European Union has identified the reduction of avoidable harm in healthcare as a key priority. Over the last 15 years, in reports such as *To Err is Human*, countries have raised patient safety as an opportunity to reduce harm. Building on this, both *Choosing Wisely, Free from Harm* and the *Patient Safety 2030* report suggest that this could be approached by developing a holistic systematic approach that extends across the professional, cultural, technological and procedural boundaries.[b,c]

The SIMPATHY (Stimulating Innovation Management of Polypharmacy and Adherence in The Elderly) consortium have explored how healthcare management programmes can be implemented to improve medication safety and prevent patient harm by addressing the appropriate use of multiple medications (polypharmacy). Fundamental to these programmes is the principle that providers work in partnership with patients to enable shared decision making regarding medication, which improves patient adherence and medicines related outcomes.

This report sets out the case for prioritising working together now to address inappropriate medication use over the next decade, to ensure the quality, economic and political systems are put in place to improve medication safety for patients. There are encouraging signs of the increasing recognition of these challenges, and the timeliness of this report. In March 2017, the World Health Organisation (WHO) launched a global challenge to address medication safety, with polypharmacy as a flagship element. A special interest group will be launched by the International Foundation on Integrated Care in May 2017.

First and foremost, the priority for polypharmacy management has to be about the quality of patient care. It is essentialy done within the economic resources available and enabled by political support.

We commend the recommendations of this report to you and call for your support in tackling together the important issues in delivering appropriate management of polypharmacy.

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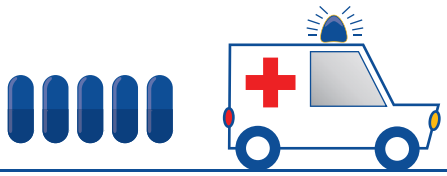
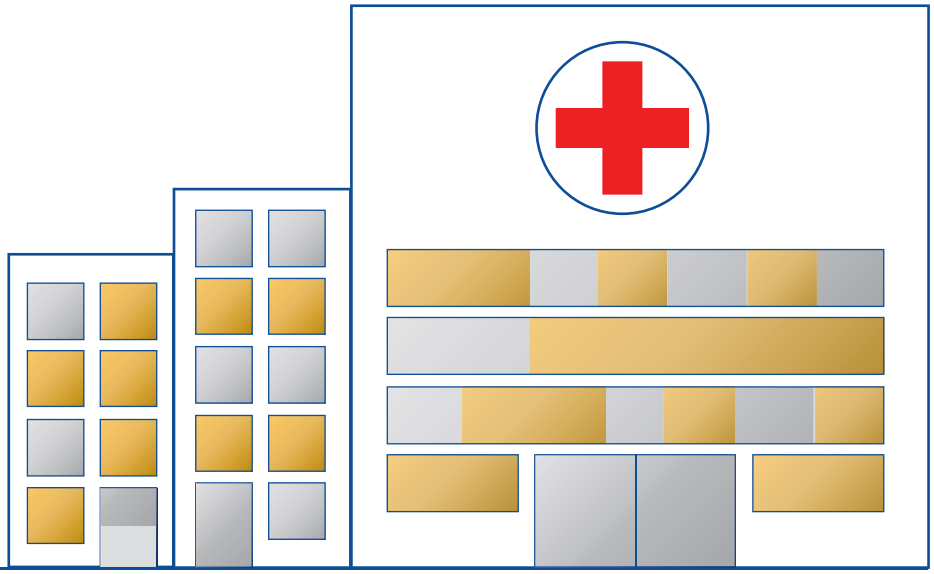
a. Kohn LT, Corrigan JM, Donaldson MS, Eds. To err is human - building a safer health system. Washington, D.C. National Academy Press; 2000. ISBN: 0-309-06837-1
b. Malhotra A, Maughan D, Ansell J, Lehman R, Henderson A, Gray M, Stephenson T, Bailey S. Choosing Wisely in the UK: the Academy of Medical Royal Colleges' initiative to reduce the harms of too much medicine. BMJ. 2015;350:h2308. doi: 10.1136/bmj.h2308.
c. Yu A, Flott K, Chainani N, Fontana G, Darzi A. Patient Safety 2030. London: NIHR Imperial Patient Safety Translational Research Centre; 2016.

UNPLANNED **HOSPITAL ADMISSIONS** CAUSED BY **ADVERSE DRUG EVENTS**

8.6 MILLION ADMISSIONS IN EUROPE **EVERY YEAR**





PREVENTABLE HOSPITAL **ADVERSE DRUG EVENTS** ADMISSIONS

PATIENTS ON **5 OR MORE MEDICINES**

PATIENTS **OVER 65** YEARS OF **AGE**

50% ARE **PREVENTABLE**

Executive Summary

Inappropriate polypharmacy and medicines adherence in the elderly is one of the most significant public health challenges of the current age. This burden is set to increase as the population ages and more people suffer from multiple long term conditions. There remains a lack of evidence-based solutions, as both medical research and healthcare delivery models have focused on single disease interventions. This challenge, and the limited range of solutions, has significant implications for how healthcare resource is used to address inappropriate polypharmacy. However, with up to 11% of unplanned hospital admissions being attributable to harm from medicines, and over 70% of these being due to elderly patients on multiple medicines there are significant opportunities to reduce this burden by timely and effective interventions.[1]

The Institute of Medicine report, *Responsible use of Medicines* demonstrates that 0.3% of the global health budget could be saved by managing polypharmacy appropriately.[2] The report identifies key areas of focus which include using risk stratification to identify vulnerable patients and a more collaborative role for pharmacists, physicians and patients.

Facing the challenge of reducing patient harm, the European Union (EU) issued a public health call to identify, develop and implement innovative solutions that can be implemented at scale to address key problems. Stimulating Innovation Management of Polypharmacy and Adherence in the Elderly (SIMPATHY) is one of the funded projects to deliver tools to implement polypharmacy management programmes throughout the EU in the context of quality, economic and political factors.

The SIMPATHY case studies, benchmarking survey and literature review demonstrate that there are some effective polypharmacy management programmes in the EU, but that they are too few in number. The project also demonstrates that patients believe inappropriate polypharmacy is an important issue to address.

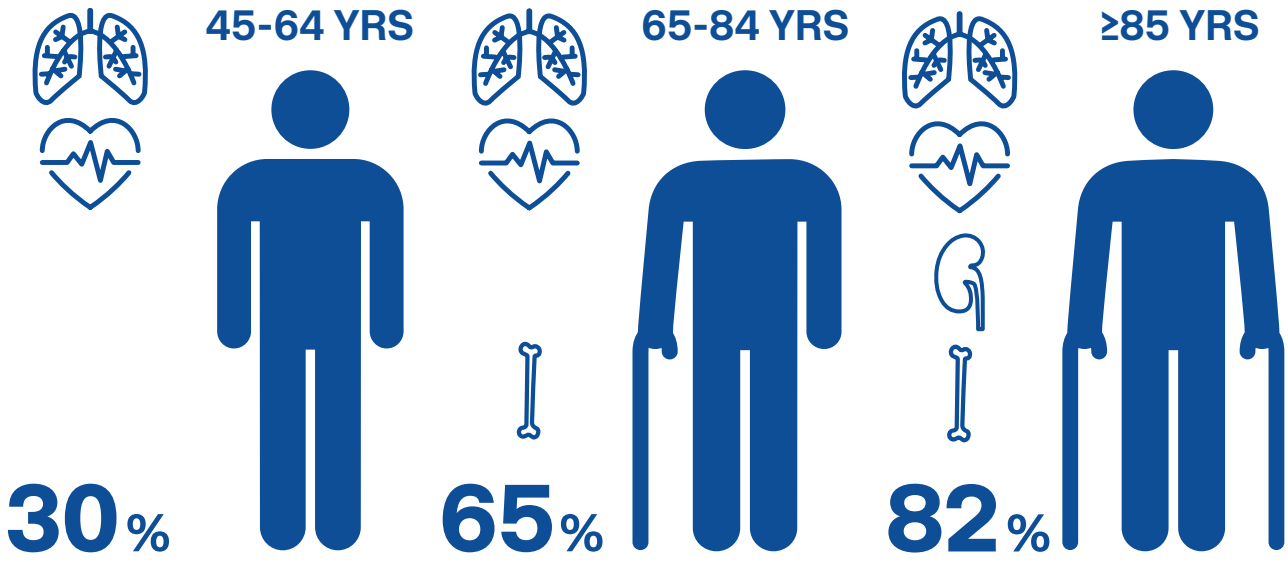
This report calls for EU countries to work together in a focused way to manage and prevent inappropriate polypharmacy, and improve medicines adherence, through the use of a change management approach that is coordinated and collaborative in order to deliver better patient outcomes.

Six key recommendations:

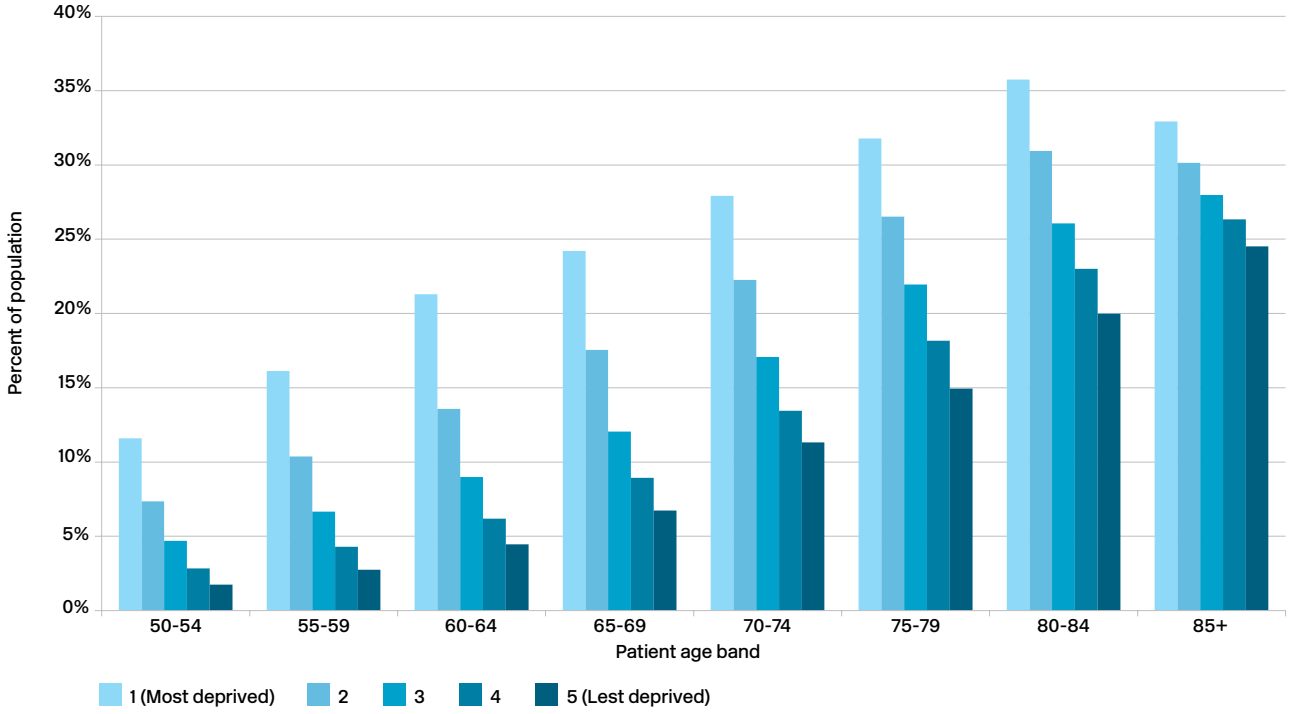
1. Use a systems approach that has multidisciplinary clinical and policy leadership
2. Nurture a culture that encourages and prioritises the safety and quality of prescribing
3. Ensure that patients are integral to the decisions made about their medications and are empowered and supported to do so
4. Use data to drive change
5. Adopt an evidenced based approach with a bias towards action
6. Utilise, develop and share tools to support implementation

Adopting these recommendations will help prepare EU countries for the WHO global challenge to improve medication safety, of which polypharmacy is an essential element.

MORE PEOPLE HAVE **MULTIMORBIDITY** THAN A SINGLE **DISEASE**



PERCENTAGE OF PATIENTS PRESCRIBED TEN OR MORE MEDICINES BY AGE GROUP AND DEPRIVATION



Introduction

The proportion of the global population over 65 years old will increase from 11% in 2010 to 22% in 2050. In Europe, advances in healthcare, education and socio-economic circumstance mean that in most countries people can now expect to live beyond the age of 80. However, evidence shows that the average healthy life years (HLY) for EU citizens is only 61 years meaning that many people are living for around twenty years in sub optimal health.

Multimorbidity is defined by the World Health Organization as the co-occurrence of two or more chronic medical conditions in one person.[3] Patients with multimorbidity may require medicines to treat each condition, which can lead to polypharmacy. Currently around 50 million EU citizens are estimated to have multimorbidity. Most of them are 65 years and over, and this number is expected to continue to increase.[4]

Linking clinical and prescribing data, from a European country, has shown that 20.8% of people with two chronic conditions were taking between four and nine medicines daily. 10.1% were taking over ten medicines, and those patients taking the most medicines are the oldest.[5]

Data also shows that multimorbidity and polypharmacy affects adults up to ten years earlier in deprived communities. The burden of multiple diseases can have a combined effect on physical health, the quality of day-to-day living and mental health.

The burden of multiple treatments can be just as problematic, causing frequent healthcare contacts and an increasing likelihood of medicine side effects, adverse drug reactions and interactions.

Non-adherence to prescribed medicines is a major public health issue, intricately related to multimorbidity and polypharmacy. Research suggests that between 50% and 80% of patients with chronic conditions may be non-adherent, depending on the clinical condition being studied. Non-adherence has been estimated to be responsible for 48% of asthma deaths, an 80% increased risk of death in diabetes and a 3.8-fold increased risk of death following a heart attack.[6] It has been estimated that non-adherence to medicines costs the European Union EU 125 billion annually.[7]

Polypharmacy

There are a number of different definitions of polypharmacy but it is generally understood as the concurrent use of multiple medicines by one individual. It can be therapeutically beneficial when appropriate or inappropriate when not.

- **Appropriate polypharmacy** is defined as prescribing for an individual for complex conditions or for multiple conditions in circumstances where medicines use has been optimised and where the medicines are prescribed according to best evidence.

- **Inappropriate polypharmacy** is defined as the prescribing of multiple medicines inappropriately, or where the intended benefit of the medication is not realised.

- **Polypharmacy Management** is a whole systems approach which optimises the care of multimoribid patients through maximising benefit while reducing the risks of inappropriate polypharmacy.

Non-adherence

There are two overlapping categories of non-adherence to medicines.

- **Intentional non-adherence**, where the individual decides not to follow the treatment recommendations perhaps because of concerns about the value or effectiveness of medicines, their side effects, and the inconvenience of taking the drugs at the prescribed times and frequency.

- **Unintentional non-adherence**, where the individual wants to follow the treatment recommendations but is prevented from doing so by practical barriers which include cognitive problems, poor organisational skills, polypharmacy and difficulty accessing medicines.

The European Innovation Partnership on Active and Healthy Ageing has a target to increase the average healthy lifespan of citizens by two years by 2020.[8] The Partnership is seeking to identify and share good practice and drive research and innovation. One of the Partnership's action groups, 'Prescribing and Adherence to Medical Plans', includes a focus on multimorbidity and polypharmacy.

