Polypharmacy Management by 2030: a patient safety challenge
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2nd edition
Stimulating Innovation Management of Polypharmacy and Adherence in The Elderly
Polypharmacy Management by 2030: a patient safety challenge

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Contents

9 Foreword
11 Executive summary
13 Introduction
14 About this handbook

17 Chapter 1: The case for appropriate polypharmacy management
19 Complex care
19 Quality
20 Economic
22 Politics and policy

27 Chapter 2: Preparing for change in polypharmacy management
29 Preparing for change in polypharmacy
29 Systems approach in health and care
32 Strategies for change management
32 Accounting for culture
32 Patient centered

35 Chapter 3: Approaches to implement polypharmacy management at scale
37 Change management framework
38 Getting ready for change
38 #1 Choosing a model
40 #2 Sharing leadership
40 #3 Assessing the scenario
40 #4 Benchmarking
42 Implementing change
42 #5 Setting the vision
45 #6 Creating guidelines
45 #7 Training the workforce
48 Spreading change
48 #8 Using data
51 Sustaining change
51 #9 Changing regulations
51 #10 Evaluating the programme

53 Chapter 4: EU collaboration for global patient safety challenge
54 Summary of recommendations
56 Short term
56 Medium term
56 Long term

59 References
Abbreviations

ADR – Adverse drug reaction
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 Organization
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. 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.

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 Organization (WHO) launched a global patient challenge to address medication safety, with polypharmacy as a flagship element. A special interest group was 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 and safety of patient care. It is essentially 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.

Liam J Donaldson
Envoy for Patient Safety
World Health Organization
Geneva, Switzerland

Edward T Kelley
Director, Service Delivery and Safety
World Health Organization
Geneva, Switzerland

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Unplanned hospital admissions caused by adverse drug events:

8.6 million admissions in Europe every year.

50% of hospital admissions due to adverse drug events are preventable.

70% of these are in patients over 65 years of age and on 5 or more medicines.
Executive Summary

All of us have a role to play in leadership to drive change to manage polypharmacy, regardless of the position we hold and whether we are patient organisations, government bodies, clinicians, managers or policymakers. 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, have 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.

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. 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 through the following 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 medicines 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 patient safety challenge to improve medication safety, of which polypharmacy is an essential element.
MORE PEOPLE HAVE MULTIMORBIDITY THAN A SINGLE DISEASE

![Pictograms](image)

- 45-64 YRS: 30%
- 65-84 YRS: 65%
- ≥85 YRS: 82%

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

<table>
<thead>
<tr>
<th>Patient age band</th>
<th>Percent of population</th>
</tr>
</thead>
<tbody>
<tr>
<td>50-54</td>
<td>1%</td>
</tr>
<tr>
<td>55-59</td>
<td>5%</td>
</tr>
<tr>
<td>60-64</td>
<td>10%</td>
</tr>
<tr>
<td>65-69</td>
<td>15%</td>
</tr>
<tr>
<td>70-74</td>
<td>20%</td>
</tr>
<tr>
<td>75-79</td>
<td>25%</td>
</tr>
<tr>
<td>80-84</td>
<td>30%</td>
</tr>
<tr>
<td>85+</td>
<td>35%</td>
</tr>
</tbody>
</table>

The chart shows the percentage of patients prescribed ten or more medicines by age group and deprivation level. The deprivation levels are labeled as 1 (Most deprived), 2, 3, 4, and 5 (Lest deprived).
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. 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.

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.

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. It has been estimated that non-adherence to medicines costs the European Union 125 billion euros annually.

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 multimorbid 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 medicines 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. 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, *Advancing the responsible use of medicines*, identified several opportunities to save healthcare spending through more responsible use of medicines worldwide. Using multiple international datasets, it was estimated that inappropriate polypharmacy contributes to 4% 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 multimorbid 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, analysis of SIMPATHY change management tools, SIMPATHY literature review and benchmarking survey, and SIMPATHY Delphi study.

