

D8: A person-centred approach to safe and effective medicines use



International Forum on
QUALITY & SAFETY
in **HEALTHCARE**
COPENHAGEN



Adapting to a changing world: equity, sustainability
and wellbeing for all



 @QualityForum #Quality2023

 Institute for
Healthcare
Improvement

BMJ

Session D8

Medicines Optimisation – A change package to support Medicine Without Harm

Gill Smith, IHI Fellow and Faculty

Professor Mike Scott, Director Regional Medicines Optimisation Innovation Centre (MOIC)

Anita Hogg, Pharmacist and Lead, Regional Medicines Optimisation Innovation Centre (MOIC)



Financial:

Gill Smith is Managing Director of Kaizen Kata

Non financial:

Gill Smith is a member of IHI Faculty

Mike Scott has no relevant financial or relevant nonfinancial relationships to disclose

Anita Hogg has no relevant financial or relevant nonfinancial relationships to disclose.

After attending this session, attendees will be able to:

- Implement a person-centred medicines optimization approach to enhance patient safety and quality
- Access medicines safety practice/activities to support a systems approach to medicines safety – and take away tools for use in your own setting
- Develop a measurement plan to demonstrate the efficiency and effectiveness of the interventions



Gill Smith

Managing Director, Kaizen Kata
& IHI Fellow & Faculty
@kaizenkata



Professor Mike Scott

Director, Regional Medicines
Optimisation Innovation Centre
(MOIC) in Northern Ireland



Anita Hogg

Lead, Regional Medicines
Optimisation Innovation Centre
(MOIC) in Northern Ireland

moic

Medicines Optimisation Innovation Centre



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Medicines Optimisation Innovation Centre (MOIC)

Work Themes



- › Focus needs of NI population
- › Accelerate adoption of innovation into practice to improve patient outcomes and experiences
- › Build culture of partnership and collaboration
- › Make meaningful contribution to NI economy

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Vibrant centre of expertise with a proven track record

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MOIC Team



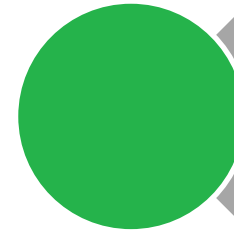
Prof Mike Scott
Director



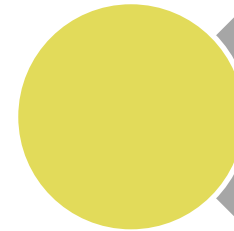
Dr Glenda Fleming
Deputy Director



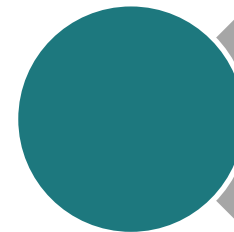
Anita Hogg
Lead



Team of experts, including 7
Programme Managers trained
to Doctoral level



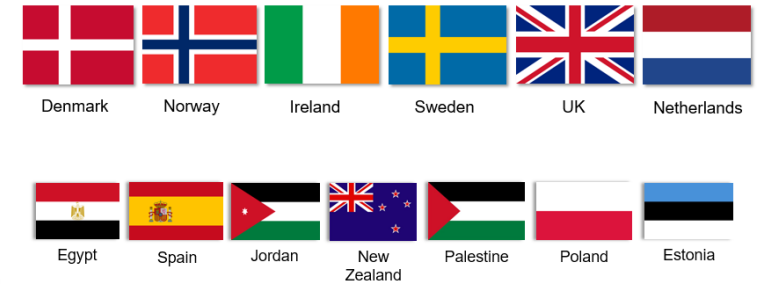
Clinical expertise throughout
Northern Ireland



Communications and
administrative support

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Engage and collaborate



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International recognition

EUROPEAN
AHA REFERENCE SITE



EUROPEAN
AHA REFERENCE SITE



silcc

Statement Implementation
Learning Collaborative Centres



Polish Society of Clinical
Pharmacy



Estonian Society of Hospital
Pharmacists (ESHP)



SOCIEDAD ESPAÑOLA
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People Engaging in Supportive Systems



The Smart & Healthy Ageing through People Engaging in Supportive Systems (SHAPES) Innovation Action intends to build, pilot and deploy a large-scale, EU-standardised open platform. The integration of a broad range of technological, organisational, clinical, educational and societal solutions seeks to facilitate long-term healthy and active ageing and the maintenance of a high-quality standard of life. Mediated by technology, in-home and local community environments interact with health and care (H&C) networks contributing to the reduction of H&C costs, hospitalisations and institutional care.

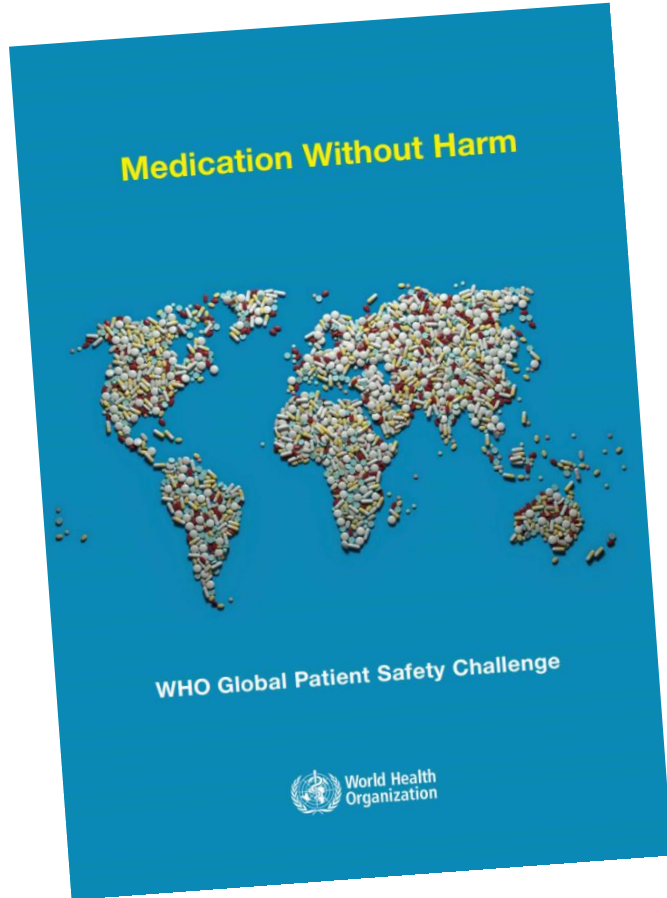


Ensuring the best medication outcomes for patients

iSIMPATY, (implementing Stimulating Innovation in the Management of Polypharmacy and Adherence Through the Years), a three year EU funded project in Northern Ireland, Scotland and the Republic of Ireland. The project aims to ensure the best and most sustainable use of medicines for patients by training pharmacists and other medical professionals to deliver medicine reviews and embedding a shared approach to managing multiple medicines.

Background – the urgent need for action

Medicines Safety: The Global Challenge (1)



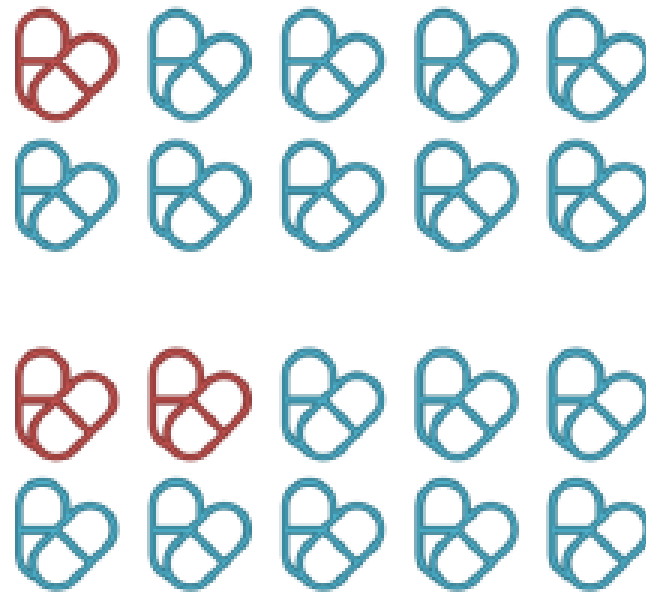
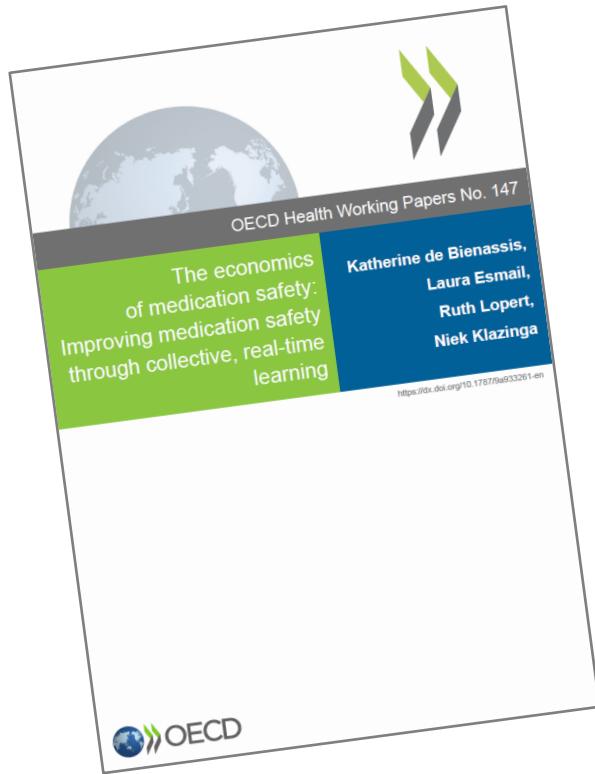
- Unsafe medication practices and medication errors are a leading cause of **avoidable harm** in health care systems
- Globally, the cost of medication errors is estimated at US\$ 42 billion annually

(Ref WHO 2017)

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Medicines Safety: The Challenge (2)



As many as **one-in-10 hospitalizations** in OECD countries may be caused by a medication-related harm and...

One-in-five inpatients experience medication-related harms during hospitalization

Ref: OECD 2022

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The patient safety and quality of life impact of medicines safety



Patients

Living well

Avoidable re/admissions, disease progression,
mental health, ability to work, social impact.....