The 2012 Institute for Healthcare Informatics report (IMS), *Advancing the responsible use of medicines,* identified several opportunities to save healthcare spending through more responsible use of medicines worldwide.[2] Using multiple international datasets, it was estimated that inappropriate polypharmacy contributes to 45% of the avoidable costs due to suboptimal medicine use. A total of 0.3% of global total health expenditure, or 18 billion US dollars worldwide, could be avoided by managing polypharmacy correctly. Specific recommendations in this report were to: invest in medical audits targeting elderly patients; develop the role of pharmacists to help patients manage their own medicines; support pharmacist collaboration with physicians for medication reviews; prepare a targeted medicines management plan and to encourage use of risk stratification processes to identify patients.

Many healthcare organisations have sought to address the problem of fragmented delivery of health and social services, through the more coordinated approach, of integrated care. Collaboration in this way is an essential aspect of addressing inappropriate polypharmacy. Building on the benefits of integrated care there is now an additional focus on population and public health in order to minimise or prevent inappropriate polypharmacy in the first place.

The SIMPATHY project was awarded funding on an EU public health call to support the use of innovative, coordinated and comprehensive community based prevention to optimise the care of multi-morbid patients. The project demonstrates the importance of a *systems approach* to developing polypharmacy management through understanding the requirements of the individual patient, carers and organisations, and the political and economic environment.

About this handbook

Funded by the EU Health Programme (2014-2020) the SIMPATHY project's goal is to stimulate and support innovation across the EU in the management of polypharmacy and adherence with specific focus on addressing inappropriate polypharmacy in the context of quality, economic and political factors.

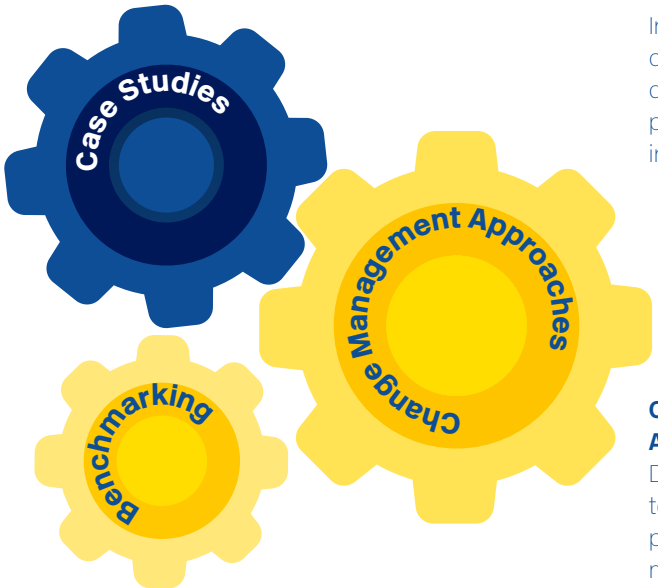
Focussing on change management, this handbook highlights the approaches that can help health systems to deliver effective polypharmacy management in order to help address the issues caused by multiple medicine use for multiple medical conditions. Included are a range of examples of good practice and tools from local, regional and national programmes.

The content is informed by the findings of the SIMPATHY case studies,[9] analysis of SIMPATHY change management tools,[10] SIMPATHY literature review and benchmarking survey,[11] and SIMPATHY Delphi study.[12]

SIMPATHY confirms the findings of *Advancing the responsible use of medicines,*[13] that there are currently too few polypharmacy management programmes. There is a consensus among all stakeholder groups for the need to address the issue of inappropriate polypharmacy. There is a recognition of the quality of existing programmes, but significant concerns expressed regarding the challenge of how to initiate polypharmacy management in countries, where services do not exist, and how to expand where services are concentrated in a small area. The project demonstrates how change management can be used as a successful approach to help initiate and implement effective polypharmacy management at scale.

Case Studies

In depth studies to understand current practices showcasing different approaches to polypharmacy management in the EU.



Benchmarking

Europe wide regional and local benchmarking survey identifying strategies of polypharmacy and non-adherence management.

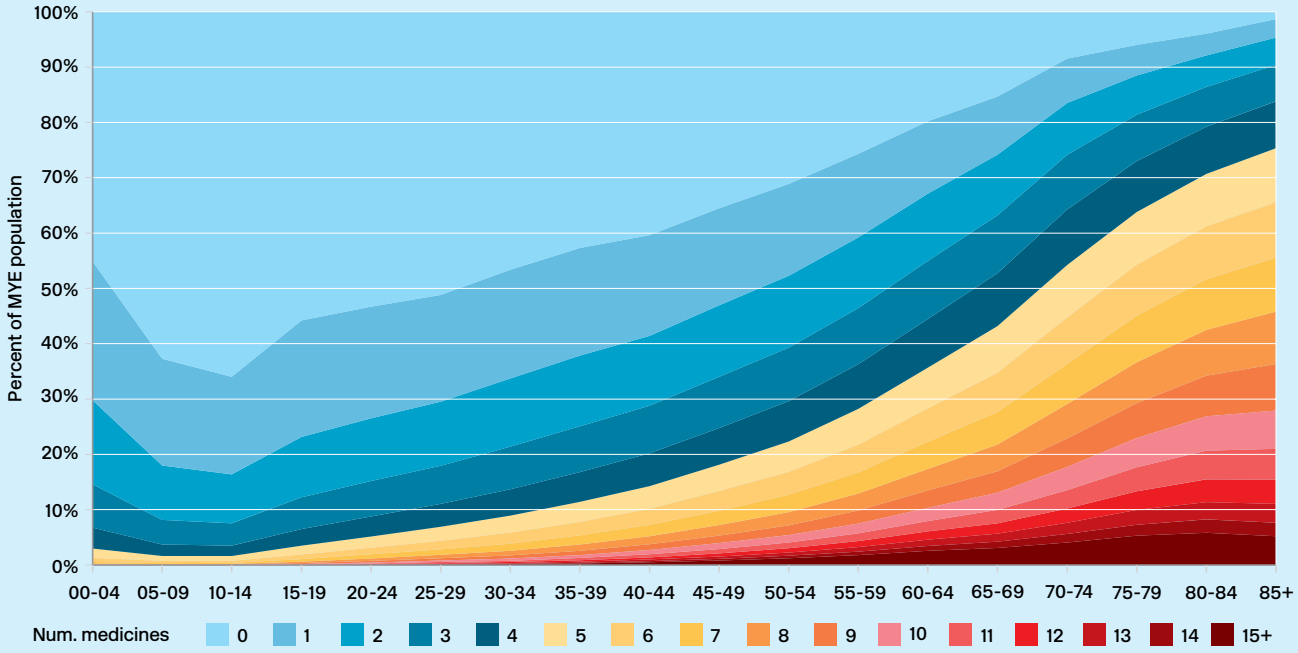
Change Management Approaches

Development of strategies and tools to support innovation in polypharmacy and adherence management.

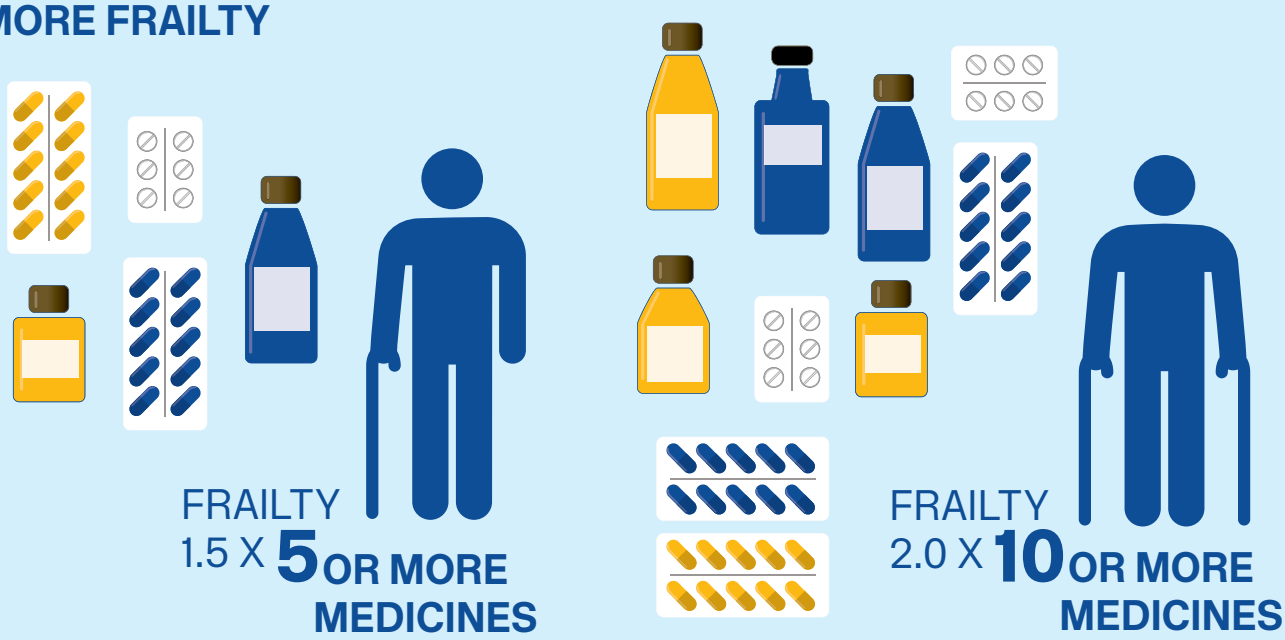
Quality	Economic	Political
Management of polypharmacy is an essential element of patient safety in an integrated care setting making a significant contribution to wellbeing	Prevention of harm due to medicines can reduce demands of the healthcare system reducing threats to service sustainability	Demographic changes are driving up public awareness of polypharmacy issues, demanding a response from politicians and policymakers

1. Use a systems approach that has multidisciplinary clinical and policy leadership
2. Nurture a culture that encourages and prioritises the safety and quality of prescribing
3. Ensure that patients are integral to the decisions made about their medications and are empowered and supported to do so
4. Use data to drive change
5. Adopt an evidenced based approach but with a bias towards action where the evidence is limited
6. Utilise, develop and share tools to support implementation

PERCENTAGE OF PEOPLE BY AGE GROUP ON MULTIPLE MEDICINES



MORE FRAILTY



MORE MEDICINES

The case for appropriate polypharmacy management

Complex Care

The shift in demographics to an aging population with increasing multimorbidity leads to increasing complexity in care. Health inequalities can add to this complexity, where long-term illness can present 10-15 years earlier in the most deprived groups.

Quality

A growing population with multimorbidity using multiple medications (polypharmacy) for long periods of their lives are at increased risk of adverse events, error and harm.

Economic

Increasing demand on constrained health budgets creates the need for change to ensure that medicines and healthcare resources are used optimally.

Political

Multimorbidity and polypharmacy are a widespread and growing challenge, adversely affecting the quality of life of EU citizens and increasing pressures on health systems. The solutions require political support for change and improvement.

Complex care

Polypharmacy is a growing problem as population longevity and the incidence of multimorbidity increases. Although not exclusive to the elderly, polypharmacy in older people presents particular challenges. Physiological decline and frailty, combined with inappropriate polypharmacy, increases the potential for harm in older people. This is compounded by the risks of non-adherence to complex treatment regimens.[14] These factors combine to increase the likelihood of morbidity, unplanned admission, readmission and prolonged length of stay in hospital.

Modern prescribing is largely based on single disease evidence-based guidance which does not generally take account of multimorbidity, despite this being the norm in those over 65 years.[15] In contrast, polypharmacy management aims to optimise outcomes by ensuring that throughout life people are prescribed the safest and most effective combination of medicines to manage their multimorbidity and to maintain well-being for as long as possible.

Caring for patients with multimorbidity treated with polypharmacy is a widespread and increasingly common global challenge. Polypharmacy management involves complex decision making and requires the combined knowledge of physicians, pharmacists and nurses supported by informed patient interaction.

Good communication and accurate sharing of information is essential, facilitated by Information Technology systems that support cohesiveness and integration across health and care systems. Re-design of services to proactively cope with an increased clinical workload related to polypharmacy can relieve pressures on services as a whole. Appropriate polypharmacy avoids unnecessary work for all health and care professionals and carers at the same time as improving patient outcomes. Consequent improved adherence with medication can also contribute to improve outcomes.

Given this evidence, the case for effective polypharmacy management is quite clear, but in a complex healthcare setting with many competing priorities it is useful to outline the quality, economic and political reasons why this should be prioritised within every EU country's health policies and plans for active and healthy aging.

The SIMPATHY benchmarking study set out to identify the status of polypharmacy management across the EU, gathering more than 1,000 responses from a spectrum of stakeholders across 26 EU countries.[11] Although responses were mainly from clinical practitioners there was 10% participation by patients.

Across the EU a lack of understanding was shown regarding the issue of polypharmacy, in terms of its definition, and any consistent framework against which to measure progress. This finding was not confined to any one stakeholder group but applied equally to clinical and non-clinical stakeholders, and patients.

This survey sought to benchmark key indicators of performance relevant to effective polypharmacy management. The findings clearly illustrated that there is an absence of knowledge and meaningful metrics across all countries and stakeholders. Of particular note was the almost complete lack of awareness of the health economics related to appropriate medicines use. However, more than 60% of respondents thought that health economic data would be useful. The existence of programmes to manage polypharmacy, where more than 10% of the country respondents indicated this, were restricted to the UK, Sweden, Portugal, Spain, Germany and The Netherlands. The activities of the reported programmes were: prescription reviews (83%); treatment reviews (77%) and clinical medication reviews (71%).

Quality

People with multimorbidities, taking multiple medications (polypharmacy), are at increased risk of potentially avoidable medicine related issues. All medicines are associated with a level of risk and it is estimated that worldwide, 3-6% of all hospital admissions are attributed to medicines, and figures ranging from 2-19% have been recorded in the USA with studies in the UK reporting up to 11%.[11-18]

Two thirds of medicines-related hospital admissions are preventable with four groups of medicines accounting for 50% of these, (antiplatelets, diuretics, anticoagulants and non-steroidal anti-inflammatory drugs).

Prescribing errors are common in all healthcare settings and another major cause of harm. The UK General

Medical Council in 2012 reported that one in 20 prescriptions in primary care contained an error with a higher prevalence associated with prescriptions for the elderly and those taking 10 or more medicines.[19] In hospital prescribing, errors are also a common occurrence, affecting 50% of hospital admissions.[20] When patients transfer between health and social care settings evidence shows that 30% to 70% of patients experience an error or unintentional change to their medicines.[21] Taking multiple medicines, long term, presents difficulties for individuals and carers managing complex medicine regimens with evidence that between 30-50% of these medicines are not taken as prescribed.[22]

The SIMPATHY literature review confirmed that there is evidence to support the principle that medication reviews reduce inappropriate polypharmacy.[23] Recent research has also begun to show improvement in outcomes due to polypharmacy management, including a reduction in hospital admissions.[24] The SIMPATHY literature review identified that there are guidance documents available relating to the management of polypharmacy in only 5 of the 28 EU countries, with only the guidance documents from Scotland, the Netherlands and Germany scoring the maximum on the AGREE II-GRS criteria for Quality.[25]

There remains an evidence gap, whilst research catches up with this fundamental shift in healthcare priority. Safety is a major concern in modern healthcare and addressing issues related to inappropriate polypharmacy should form part of this. The literature review supports the principle that it is important to adopt an evidence based approach, but with a bias towards action where the evidence is limited. It should also be recognised that there is further emerging evidence to support polypharmacy management and knowledge of research that is in process, and yet to publish.

Economic

The demand for health and social care is increasing globally in response to demographic shift and pharmaceutical and technological advances. This creates budgetary pressure between the healthcare needs and the resources available in most EU countries. Constrained budgets call for the prudent use of resources to gain the best possible outcomes from investment. Evidence based approaches that deliver clinical and cost-effective care are of interest to all Governments and this has been increasingly supported by policy documents.[26]

Throughout Europe, 16% of total Government expenditure is dedicated to healthcare, ranging from 6% in Cyprus to 22% in Switzerland.[4] After inpatient and outpatient care, pharmaceuticals represent the third largest expenditure in healthcare and accounted for around a sixth of total health expenditure in 2014, not taking into account spending in hospitals.[27] In 2014 the total pharmaceuticals bill across the EU was EUR 200 billion and the average spend per head of population was EUR 402 with wide variation between countries, from EUR 201 in Denmark to EUR 551 in Germany.