SIMPATHY confirms the findings of *Advancing the responsible use of medicines*, 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.
THE SIMPATHY PROJECT

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
Management of polypharmacy is an essential element of patient safety in an integrated care setting making a significant contribution to well-being

Economic
Prevention of harm due to medicines can reduce demands on the healthcare system reducing threats to service sustainability

Political
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 medicines and are empowered and supported to do so
4. Use data to drive change
5. Adopt an evidence based approach with a bias towards action
6. Utilise, develop and share tools to support implementation
PERCENTAGE OF PEOPLE BY AGE GROUP
ON MULTIPLE MEDICINES

FRAILTY AND THE NUMBER OF MEDICINES

MORE FRAILTY

FRAILTY
1.5 X 5 OR MORE MEDICINES

FRAILTY
2.0 X 10 OR MORE MEDICINES

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 medicines (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.

Politics and policy

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 and policy support for change and improvement.
Complex care

There are many factors that are creating favorable circumstances to address the polypharmacy challenge. Resources are constrained and under increasing demand as people live longer with multiple morbidities. There is a focus on improving safety and quality of healthcare and avoiding harm. Workforce pressures mean that healthcare professionals and policymakers are more open to multidisciplinary working.

Polypharmacy is a growing problem as population longevity and the incidence of multimorbidity increase. 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. 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. 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. Although responses were mainly from clinical practitioners, 10% of responses were from 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%. Over half of medicines-related hospital admissions in the over 65s on multiple medications are preventable, with four
groups accounting for 50% of these (antiplatelets, diuretics, anticoagulants and non-steroidal anti-inflammatory drugs).\(^1\)

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.\(^2\) In hospital prescribing, errors are also a common occurrence, affecting 50% of hospital admissions.\(^3\) 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.\(^4\) 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.\(^5\)

The SIMPATHY literature review confirmed that there is evidence to support the principle that medication reviews reduce inappropriate polypharmacy.\(^6\) Recent research has also begun to show improvement in outcomes due to polypharmacy management, including a reduction in hospital admissions.\(^7\) 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.\(^8\)

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 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, 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.\(^9\)

Throughout Europe, 16% of total government expenditure is dedicated to healthcare, ranging from 6% in Cyprus to 22% in Switzerland.\(^10\) 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.\(^11\) In 2014 the total pharmaceuticals bill across the EU was 200 billion euros and the average spend per head of population was 402 euros with wide variation between countries, from 201 euros in Denmark to 551 euros 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 medicines to treat, for example, hepatitis C or oncological conditions.\(^12\)

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, re-admissions 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”.\(^13\)

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 200 euros 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:

<table>
<thead>
<tr>
<th>Range of estimates of savings from polypharmacy reviews</th>
<th>Unit cost/saving Scotland</th>
<th>Age 75+, 10+ medicines, plus high risk ones</th>
<th>75+ group plus all care home residents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients with high risk medicines</td>
<td>40,585</td>
<td>64,729</td>
<td></td>
</tr>
<tr>
<td>Cost estimates based on savings per case p.a</td>
<td>GBP</td>
<td>GBP M</td>
<td>GBP M</td>
</tr>
<tr>
<td>1 Med stopped; 6 repeats; 1 yr; unit cost GBP 9.87</td>
<td>9.87</td>
<td>2.4</td>
<td>3.8</td>
</tr>
<tr>
<td>2 Meds stopped; 6 repeats; 1 yr; unit cost GBP 9.87</td>
<td>19.74</td>
<td>4.8</td>
<td>7.7</td>
</tr>
<tr>
<td>Lower estimate of value of medications stopped</td>
<td>66</td>
<td>2.7</td>
<td>4.3</td>
</tr>
<tr>
<td>Base-case: change medication only</td>
<td>90</td>
<td>3.7</td>
<td>5.8</td>
</tr>
<tr>
<td>Upper estimate: change medication + switching to cost effective + cost avoidance measures</td>
<td>155</td>
<td>6.3</td>
<td>10.0</td>
</tr>
</tbody>
</table>
Politics and policy

The politics of policy making is an important aspect to consider. The political case for more effective polypharmacy management is to improve patient outcomes and patient well-being of the citizen as they age. This is set out in the EU led European Innovation Programme on Active and Healthy Aging (EIP AHA). This should improve the outcomes for patients by improving quality and patient safety and deliver economic benefits. Innovative models that deliver this care through multiprofessional working can also help address the capacity of the traditional workforce models that are under extra pressure, due to challenges of an aging population with increasing multiple morbidities.