Antimicrobial Resistance



- 4.95 million deaths globally due to AMR in 2019
- All-age death rate highest in Western Sub-Saharan Africa (27.3/100,000) and lowest in Australasia (6.5/100,000)
- 1.5 million deaths caused by AMR lower respiratory tract infections
- By 2050 10 million/year could die from AMR infections

(Ref: Lancet 2022)

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Antimicrobial Stewardship



- Highly effective hospital AMS programs have **pharmacists** as co-/leader
- Five ways hospital pharmacists can be antibiotic aware
 1. Verify penicillin allergy
 2. Avoid duplicate anaerobic cover
 3. Review antibiotic therapy
 4. Avoid therapy of asymptomatic bacteruria
 5. Use the shortest antibiotic duration

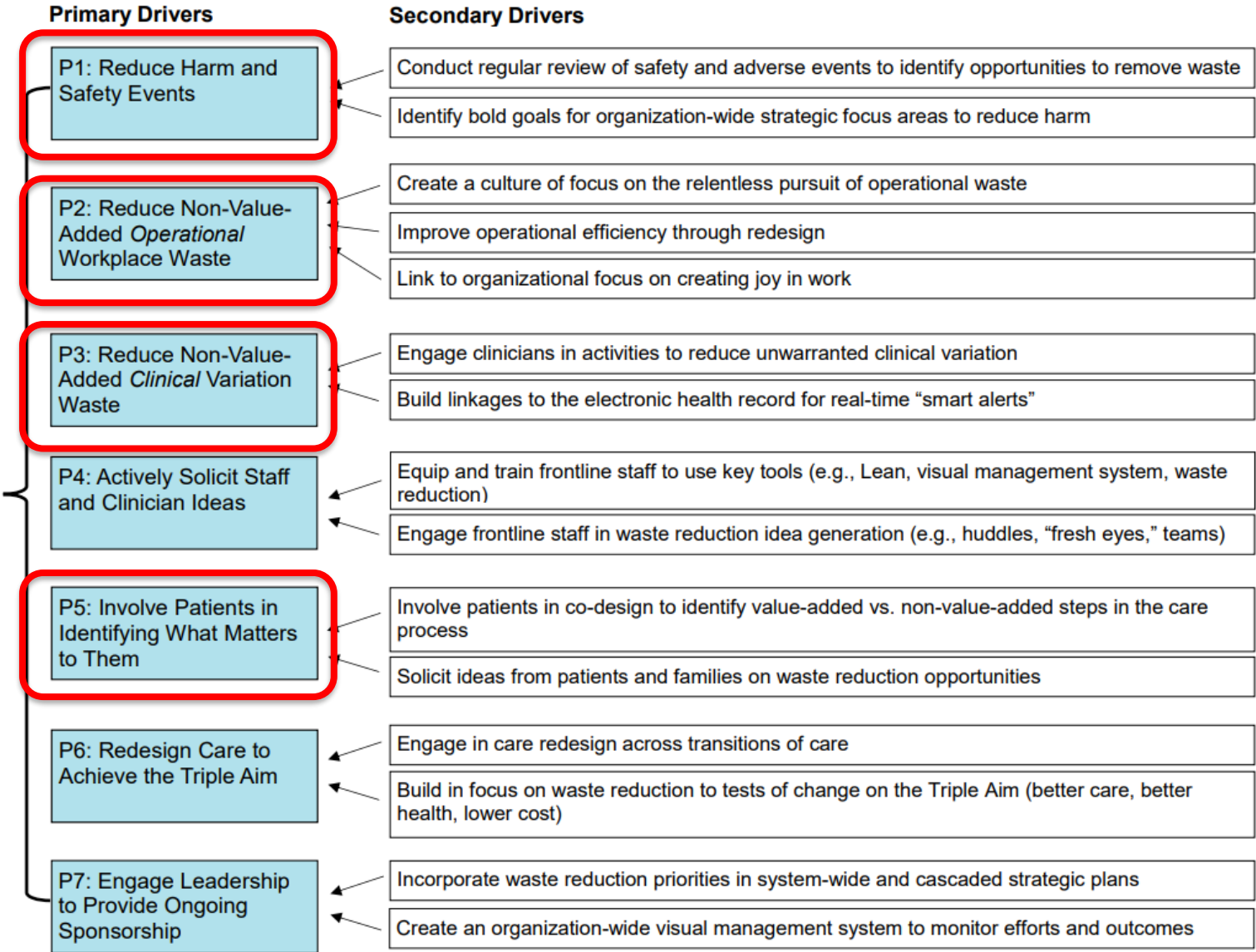
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Waste and Environmental impact of medicines

A Driver Diagram to Systematically and Proactively Identify and Eliminate Non-Value-Added Waste in the US Health Care System by 2025

Aim

Systematically and proactively identify and eliminate 50% of non-value-added waste in the US health care system by 2025



Trillion Dollar
Cheque Book

Medicine waste: medicine review, ordering, adherence....



Up to 90% of orally administered pharmaceuticals are excreted into wastewater as active substances in the faeces and urine of patients



<https://noharm-europe.org/documents/pharmaceutical-residues-hospital-wastewater>

**In the UK alone
50million inhalers
prescribed a year. The
majority of those
inhalers (approx. 70%)
are pressurised
Metered Dose Inhalers
(pMDIs) containing
propellants called
hydrofluorocarbons
(HFCs).**

280kgCO₂e



0.28kgCO₂e

2.8kgCO₂e

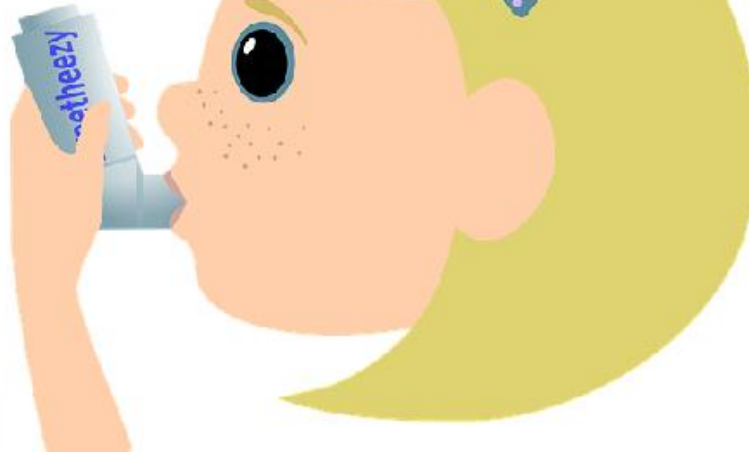
28kgCO₂e

What is the whole
life carbon
equivalent emission
of the most
commonly
prescribed inhaler
in the UK?

These carbon emissions make up 25% General Practice prescribing footprint

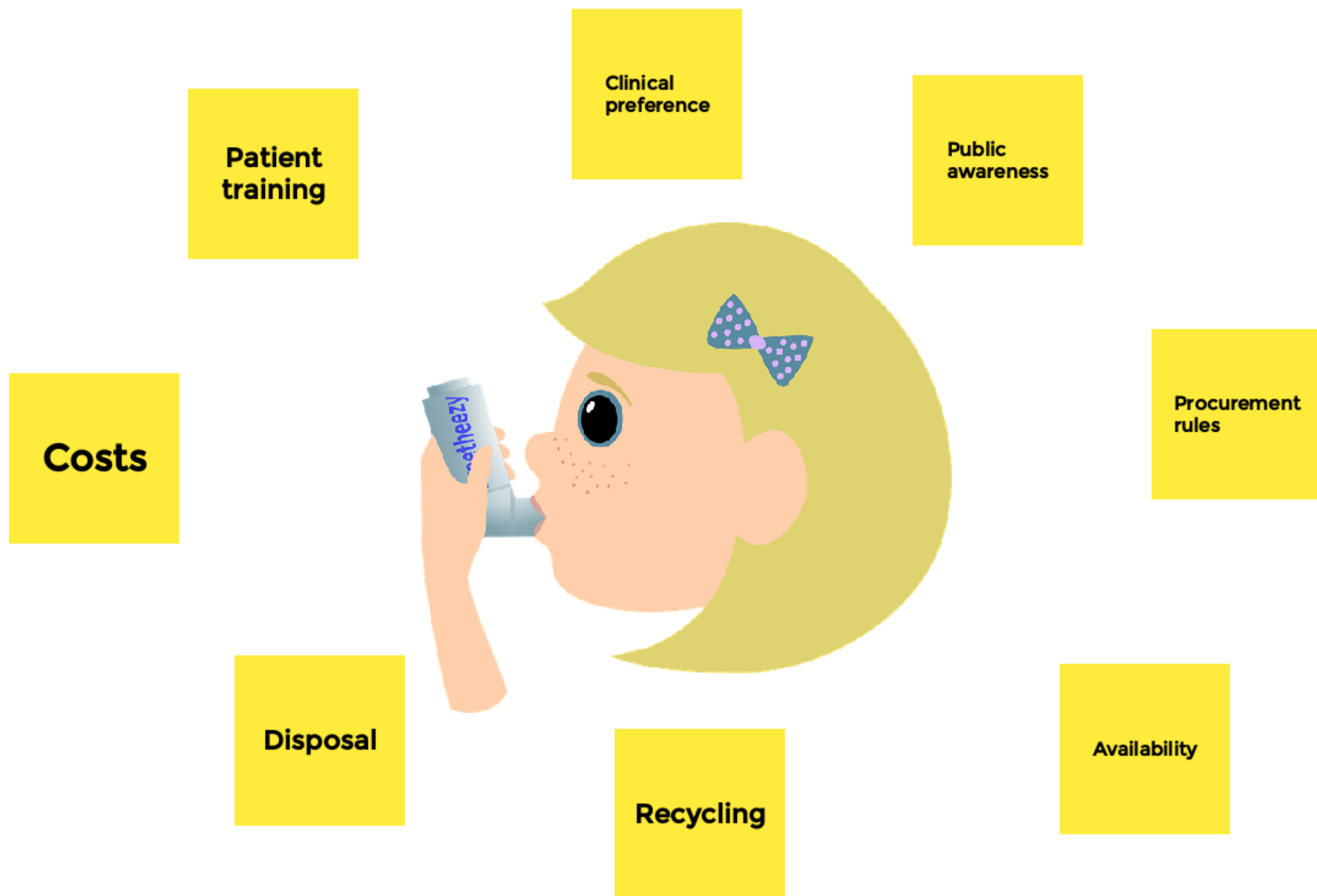
28kgCO₂e

Dry powder inhalers have now been developed reduce the carbon impact of use by 20-30



What are the other issues that should be considered here?