Medicines are one of the highest costs in EU healthcare systems and are consequently one of the most commonly targeted areas for efficiency savings. Post financial crisis, between 2009 and 2014, expenditure on pharmaceuticals dropped by 1.1% in real terms on average in the EU, mainly triggered by cuts in public spending. However, there are signs that spending is increasing again in some countries due to the steep growth in spending on high cost drugs to treat, for example, Hepatitis C or oncological conditions.[27]

Effective polypharmacy management can deliver improved safety and health outcomes plus economic benefits. Avoiding harm from adverse drug events improves patient outcomes in addition to delivering economic benefit through fewer hospital admissions, readmissions and reduced length of hospital stay. Economic modelling has found there may be cost savings related to optimising the number and combination of medicines, avoiding waste, reducing utilisation of acute healthcare services and freeing health service capacity.

The SIMPATHY Delphi survey failed to report consensus about the importance of economic data but highlighted a lack of understanding that better care can lead to economic benefit with comments such as, 'economic outcomes are not the main goal. Our priority and main goals are the patient safety and efficacy, and efficiency'.[12]

The SIMPATHY case studies provide examples of good practice that have demonstrated cost savings relating to medicines costs and reduced hospital admission, readmission rates and length of inpatient stay.

Sweden
Improved quality leading to economic benefits

In a randomised controlled trial in Sweden, clinical pharmacists performed comprehensive medication reviews on elderly hospitalised patients. Patients who received a medication review had 16% fewer hospital visits and 47% fewer visits to the emergency department within a 12-month follow-up period compared to usual care. Medication-related readmissions were even reduced by 80%. After inclusion of the intervention costs, the total hospital based healthcare costs per patient in the intervention group was approximately EUR 200 lower than in the control group. The researchers concluded that, if implemented on a population basis, the addition of clinical pharmacists to healthcare teams would lead to major reductions in morbidity and healthcare costs.

Scotland
Economic benefits of implementing good practice

The implementation of the Scottish Polypharmacy Management Programme was underpinned by detailed economic analysis. The data demonstrates notable savings, even when taking into account the cost of reviews:

Range of estimates of savings from polypharmacy reviews

	Unit cost/saving Scotland	Age 75+, 10+ medicines, plus high risk ones	75+ group plus all care home residents
Number of patients with high risk medicines		40,585	64,729
Cost estimates based on savings per case p.a	GBP M	GBP M	GBP M
Number of patients with high risk medicines	9.87	2.4	3.8
Cost estimates based on savings per case p.a	9.87	4.8	7.7
Number of patients with high risk medicines	66	2.7	4.3
Base-case: change medication only	90	3.7	5.8
Upper estimate: change medication + switching to cost effective + cost avoidance measures	155	6.3	10.0

Political

In addition to establishing integrated care there is a call to look at population care systems that aim to address the wide range of influences affecting health, as many health problems are preventable.[28] For example, although there may be a focus on care of the elderly, in reality, 29% of the people likely to have multiple morbidities and are under 65 years of age, and come from the most deprived communities. Reflecting this, polypharmacy management must be considered for whole populations. Since the publication of *Choosing Wisely* many policy documents have raised awareness of using resources wisely, and also about the importance of the greater role of the patient in decision making about their healthcare, including, medication.[26]

Whilst awareness of the benefits of polypharmacy management is growing, there is need identified through both the SIMPATHY benchmarking and Delphi surveys to increase understanding about the benefits of effective polypharmacy management across the EU.[11,12] Further change is needed to raise awareness and to share and scale up good practice.

Political support across EU countries can facilitate im¬plementation of effective polypharmacy management to improve health and wellbeing throughout life and protect independence into older age. The political work is not solely policy-focused. Nurturing deep change in how health professionals, policy makers, and patients think about and practice medication safety in general and polypharmacy in particular will generate some resistance no matter how compelling is the evidentiary-based case. Everyone involved will have to re-order priorities and adapt to new, unfamiliar and sometimes even uncomfortable ways of interacting with each other. Helping people through that process is a different kind of work than convincing them of the merits, but just as essential to policy and implementation success. SIMPATHY consortium engaged with the expertise of Marty Linsky in addressing political challenges and recordings are offered on the SIMPATHY website (www.simpathy.eu).

Italy
Political support helping spread change

In Italy, the SIMPATHY project stimulated collaboration among the many different stakeholders of the regional health system in the Campania region, raising awareness about the implications of polypharmacy in the Regional Health System.
The Campania region is integrated in the national network for the internationalisation of regional health systems, therefore Campania stakeholders involved in the SIMPATHY project had the opportunity to share their experience. The results of the project were shared with other Italian Regions, as well as with the Italian Ministry of Health. This, in turn, has fostered the exchange of good practices and contributed to the national plan for chronic diseases.
Sharing the SIMPATHY experience within the national network facilitated the identification of a shared priority to respond to a research call by the Ministry of Health leading to an interregional project on the management of multimorbidity in community-dwelling older adults, with a focus on integrated polypharmacy and rehabilitative robotics. For this project Campania, Liguria, Piemonte and Calabria along with the Ministry of Health co-financed a total budget of EUR 4.2 M.

Scotland
Using policy to drive polypharmacy management

In Scotland, the existence of clinical leaders with a National policy role meant that effective polypharmacy management developed regionally in some National Health Service Boards, could be scaled up through the development of a polypharmacy guidance document that was support through an official Chief Executive Letter and included in the General Practice contract.

Scotland has a well developed polypharmacy review programme.
The National Polypharmacy Guidance (2015) has been adopted by all 14 health boards (100%), with each board developing plans to identify priority patients who have potentially inappropriate elements to their polypharmacy, and to implement reviews for those patients at highest risk of harm.
Introduction of mobile app has sustained acceleration.

http://www.polypharmacy.scot.nhs.uk/

Create

The sense of urgency was created by highlighting that current prescribing of medicines was not fit to meet the changing needs of an aging population with increasing multiple long term conditions, particularly in terms of the increasing potential to cause harm and risk to financial sustainability of prescribing patterns.

Build

Building the guiding coalition came from linking the pioneering work by NHS Highland and NHS Tayside with **key clinical policy makers**. Crucial was the early engagement of **clinicians** and **operational leaders**.

Form

Formation of the strategic vision came through refinement of the adoptive work by NHS Lothian and the Scottish Government. **Policy leadership** was essential with **clinical leadership** to meet the needs of patients and prescribers.

Enlist

Enlisting the volunteer army was exemplified by NHS Greater Glasgow and Clyde, who serve 25% of the Scottish population, and were able to **implement** the Polypharmacy Guidance at **scale** through using established means of implementation through practice pharmacist networks working with GPs.

Enable

Removing barriers to implementation included successful addition of a contractual requirement for GPs, and recognising the potential role of Pharmacist non-medical prescribers. **Design delivery process** to enable care to be integrated into existing patient pathway.

Generate

Generating short term wins includes the evidence that on average **one or two medicines were stopped** at each polypharmacy review. There are approximately 12,000 polypharmacy reviews every year in Scotland.
Of those patients identified to be at high risk of hospital admission, pilot work suggested a 40% reduction in hospital admissions following a polypharmacy review. Further reduction in high risk medication related issues is expected from roll out.

Sustain

All 14 Scottish Health Boards use the Polypharmacy Guidance.

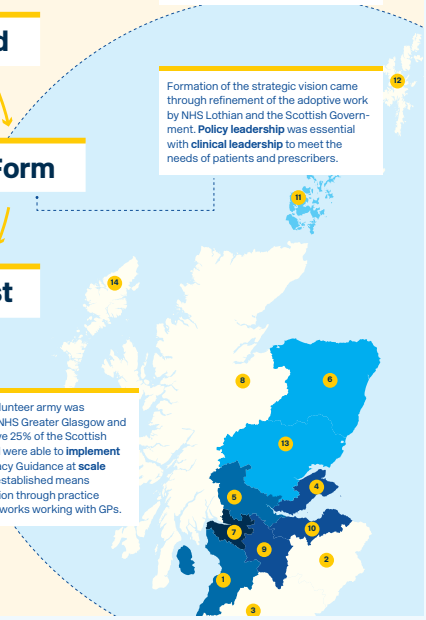
€20 m

is being invested to increase the number of **pharmacists** working in GP practices
Mobile App for clinicians developed

Institute

Management of polypharmacy using the Scottish multi-disciplinary approach helped develop therapeutic partnerships between doctors and pharmacists in primary care that has been **integrated** into national program of work.

A reduction in admissions due to medicines related issues is expected following polypharmacy review



1 NHS Ayrshire and Arran 2 NHS Borders 3 NHS Dumfries and Galloway 4 NHS Fife 5 NHS Forth Valley 6 NHS Grampian 7 NHS Greater Glasgow and Clyde
8 NHS Highland 9 NHS Lanarkshire 10 NHS Lothian 11 NHS Orkney 12 NHS Shetland 13 NHS Tayside 14 NHS Western Isles

Poland
Policy driving change

The Polish Ministry of Health has created a group whose aim is to develop a model and strategy on polypharmacy management in the elderly. The group was established on August 27th, 2015 by the Minister of the Health Directive. It includes representatives of the National Health Fund, the Ministry of Health, pharmacists, lawyers, pharmaceutical inspectors and pharmaceutical societies. The team's task is 'to develop a project of pharmaceutical care which will be supported by public funding'.

Germany
Political influence driving systems change

Since October 2016 a uniform standard medication chart has been introduced for mandatory use by all doctors and pharmacists. Every person with three or more medications is entitled to receive such a medication chart on paper, equipped with a QR-code, so that pharmacists and doctors can digitally read, update and exchange information on medicines.
This initiative has been supported and driven by the Federal Ministry of Health and has been agreed by all relevant stakeholders on the Federal level. The standard medication chart is part of the „E-Health Law" and insures that all prescribed medication data are documented in this digital format. It can be printed out in doctors' offices in the consultation as a paper version for the patient.
The governmental aims are clear and input is strong in this field considering that Germany has a system of sharing powers between the government, the health insurances as self-regulated non-profit organisations and the health professional entities.
Now GPs receive a small fee for service remuneration to incentivise the new practice. By 2018 the interim solution of using a paper medication chart kept with the patient will be replaced by the electronic health card issued by the health insurances.

Medikationsplan
Seite 1 von 1
ARZNEIMITTEL THERAPIESICHERHEIT
für: Armin Müller
geb. am: 19.10.1959
ausgedruckt von:
Apotheke am Sachsendamm
Thüringer Str. 22, 10666 Berlin
Tel.: 030-1234567
apo-sachsendamm@kbv-net.de
ausgedruckt am: 27.03.2014

Wirkstoff	Handelsname	Stärke	Form	Mo	Mi	Ab	Nr	Einheit	Hinweise	Grund
Metoprololsuccinat	[illegible]	95 mg	TAB	1	0	0	0	Stück	Mit 1 Glas Wasser	Herz/Blutdruck
Ramipril	Ramipril-ratiopharm®	5 mg	TAB	1	0	0	0	Stück	Mit ausreichend Flüssigkeit	Blutdruck
Clopidogrel	Clopidogrel Zentiva®	75 mg	FTA	0	0	1	0	Stück		Herz
Pantoprazol	Pantoprazol-dasa®	20 mg	TMR	1	0	0	0	Stück	1 Stunde vor der Mahlzeit	Magen
Insulin aspart	Novorapid® Penfill®	100 E/ml	FAT	20	0	20	0	I.E.	[illegible]	Diabetes
Simvastatin	Simva Actio®	40 mg	FTA	0	0	1	0	Stück	Mit ausreichend Flüssigkeit	Blutfette
Torasemid	Torasemid Hexal®	5 mg	TAB	1	0	0	0	Stück	Mit etwas Flüssigkeit	Blutdruck
Zeitlich befristete Medikation										
Clarithromycin	Clarithromycin TEVA®	250 mg	FTA	alle 12 Std. 1				Stück	von 1.4. bis 0.4.	Bronchitis
Selbstmedikation										
Metoi	Galoldyrol®	120 mg	KPS	2	2	2	0	Stück	[illegible]	Bronchitis
Johanniskraut	Lef® Balance	900 mg	FTA	1	0	0	0	Stück	Nach dem Frühstück	Stimmung
Selbstmedikation bei Bedarf										
Magnesium	Magnesium® Verla	121,5 mg	BTA	bei Bedarf 1-2				Stück		Wadenkrämpfe
Diphenhydramin HCl	[illegible]	50 mg	TAB	0	0	0	1	Stück	[illegible]	Schlafstörungen

Northern Ireland
Policy commitment across the healthcare system

Optimising the health benefits from medicines is an important enabler of active and healthy aging in Northern Ireland. In March 2016 the Minister of Health announced the publication of a new strategy 'The Medicines Optimisation Quality Framework' to help people to gain the best possible outcomes from medicines. In addition there was a formal commitment to implementing the Framework through an innovation and change programme which seeks to develop, test and scale up best practices to support a national medicines optimisation model. In the next three years there will be a focus on the needs of older people specifically relating to pharmacy roles, services and smart technologies which support appropriate polypharmacy and better adherence.
Outputs include a national medicines optimisation model to support appropriate polypharmacy and better adherence and a Medicines Optimisation Innovation Centre to support research, service development and knowledge sharing nationally and internationally.