Kingdon suggests that there is usually a window of opportunity for concepts to be accepted and adopted politically which are dependent on three components being essential: problem recognition; generation of policy proposals; and political events. For addressing polypharmacy, the window is open and policies are being driven that acknowledge the problems, as governments seek to improve the health of their populations with resources that have competing demands.

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. 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.

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

Political support across EU countries can facilitate implementation of effective polypharmacy management to improve health and well-being throughout life and protect independence into older age. The political work is not solely policy-focused. Nurturing deep change in how health professionals, policymakers 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 of polypharmacy management, 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 inter-regional 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 4.2 million euros.
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 supported 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/

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.

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

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.

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

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

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.

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

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

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.
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 medicines 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 medicines 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.
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

KOTTER
- CREATE
- INSTITUTE
- BUILD
- SUSTAIN
- GENERATE
- FORM
- ENLIST
- ENABLE

Policymakers
Educators
Commissioners
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. Embedding polypharmacy management into integrated care initiatives will help create synergies with ongoing activities that also 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 create 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 medicines 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. From the patient perspective, this will address “What matters to me?".
Preparing for change in polypharmacy

Anyone can exercise leadership in driving change in how we address effective polypharmacy management. This is possible wherever you work in the health and care system, or even if you are outside the system as a patient or an organisation that acts as an advocate for patients and carers. The evidence for the need to address polypharmacy is compelling, but the challenge of leading change goes beyond the evidence to the politics and the culture of organisations. This will include policymakers, health professionals and managers as well as carers and patient advocates. As discussed earlier, often the window of opportunity to ensure a change is implemented is small, with the three components being essential: problem recognition; generation of policy proposals; and political events. Currently, healthcare resources are under constraint. There are workforce issues and challenges of supporting an aging population, but there is the need to improve quality and outcomes for patients whilst preventing harm.

Leadership and the solutions to facilitate success need to consider the system in which they are working. Not the technical solutions to the problem alone, but understanding the changes, pressures and conflicts that might need to be addressed to deliver the solution. Solutions therefore need to be adaptive and open to tackling any conflicts that might arise.

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, policymakers, and patients.” 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 multi-morbidity, 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. 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.

A systems approach has been used by organisations such as the WHO, Institute of Healthcare Improvement and Institute of Medicine to address complex issues such as tobacco control, obesity prevention, or expansion of antiretroviral treatment.

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.

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:

1. **Service delivery**: how does introducing polypharmacy management affect existing practice and other services?

2. **Health workforce**: does polypharmacy management involve new roles and responsibilities and do they require training?
3. **Health information**: is individual and population level data related to polypharmacy management available for all healthcare professionals?

4. **Medical technologies**: what disease-specific clinical practice guidelines are professionals using and how does this affect polypharmacy management?

5. **Health financing**: are reimbursement and payment schemes aligned with the goals of polypharmacy management?

6. **Leadership and governance**: do existing legislation and policies support implementation of polypharmacy management?

The example from Uppsala, Sweden is shown above. 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 policymakers 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.
Improving cost-effectiveness of care systems
Improving the patient’s care experience (satisfaction confidence and trust)
Improving the health of people and populations (morbidity, mortality and quality of life)

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,\textsuperscript{10} and the SIMPATHY PESTEL and SWOT analyses.\textsuperscript{11}

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.\textsuperscript{37}

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 (diagram above) of improving: patient experience; population health and the cost-effectiveness of care systems.\textsuperscript{38} The patient experience is central, a fact emphasised in the WHO global strategy on people-centred and integrated health services.\textsuperscript{39} A patient perspective is captured by, \textit{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}.\textsuperscript{40}

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.\textsuperscript{10,13}

Although the concept of integrated care is receiving more attention, the role of the pharmacist has not always been addressed within this context.\textsuperscript{41} 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,\textsuperscript{41,42}

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.\textsuperscript{43-45} The latter has demonstrated positive effects on hospital readmissions, detection of adverse drug events, and the quality of prescribing.