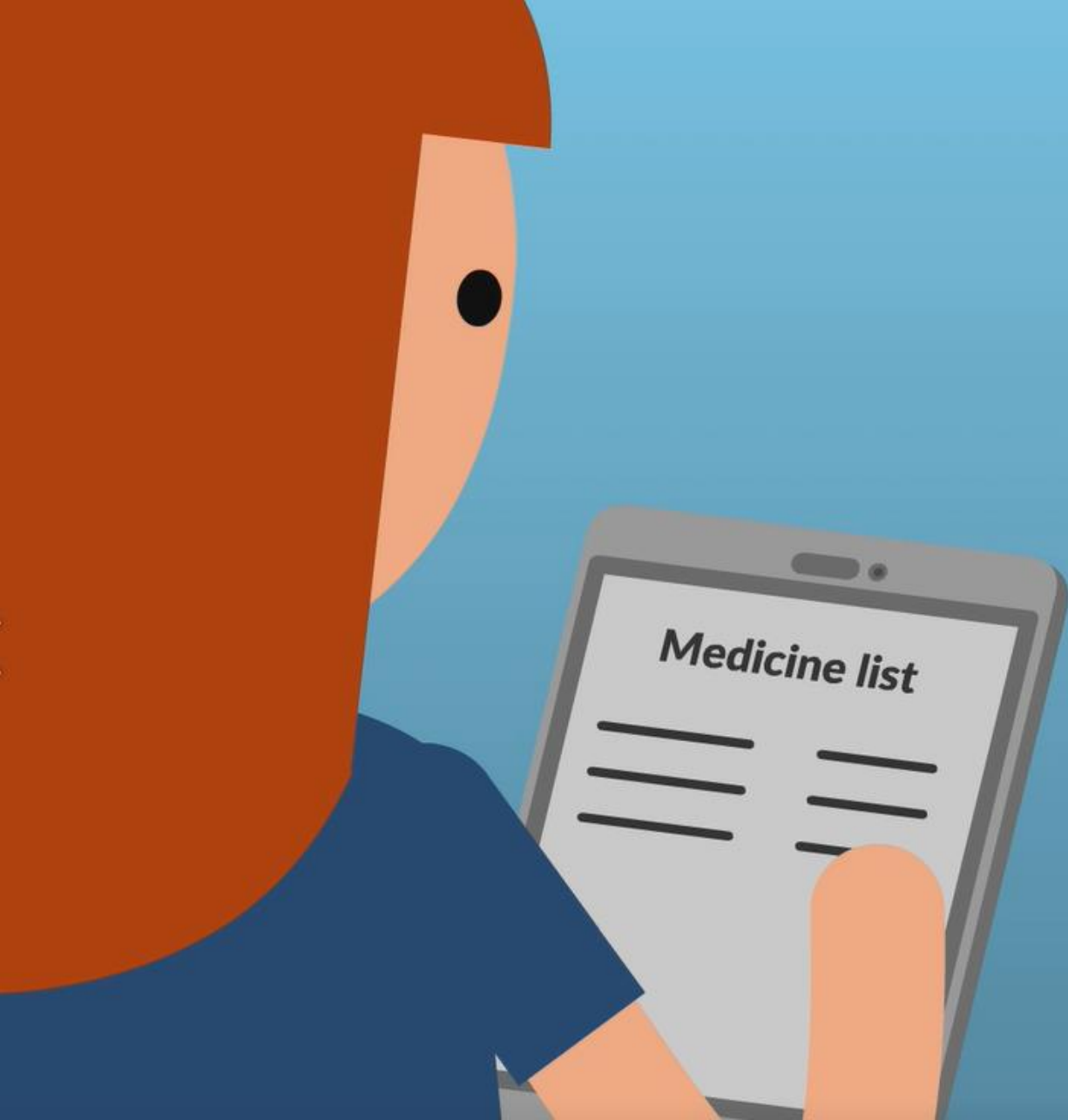


A complete package supporting the entire patient journey
(whole system approach, multiple settings)

Anita Hogg

TEAM





Did you know
that pharmacists
can
PRESCRIBE
medicines?

In 2026 UK newly qualified pharmacists will be independent prescribers at registration

Hospital



- System redesign
- Interface
- LOS (2 days)
- Readmission
NNT=12
- MAI

(Ref Scullin)

Post Discharge follow up

High Level patient satisfaction

15.2% reduction in 90 day readmission rates

9.9% reduction in 30 day readmission rates

Positive health economic benefit return in investment £51 per £1 spent at 50 days



(Ref Odeh 2021)

Out-patient

- Medicines optimisation clinic
- Reduced readmission rate & ED visits, improved QoL

(Ref Odeh 2020)



General practice

- Clinical pharmacist case management
- Reduced medicine related problems and improved MAI

(Ref Syafhan)



Intermediate care & Nursing Home

Consultant Care of the
Elderly Pharmacist Network



15 specialist elderly care
pharmacists

Nursing Homes

Improved MAI

2.7 interventions made
per patient

Reduced ED attendances

ROI £2.39-3

Intermediate Care

Improved MAI

1122 interventions in 453 patients


42.9% patients phoned post discharge
required one or more interventions

ROI £2.35-4

(Refs: Miller, McKee)

**Sweden, Ireland,
Norway, Poland**





Ensuring the best medication outcomes for patients

7 STEPS TO APPROPRIATE POLYPHARMACY



Step 1: What matters to the patient

WMTY

Step 2: Identify essential drug therapy

Step 3: Does the patient take unnecessary drug therapy?

Step 4: Are therapeutic objectives being achieved?

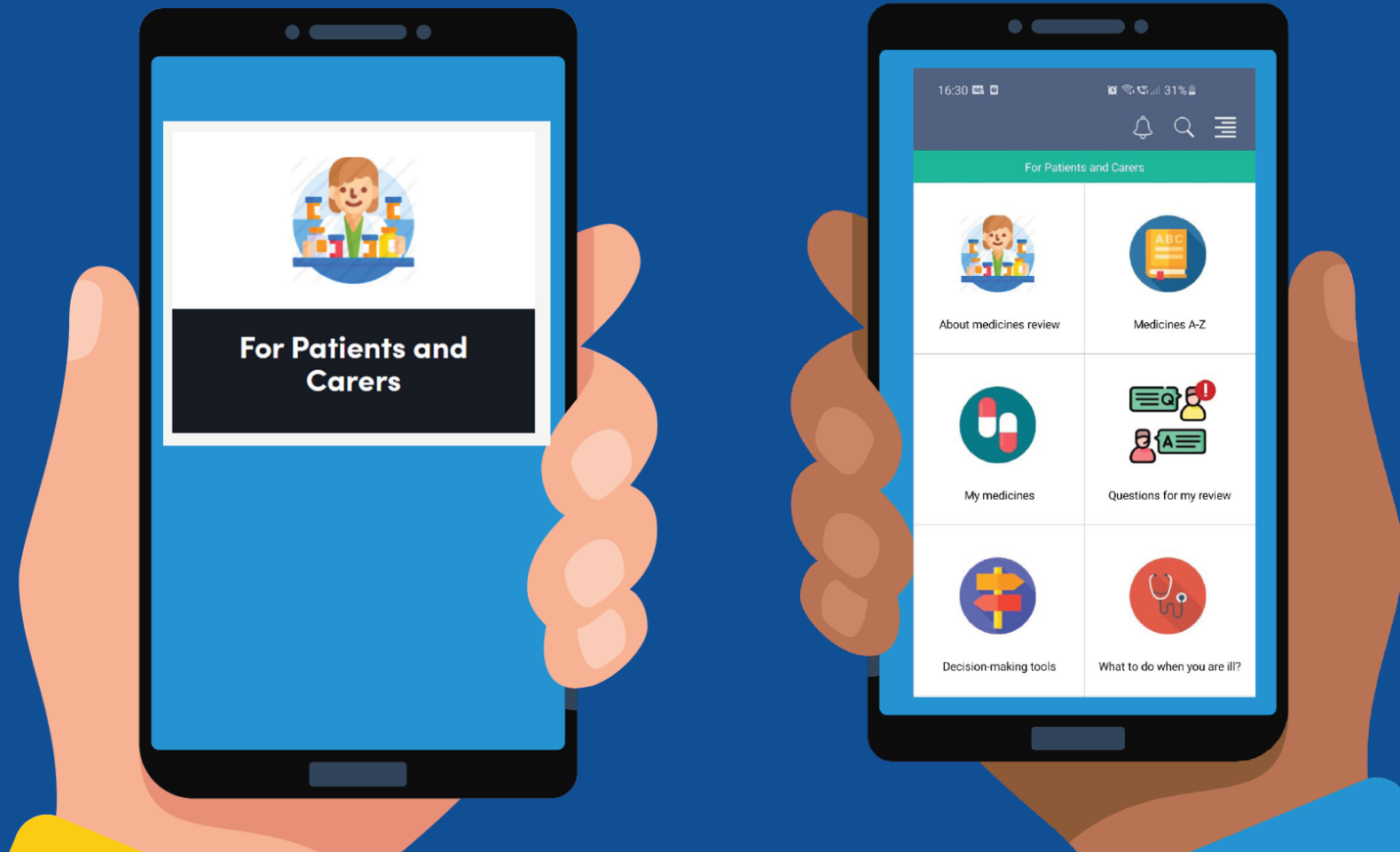
Step 5: Is the patient at risk of ADRs or suffers actual ADRs?

Step 6: Is drug therapy cost-effective?

Step 7: Is the patient willing and able to take drug therapy as intended?

Supporting reviews with the Manage Medicines app

The Manage Medicines app is a key way to support the medicines reviews process. With easy to navigate toolkits for both professionals and patients or carers, the app also lets patients answer questions ahead of their reviews. As well as giving practitioners this information in advance, it helps patients get the most out of their medicines reviews. Look out for our short animation explaining the app and the PROMs (Patient Reported Outcomes Measures) questionnaire coming soon on our website and twitter.



Modules:

ONE – Why should we address Polypharmacy

- Definition and dangers of Polypharmacy
- Medication Adherence
- Adverse Drug reactions
- Criteria for selection for Polypharmacy reviews
- Short introduction to the '7 step' medication review process

TWO – 7 Steps Methodology

- The 7 Step Medication review process
- Numbers Needed to Treat
- The 7 steps review process in practice
- High risk medicines combinations

THREE – Change Methodology and Numbers Needed to Treat

- Implementing Change Methodology,
- Case study example of the 7 steps in practice
- 'Understanding NNT's' - Numbers Needed to Treat

Accredited online training



<https://learn.nes.nhs.scot/59670>

What patients say...



No one has ever sat down with me and taken time to go through all my medicines with me

The review considered me as a whole person, not just my medical conditions
Seamus, 62 years

A wonderful person. It was the first time anyone had ever listened and understood what I was coping with and helped me in so many ways

It means so much to me to be involved in decision about my brother's care. He is non-verbal and I do everything for him

My review was not rushed and hugely beneficial to my care
Steven, 45 years



Improved patient safety

82% interventions **clinically significant** including potentially preventing major organ failure, adverse drug reactions or incidents of similar clinical importance (Eadon)

Reduced waste

53% reviews reduction in number of medicines
91% reviews resulted in more appropriate medicines (MAI)
£120 patient/yr* saved on medicines expenditure per review, Scotland, €376 Ireland

*Additional savings expected eg preventable admissions to hospital

The change package

Gill Smith

Our approach:

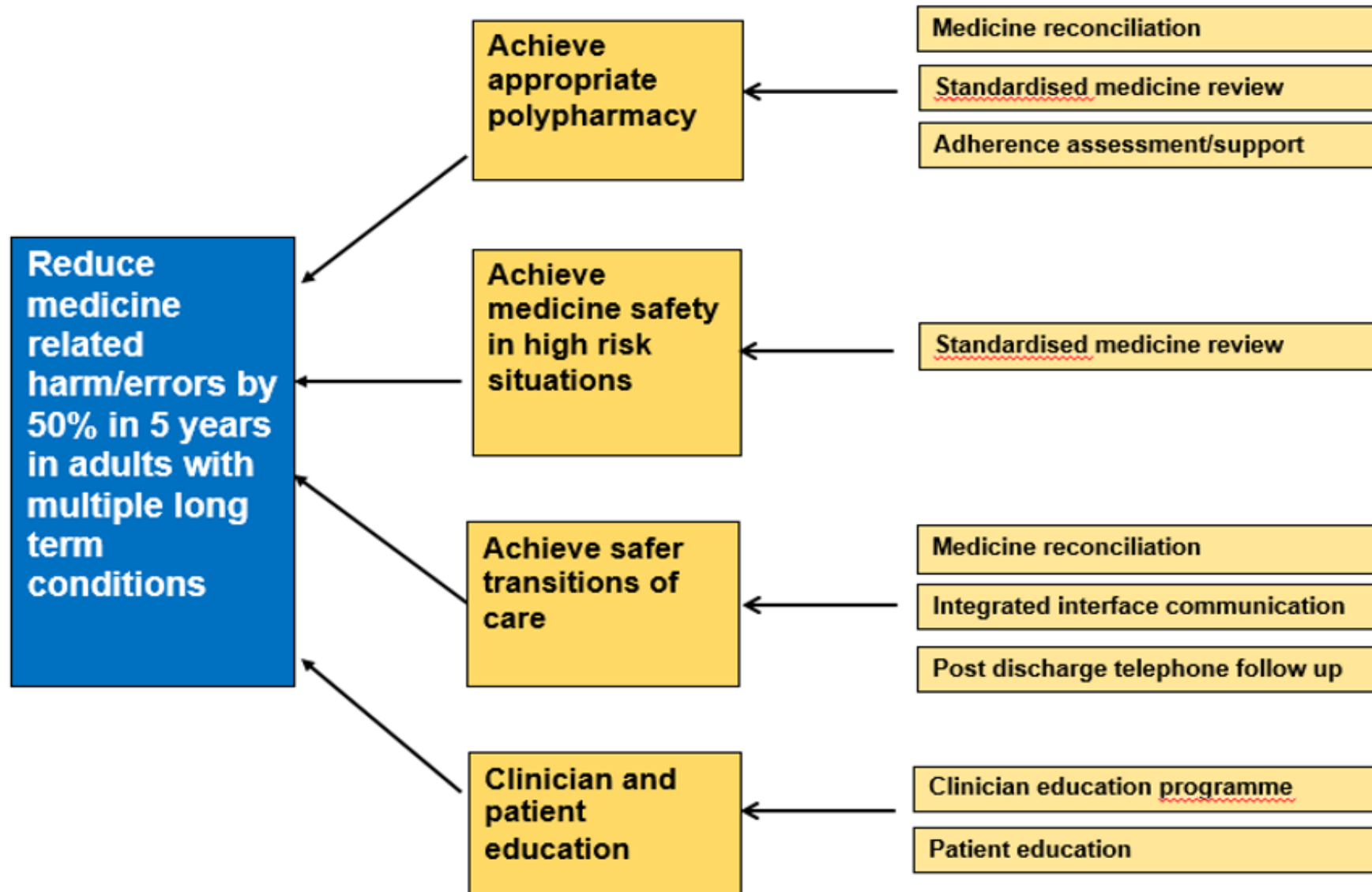
- Has examined the methods and factors that best work to facilitate quality improvement (is evidence based)
- Provides a package (interventions) to make changes in the most effective way
- Is based on a theory of change, with an associated logic model
- Is underpinned by measurement

Driver Diagram

AIM

PRIMARY DRIVERS

SECONDARY DRIVERS



Linking Drivers, Interventions and Measures

PRIMARY DRIVERS

SECONDARY DRIVERS

Intervention

Process measures

Outcome measures

Balancing measures

Achieve appropriate poly-pharmacy

Medicine reconciliation

Standardised medicine review

Adherence assessment

SOP applied at admission

7 STEPS Medicine review

Develop process to introduce PROMS pre & post medicine review

95% completed within 48hr

% compliance with 7 STEPS

PROMS completed by x% patients

Reduced LOS, readmission, ED attendance, GP/CP attendances, number of interventions Gd 4-6 & cost avoidance

Improved adherence on PROMS

Increased medicine lab, diagnostic costs

Achieve medicine safety in high risk situations

Standardised medicine review

7 STEPS Medicine review

% compliance with 7 STEPS

Reduced LOS, readmission, ED attendance, GP/CP attendances, number of interventions Gd 4-6 & cost avoidance

Achieve safer transitions of care

Medicine reconciliation

Integrated interface communication

Post discharge telephone follow up

SOP applied at discharge

Reconciled discharge note on ECR

SOP

x% completed prior to discharge

80% reconciled discharge note on ECR

x% discharge telephone follow up

Reduced LOS, readmission, ED attendance, GP/CP attendances, number of interventions Gd 4-6 & cost avoidance

Clinician & patient education

Clinician education programme

Patient education

Deliver education programme

SOP applied prior to discharge

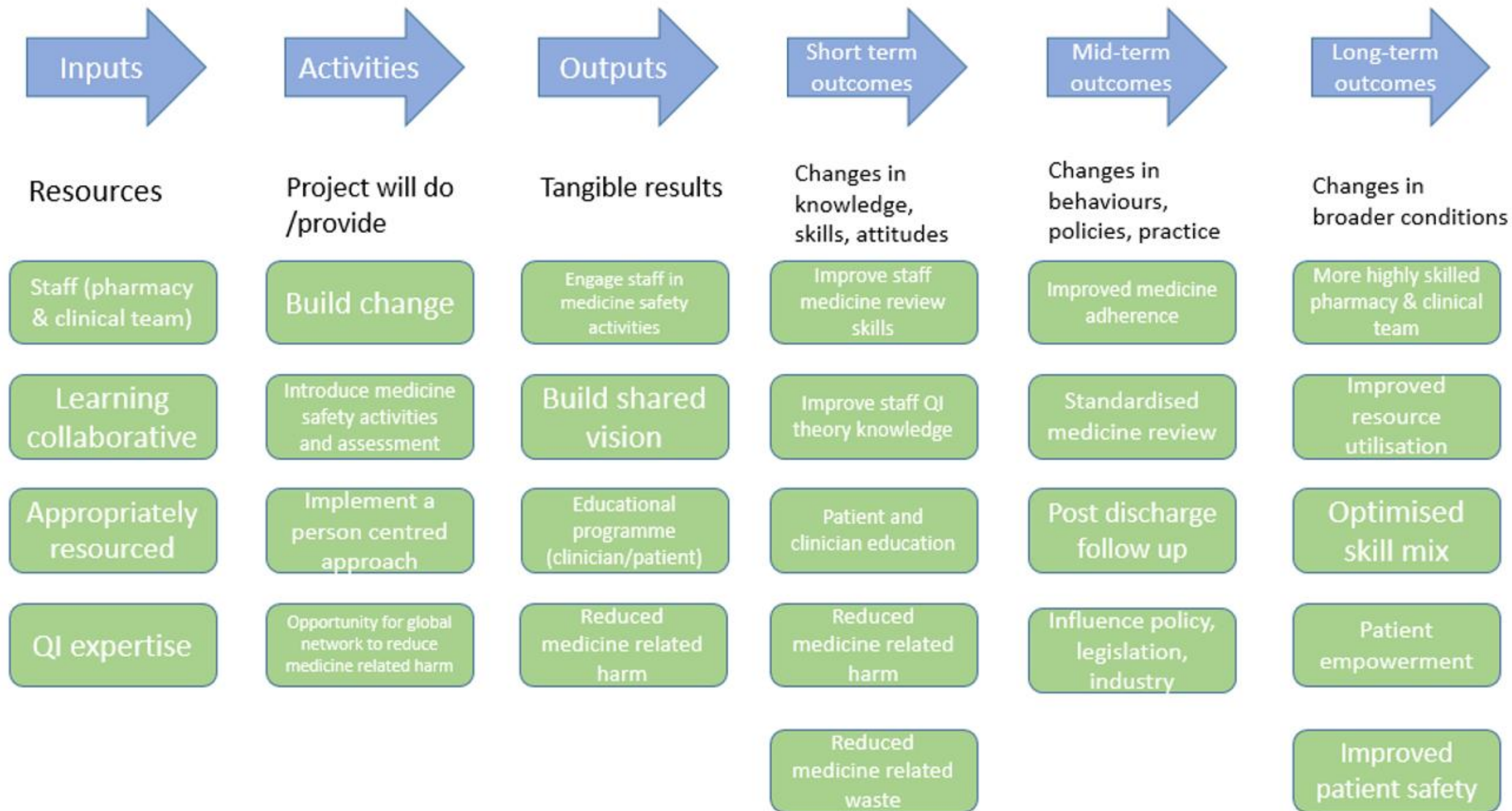
80% clinicians educated

x% Patients educated

Increased knowledge and skills post education

Reduced LOS, readmission, ED attendance, GP/CP attendances, number of interventions Gd 4-6 & cost avoidance

Logic Model



7 STEPS	Standardised medicine review tool published in the Polypharmacy Guidance: Realistic Prescribing	https://www.therapeutics.scot.nhs.uk/wp-content/uploads/2018/04/Polypharmacy-Guidance-2018.pdf
PROMs	Patient reported outcome measures	https://managemeds.scot.nhs.uk/for-patients-and-carers/questions-for-my-review/
Eadon intervention scale	Tool to grade clinical interventions according to clinical significance to individual patient for example, Grade 4: intervention is clinically significant to patient and improves standard of care; Grade 6: potentially life-saving	https://academic.oup.com/ijpp/article-abstract/1/3/145/6138838
Medication Appropriateness Index (MAI)	A validated tool to assess the appropriateness of medicines. The evaluator rates each medicine appropriate, marginally appropriate or inappropriate across a range of criteria. Each criterion is assigned a weighted score. The tool has been adapted to reflect a person-centred approach and is currently being used as a measurement in the iSIMPATY project	Hanlon, J.T., Schmader, K.E., Samsa, K.E., Weinberger, M., Uttech, K.M., Lewis, I.K., Cohen, H.J. & Feussner, J.R. (1992). A method for determining drug therapy appropriateness. <i>Journal of Clinical Epidemiology</i> 45 (10) 1045-1051.



Are you ready to take up the challenge?....

- How can you implement the change package to impact on your system, organisation and patients?
- Interested in connecting? Why not send us an expression of interest to:

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www.linkedin.com/company/moic/

www.themoic.hscni.net



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References

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Some helpful resources

- **Model to Reduce Waste in Healthcare and Add Value, BMJ Open Quality (2022)** [Model to reduce waste in healthcare and add value | BMJ Open Quality](#)
- **Podcast - Saving the planet – reducing healthcare waste to improve environmental impact** [Stream episode Gill Smith And Elaine Mead by National Elf Service podcast | Listen online for free on SoundCloud](#)
- **OECD (2017), Tackling Wasteful Spending on Health, OECD Publishing, Paris** :<https://dx.doi.org/10.1787/9789264266414-en>

Some helpful resources

- **Delivering a Net Zero NHS** (2020), NHS England and Improvement
<https://www.england.nhs.uk/greenernhs/wp-content/uploads/sites/51/2020/10/delivering-a-net-zero-national-health-service.pdf>
- Bueno B, Leo JD, Macfie H. IHI Leadership Alliance. **Trillion Dollar Checkbook: Reduce Waste and Cost in the US Health Care System.** Boston: IHI, 2019 (available at www.ihl.org).
- [Climate Ergonomics - embedding sustainability into everyday business.pdf](#)

A horizontal banner with a green background and the word 'Medicines' in white text. Above the banner are four small colored squares: purple, green, pink, and orange.

Medicines

Creating a context for improvement: learning from a national medicines safety initiative

James Innes & Ruth Dales

 @NatPatSIP / #MedSIP

[Future.nhs.uk/medicinessafetyimprovement/](https://future.nhs.uk/medicinessafetyimprovement/)

Delivered by:
The Medication Safety Officer Network
*The***AHSN***Network*

Led by:
NHS England



It's great to be with you...