Catalonia
Policies leading to polypharmacy and adherence guidelines

Catalan Health Plan 2010-2015: Guiding policy for all health programmes in Catalonia

↓

Strategic work line: A system oriented toward patients with chronic disease

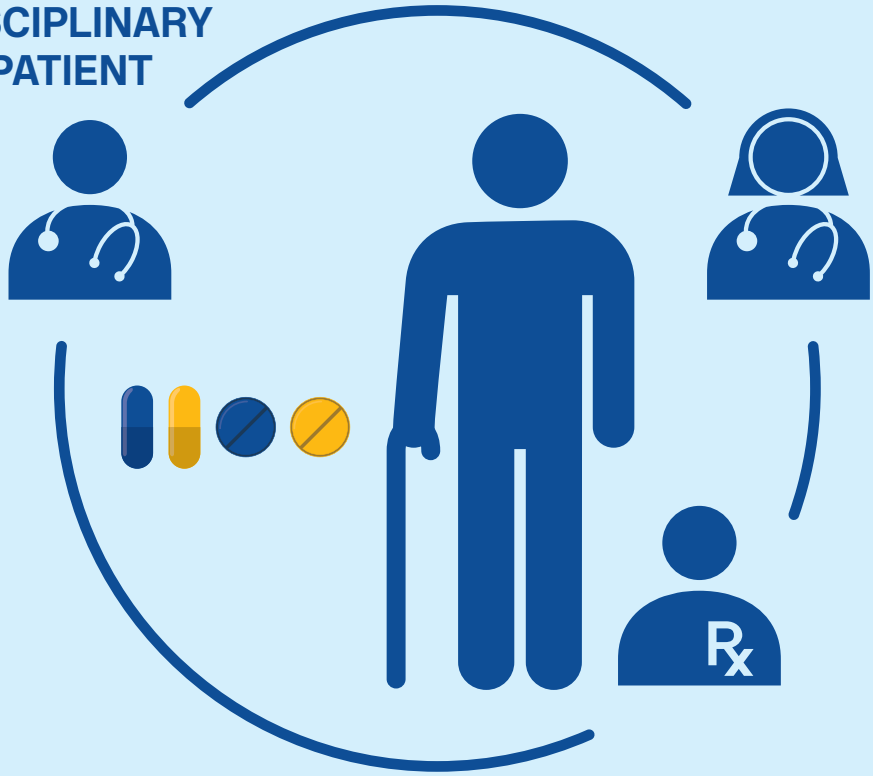
↓

Programme for the prevention and care of chronic disease (PPAC) 2011-2014: Working group implemented to meet Health Plan goals

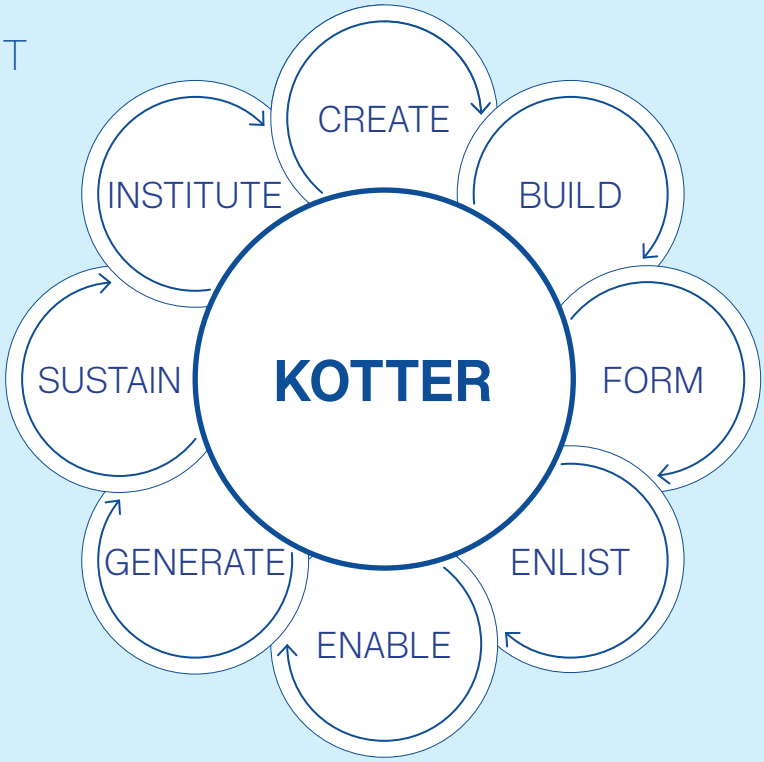
↓

Rational drug use. Medication management in the complex chronic patient: reconciliation, revision, deprescription and adherence: Specific clinical practice recommendation

MULTI-DISCIPLINARY
HOLISTIC **PATIENT**
CARE



USE **CHANGE**
MANAGEMENT



Preparing for change in polypharmacy management

Systems thinking

Polypharmacy management touches multiple aspects of health and care systems and is ideally team-based and patient-centred. Imbedding polypharmacy management into integrated care initiatives will help create synergies with on-going activities with the aim to prevent inappropriate polypharmacy.

Strategies for change management

Polypharmacy management initiatives are complex and require strong leadership and management. Employing a change management strategy when designing a polypharmacy management initiative can help maximise the odds of successful implementation.

Organisational culture

Assessing organisational culture and working to foster an environment that values teamwork, innovation, and risk taking will help ensure polypharmacy initiatives are successful and sustainable. Organisations should foster openness to discussion of harm caused by medication and a willingness to work collaboratively with patients to improve outcomes with medicines.

Patient-centred

Empowering patients to be involved with the medication review process and decision making about their medicines will lead to coproduction in the management of polypharmacy. This will address “What matters to me?”.

Systems approach in health and care

A systems approach has been defined as *'an operating mechanism where the sub-parts work jointly towards achieving an outcome, and the success of the system is dependent upon this collaboration.* In patient safety, these sub-parts include provider organisations across different care settings, regulators, policy-makers, and patients'.[29,30] It is important that all stakeholders understand and agree the outcomes to be achieved. In the case of polypharmacy management, the goal of a systems approach is the optimal and sustainable use of medicines in patients with multimorbidity. Supporting them to live active and healthy lives.

There is no one blueprint for implementing complex initiatives, and a systems approach prevents an overly narrow view to a particular problem.[30] The Scottish polypharmacy programme used a systems approach in the selection of a diverse group of stakeholders, with representation across different care settings to form the membership of a group to develop a national policy and guidance for its implementation.[31]

A systems approach has been used by organisations such as the World Health Organization (WHO), Institute of Healthcare Improvement and Institute of Medicine to address complex issues such as tobacco control, obesity prevention, or expansion of antiretroviral treatment.[32-35]

The use of a systems approach to polypharmacy management is supported by both the SIMPATHY case studies and the Delphi survey, where there was strong agreement that polypharmacy management initiatives should include a broad range of stakeholders and be implemented 'across care settings and boundaries'.[12]

Application of systems approach
Process mapping

When Northern Ireland set out to enact the priorities outlined in the National Service Framework for Older People, one early step they took was to conduct process mapping with a multidisciplinary team including managers, pharmacists, and physicians. Process mapping is a set of tools that can help clarify processes and identify bottlenecks of inefficient steps within a system. As a result, they gained consensus and a clear vision of where their medicines optimisation efforts should focus.

An important first step in applying systems thinking to polypharmacy management is to consider the building blocks of the existing healthcare service. The WHO describes six building blocks that make up a complete healthcare system. Here we describe how these building blocks can be adapted to polypharmacy management, developing from the lessons learned from the SIMPATHY case studies:[9]

- **Service delivery:** how does introducing polypharmacy management affect existing practice and other services?
- **Health workforce:** does polypharmacy management involve new roles and responsibilities and do they require training?
- **Health information:** is individual and population level data related to polypharmacy management available for all healthcare professionals?
- **Medical technologies:** what disease specific clinical practice guidelines are professionals using and how does this affect polypharmacy management?
- **Health financing:** are reimbursement and payment schemes aligned with the goals of polypharmacy management?
- **Leadership and governance:** do existing legislation and policies support implementation of polypharmacy management?

Health systems are dynamic and change constantly, with feedback loops that positively and negatively affect both, the intervention and its effects. One practical implication of this is that managers and policy makers should be prepared for an iterative process of implementation and evaluation. SIMPATHY demonstrates that this was the case in Scotland, where polypharmacy guidance was launched nationally, but after observing the real world effects of the policy on physicians, pharmacists, and their patients, substantial changes were made to the guidance. In particular, the review process and the target population for review were both adapted to help implementation.

Systems complexity may influence resistance to change. The competing interests of different professionals who have a stake in managing polypharmacy, particularly those of physicians and pharmacists, can be a particular challenge in designing innovative polypharmacy management initiatives, especially if there is a change in the work undertaken across professional boundaries. This barrier was reported multiple times throughout the SIMPATHY case studies,[9] and the SIMPATHY PESTEL and SWOT analyses.[10]

Integrated care recognises the need to create linkages between different components of the healthcare delivery system taking a holistic view of patient care. Integrated care is an important principle to consider in discussions of health system reforms, especially when referring to those with complex needs, such as older patients and those with multimorbidity who are at risk of inappropriate polypharmacy.[36]

The overarching goals of integrated care are closely aligned with the end goals of polypharmacy management. This can place polypharmacy initiatives within the context of wider health systems planning and facilitates creating synergies between health policy initiatives. These goals can be summarised as the triple aim of improving: patient experience; population health and the cost-effectiveness of care systems.[37] The patient experience is central, a fact emphasised in the WHO global strategy on people-centred and integrated health services.[38] A patient perspective is captured by, 'my care

is planned with people who work together to understand me and my carer(s), put me in control, co-ordinate and delivery services to achieve my best outcomes'.[39]
The focus on patient-centred care is also reflective of opinions of key stakeholders both within the SIMPATHY case studies and confirmed by the Delphi Survey, where patient health outcomes were consistently cited as a primary motivator for addressing polypharmacy management.[9,12]

Although the concept of integrated care is receiving more attention, the role of the pharmacist has not always been addressed within this context.[40] There is good evidence of the benefit of pharmacist involvement in medicines management, and more recently there have been calls to include pharmacists in integrated care teams which closely resembles the primary care polypharmacy management model in Scotland, demonstrated in SIMPATHY.[40,41]

Polypharmacy management should be addressed in all care settings, even though primary care may be the main location for delivery of the programme. Examples of this from SIMPATHY can be seen in the Northern Ireland consultant clinical pharmacist model in intermediate care, the Swedish hospital ward based model, or the Catalan multidisciplinary management of older patients in acute geriatric units and nursing homes. The latter has demonstrated positive effects on hospital readmissions, detection of adverse drug events, and the quality of prescribing.[42-44]

Italy
Systems approach to healthcare

The involvement of Campania in the SIMPATHY project raised the urge to measure the impact of hospital admissions on polypharmacy, through the FRIENDD study (Drugs Reviewed Together: Empowerment In Different Specialties). Medical specialists, pharmacists and clinical pharmacologists took part in this study aiming to test and implement in a real-world setting what had been learnt from the SIMPATHY on polypharmacy management across whole systems. The activity performed both a retrospective and prospective analysis aiming to minimise drug interactions in the therapy prescribed at hospital discharge.

Strategies for change management

Skilfully employing a change management strategy can maximise the odds of successful implementation.[45] Throughout the SIMPATHY case studies, sites with successful polypharmacy management initiatives were able to point to a specific change management strategy. Programmes with a systems approach enabled overview of development and implementation by a range of stakeholders. If a strategy was not explicitly mentioned, elements of change management could still be identified throughout the development and implementation process. In countries without programmes, there was a recognised need to manage change in a systematic manner. When discussing the potential implementation of a polypharmacy management initiative, a pharmacist leader in Greece identified that, 'we need a step by step approach'.[9]

A change management strategy does not in itself guarantee success, but it can diminish the potential for failure. Literature provides different change management models from different disciplines including business, psychology, and sociology, with a handful coming directly from healthcare.[46] Application of key change management models is an important aspect of SIMPATHY.

Accounting for culture

Underlying all of these models: systems thinking; integrated care and change management, is culture. Culture in terms of healthcare is used to capture what it is like to work in or receive care from an organisation. It is not about appropriate polypharmacy management and improved quality of life for patients, but about who we are as people. Organisational culture is complex, and affects all of the building blocks within the healthcare system. It includes the values, assumptions, and beliefs held by those within the organisation or, more simply put, 'culture is the way we do things around here'.[47,48]

The way we do things influences not only how things are currently done, but also the likelihood that a newly introduced initiative will fail or succeed. Culture can help or hinder the implementation of a new innovation like polypharmacy management. In fact, failure to account for organisational culture is one of the main reasons cited when evaluating why planned change initiatives are not able to overcome barriers.

Not only should the culture of the health system as a whole be considered, but also cultural norms within given professions.

The results from the SIMPATHY Delphi study support this understanding of organisational culture. There was strong agreement that, 'Prior to implementation of polypharmacy management, the culture of the organisation should be assessed for both strengths and potential barriers to implementation'.[12]

There were also a number of examples from the SIMPATHY cases studies, where culture acted as either a facilitator or barrier, both at the system and individual level. From a systems perspective, Northern Ireland described itself as *'outwardly-focused'* with a *'keen interest'* in work being done on quality and safety throughout the United Kingdom.[9] Likewise, a hospital Chief Executive Officer in Catalonia, Spain described his job as *'managing innovation'* and that the institution had *'a culture, a way of doing things that greatly facilitates the implementation of these* [polypharmacy management] *programmes'*. These are both places where a polypharmacy management initiative had been successfully implemented within a hospital and care home setting.

In contrast countries without a polypharmacy initiative, like, Greece, Poland, and Portugal, a lack of culture supporting teamwork and multidisciplinary teams was identified as a primary barrier to polypharmacy management. For example, a comment made by a geriatrician was *'Only they* [geriatricians] *are qualified enough to coordinate treatment of patients with multi-morbidities and polypharmacy'*, illustrating the types of professional-centric views that might prohibit implementation of a true multidisciplinary team.[9] Successful implementation would require consideration of how to overcome such barriers and attitudes.

As with change management and systems thinking, there are multiple tools and frameworks available to help diagnose and change organisational culture and it may be appropriate to do this in parallel with patient safety culture.[45]

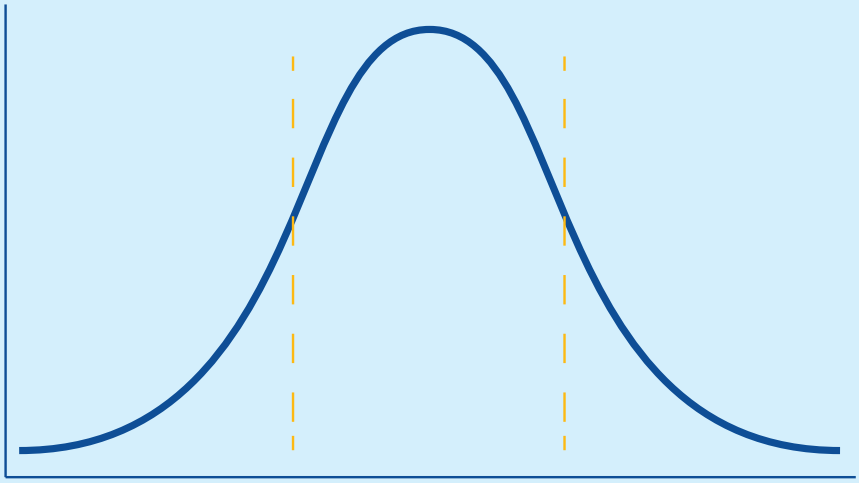
Catalonia
Delivering a systems approach to healthcare

Service delivery: All patients meeting criteria for the designation of "complex chronic patient" are required to have their medications reviewed. To facilitate this, patients meeting the criteria are flagged in the shared electronic medical record and physicians review their medication list at least once a year. Electronic medical records are available in all public health care institutions, facilitating the implementation of this initiative. In addition, e-Prescription is deployed in full in Catalonia.

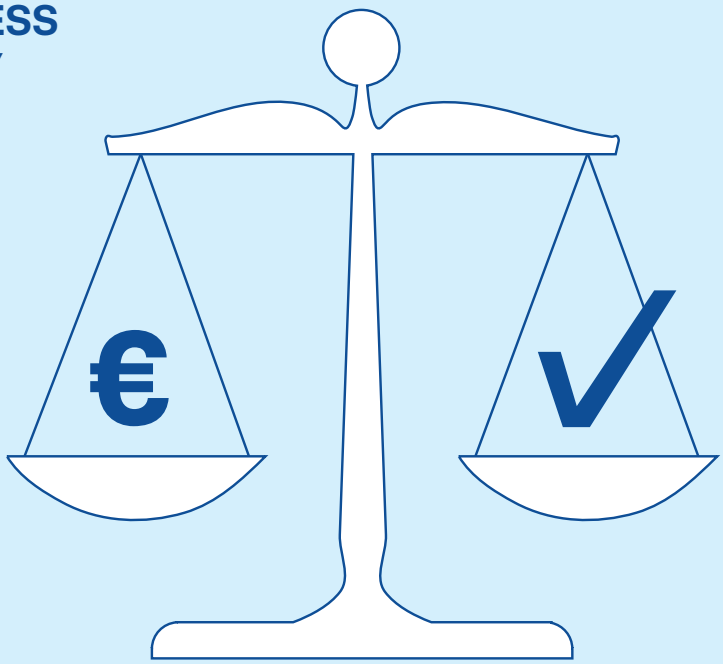
Health workforce: At least one physician in every primary care centre in Catalonia has received training developed jointly by the Agency for Health Quality and Assessment of Catalonia, the Catalan Health Service and the Catalan Institute of Health. The training is case-based covering medicine reconciliation during care transitions and conducting medication reviews in complex chronic patients. Guidelines have also been developed by the Catalan Health Service to assist physicians with the management of polypharmacy and adherence in the primary care setting.