\textbf{Italy}

\textbf{Systems approach to healthcare}

The involvement of Campania in the SIMPATHY project raised the urgency 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 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.
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 medicines 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.

Strategies for change management

Skilfully employing a change management strategy can maximise the odds of successful implementation. 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”.

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. 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’.

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’.

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. 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 multimorbidities and polypharmacy”, illustrating the types of professional-centric views that might prohibit implementation of a true multidisciplinary team. 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.

**Patient centered**

Empowering patients and their carers to be involved with the medication review process and decision making about their medicines will lead to co-production in the management of polypharmacy. This will address ‘What matters to me?’. This is important as we know that half of the patients taking four or more medicines do not take them as prescribed. As discussed previously, this can lead to patient harm, where non-adherence to prescribed medicines is a major public health issue, that is 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. It has been estimated that non-adherence to medicines costs the EU 125 billion euros annually. By asking patients ‘What matters to me?’, patients are able to engage in prioritisation and decisions about their medicines. Patients should be made aware that they can apply the same reasoning and principles when deciding to take medicines that are either over the counter or prescribed.

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 the impact of additional medication, or stopping treatment. This can be in either paper or electronic form so that it is accessible for all patients.

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 the 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 rule 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.

Ten per cent of the respondents in the SIMPATHY benchmarking survey were patients, and they felt that polypharmacy reviews were important. Patients have a key role through patient organisations to ensure that they have access to these services. Building on recommendations of reports such as Choosing Wisely suggest joint decision making with patients, is important.

In the Scottish Polypharmacy guidance there are 7 key steps that have been designed to be used by both the patient and the healthcare professionals when making decisions about medicines both at initiation of prescribing and at review. These are described in the bullets below:

**Step 1:** What matters to the patient?
**Step 2:** Identify essential drug therapy.
**Step 3:** Does the patient take unnecessary drug therapy?
**Step 4:** Are therapeutic objectives being achieved?
**Step 5:** Is the patient at risk of side effects or suffers actual side effects?
**Step 6:** Is drug therapy cost-effective?
**Step 7:** Is the patient willing and able to take drug therapy as intended?
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.

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.

Getting ready for change

The current situation can be assessed utilising the SWOT and PESTEL analysis and this can inform strategic plans. 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.

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 have used Kotter’s 8-steps in combination with strong leadership that is adaptive to drive change. There is a distinction between adaptive leadership and an authoritative solution to tackle problems. 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**: 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 an adaptive and iterative 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**: A common criticism of change management models is that the emphasis is on the role of managers without accounting for the role of employees. Successful implementation of innovative polypharmacy management will require strategic leadership from managers and clinicians and policymakers.

- **The up-front investment of time developing a strategy is time well spent**: 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: 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: 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. Local managers then worked to adopt the policy at a regional level. Further work was undertaken to collaborate with clinicians and policymakers 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. Kotter’s 8-step process for leading change has been integrated with these general change categories. 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.

<table>
<thead>
<tr>
<th>Stages of Change and Kotters 8 step model</th>
<th>Questions for managers</th>
<th>Kotter’s 8-Step Change Model</th>
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</table>
| **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 organisation 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 |
| | | Step 8. Institute change by anchoring new approach in the culture |
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 to successfully implement a polypharmacy management programme.