James Innes

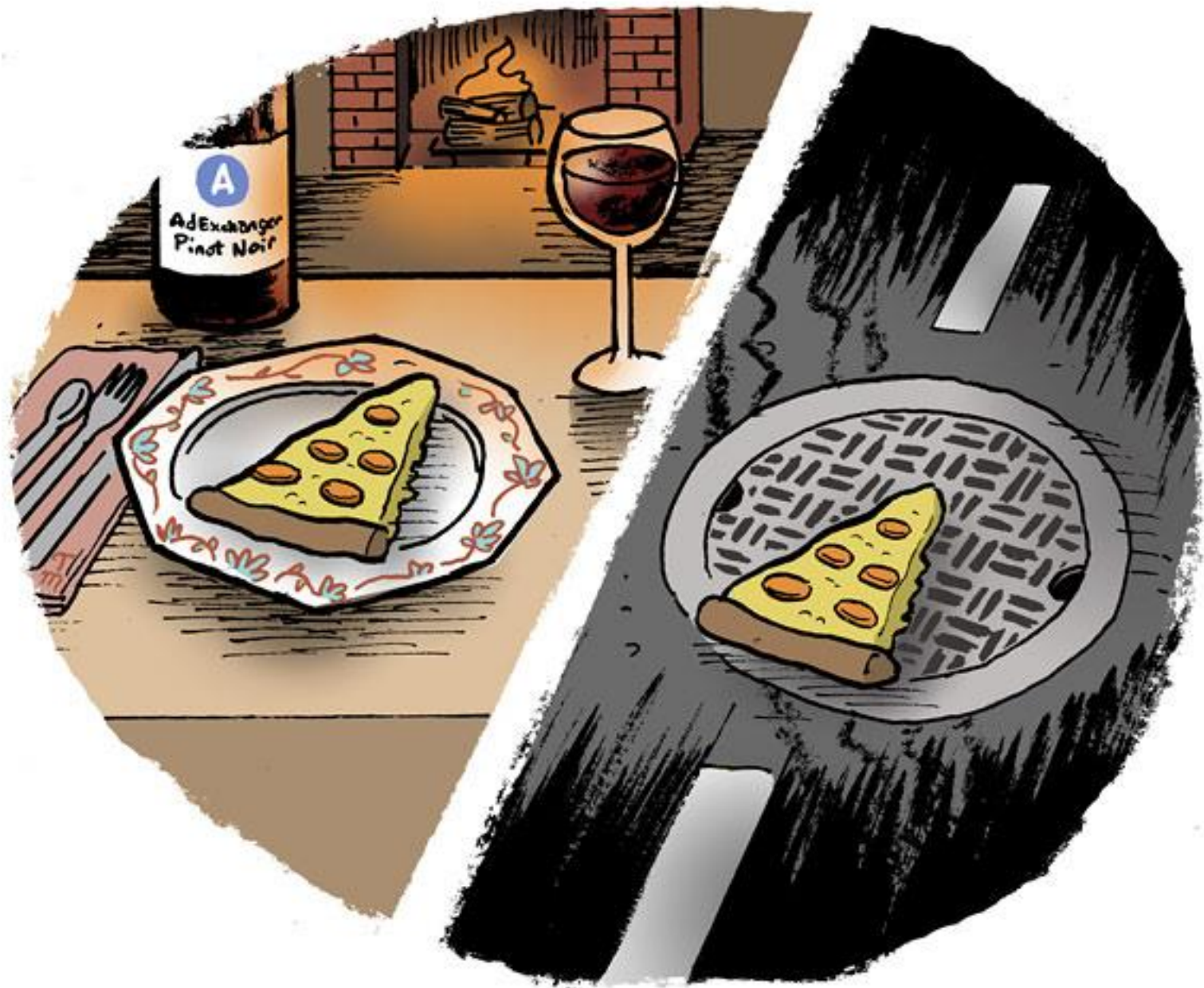
Formerly Senior QI Advisor, NHS
England
Improvement Director, NSFT
Improvement Advisor, IHI



Ruth Dales

Senior Improvement Manager,
NHS England

- Context, key literature and conceptual models
- National patient safety to reduce unsafe oral methotrexate prescribing
- Creating a context for improvement: key learning and next steps



A wealth of literature focused on context...



Coles et al. *Systematic Reviews* (2020) 9:94
https://doi.org/10.1186/s13646-020-01344-3

RESEARCHOpen Access

The influence of contextual factors on healthcare quality improvement initiatives: a realist review

Emma Coles¹, Julie Anderson², Margaret Maxwell³, Fiona M. Harris¹, Nicola M. Gray⁴, Gill Milner² and Stephen MacGillivray²

Abstract
Background: Recognising the influence of context and the context-sensitive nature of quality improvement (QI) interventions is crucial to implementing effective improvements and successfully replicating them in new settings, yet context is still poorly understood. To address this challenge, it is necessary to capture generalisable knowledge, first to understand which aspects of context are most important to QI and why, and secondly to explore how these factors can be managed to support healthcare improvement, in terms of implementing successful improvement initiatives, achieving sustainability and scaling interventions. The research question was how and why does context influence quality improvement initiatives in healthcare?
Methods: A realist review explored the contextual conditions that influence healthcare improvement. Realist methodology integrates theoretical understanding and stakeholder input with empirical research findings. The review aimed to identify and understand the role of context during the improvement cycle, i.e. planning, implementation, sustainability and transferability, and distil new knowledge to inform the design and development of context-sensitive QI initiatives. We developed a preliminary theory of the influence of context to arrive at a conceptual and theoretical framework.
Results: Thirty-five studies were included in the review, demonstrating the interaction of key contextual factors across healthcare system levels during the improvement cycle. An evidence-based explanatory theoretical model is proposed to illustrate the interaction between contextual factors, system levels (macro, meso, micro) and the stages of the improvement journey. Findings indicate that the consideration of these contextual factors would enhance the design and delivery of improvement initiatives, across a range of improvement settings.
Conclusions: This is the first realist review of context in QI and contributes to a deeper understanding of how context influences quality improvement initiatives. The distillation of key contextual factors offers the potential to inform the design and development of context-sensitive interventions to enhance improvement initiatives and address the challenge of spread and sustainability. Future research should explore the application of our conceptual model to enhance improvement planning processes.
(Continued on next page)

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The BMC logo, consisting of the letters 'BMC' in a bold, sans-serif font.

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The Health Foundation

Context for successful quality improvement

Naomi Fulop, Glenn Robert

An illustration of a landscape with a rainbow and a sun. The word 'these' is written in the sky. The landscape features green hills, a blue sky, and a rainbow. The sun is a large yellow circle. The word 'these' is written in a large, white, sans-serif font.

Evidence review
October 2015

The Health Foundation

Perspectives on context

A selection of essays considering the role of context in successful quality improvement

An illustration of a landscape with a rainbow and a sun. The word 'these' is written in the sky. The landscape features green hills, a blue sky, and a rainbow. The sun is a large yellow circle. The word 'these' is written in a large, white, sans-serif font.

Original research
March 2014

THE MILBANK QUARTERLY
A MULTIDISCIPLINARY JOURNAL OF POPULATION HEALTH AND HEALTH POLICY

The Influence of Context on Quality Improvement Success in Health Care: A Systematic Review of the Literature

HEATHER C. KAPLAN, PATRICK W. BRADY, MICHELLE C. DRITZ, DAVID K. HOOPER, W. MATTHEW LINAM, CRAIG M. FROEHLE, and PETER MARGOLIS

Cincinnati Children's Hospital Medical Center; University of Cincinnati; University of Arkansas for Medical Sciences; Arkansas Children's Hospital

Context: The mixed results of success among QI initiatives may be due to differences in the context of these initiatives.
Methods: The business and health care literature was systematically reviewed to identify contextual factors that might influence QI success, to categorize, summarize, and synthesize these factors, and to understand the current stage of development of this research field.
Findings: Forty-seven research articles were included in the final review. Consistent with current theories of implementation and organization change, leadership from top management, organizational culture, data infrastructure and information systems, and years involved in QI were suggested as important to QI success. Other potentially important factors identified in this review included: physician involvement in QI, microsystem motivation to change, resources for QI, and QI team leadership. Key limitations in the existing literature were the lack of a practical conceptual model, the lack of clear definitions of contextual factors, and the lack of well-specified measures.
Conclusions: Several contextual factors were shown to be important to QI success, although the current body of literature lacks adequate definitions and is characterized by considerable variability in how contextual factors are measured across studies. Future research should focus on identifying and developing measures of context tied to a conceptual model that examines context across all

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The Milbank Quarterly, Vol. 88, No. 4, 2010 (pp. 500-559)
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500

The structure of improvement knowledge

Understanding the conditions for improvement: research to discover which context influences affect improvement success

John Ovreteit

ABSTRACT
Context can be defined as all factors that are not part of a quality improvement intervention itself. More research indicates which aspects are 'conditions for improvement', which influence improvement success. However, little is known about which conditions are most important, whether these are different for different quality interventions or whether some become less or more important at different times in carrying out an improvement. Knowing more about these conditions could help speed up and spread improvements and develop the science. This paper proposes ways to build knowledge about the conditions needed for different changes, and to create conditional-attribution explanations to provide qualified generalizations. It describes theory-based, non-experimental research designs. It also suggests that 'practical improvement' can make that changes more effective by reflecting on and raising their own 'assumption-theories' about the conditions which will help and hinder the improvements they aim to implement.

INTRODUCTION
Does a proven quality improvement (QI) vary in its effectiveness in different settings and if so, how and why? If there are variations, should we only try to implement it in some settings? These are questions I had of the Michigan Keystone programme, as many of us in Europe and elsewhere are trying to implement 'similar programmes'.¹ This programme implemented a similar set of changes across 108 different ICUs in the state. What caught the headlines was the dramatic overall reduction in infections. But what was noticed by implementers elsewhere was the variation of results between the projects. Intriguingly one of the studies reported that, 'the intervention was modestly

Box 1: What is 'context' in quality and safety improvement?
• Context can be defined as all factors that are not part of a quality improvement (QI) intervention itself.
• Only some of these 'surroundings' may influence improvements and their effectiveness—termed here the 'conditions for improvement'.
• 'Conditions for improvement' are those internal to the implementing organisation (e.g. information technology) and those external to it (e.g. payment and regulation systems), and are made by, and operate on, different levels of the health system.
• The definition of a boundary between the improvement 'intervention' and the 'context' is relatively arbitrary. To be useful to others, reports need to describe precisely the intervention implemented and any evidence of the conditions which influenced the intervention.
• The aim of some QI research is to understand what conditions influence improvement and how they do so.