Health information: Multiple population level health indicators are currently available that relate to polypharmacy, although indicators of adherence are not as clearly defined or captured. Members of the public (including health professionals) can make specific data requests for research.

USE DATA TO INFORM **POLYPHARMACY MANAGEMENT**



DEMONSTRATE THE **COST-EFFECTIVENESS** OF **POLYPHARMACY MANAGEMENT**



Approaches to implement polypharmacy management at scale

Change Management Framework

The selection of a change management model appropriate to a polypharmacy management initiative is essential. The Kotter 8-steps change management model presents a recognisable framework to which most stakeholders can relate to, and it has broad applicability.

Getting ready for change

The current situation can be assessed utilising the SWOT and PESTEL analysis and this can inform strategic plan. Identification of key stakeholders and assessment of the economic benefits can be used to establish the sense of urgency and influence the implementation of a polypharmacy management programme.

Implementing change

The vision should set out clearly the need for the change and the goal of change. Clinical and policy leadership is essential to remove potential barriers and there should be a focus on education and the development of guidance documents for use in multiprofessional teams.

Spreading and sustaining change

Data and indicators can be used to help spread and sustain change. Polypharmacy management should be integrated into routine practice so that additional workload is not created. There may be the option to support this through the use of contractual arrangements.

The EU spends almost a sixth of its healthcare budget on medicines and so dealing with the challenge of an aging population with increasing numbers of multiple morbidities that require additional numbers of medicines is a challenge that needs to be addressed as a matter of urgency. This issue is likely to be a challenge beyond the current economic crisis as not only is it a patient safety issue but also one that needs addressing as a public health challenge. Potential harm from inappropriate polypharmacy includes both harm to patients and also the additional healthcare costs that are associated with this.

Successful organisations that have transformed their delivery and performance using Kotter's 8-steps in combination with strong leadership that is adaptive to drive change.[49] There is a distinction between adaptive leadership and an authoritative solution to tackle problems.[50] The latter approach tends to develop short term solutions to underlying problems that will often remain once the crisis has passed.

Addressing complex problems like polypharmacy management requires change in the way that things are done. This can generate anxieties, which may be due to the fact that the activities required are different, and that there may be a loss of existing roles. Individuals may need to be challenged with the reasons why not to maintain the status quo. Major change often requires that the whole organisation needs to change and allowing individuals a role in a collaborative solution development helps to build momentum, ownership and sustainability. Leadership needs to acknowledge that there will be resistance to change and that it is best to anticipate the barriers that this may create. Continual reflection in this aspect of change is important, and resolving individual's anxieties is often one of the most challenging aspects of this type of work.

This chapter addresses the approaches and techniques for successful integration of theory and practice, which support the process of putting the management of polypharmacy into practice. These techniques have been successfully deployed and developed across the EU within the SIMPATHY programme.

Change management framework

There are some important key concepts to consider when using change within large organisations:

• **Change is not a linear process:**[46] although the idea of transformation change, moving from state A to state B, implies that there is a clear path between those states, the reality is more nuanced. Implementing a polypharmacy management initiative will be a fluid and organic process, and managers should be prepared to be flexible and take advantage of opportunities as they present themselves.

• **Managing change is a combination of top down and bottom up leadership:** [51] a common criticism of change management models is that the emphasis is on the role of managers without accounting for the role of employees.[52] Successful implementation of innovative polypharmacy management will require strategic leadership from managers and clinicians and policy makers .

• **The up-front investment of time developing a strategy is time well spent:**[53] although taking the time to create a change management strategy might seem like another exercise in bureaucracy or waste of valuable employee time, as with systems thinking, the development of a plan will help both managers and clinicians anticipate and plan for implementation challenges.

Change management from the middle out: the case of Catalonia

When designing a regional multidisciplinary model to address polypharmacy in older patients, the directors of pharmacy and medicine began by creating a common vision to apply within a single hospital. Success was dependent on both empowering clinical leaders within their departments to take the lead on implementation, and on gaining support from the hospital Chief Executive Officer who could influence diffusion of the model to intermediate care facilities and nursing homes within the region. Leadership at all levels is helping support the expansion of the model throughout the region.

Change management from the middle out: the case of Scotland

In Scotland, local clinical leadership developed the ideas and concepts creating the sense of urgency and provided the data to illustrate the wins from implementing the programme locally at primary care practice level and then worked with local managers to adopt the policy at a regional level. Work was then undertaken to collaborate with clinicians and policy makers to scale up the programme for national implementation. This synergy between frontline clinicians, managers and government was crucial to successful implementation and roll out.

Getting ready for change

#1 Choosing a model

It is not essential that managers know all the details of various change management models, but it is beneficial for them to identify where they are in the change management process and work with *a* model. The table below describes some general categories of change to consider.[53] Kotter's 8-step process for leading change has been integrated with these general change categories.[49] A change management framework can be used as a tool for both planning and progress evaluation, by reflecting on the different steps of a specific implementation process.

Reviews of change management strategies, with guides on selecting and applying specific change management tools tailored to a particular organisation's needs have been conducted for both the Canadian health systems and the National Health Service in England.[46,51]

Stages of change	Questions for managers	Kotter's 8-Step Change Model
Getting ready for change	What external factors will influence this change? Who are the stakeholders and who can I partner with to create synergies? Is my organization and staff ready?	Step 1. Create a sense of urgency Step 2. Build a guiding coalition
Implementing change	What is our vision? How will we know when we've achieved it? What barriers (technology, personnel, budget) might slow the change? What data are we already collecting that can be used to demonstrate impact?	Step 3. Develop a strategic vision and initiatives Step 4. Enlist a volunteer army Step 5. Enable action by removing barriers Step 6. Generate short term wins
Spreading & Sustaining change	What data will we need to scale up? What new resources will we need to spread change?	Step 7. Sustain acceleration
	How will we continuously monitor? How will we recognize and celebrate successes? What mechanisms do we have (contracts, pay for performance) that can help institute this change?	Step 8. Institute change by anchoring new approach in the culture

Stages of change

The Kotter 8-step process is a core tool which can enable a healthcare organisation to analyse their existing polypharmacy management programme and identify the stage of development in order to inform the next steps. Recognised as identifying important elements of organisational change, the model is based around a clear vision, good communication, empowering employees, leading by example and celebrating success. An important principle of the model is that it is most successful when used for continuous improvement, where leadership will support iterative changes and testing of delivery models. SIMPATHY demonstrates how the Kotter 8-step process can be used in to successfully implement a polypharmacy management programme.[10]

Application of the eight steps in transforming change in Polypharmacy Management:

1 Establishing a sense of urgency
Communicating to stakeholders the need to change current ways of reviewing medication to benefit patient care- improvement in patient safety and outcomes from medicines. Examining other projects that are developing and whether they pose a threat to the development of the framework. Existing projects may focus on cost efficiencies rather than on patient safety due to budgetary pressures.

2 Forming a powerful guiding coalition
A project group is assembled including both primary and secondary care clinicians made up of doctors, pharmacists and geriatricians and Long-term Conditions collaborative leads locally and nationally. Have discussions about working together to inform work of Director of Pharmacy and public health both locally and nationally.

3 Creating a vision
A vision is created as to what the project might achieve for patient care and for the Healthcare Provider. Project plan outlines strategies for achieving the vision.

4 Communicating the vision
Share this in written communication and have face to face dialogue with people both locally and nationally.

5 Empowering others to act on the vision
Looking at the obstacles to change the biggest one will be ownership so provide feedback and adaptation of the protocol e.g. link with anticipatory care plans

6 Planning for and creating short-term wins
To gather data and provide feedback within a relatively short space of time after review framework is piloted; share data from pilots and used to build the business case. Break the project down into smaller tasks so that results can be seen and shared. E.g. design of guidance for review.

7 Consolidating improvements and producing still more change
Engage with individuals that might influence change in policy to adopt the vision. Transfer of project to other areas to reinvigorate the project e.g. running project in another locality and other health care providers.

8 Institutionalising new approaches
Sharing of benefits to the new process to the organisation e.g. reduced admissions and improved patient care. Adoption of project into nationally delivered service development, e.g. sharing outcomes with local and national leads on service development.

Normalization process theory (NPT) can also be used, predominantly as a research framework, to support the evaluation and implementation of complex interventions, such as healthcare.[54] It studies what people do (action) rather than how they feel about what they do (attitudes), or what they say they are going to do (intentions). NPT helps to understand complex interventions by studying how people make sense (coherence), engage with (cognitive participation), act in (collective action) and appraise (reflexive monitoring) work.

#2 Sharing leadership

Leadership is a core element in change management and needs to be present at different organisational levels. Within healthcare, there is a need for strategic political, managerial and clinical leadership at a national, regional and local level. Throughout the change process, on-going work needs to be done to ensure that as many opinion leaders in clinical and management roles feel they are involved and have personal investment in the programme. This helps to recruit the programme champions, who are essential to driving change within all levels.

> *'Crucial to the move from theory to practice was the early engagement of clinicians and operational leaders given the need to ensure that the strategy was felt to be 'owned' by the country as a whole rather than imposed from one area to another'.*[10]

When implementing a programme at scale, it is essential to ensure that there is both clinical and political leadership.

#3 Assessing the scenario

Identification of key stakeholders and potential partners are important first steps to consider for any polypharmacy management programme. The importance of creating multidisciplinary leadership teams has been reported in case studies, and also endorsed by participants in the Delphi study.[12] The combination of healthcare professionals, managerial staff and policymakers creates the ideal coalition in charge of a new polypharmacy management programme. It is also important to include the patient when designing public services and including the patient representation in the initial guiding coalition will ensure and maintain a focus on patient empowerment and centeredness.[55]

Identifying the internal and external factors that will influence strategic choices is also an important early step. These factors can be assessed using the Political, Economic, Social, Technological, Environmental and Legal (PESTEL) framework and Strengths, Weaknesses, Opportunities and Threat (SWOT) analyses.[56]

In SIMPATHY the PESTEL domains have been adapted in order to specifically address the factors which are relevant to polypharmacy management. The purpose of the PESTEL is two-fold:

- **To systematically examine the external environment** in which the project exists in order to detect the factors which most impinge upon it. The aim is to capture the impact of these factors on polypharmacy not only today but also in the future, by 2030.

- **To future-proof Polypharmacy Management plans** by helping anticipate external factors that may potentially de-rail a polypharmacy management programme, and ensuring a robust strategy is in place.

SWOT analysis is a supporting strategic tool that focuses not only on the external but also on the internal environment. The results of these analyses cannot be seen as stand-alone and should be linked to implications for organisational action. Polypharmacy management-specific PESTEL framework and examples of SWOT analyses performed in various EU healthcare settings are provided for general use.[10]

#4 Benchmarking

Benchmarking data can offer important insights into building change management programme plans. The SIMPATHY benchmarking survey data identifies contrasts between countries in terms of the stakeholders and teams recommended to lead and be involved in polypharmacy management.[11]

For example, the reported professionals delivering polypharmacy management programmes in Belgium, the Netherlands, Spain, Sweden and the UK are predominantly pharmacists (80% of programmes). However, when stakeholders are asked who should be delivering programmes then a discrepancy is identified between actual practice and the perception of what should be happening.

ANALYSE **YOUR INFRASTRUCTURE** FOR **POLYPHARMACY MANAGEMENT**

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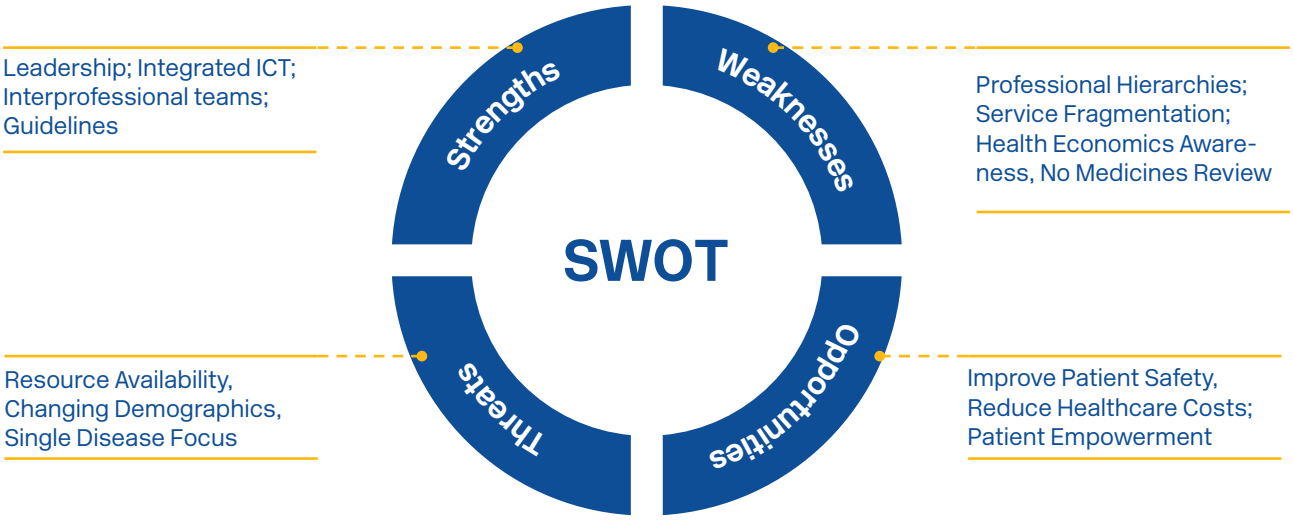


Physicians and nurses are currently involved in 50% and 22% respectively, of programmes. The view of stakeholders is that this should be 73% and 39% respectively. Only Belgium and the UK indicating that pharmacists should have a greater role than physicians.

The motivation for professionals to provide effective polypharmacy management showed wide variation between countries, where overall financial incentives were reported as the most frequent motivation, while in Greece, Sweden and the UK legal or contractual responsibilities were a more frequently reported driver.

Significantly, more than 90% of the respondents who had data on a programme, reported a positive effect on healthcare professional's satisfaction in providing the programme.

Where programmes existed the main aim was to improve patient safety by reducing medication errors and to reduce hospitalisations due to adverse drug reactions. In terms of infrastructure and systems to support management of polypharmacy less than 4% reported current ICT systems as being sufficient, while more than 40% reported ICT as not being fit-for-purpose.

Although the number of patient and public participants in the survey was limited, where programmes had data on patient satisfaction, 100% of them reported a positive effect. The majority (85%) of patients and public reported that they or those they cared for would benefit from support to manage multiple medicines.

Benchmarking will enable countries to map out their own ambitions to deliver a programme by 2030. An example of the SIMPATHY vision routemap is shown below. The time frame has been extended from 2025 to 2030 after reflection on comments made in both the benchmarking survey and the Delphi.[12]

Implementing change

#5 Setting the vision

A crucial early step in Kotter's process involves creating and sharing a strategic vision. The importance of this was also something endorsed by experts in the SIMPATHY Delphi study.[12] The strategic vision helps steer the effort both at management and clinician levels. Ideally, have a very clear picture of what you are trying to deliver and make sure this includes: what; by how much; when and by whom. Case studies with a clear vision were found to be the most successful in implementing polypharmacy programmes.

The SIMPATHY project has tested and developed a range of tools which can be used to support leaders in planning for and implementing changes in polypharmacy management. Using Kotter's framework these tools can be referenced and deployed at key steps in the change management cycle.