Application of the Kotter 8-step 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 medical, pharmacy and public health directors, 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 use 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 of 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.\textsuperscript{56} 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, ongoing 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”\textsuperscript{11}

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 multi-disciplinary leadership teams has been reported in case studies, and also endorsed by participants in the Delphi study.\textsuperscript{13} 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.\textsuperscript{56}

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.\textsuperscript{57}

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 derail 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.\textsuperscript{11}

\#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.\textsuperscript{12}

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

PESTEL

- Prescribing Legislation; Medicines Regulation; Patient Rights
- National Priorities; Influence of Elderly Population
- Population Health and Well-being; Public Health
- Economic Growth; Funding for Healthcare
- Health and Medicines Innovation; ICT advances
- Education; Behaviours and Beliefs; Care Cultures

SWOT

- Leadership; Integrated ICT; Interprofessional teams; Guidelines
- Professional Hierarchies; Service Fragmentation; Health Economics Awareness, No Medicines Review
- Resource Availability, Changing Demographics, Single Disease Focus
- Improve Patient Safety, Reduce Healthcare Costs; Patient Empowerment
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 professionals’ 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 on page 44. The time frame has been extended from 2025 to 2030 after reflection on comments made in both the benchmarking survey and the Delphi.

### 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. 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.)

### Key questions for benchmarking and subsequent action:

1. State the structure – does your programme cover an institution, region or nation?
2. What population 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-step process?
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
**ROUTE MAP**

**HOW DO WE GET THERE?**

- **Policy**
  - Increased awareness of polypharmacy across EU
  - Policy commitment to creating structure for polypharmacy reviews
  - Estimated savings potential from medicines ceased: 4.32bn euros

- **Healthcare Services**
  - Patients possibly using inappropriate medicines
  - Literature review conclusions
  - Case studies outputs

- **Economic Sustainability**
  - Case studies outputs
  - Literature review conclusions

- **Healthcare Teams**
  - SP SIMPATHY VISION
  - 100% Professional & patient education
  - Reduced patient admissions due to ADR
  - Low professional & patient education

2015
- Think differently
  - Identifying good practice for evidenced-based change

2017
- Make change for the better
  - 50% Professional & patient education

2020
- Consolidate/accelerate
  - 50% Professional & patient education

2030
- Policy commitment to creating structure for polypharmacy reviews
  - Integration towards single institution in healthcare
  - No patients on inappropriate meds

- Reduced patient admissions due to ADR

- Patient empowerment

- Good practice polypharmacy guidance

- Workshops & knowledge-sharing

- Spreading good practice

- Demonstration, prevention studies

- Net productive opportunity of reviews: 10.41Bn euros

- 2.2m ADR-related bed days avoidable

- Good practice polypharmacy guidance
**#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, the Netherlands and Germany score the maximum on the AGREE II-GRS criteria for quality. Within Scotland, the development of the guidance was essential to provide the training, evidence and support that the clinicians needed for the implementation of medication reviews to manage multiple morbidities. Through this, a powerful coalition was built as well as the 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. 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.

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 focal 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.

Polypharmacy management guidance documents that scored maximum on the AGREE-II GRS

<table>
<thead>
<tr>
<th>Guidance document details</th>
<th>Country of origin</th>
</tr>
</thead>
</table>

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 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. 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. 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.
NUMBER OF POLYPHARMACY GUIDANCE DOCUMENTS PER COUNTRY

- 1 country with 1 document
- 1 country with 2 documents
- 1 country with 4 documents
- 1 country with 4 documents
- 1 country with 8 documents
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. Findings also show that clear quality indicators and measures of polypharmacy are critical, both for the development of the management programme, and for the ongoing monitoring for evidence of success. This view was also endorsed by the Delphi survey participants. The table on page 49 provides 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. Policymakers 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 is available on the SIMPATHY web site.
### Polypharmacy management indicators