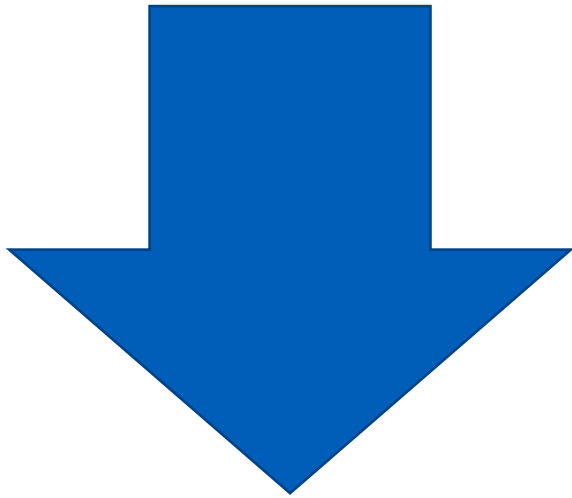
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1. [Coles et al \(2020\) The influence of contextual factors on healthcare quality improvement: a realist review](#)
2. [Fulop et al \(2015\) Context for successful quality improvement](#)
3. [Bate et al \(2014\) Perspectives on context](#)
4. [Kaplan et al \(2010\); The influence of context on quality improvement success in health care: a systematic review of literature](#)
5. [Ovreteit \(2010\) Understanding the conditions for improvement: research to discover which context influences affect improvement success](#)

A definition of context

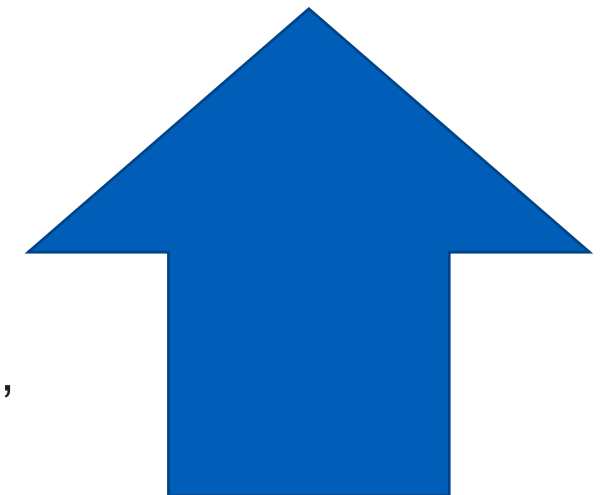
The 'why' and 'when' of change and concerns itself both with influence from the outer context (such as the prevailing economic, social, political environment) and influences internal to the focal organisation under study (for example, its resources, capabilities, structure, culture and politics).

Top Down or Bottom Up?



- Driven from the centre
- Often tackles strategic priorities
- May feel imposed
- Risk of reduced local engagement

- Driven locally based on local needs
- Higher likelihood of engagement
- Risk of a 'thousand flowers blooming'



Creating a Receptive Context for Change-Pettigrew, Ferlie and McKee 1992



Environmental
Pressure

Supportive
organisational
culture

Change agenda
and its locale

Simplicity and
clarity of goals

Cooperative
inter-
organisational
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Managerial
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Key people
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Quality and
coherence of
policy

Medicines

Reducing National High Risk Oral Methotrexate Prescribing

 @NatPatSIP / #MedSIP

[Future.nhs.uk/medicinessafetyimprovement/](https://future.nhs.uk/medicinessafetyimprovement/)

Delivered by:
The Medication Safety Officer Network
*The **AHSN** Network*

Led by:
NHS England



Medicines Safety Improvement in England

The Policy Research Unit in Economic Evaluation of Health and Care Interventions (EEPRU) identified that:

- > There are an estimated 237 million 'medication errors' per year in health and care services in England, with 66 million of these potentially clinically significant.
- > 'Definitely avoidable' adverse drug reactions collectively cost £98.5 million annually, contribute to 1700 deaths, and are directly responsible for, approximately 700 deaths per year in England.

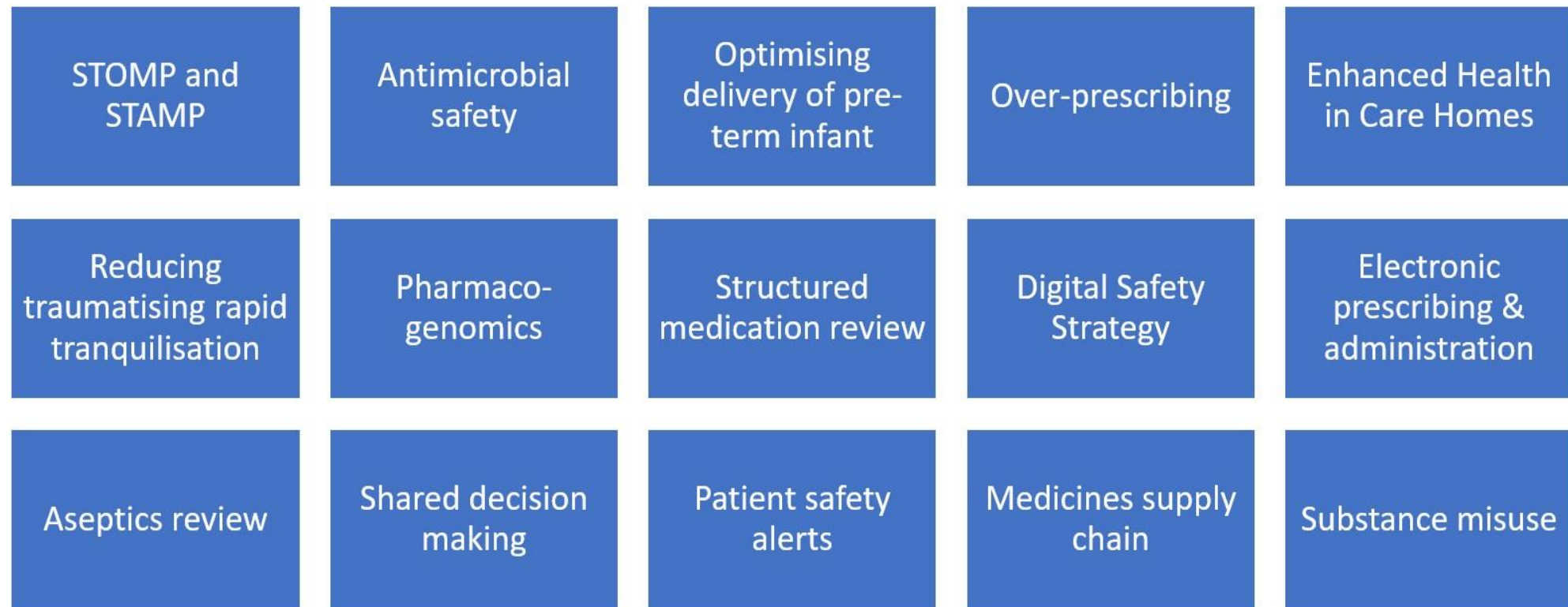
In response to the World Health Organisation's (WHO's) Global Challenge in 2017, a Short Life Working Group (SLWG) was set up, chaired by the Chief Pharmaceutical Officer for England which recommended the establishment of a medication error and safety programme. Thus the Medication Safety Programme (MSP) was established in 2018 in response to this.

In 2019 the MSP was aligned with National Patient Safety Strategy and became known as the Medicines Safety Improvement Programme (MedSIP).

<https://www.england.nhs.uk/patient-safety/the-nhs-patient-safety-strategy/>

Medicines Safety Improvement in England

The MedSIP recognises the contributions to medicines safety improvement from across NHS England:



Medicines Safety Improvement in England

MedSIP Board defines specific priority areas in which to focus improvement, with the aim:

To address the most important causes of severe harm associated with medicines, most of which have been known about for years but continue to challenge the health and care systems in England. The programme affects safety culture, safety systems and the high-risk medicines in common use.

Priority areas for 2020/21 – 2021/22 were:

- > Drug administration in care homes
- > Opioids for chronic non-cancer pain
- > Prescribing of Methotrexate 10mg tablets to community patients

Two further topics were identified to be in the pipeline for development:

- > Problematic polypharmacy
- > Anticoagulation safety

Medicines Safety Improvement in England

NHS England Framework for involving patients in patient safety

- > The framework is split into two parts:
 - Part A: Involving patients in their own safety
 - Part B: Patient safety partner (PSP) involvement in organisational safety

Wrt Methotrexate:

- > Part A: = Shared decision-making ensures that individuals are supported by their clinician to make decisions that are right for them.
- > Part B: Patient safety partners (PSP) contribute to the MedSIP Board priority setting process

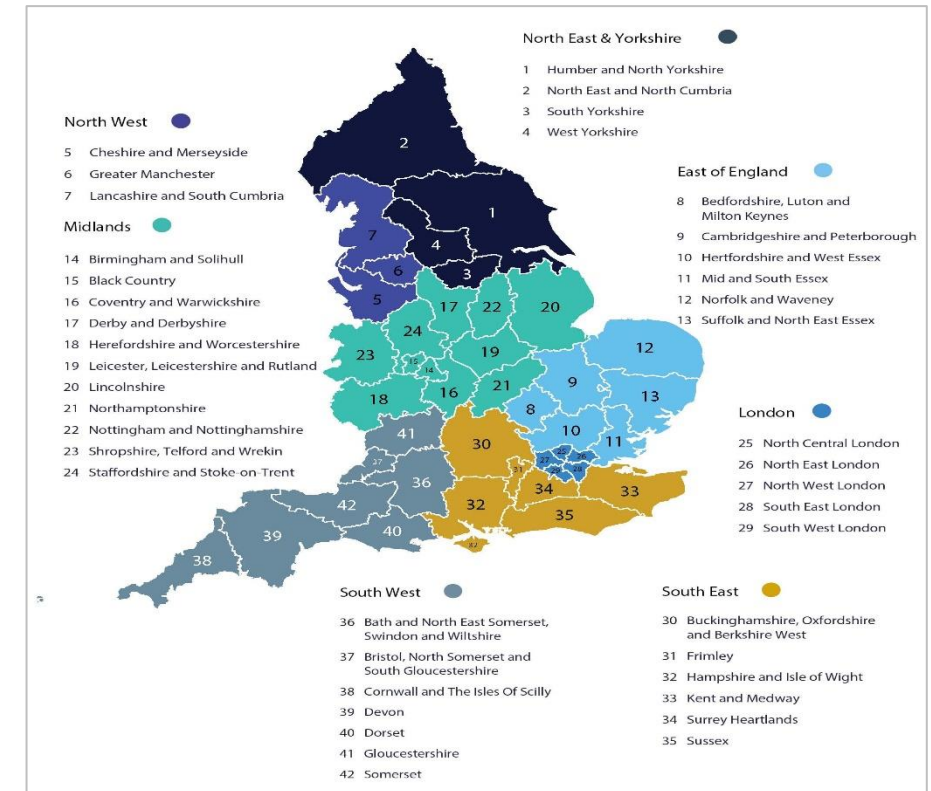
<https://www.england.nhs.uk/patient-safety/framework-for-involving-patients-in-patient-safety/>

<https://www.england.nhs.uk/personalisedcare/>

- Commonly prescribed medicine for treatment of rheumatoid arthritis, Crohn's disease and severe arthritis, with ≥ 1.7 million items issues in England during 20/21
- At least 25 deaths and 39 cases of severe harm related to accidental overdose.
- Resulted in 2 NPSA Patient Safety Alerts, and inclusion in NHS I 'Never Event's list. Range of strategies in place to reduce accidental overdose, including reducing co-prescription of 2.5mg and 10mg tablets, as they look incredibly similar, may be confused with each other, leading to accidental over or underdose.
- BNF states: *'To avoid error with low-dose methotrexate, it is recommended that only one strength of methotrexate tablet (usually 2.5mg) is prescribed and dispensed'*
- Retrospective cohort study by Mackenna et al¹ identified practice of co-prescribing methotrexate 2.5mg and 10mg widespread, with large variation between CCGs

How is Methotrexate Prescribed in England?