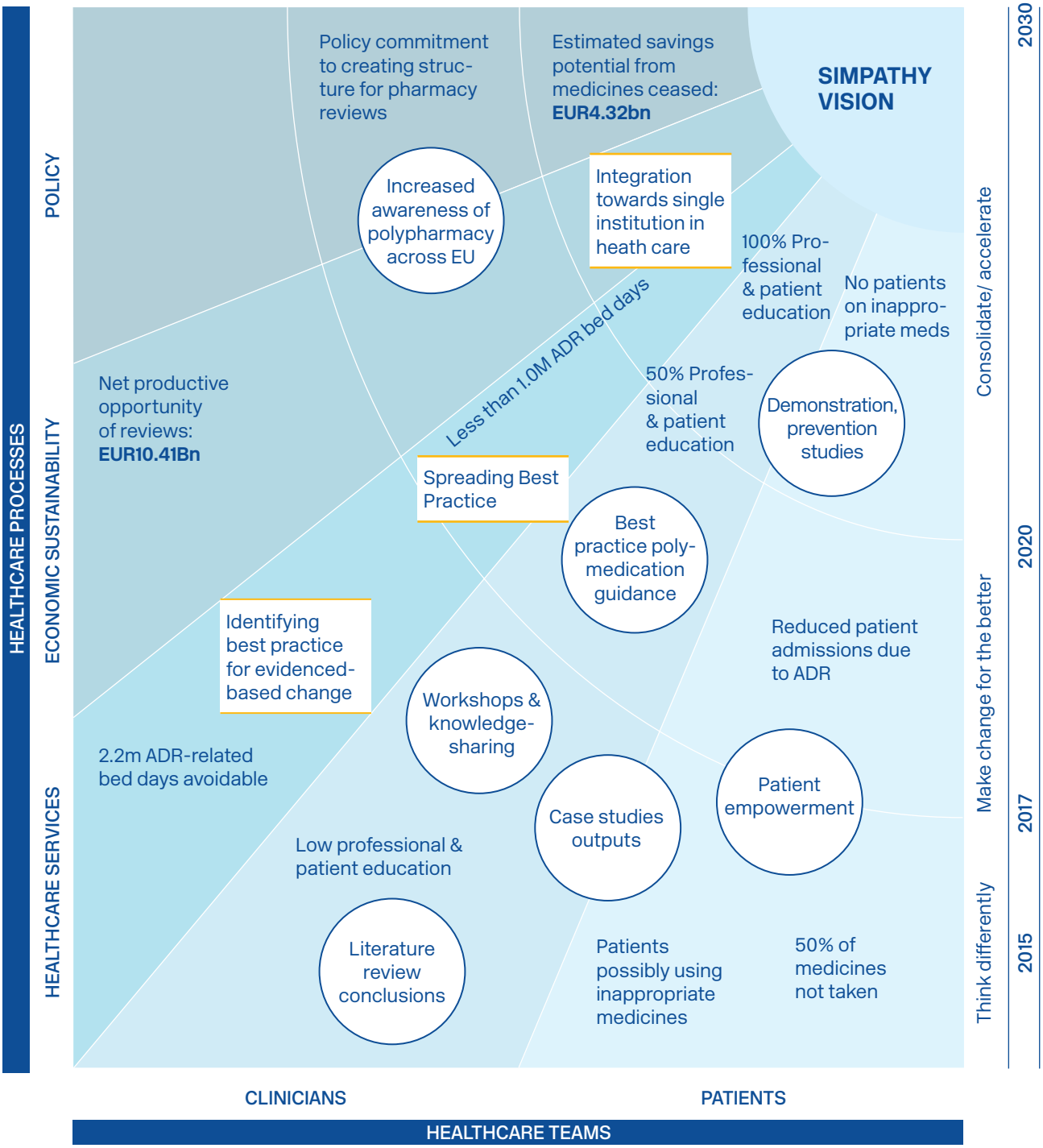
> *'Communicating the vision became vital to making sure that the team was motivated and able to champion the programme of care. One of the initial goals was the establishment of a momentum to ensure that barriers to the successful implementation of the programme were either removed or reduced to manageable proportions'.* – an example from Northern Ireland.[10]

Key questions for benchmarking and subsequent action:

1. State the structure – does your programme cover an institution, region or nation?
2. What poulation will you cover?
3. How will your programme look by 2030?
4. Do you have a change management plan? Have you done a PESTEL, SWOT and economic analysis? Have you mapped against Kotter's 8-steps?
5. Does your programme address patient safety and improving health outcomes?
6. Are you delivering through multidisciplinary teams?
7. Does your review process involve the patient?
8. Do you have indicators to monitor implementation, economic benefits and patient outcomes?

BENCHMARK TO UNDERSTAND

ROUTEMAP
HOW DO WE GET THERE?



Kotter		Tools and Approaches					
STEP	DESCRIPTION	Vision slides and videos	Case Studies	Polypharmacy Guidance	PESTEL and SWOT Analysis	Economic Analysis	Benchmarking & Delphi surveys
1	Establish a sense of urgency			x		x	x
2	Form a powerful coalition		x	x		x	x
3	Create a vision	x		x	x	x	x
4	Communicate the vision	x		x			
5	Empower others		x	x			
6	Plan for and create short-term wins		x	x		x	x
7	Consolidate improvements		x	x	x	x	
8	Institutionalise change	x	x	x	x		

SIMPATHY toolkit cross-reference table

#6 Creating guidelines

The literature review identified that there are guidance documents available relating to the management of polypharmacy in only 5 of the 28 EU countries. Only the guidance documents from Scotland, Netherlands and Germany score the maximum on the AGREE II-GRS criteria for quality.[25] Within Scotland, the development of the guidance was essential to provide the training, evidence and support that the clinicians needed for the implantation of medication reviews to manage multiple morbidities. Through this, a powerful coalition was built as well as support for political and economic case.

> *'Not all EU countries have the potential, experience and resources to develop their own national or regional evidence based guidelines. Better sharing of information, experience, and effective collaboration could be cost effective solution to this'.*

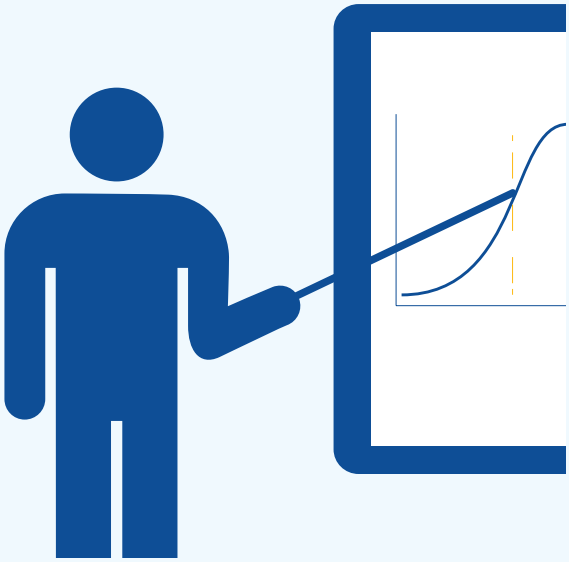
#7 Training the workforce

Education at an undergraduate and postgraduate level is essential for translation from theory into practice. Case studies have shown that education is critical for the successful implementation of a polypharmacy programme, but university training to specifically address this field is lacking in many EU countries.[9] In countries with successful programmes, postgraduate training has been a key development facilitator. EU experts are in agreement that there is a need for both undergraduate and continuing professional development in polypharmacy management to ensure that change is both sustained and embedded into daily practice.[12]

Education also helps to shape professional culture. With consensus that multidisciplinary teams are an integral part of polypharmacy management, promoting collaborative working to develop productive professional personal relationships needs to be a focus point in the workforce training.

Vision slides and video

The SIMPATHY Vision slides are offered for use by any agent of change management seeking to address improvements in management of polypharmacy. The slides can be downloaded from www.simpathy.eu/resources/change-management, where a video explains the thoughts behind each slide. The slides are fully editable to enable the specific context of the initiative in different organisational, regional and national settings to be edited or added. These slides offer material and ideas for developing and communicating the vision for polypharmacy management.



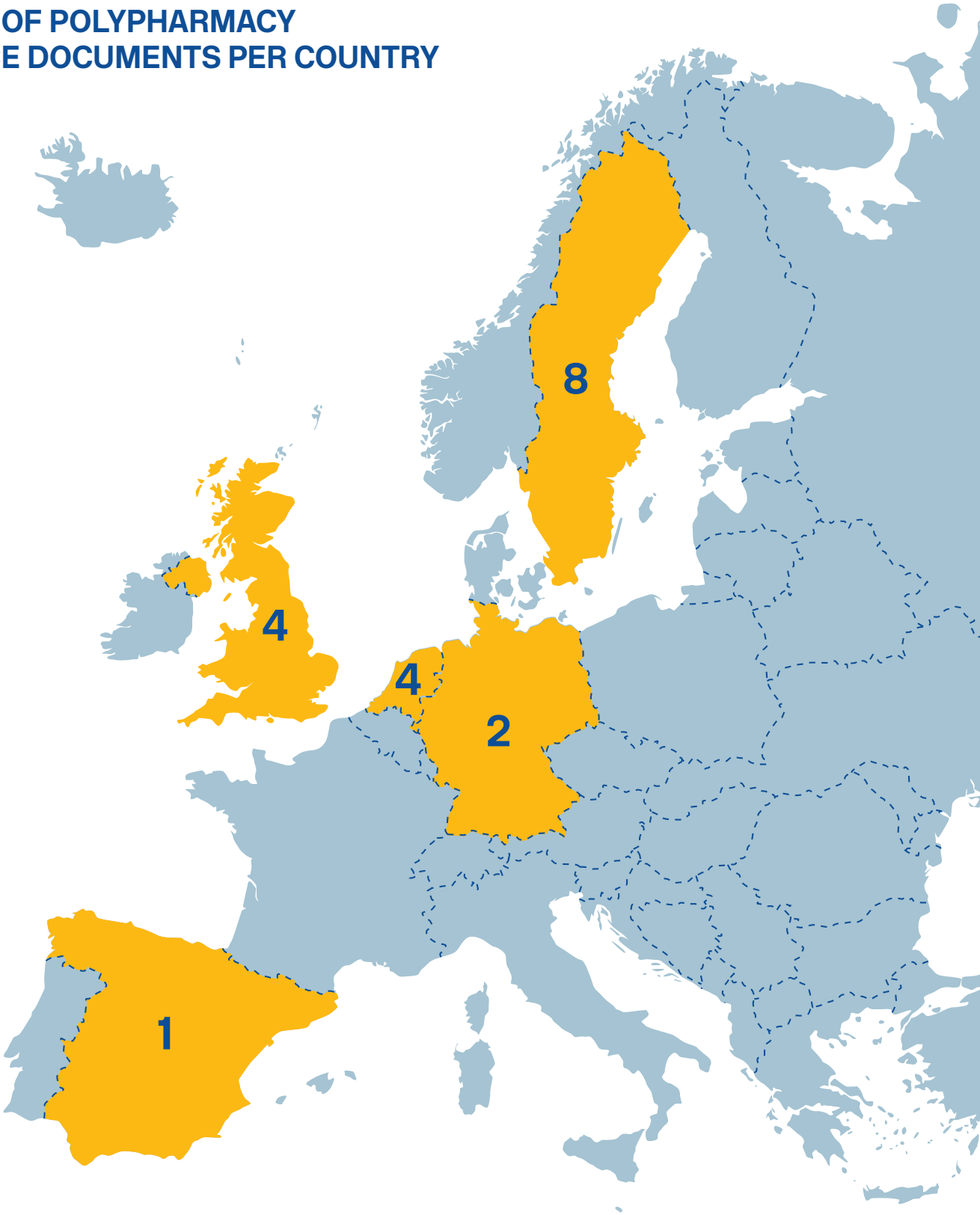
Each country or organisation determines their specific requirements for additional university training, undergraduate and postgraduate education, depending on the national or local situation. SIMPATHY suggests that different approaches need to be been taken within different countries and within different contexts. For example, master programmes were established in the 1980's in the United Kingdom to support the development and delivery of clinical pharmacy services in hospital.[9] More recently polypharmacy management has been integrated into the curriculum of pharmacists, nurses, and physicians and into postgraduate clinical and prescribing programmes.

The polypharmacy management initiatives in Sweden have also been supported by changes in pharmacy education that began there in the late 20th century.[9] New elective clinical pharmacy courses were introduced into the basic pharmacy curriculum. About ten years later, a master degree in clinical pharmacy, based on the Scottish clinical pharmacy model, was initiated. At the same time polypharmacy management was also being incorporated into physician training as part of the basic degree and during specialisation.

Guidance document details	Country of origin
Scottish Government Model of Care Polypharmacy Working Group. Polypharmacy Guidance (2nd edition). March 2015.[31]	Scotland
Bergert FW, Braun M, Ehrenthal K, et al. Recommendations for treating adult and geriatric patients on multimedication, 2014.[57]	Germany
Verenso. Multidisciplinaire richtlijn diabetes bij kwetsbare ouderen. Utrecht: Verenso. 2011.[58]	The Netherlands

Polypharmacy Management Guidance documents

NUMBER OF POLYPHARMACY GUIDANCE DOCUMENTS PER COUNTRY



Spreading change

#8 Using data

Demographic data depicting the problem of polypharmacy, and its implications on the healthcare system, are key to creating a sense of urgency. However, data is also essential to show the outputs of polypharmacy management. The ability to electronically monitor prescription data and the ability to share electronic medical records between institutions were identified in the SIMPATHY case studies as important features that can support implementation.[9] Findings also show that clear quality indicators and measures of polypharmacy are critical, both for the development of the management programme, and for the on-going monitoring for evidence of success. This view was also endorsed by the Delphi survey participants.[10,12]

The table below example indicators currently in use in Catalonia (Spain), Scotland (United Kingdom), and Sweden.

In the SIMPATHY case studies, patient data was used for risk stratification to help identify patients most in need of an intervention, and in guiding decision making. Policy makers especially value local data, with an emphasis on both economic and clinical outcomes. Participants in both the SIMPATHY case studies and Delphi noted that, although economic data is important, clinical outcomes are the primary drivers for most stakeholders. As soon as clinical results from pilot studies are available, an economic analysis can be made to estimate potential benefits associated with carrying out the programme. To make such an analysis for programmes in which the performance of medication reviews plays a central role, the SIMPATHY Economic Analysis tool can be used. The tool itself will be made available on the SIMPATHY web site.

Location	Practice setting, target audience	Sponsoring Institution	Description
Lower Saxony, Germany	Community pharmacy, community pharmacists	Chamber of Pharmacy, Lower Saxony	Two day in-person and four month practical training with tutor supervision (ATHINA)
Catalonia, Spain	Primary care	CatSalut (public insurer in Catalonia, Spain)	In-person and online case based training in managing patients with complex chronic disease
Uppsala, Sweden	Hospital and primary care	Uppsala University	Master programme in clinical pharmacy for graduated pharmacists
Scotland	Hospital, intermediate care, primary care	NHS Education for Scotland	Multiple courses in advanced pharmacy practice ranging from pre-registration training to independent prescribing
Northern Ireland	Hospital, intermediate care, primary care	Northern Ireland Centre for Pharmacy Learning and Development	Multiple courses in advanced pharmacy practice ranging from pre-registration training to independent prescribing

Polypharmacy management educational initiatives

Country	Example Indicators
Catalonia	**General pharmacy indicators** • Number of prescriptions per user • Average cost of prescription per patient **Polypharmacy management Specific Indicators** • % of patients with polypharmacy[a] • Index of prescription quality[b] **Pharmacy cost Indicators** • Cost per patient treated with ACEI or ARB • Cost per patient treated with cholesterol lowering agents • Cost per patient treated with antidepressants
Scotland	**Standard polypharmacy indicator** • 10 or more BNF paragraphs dispensed in a 6 month period with at least one high risk drug **High risk prescribing indicators:** • Older person (→=75 years) prescribed an antipsychotic drug • Older person (→=65 years) currently taking an ACE inhibitor/Angiotensin Receptor Blocker and a diuretic, who is prescribed an NSAID (the 'triple whammy') • Older person (→=75 years) prescribed an NSAID without gastroprotection • Older person (→=65 years) currently taking either aspirin or clopidogrel who is prescribed an NSAID without gastroprotection • Current anticoagulant user prescribed an NSAID without gastroprotection • Current anticoagulant user prescribed aspirin or clopidogrel without gastroprotection
Sweden[98]	**Drug specific indicators[c]** • Drugs that should be avoided unless a specific reason exists: long-acting benzodiazepines, drugs with significant anticholinergic properties, tramadol. **Diagnosis specific indicators[c]** • COPD: Irrational use, oral ß-2 receptor agonist; Hazardous use, non-selective ß-receptor blocker.