<table>
<thead>
<tr>
<th>Country</th>
<th>Example indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Catalonia</strong></td>
<td><strong>General pharmacy indicators</strong></td>
</tr>
<tr>
<td></td>
<td>• Number of prescriptions per user</td>
</tr>
<tr>
<td></td>
<td>• Average cost of prescription per patient</td>
</tr>
<tr>
<td></td>
<td><strong>Polypharmacy management specific indicators</strong></td>
</tr>
<tr>
<td></td>
<td>• % of patients with polypharmacy(^a)</td>
</tr>
<tr>
<td></td>
<td>• Index of prescription quality(^b)</td>
</tr>
<tr>
<td></td>
<td><strong>Pharmacy cost indicators</strong></td>
</tr>
<tr>
<td></td>
<td>• Cost per patient treated with ACEI or ARB</td>
</tr>
<tr>
<td></td>
<td>• Cost per patient treated with cholesterol lowering agents</td>
</tr>
<tr>
<td></td>
<td>• Cost per patient treated with antidepressants</td>
</tr>
<tr>
<td><strong>Scotland</strong></td>
<td><strong>Standard polypharmacy indicator</strong></td>
</tr>
<tr>
<td></td>
<td>• 10 or more BNF paragraphs dispensed in a 6 month period with at least one high-risk medicine</td>
</tr>
<tr>
<td></td>
<td><strong>High risk prescribing indicators:</strong></td>
</tr>
<tr>
<td></td>
<td>• Older person (≥75 years) prescribed an antipsychotic drug</td>
</tr>
</tbody>
</table>
|             | • 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**  | **Drug-specific indicators\(^c\)** |
|             | • Medicines that should be avoided unless a specific reason exists: long-acting benzodiazepines, medicines with significant anticholinergic effects, tramadol. |
|             | **Diagnosis specific indicators\(^c\)** |
|             | • COPD: irrational use, oral β-2 receptor agonist; hazardous use, non-selective β-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 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.

<table>
<thead>
<tr>
<th>Population</th>
<th>Cost of reviews</th>
<th>Potential direct savings from reviews</th>
<th>Potential indirect benefits of reviews</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identified risk group</td>
<td>Minutes per review by staff type</td>
<td>Net reduction in drug expenditure</td>
<td>Avoided Adverse Drug Reactions (ADRs)</td>
</tr>
<tr>
<td>Maximum number of polypharmacy reviews</td>
<td>Staff cost</td>
<td></td>
<td>Prevented hospital admissions related to ADRs</td>
</tr>
<tr>
<td>Net of charge per review</td>
<td></td>
<td></td>
<td>Bed days/cost associated with prevented admissions</td>
</tr>
</tbody>
</table>

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 medicines 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 users the 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 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](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. 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.

Payment models also need to be realigned with the goals and objectives 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 positions 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 the practice of pharmacists facilitated the development of a programme at regional level. 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”. 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). 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. When you are planning a process evaluation, NPT may help you to structure this evaluation. 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 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 patient safety 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. 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) and this will be achieved on an ongoing 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 4.23 billion euros 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. Policymakers 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
Policies 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 utmost 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 take place.

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 medicines 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 medicine 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 rule guidance is shown above, 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 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. Recent research has begun to show improvement in outcomes including hospital admission. 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. 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. Embedding polypharmacy management into integrated care initiatives will help create synergies with ongoing 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 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 achieved.
Use of existing guidance and mobile apps that incorporate the guidelines and key steps should be shared to spread good practice. Scottish Polypharmacy app launched in April 2016 can be found at http://www.polypharmacy.scot.nhs.uk/

This recommendations can be summarised into short, medium and long term.

**Short term**
- Raise awareness about the problems with polypharmacy with healthcare professionals and patient groups
- Launch of Polypharmacy Special Interest Group (SIG) at the International Foundation on Integrated Care
- EU adopt leadership role in the WHO global patient safety medication challenge
- Share change management tools to support implementation of polypharmacy programmes across Europe, including benchmarking tools
- Share tools to undertake polypharmacy reviews across Europe for clinicians and for patients that enable them 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
- Ensure appropriate polypharmacy is integral to medical, pharmacy and nursing undergraduate and postgraduate 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


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
42. Case Study Summary Scotland (UK): SIMPATHY Consortium; 2016 [Cited 1-Apr-17]. Available at: http://simpathy.eu/sites/default/files/CaseStudy_Scotland.pdf