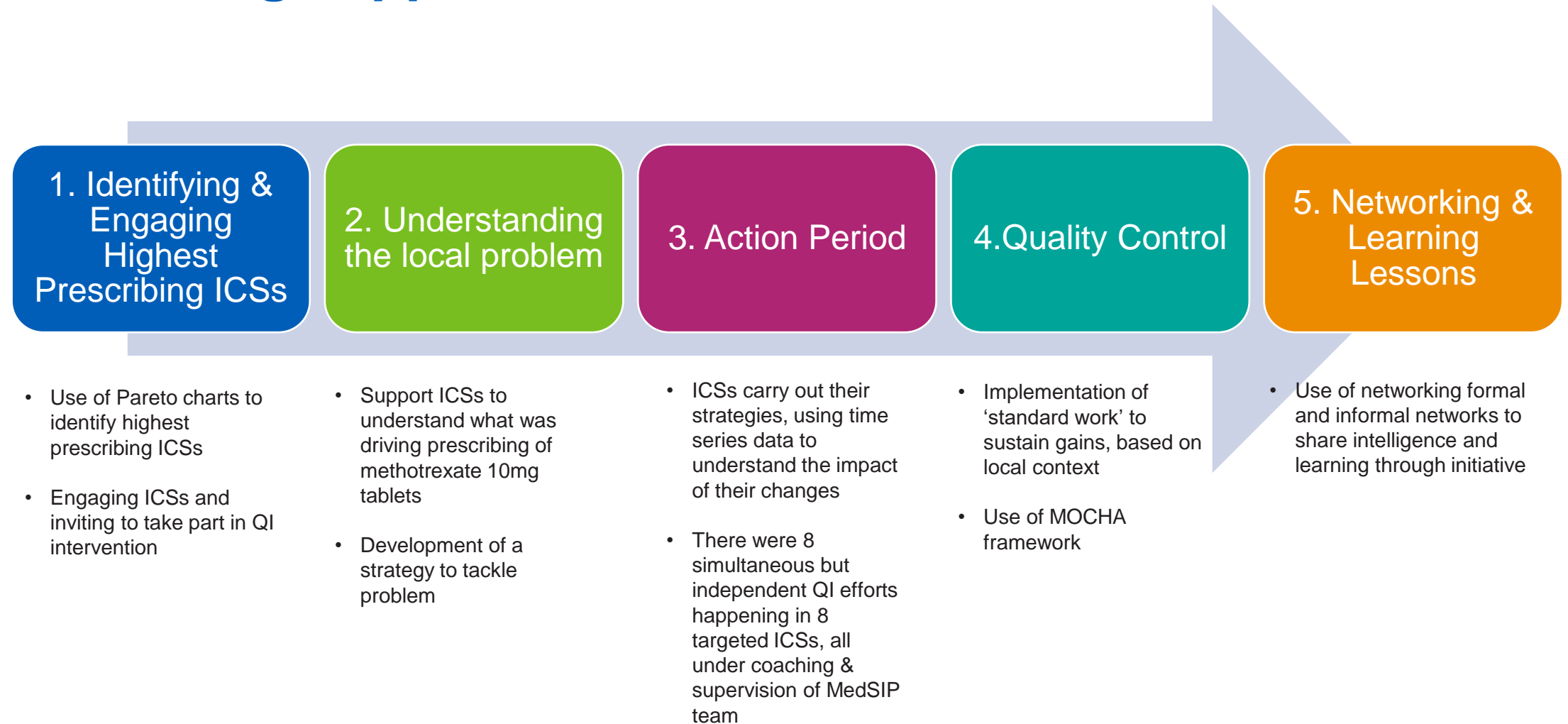
- Local oversight provided by 42 Integrated Care Systems (ICS) each covering population size \approx 1.2 million people
- Prescribing takes place by 'shared care agreements' between hospital specialists and general practitioners
- Each ICS also has a prescribing support team in place as well as a range of prescribing data



“To reduce national variation in the prescription and supply of oral methotrexate 10mg tablets, for non-cancer treatment, by November 2021.”

This was a centrally led intervention, where the national MEDSIP team provided coordination, coaching and improvement expertise to participating ICSs

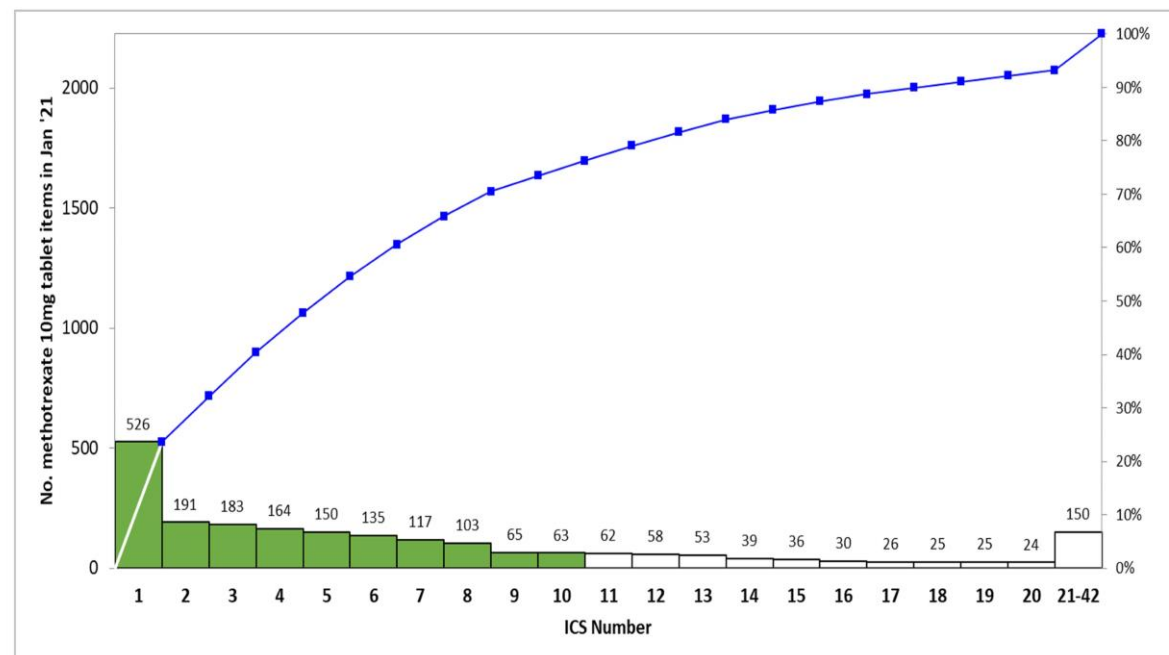
Our 5 stage approach



1. Identifying & Engaging Highest Prescribing ICSs

- Pareto Principle almost true! 10/42 ICSs (23%) responsible for 76% of national prescribing
- Eight ICSs agreed to take part in stages 2-5 of the QI intervention.
- Two ICSs were unable to participate owing to operational pressures as a result of COVID vaccination programmes.

Pareto chart of number of items of methotrexate 10 mg tablets issued per ICS during January 2021



2. Understanding the Local Problem

Four common issues were identified as driving methotrexate 10mg tablet prescribing:

- 1) Prescribing was driven by specific localities (5/8 ICSs)
- 2) Prescribing was driven by hospital specialists (2/8 ICSs)
- 3) Prescribing was a result of historical practice that had gone unchallenged (8/8 ICSs)
- 4) Prescribing was driven by sub-populations of patients unwilling to convert to 2.5mg tablets owing to increased pill burden (3/8 ICSs)

3. Action Period

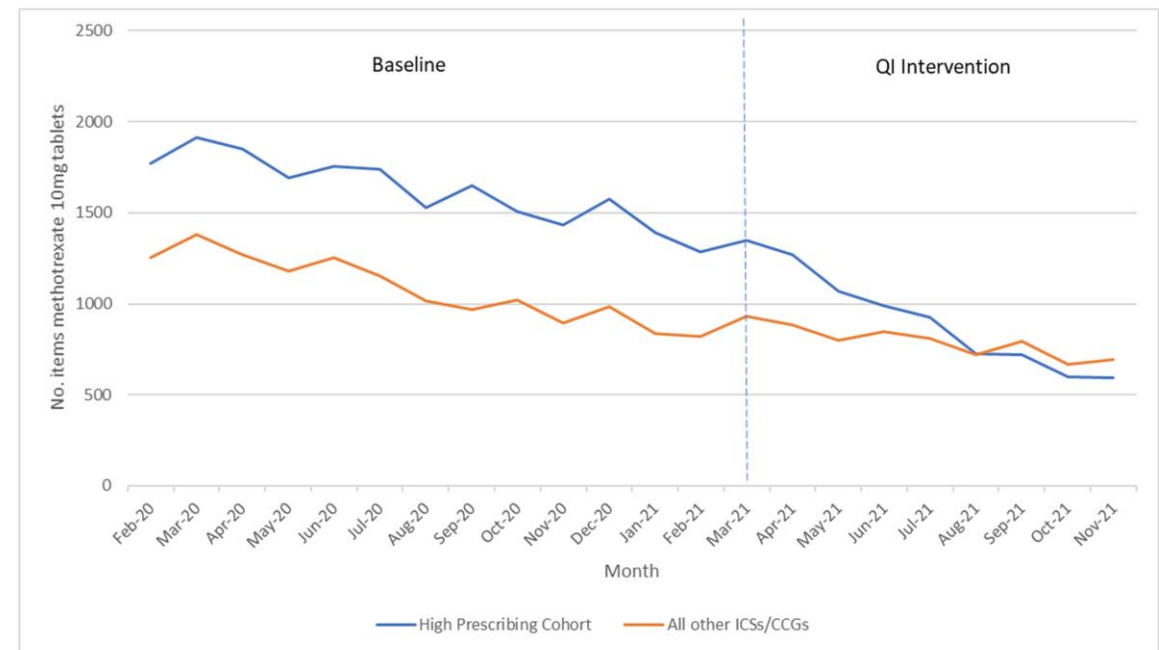
Measure type	Measure name	Operational definition	Analysis	Validity and reliability
Outcome measure	No. of items prescribed for methotrexate 10mg tablets for high prescribing cohort versus all other ICSs/CCGs in England.	Data sourced from OpenPrescribing 'Methotrexate 10mg tablets by all STPs or CCGs' and aggregated into respective cohorts. ^{20 25} ICS (STP) data used where the ICS focused on reducing methotrexate 10mg tablet prescribing across all CCGs in their geographical footprint. ²⁰ CCG data used where the ICS focused on reducing methotrexate 10mg prescribing in specific CCGs in their geographical footprint. ²⁵	Line graph comparing ICSs/CCGs participating in QI intervention versus all other ICSs/CCGs Individual Moving Range (XmR) control chart for both cohorts.	OpenPrescribing uses prescribing data published by NHS Business Services Authority (NHSBSA) Prescription services. Data processes are internally audited and exceed 99.5% accuracy at all times. Accuracy data are published on NHSBSA website for transparency. ²⁶ Well-established and managed processes to ensure reliability of data, with data collected and processed in the same manner from a single source, NHSBSA.
Process measure	No. of items prescribed for methotrexate 10mg tablets for each individual ICS in high prescribing cohort	Data sourced from OpenPrescribing 'Methotrexate 10mg tablets by all STPs or CCGs'. See previous for how data were selected based on ICS/CCG focus.	Time series analysis using an Individual Moving Range (XmR) control chart.	
Balancing measures	<ol style="list-style-type: none"> No. of patient safety incidents, resulting in harm, reported to National Reporting & Learning system (NRLS) following methotrexate 2.5mg/10mg tablet misadministration. No. of patient safety incidents, related to methotrexate 2.5mg/10mg tablet misadministration in high prescribing cohort. ICS reported patient experience of QI intervention in high prescribing cohort. ICS reported staff experience of QI intervention in high prescribing cohort. Total cost of methotrexate tablets for high prescribing cohort. 	<ol style="list-style-type: none"> Methotrexate 2.5mg/10mg tablet misadministration safety incidents identified from free-text search of NRLS database for all incidents containing methotrexate.²⁷ Stratified by level of harm. Methotrexate 2.5mg/10mg tablet misadministration safety incidents shared with MedSIP team from ICS/CCG leads involved in QI intervention. Patient experience feedback shared with MedSIP team from ICS/CCG leads involved in QI intervention. Staff experience feedback shared with MedSIP team from ICS/CCG leads involved in QI intervention. Data sourced from OpenPrescribing 'Analyse' webpage, with prescribing of 'methotrexate 10mg tablets' and 'methotrexate 2.5mg tablets' highlighted by STP or ICS.²⁸ 	<ol style="list-style-type: none"> Count of safety incidents, with accompanying themes. Count of safety incidents, with accompanying themes. 3 and 4. Approach, based on Woods <i>et al</i>,²³ was used to gather and collate data. 5. Time series analysis using an Individual Moving Range (XmR) control chart. 	<ol style="list-style-type: none"> Systems and processes in place to increase validity and reliability of patient safety incident reporting. NRLS is a systematic and nationally managed system. However, levels of reporting between different organisations can vary greatly, with reporting far greater in secondary care than primary care. ICS staff may be aware of incidents or near misses that have not been reported through incident reporting systems. Information reported through this route not systematic and dependent on strength of networks and connections in ICSs. 3 and 4. ICS well placed to receive patient and staff experience as they led work locally. However, information reported through this route not systematic and dependent on strength of networks and connections in ICSs. 5. See previous for validity and reliability of OpenPrescribing data.