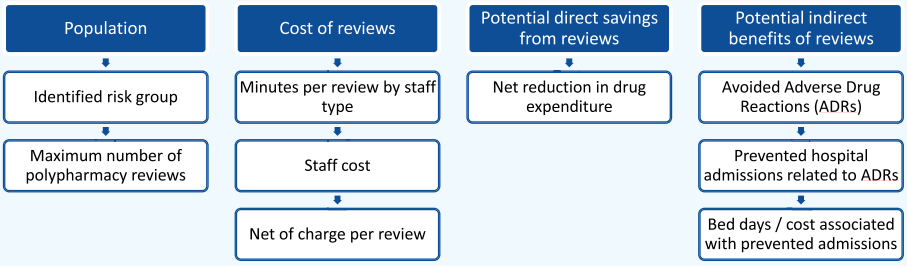
Key: a) defined as 18 or more different active ingredients dispensed in one month, b) composite index to evaluate overall prescription quality, c) Only one drug specific indicator and one diagnosis specific indicator are presented in this table. There are 20 indicators with 63 items in total.

SIMPATHY Economic Analysis tool

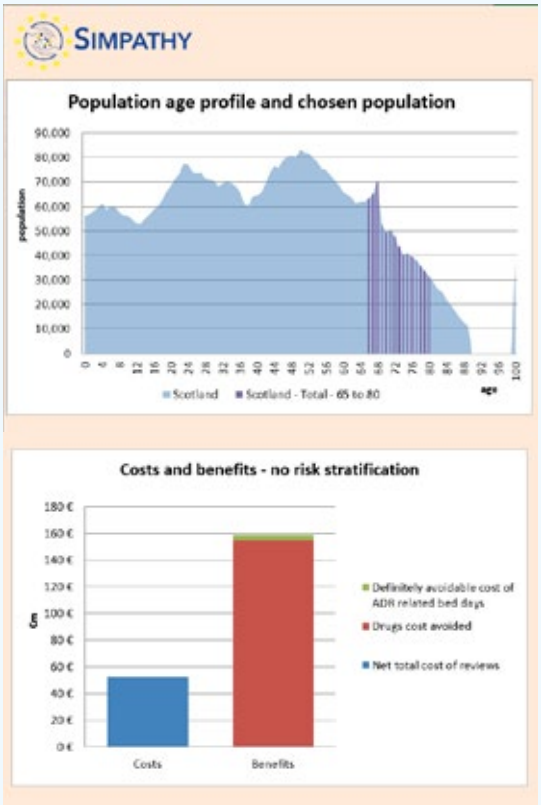
The goal of the SIMPATHY Economic Analysis tool[a] is to provide a high-level analysis of the economic costs and benefits associated with carrying out polypharmacy reviews.

The analysis follows a top-down approach and estimates maximum costs and benefits associated with activity. Activity is driven by the selected population for whom reviews are intended to be carried out.

Costs of reviews are based on the resource (staff) cost of carrying out a review, net of any potential review charge. The direct potential financial benefit of reviews will consist of the net reduction in drugs prescribed, and associated expenditure. Potential indirect benefits (non-cash releasing) centre around potentially avoided Adverse Drug Reactions (ADRs), preventable hospital admissions associated with these ADRs, and the associated number of hospital bed days avoided.



Ultimately, the tool is intended to add to the package of change management tools by offering a bespoke analysis of the micro-economic impacts, the costs and benefits of introducing and carrying out reviews. It is thought that this will give a broad overview around resource needs and potential benefits to interested userscost of carrying out a review, net of any potential review charge. The direct potential financial benefit of reviews will consist of the net reduction in drugs prescribed, and associated expenditure. Potential indirect benefits (non-cash releasing) centre around potentially avoided Adverse Drug Reactions (ADRs), preventable hospital admissions associated with these ADRs, and the associated number of hospital bed days avoided.



a. http://www.simpathy.eu/resources/SIMPATHY_Economic_ Analysis_Tool

Sustaining change

#9 Changing regulations

Regulation and governance help to institutionalise polypharmacy management as a priority, establishing minimum standards, holding providers accountable, and enabling enforcement actions, if necessary. The SIMPATHY case studies have shown that government policies and legislation specifically related to polypharmacy facilitate implementation, but are not essential to start a new or pilot programme, and Delphi participants confirmed the importance of integrated polypharmacy management into health policies.[9] Most SIMPATHY programmes originated in health systems where local government exercise some control over policy and practice decisions. Specifically, the existence of local governance models with power to make policy reallocate resources and create new practice models seemed to play a role in the emergence of programmes.

> *'A key political strength has been the recognition of appropriate polypharmacy work as a core part of the governments clinical strategy and realistic medicines agenda, and its inclusion as a key priority area* [...] *supported by the NHS Scotland Chief Executive and the Cabinet Secretary for Health'.*
> – an example from Scotland.[10]

Payment models also need to be realigned with the goals and objective of new clinical activities, although how exactly this should be done will depend on the local situation. Some strategies that have been successful in integrating polypharmacy management into clinical practice include creating contractual requirements or instituting pay for performance objectives tied to medication reviews. New clinical positions specific to medication reviews and polypharmacy have also been created. SIMPATHY shows how in Sweden, support was provided by the government and professional bodies for short term demonstration projects, and this funding was used to establish the clinical and economic impact of the programme, which resulted in new position for clinical pharmacists. In Scotland, the government started to invest in ensuring all primary care centres had a pharmacist that worked as part of the multidisciplinary team to deliver polypharmacy reviews.

Identifying already existing regulations relating to polypharmacy management can act as a foundation to build a formal programme. For example, work regulations in Germany stating that medication reviews are within the scope of practice of pharmacists facilitated the development of a programme at regional level.[10] In Poland, a policy that relates to polypharmacy management is an Act on Pharmaceutical Chambers [Act of 19.04.1991]. It states that pharmacists should 'implement pharmaceutical care based on a documented process, in which the pharmacist, cooperating with patient and physician and if needed other healthcare professionals, takes care of proper pharmacotherapy in order to improve the patient's quality of life'.[10] Both of these countries have used this legislation to implement medication management activities in community pharmacies.

#10 Evaluating the programme

In this phase, it is helpful to understand how healthcare professionals have integrated the work as part of routine practice by making use of normalization process theory (NPT).[54] For example, one challenge of a new programme is the changes required in time management to integrate a new service. By applying NPT construct of collective action, the SIMPATHY case studies clearly showed that polypharmacy management cannot be added on top of existing work. Redesign of workflow is essential.[9] When you are planning a process evaluation, NPT may help you to structure this evaluation.[54] NPT will encourage you to focus on the range of people, situations, times and places that are involved in all aspects of enacting that process of providing the intervention (or comparator). NPT can help inform, guide or structure your emerging interpretations, conclusions and recommendations.

EU collaboration for global patient safety challenge

In order to address appropriate polypharmacy, groups that are interested in, need to work in partnership to avoid duplication of efforts, and this needs to be coordinated across policy and practice and include all stakeholders, in particular patients and the public. Patients and the public should be integral to groups that develop policy and tools for implementation, and act as ambassadors to raise the issue of polypharmacy among low and middle income countries.

In March 2017, the WHO launched the global challenge to improve medication safety and identified polypharmacy as a flagship area to address across all care settings, due to the potential patient harm from inappropriate polypharmacy. The tools developed to support implementation of a polypharmacy programme can be used by low to high income countries across Europe. The challenges that Europe faces in managing polypharmacy are found globally.[60] The EU should take a leadership role in the implementation of the global challenge to improve medication safety and polypharmacy.

Patient adherence with multiple medications is 50% for those taking 4 or more medicines. Through collaboration with The SIMPATHY project, addressing appropriate polypharmacy will be undertaken as part of the European Society for Patient Adherence, COMPliance and persistence (ESPACOMP) group and this will be achieved on an on-going basis through their work programme.

The SIMPATHY routemap illustrates the key actions that would need to be undertaken to ensure that patients across Europe are not exposed to inappropriate polypharmacy Addressing this patient safety issue would also realise economic benefits, to help deliver the triple aim of potentially EUR4.23 billion across the EU.

In order to raise the awareness of the impact of polypharmacy on patient safety, the SIMPATHY project has provided the leadership to establish a special interest group with the International Foundation on Integrated Care (IFIC) on appropriate polypharmacy and complex care. Policy makers need to be integral to this work in order that policy helps determine the role of health professionals for medicines safety and the implementation of programmes across health and care systems. Adopting a systems approach will help to ensure that appropriate polypharmacy is considered and addressed when prescribing new medicines, reviewing treatment plans, and at care interfaces. This will support the appropriate use of medicines for all patients with multiple morbidities.

Summary of Recommendations

1. Use a systems approach that has multidisciplinary clinical and policy leadership

Polices should be supported with implementation plans that will enable delivery of polypharmacy reviews at scale, and in order to build capacity that is sustainable, use the multidisciplinary team to deliver. Barriers to implementation such as a lack of interprofessional working and training need to be addressed in order to enable this to be delivered. Health professionals need to work in multidisciplinary teams to deliver optimum outcomes for patients.

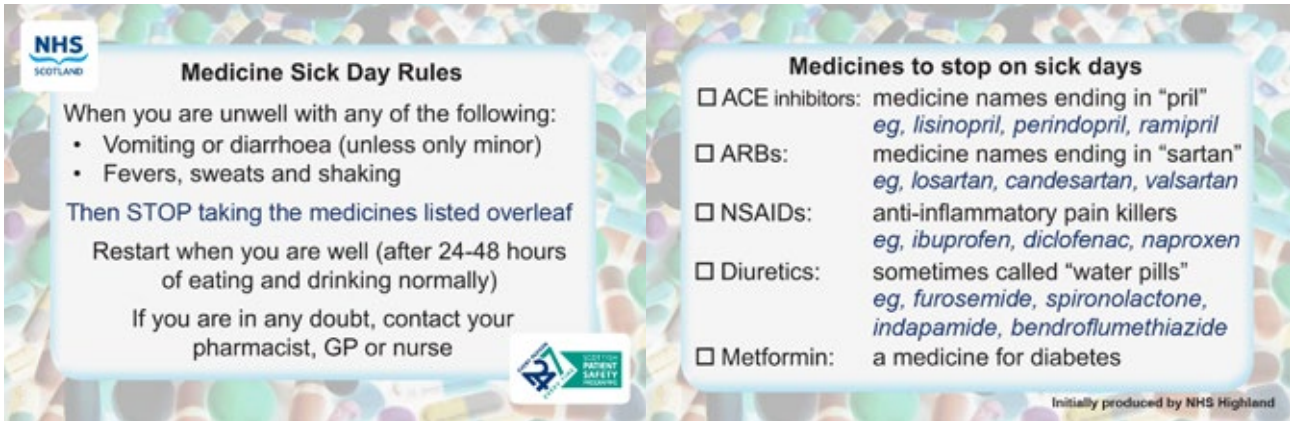
Promoting appropriate polypharmacy at the point of medicines initiation or during medicines review is therefore of the upmost importance and deserves greater attention. When patients are admitted to hospital, records should routinely monitor if an adverse drug reaction or if a medication has led to the symptoms that has caused the admission. Health and care providers need to have monitoring systems in place that capture data that record where medication harm is the cause of admissions to hospital so that improvement can be measured and learning from feedback can provide learning.

2. Nurture a culture that encourages and prioritises the safety and quality of prescribing

Address the safety culture to enable health care professionals to discuss issues of polypharmacy, especially where they are not responsible for prescribing, but also so that patients feel that it is safe to ask questions. Patients should expect to have their medicines reviewed and patients should expect integrated care and a systems approach so that decisions made about their medicines are communicated to all relevant parties across the patient pathway.

3. Ensure that patients are integral to the decisions made about their medications and are empowered and supported to do so

Raising patient awareness about the problems of polypharmacy and non-adherence and how to prevent harm from medication related side effects is essential. Patients should hold a record of medication that they take and share at each care interface to allow clinicians to consider impact of additional medication or stopping



treatment. This can be in either paper or electronic form so that it is accessible for patients in low and middle income countries as well.

Patients need to be provided with information and tools need to be developed that enable patients to ask questions and understand how to make decisions regarding management of their long-term conditions. Information should be consistent across all parts of the healthcare system. Patients should have access to mobile apps and tools that help them understand appropriate polypharmacy and enable them to be active participants in medication reviews. An example of a patient card, known as sick day guidance is shown below, which is also available on a patient polypharmacy app where the patient and clinician can agree tailored guidance for the individual.

4. Use of data to drive change

Data should be used where possible to monitor and evaluate any programmes. Polypharmacy measures and indicators that address review of prescribing that has the potential to cause harm should be developed where country systems allow, with learning and sharing of the information.

Where possible, there should be electronic sharing of prescribing information across the interface; in many countries, this is not possible and does not exist in either paper or electronic form.

5. Adopt an evidenced based approach but with a bias towards action

Safety is a major concern in modern healthcare. The SIMPATHY literature review confirmed that there is evidence to support the principle that medication reviews reduce inappropriate polypharmacy.[23] Recent research has begun to show improvement in outcomes including hospital admission.[24] The literature review identified that there are guidance documents available relating to the management of polypharmacy in only 5 of the 28 EU countries, with only the guidance documents from Scotland, the Netherlands and Germany scoring the maximum on the AGREE II-GRS criteria for Quality.[25] There remains an evidence gap, whilst research catches up with this fundamental change in healthcare. The SIMPATHY literature review supports the principle that it is important to adopt an evidence based approach, but with a bias towards action where the evidence is limited.

6. Utilise, develop and share tools to support implementation

Polypharmacy management touches multiple aspects of the health and care systems and is ideally team-based and patient-centred. Imbedding polypharmacy management into integrated care initiatives will help create synergies with on-going activities with the aim to prevent inappropriate polypharmacy. Polypharmacy management initiatives are complex and require strong leadership and management. Employing a change management strategy when designing a polypharmacy management initiative can help maximise the odds of successful implementation. All healthcare professionals need to follow a standard set of principles when reviewing medication and involve the patients/ and of their carer's in the reviews by asking "what matters to you" in order to take a patient centred approach. Tools that deliver this should be shared across all countries to enable this to be delivered.

Use of existing guidance and mobile apps that incorporate the guidelines and key steps should be shared to spread best practice. Polypharmacy app launched in April 2016 can be found at http://www.polypharmacy.scot.nhs.uk/

Short Term

• Raise awareness about the problems with polypharmacy with healthcare professionals and patient groups
• Launch of Polypharmacy Special Interest group at the International Foundation on Integrated care
• EU adopt leadership role in the WHO Global medication challenge
• Share change management tools to support implementation of polypharmacy programmes cross Europe, including benchmarking tools
• Share tools to undertake polypharmacy reviews across Europe for clinicians and for patients that enable to take an active role in their care
• Tools available to organisations at local, regional and national level to enable leaders to establish and sustain a safety culture

Medium term

• Ensure appropriate polypharmacy is integral to care pathways for patients with multiple morbidities and
• Ensure appropriate polypharmacy is integral to medical, pharmacy and nursing undergraduate and post graduate teaching
• Develop indicators for use to demonstrate improvement in polypharmacy management and patient outcomes
• Review of policy to enable multidisciplinary working

Long term

• All countries across the EU implement programmes to address polypharmacy
• All patients at risk of harm from medication have access to polypharmacy reviews
• When patients have a hospital admission caused by an adverse effect due to medication, this should be captured in the electronic data base
• Ensure technology is safe and optimised to support benefits of appropriate polypharmacy

References

1. Kongkaew C, Hann M, Mandal J, Williams SD, Metcalfe D, Noyce PR, Ashcroft DM. Risk factors for hospital admissions associated with adverse drug events. Pharmacotherapy. 2013;33(8):827-37. doi:10.1002/phar.1287
2. Responsible Use of Medicines Report 2012. Research Triangle Park, NC: IMS; 2012 [Cited 1-Apr-17]. Available at: http://www.imshealth.com/en/thought-leadership/quintilesims-institute/reports/responsible-use-of-medicines-report
3. The World Health Report 2008 - primary Health Care (Now More Than Ever). Geneva: WHO; 2008 [Cited 1-Apr-17]. Available at: http://www.who.int/whr/2008/whr08_en.pdf
4. OECD Health Statistics 2016. Available at: http://www.oecd.org/els/health-systems/health-data.htm. [Accessed 1-Apr-17]
5. Payne RA, Avery AJ, Duerden M, Saunders CL, Simpson CR, Abel GA. Prevalence of polypharmacy in a Scottish primary care population. Eur J Clin Pharmacol. 2014;70(5):575-81. doi:10.1007/s00228-013-1639-9
6. Elliott R. Non-adherence to medicines: not solved but solvable. J Health Serv Res Policy. 2009;14(1):58-61. doi:10.1258/jhsrp.2008.008088
7. Targeting adherence. Brussels: PGEU; 2008.
8. European Commission. European Innivation Partnership on Active and Healthy Ageing. Available at: https://ec.europa.eu/eip/ageing/home_en. [Accessed 1-Apr-17]
9. McIntosh J, Alonso A, Codina C, SIMPATHY Consortium. D4.1 Report on case studies: SIMPATHY Consortium; 2016 [Cited 1-Apr-17]. Available at: http://www.simpathy.eu/sites/default/files/D4_1.pdf
10. D5.2: Model strategic plan: SIMPATHY Consortium; 2016 [Cited 1-Apr-17]. Available at: http://www.simpathy.eu/sites/default/files/D5_2.pdf
11. Kardas P, Lewek P. D6.1: Literature review & benchmarking survey report: SIMPATHY Consortium; 2017 [Cited 1-Apr-17]. Available at: http://www.simpathy.eu/sites/default/files/D6_1.pdf
12. Stewart D, Gibson-Smith K, MacLure K, SIMPATHY Consortium. D3.2 Report on results of Delphi validation study: SIMPATHY Consortium; 2017 [Cited 1-Apr-17]. Available at: http://www.simpathy.eu/sites/default/files/D3_2.pdf
13. Advancing the responsible use of medicines - Applying levers for change. Parsippany, NJ: IMS Institute for Healthcare Informatics; 2012 [Cited 1-Apr-17]. Available at: http://www.imshealth.com/en/thought-leadership/quintilesims-institute/reports/responsible-use-of-medicines-report
14. Saum KU, Schottker B, Meid AD, Holleczek B, Haefeli WE, Hauer K, Brenner H. Is Polypharmacy Associated with Frailty in Older People? Results From the ESTHER Cohort Study. J Am Geriatr Soc. 2017;65(2):e27-e32. doi:10.1111/jgs.14718
15. Barnett K, Mercer SW, Norbury M, Watt G, Wyke S, Guthrie B. Epidemiology of multimorbidity and implications for health care, research, and medical education: a cross-sectional study. Lancet. 2012;380(9836):37-43. doi:10.1016/S0140-6736(12)60240-2
16. Einarson TR. Drug-related hospital admissions. Ann Pharmacother. 1993;27(7-8):832-40. doi:10.1177/106002809302700702
17. D'Arcy PF, Brandon M, Ellis S. Iatrogenic disease as a cause of hospital admissions. Pharm J. 1999;247(Suppl):R7.
18. Balla N, Duggan C, Dhillon S. The incidence and nature of drug-related admissions to hospital. Pharm J. 2003;270:583-6.
19. Avery T, Barber N, Ghaleb M, Franklin BD, Armstrong S, Crowe S, Dhillon S, Freyer A, Howard R, Pezzolesi C, Serumaga B, Swanwick G, Talabi O. Investigating the prevalence and causes of prescribing errors in general practice: The PRACtICe Study. Nottingham: University of Nottingham; 2012 [Cited 1-Apr-17]. Available at: http://www.gmc-uk.org/Investigating_the_prevalence_and_causes_of_prescribing_errors_in_general_practice___The_PRACtICe_study_Reoprt_May_2012_48605085.pdf
20. Lewis PJ, Dornan T, Taylor D, Tully MP, Wass V, Ashcroft DM. Prevalence, incidence and nature of prescribing errors in hospital inpatients: a systematic review. Drug Saf. 2009;32(5):379-89. doi:10.2165/00002018-200932050-00002
21. Campbell F, Karnon J, Czoski-Murray C, Jones R. A systematic review of the effectiveness and costeffectiveness of interventions aimed at preventing medication error (medicines reconciliation) at hospital admission: The University of Sheffield, School of Health and Related Research (ScHARR); 2007 [Cited 1-Apr-17]. Available at: https://www.researchgate.net/publication/255607389

22. Horne R, Weinman J, Barber N, Elliott R, Morgan M. Concordance, adherence and compliance in medicine taking: NCCSDO; 2005 [Cited 1-Apr-17]. Available at: http://www.netscc.ac.uk/hsdr/files/project/SDO_FR_08-1412-076_V01.pdf
23. Patterson SM, Cadogan CA, Kerse N, Cardwell CR, Bradley MC, Ryan C, Hughes C. Interventions to improve the appropriate use of polypharmacy for older people. Cochrane Database Syst Rev. 2014(10):CD008165. doi:10.1002/14651858.CD008165.pub3
24. Dreischulte T, Donnan P, Grant A, Hapca A, McCowan C, Guthrie B. Safer Prescribing – A Trial of Education, Informatics, and Financial Incentives. N Engl J Med. 2016;374(11):1053-64. doi:10.1056/NEJMsa1508955
25. Brouwers MC, Kho ME, Browman GP, Burgers JS, Cluzeau F, Feder G, Fervers B, Graham ID, Grimshaw J, Hanna SE, Littlejohns P, Makarski J, Zitzelsberger L. The Global Rating Scale complements the AGREE II in advancing the quality of practice guidelines. J Clin Epidemiol. 2012;65(5):526-34. doi:10.1016/j.jclinepi.2011.10.008
26. Malhotra A, Maughan D, Ansell J, Lehman R, Henderson A, Gray M, Stephenson T, Bailey S. Choosing Wisely in the UK: the Academy of Medical Royal Colleges' initiative to reduce the harms of too much medicine. BMJ. 2015;350:h2308. doi:10.1136/bmj.h2308
27. Health at a glance: Europe 2016 – State of health in the EU cycle: OECD/European Union; 2016 [Cited 1-Apr-17]. Available at: http://www.oecd.org/health/health-at-a-glance-europe-23056088.htm
28. Alderwick H, Ham C, Buck D. Population health systems - Going beyond integrated care. London: The King's Fund; 2015 [Cited 1-Apr-17]. Available at: https://www.kingsfund.org.uk/sites/files/kf/field/field_publication_file/population-health-systems-kingsfund-feb15.pdf
29. Pronovost PJ, Ravitz AD, Stoll RA, Kennedy SB. Transforming patient safety - a sector-wide systems approach. Doha: Qatar Foundation; 2015. Available at: http://www.wish-qatar.org/app/media/1430
30. Peters DH. The application of systems thinking in health: why use systems thinking? Health Res Policy Syst. 2014;12:51. doi:10.1186/1478-4505-12-51
31. Scottish Government Model of Care Polypharmacy Working Group. Polypharmacy Guidance (2nd edition). Edinburgh: Scottish Government; 2015 [Cited 1-Apr-17]. Available at: http://www.sign.ac.uk/pdf/polypharmacy_guidance.pdf
32. De Savigny D, Adam T, eds. Systems thinking for health systems strengthening.Geneva: WHO; 2009 [Cited 1-Apr-17]. Available at: http://apps.who.int/iris/bitstream/10665/44204/1/9789241563895_eng.pdf
33. National Cancer Institute. Greater than the sum: systems thinking in tobacco control. Tobacco Control Monograph No. 18. Bethesda, MD: National Institutes of Health; 2007 [Cited 1-Apr-17]. Available at: https://cancercontrol.cancer.gov/brp/tcrb/monographs/18/m18_complete.pdf
34. Amed S, Shea S, Pinkney S, Wharf Higgins J, Naylor PJ. Wayfinding the Live 5-2-1-0 Initiative-At the Intersection between Systems Thinking and Community-Based Childhood Obesity Prevention. Int J Environ Res Public Health. 2016;13(6). doi:10.3390/ijerph13060614
35. Windisch R, Waiswa P, Neuhann F, Scheibe F, de Savigny D. Scaling up antiretroviral therapy in Uganda: using supply chain management to appraise health systems strengthening. Global Health. 2011;7:25. doi:10.1186/1744-8603-7-25
36. Goodwin N. Understanding integrated care: a complex process, a fundamental principle. Int J Integr Care. 2013;13:e011.
37. Berwick DM, Nolan TW, Whittington J. The triple aim: care, health, and cost. Health Aff (Millwood). 2008;27(3):759-69. doi:10.1377/hlthaff.27.3.759
38. WHO global strategy on people-centred and integrated health services. Geneva: WHO; 2015 [Cited 1-Apr-17]. Available at: http://apps.who.int/iris/bitstream/10665/155002/1/WHO_HIS_SDS_2015.6_eng.pdf
39. A narrative for person-centred coordinated care. London: National Voices; 2013 [Cited 1-Apr-17]. Available at: http://www.nationalvoices.org.uk/sites/default/files/public/publications/narrative-for-person-centred-coordinated-care.pdf
40. Smith M, Bates DW, Bodenheimer TS. Pharmacists belong in accountable care organizations and integrated care teams. Health Aff (Millwood). 2013;32(11):1963-70. doi:10.1377/hlthaff.2013.0542
41. Case Study Summary Scotland (UK): SIMPATHY Consortium; 2016 [Cited 1-Apr-17]. Available at: http://simpathy.eu/sites/default/files/CaseStudy_Scotland.pdf
42. Miller R, Darcy CM, Friel A, Scott MG, Toner SB. Consultant pharmacist case management of older people in intermediate care: a new innovative model. Eur J Pers Cent Healthc. 2016;4(1):46-52.

doi:10.5750/ejpch.v4i1.1056
43. Gillespie U, Alassaad A, Henrohn D, Garmo H, Hammarlund-Udenaes M, Toss H, Kettis-Lindblad A, Melhus H, Morlin C. A comprehensive pharmacist intervention to reduce morbidity in patients 80 years or older: a randomized controlled trial. Arch Intern Med. 2009;169(9):894-900. doi:10.1001/archinternmed.2009.71
44. Sevilla-Sanchez D, Molist-Brunet N, Amblas-Novellas J, Roura-Poch P, Espaulella-Panicot J, Codina-Jane C. Adverse drug events in patients with advanced chronic conditions who have a prognosis of limited life expectancy at hospital admission. Eur J Clin Pharmacol. 2017;73(1):79-89. doi:10.1007/s00228-016-2136-8
45. Brach C, Lenfestey N, Roussel A, Amoozegar J, Sorensen A. Will it work here? A decisionmaker's guide to adopting innovations: AHRQ; 2008 [Cited 1-Apr-17]. Available at: https://innovations.ahrq.gov/sites/default/files/guides/InnovationAdoptionGuide.pdf
46. Iles V, Sutherland K. Organisational change: A review for health care managers, professionals and researchers. London: NCCSDO; 2001 [Cited 1-Apr-17]. Available at: http://www.netscc.ac.uk/hsdr/files/adhoc/change-management-review.pdf
47. Cameron KS, Quinn RE. Diagnosing and changing organizational culture: based on the competing values framework. San Francisco, CA: John Wiley & Sons; 2006. ISBN: 978-0-7879-8283-6
48. Deal T, Kennedy A. Corporate cultures: the rites and rituals of corporate life. New York: Perseus; 2000. ISBN: 0-7382-0330-0
49. Kotter International. Kotter's 8-step process for leading change. Available at: https://www.kotterinternational.com/. [Accessed 1-Apr-17]
50. Heifetz RA, Linsky M, Grashow A. The practice of adaptive leadership: tools and tactics for changing your organization and the World. Cambridge, MA: Cambridge Leadership Associates; 2009. ISBN: 978-1-4421-0576-4
51. Antwi M, Kale M. Change management in healthcare: Literature review. Kingston, ON: Queens School of Business; 2014 [Cited 1-Apr-17]. Available at: https://smith.queensu.ca/centres/monieson/knowledge_articles/files/Change%20Management%20in%20Healthcare%20-%20Lit%20Review%20-%20AP%20FINAL.pdf
52. Branford M, Daniel S. A case study of change management effectiveness within the NHS. J Change Manag. 2005;5(4):391-406. doi:10.1080/14697010500287360
53. Dickson G, Lindstrom R, Black C, Van der Gucht D. Evidence-informed change management in Canadian healthcare organizations. Ottawa, ON: Canadian Health Services Research Foundation; 2012 [Cited 1-Apr-17]. Available at: http://www.cfhi-fcass.ca/Libraries/Commissioned_Research_Reports/Dickson-EN.sflb.ashx
54. May C, Rapley T, Mair FS, Treweek S, Murray E, Ballini L, Macfarlane A, Girling M, Finch TL. Normalization Process Theory On-line Users' Manual, Toolkit and NoMAD instrument. . 2015; Available at: http://www.normalizationprocess.org. [Accessed 1-Apr-17]
55. Moore MH. Creating Public Value - Strategic Management in Government. Cambridge, MA: Harvard University Press; 1997. ISBN: 9780674175587
56. Mair A, Balaso A, McKenzie D, Gietona M, Weise B, Latsou D, Michael N, SIMPATHY Consortium. D5.1: Model change management process for managing appropriate Controlling Polypharmacy: SIMPATHY Consortium; 2015 [Cited 1-Apr-17]. Available at: http://www.simpathy.eu/sites/default/files/D5_1.pdf
57. Bergert FW, Braun M, Ehrenthal K, Fessler J, Gross J, Huttner U, Kluthe B, Liesenfeld A, Seffrin J, Vetter G, Beyer M, Muth C, Popert U, Harder S, Kirchner H, Schubert I. Recommendations for treating adult and geriatric patients on multimedication. Int J Clin Pharmacol Ther. 2014;52 Suppl 1:1-64. doi:12716 [pii]
58. Multidisciplinaire Richtlijn Diabetes. Utrecht: Verenso; 2011 [Cited 1-Apr-17]. Available at: http://www.verenso.nl/assets/Uploads/Downloads/Richtlijnen/VERRichtlijnDiabetesDeel22011web.pdf
59. Fastbom J, Johnell K. National indicators for quality of drug therapy in older persons: the Swedish experience from the first 10 years. Drugs Aging. 2015;32(3):189-99. doi:10.1007/s40266-015-0242-4
60. Mair A, Kempen T, Lewek P, Hurding S, Illario M, MacLure K, Menditto E. WHO Global Challenge Report: Appropriate Polypharmacy. Geneva: WHO; 2016.

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