CCG, clinical commissioning groups; ICS, integrated care systems; QI, quality improvement; STP, Sustainability and Transformation Partnerships.

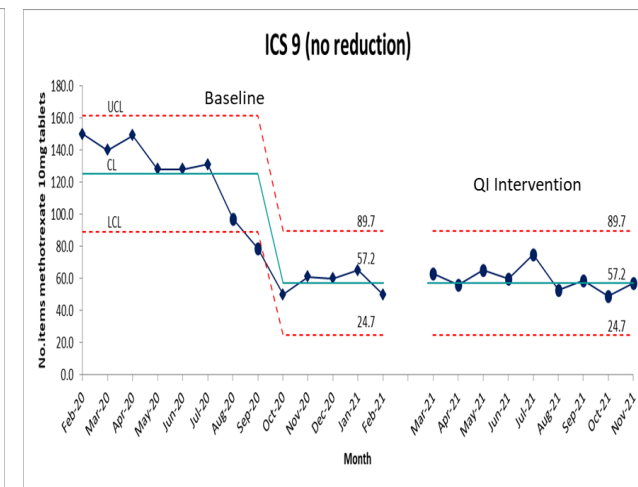
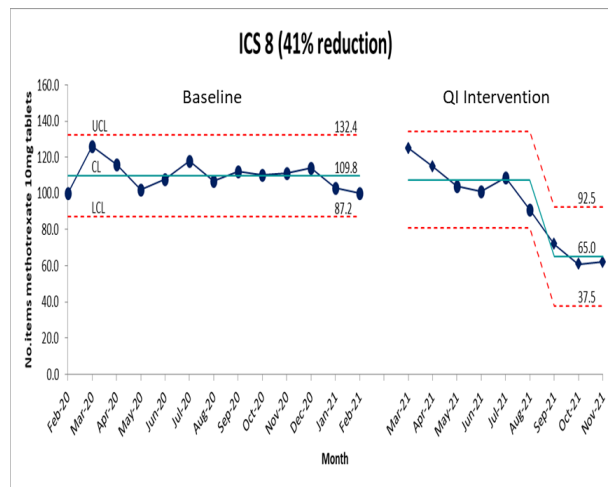
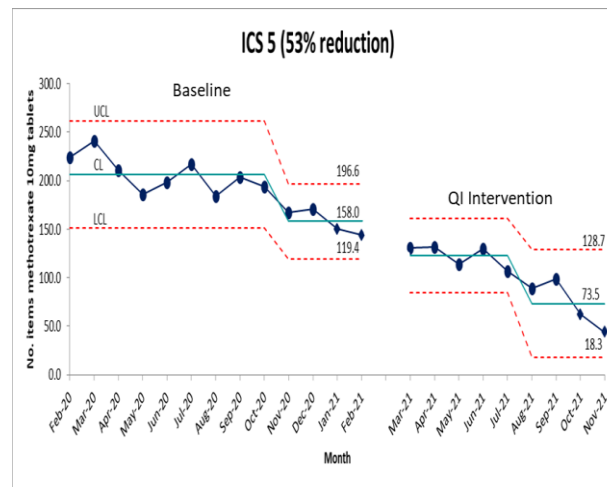
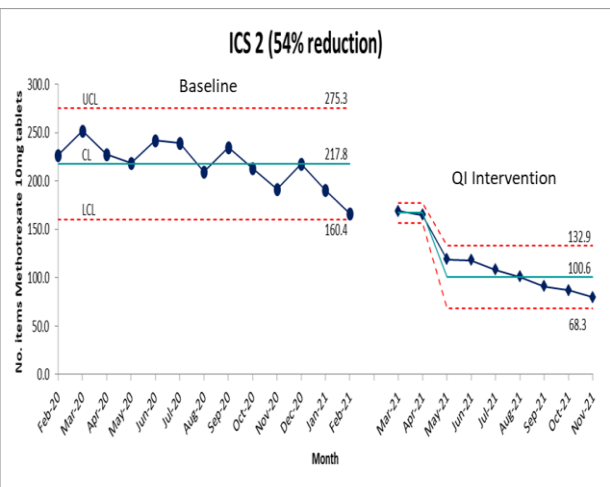
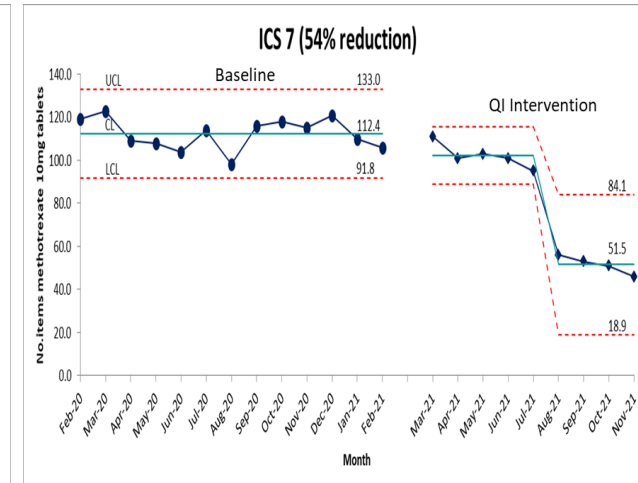
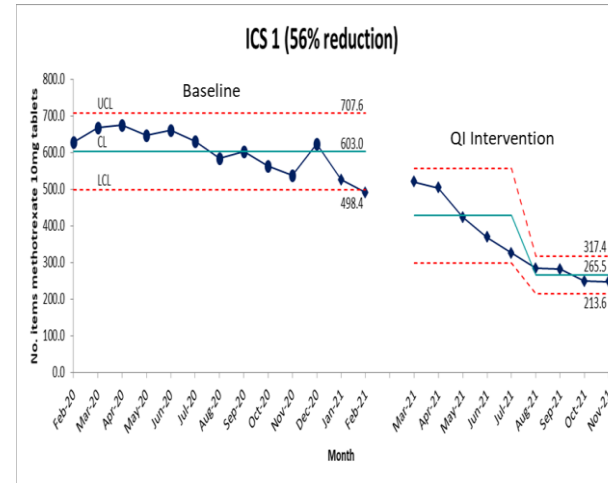
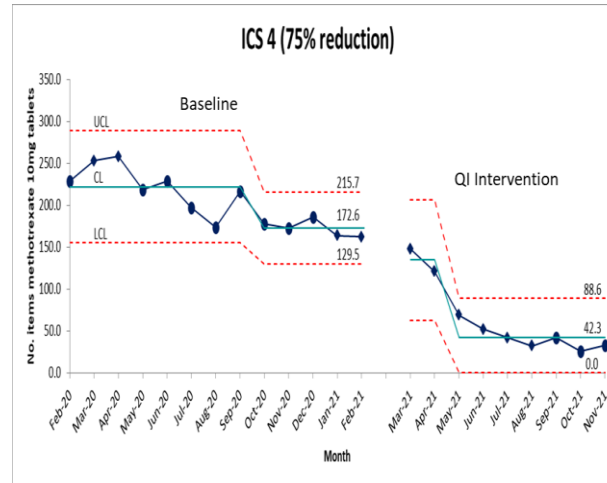
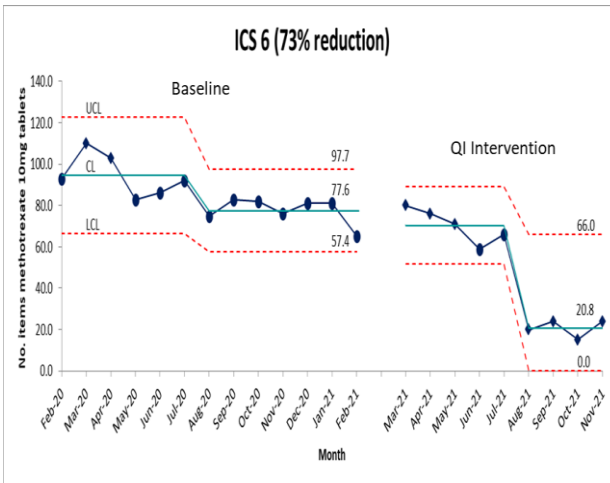
3. Action Period

- Before the QI intervention started, a reduction in methotrexate 10mg tablet prescribing was already taking place, with both the high prescribing cohort and all other ICSs/CCGs reducing at approximately the same pace
- During the action period, the pace of reduction for the high prescribing cohort exceeded that of all other ICSs/CCGs
- The high prescribing cohort saw a 54% reduction in prescribing vs 23% for the remaining ICSs/CCGs

Line graph of methotrexate 10 mg tablet prescribing for high prescribing cohort versus all other ICSs/CCGs.



3. Action Period



3. Action Period

- No safety incidents were reported to the English National Reports and Learning Service, although were made aware of 3 near misses where patients were switched to new strengths of tablets, but there was ineffective counselling. This information was rapidly shared across the network
- In general, the intervention was well received by patients. However, several ICSs identified small populations of patients unwilling to switch from 10mg to 2.5mg tablets, owing to increased tablet burden.
- This initiative had no impact on financial expenditure of methotrexate tablets in the high prescribing cohort

4. Quality Control

All ICSs made changes to their existing structures and processes to ensure that they were able to hold the gains:

- 7 ICSs created 'position statements' setting out methotrexate 10mg tablets should not be prescribed
- 6 ICSs created prescribing alerts on their electronic prescribing systems
- 3 ICSs made methotrexate 10mg tablets non-formulary of non-cancer use
- 1 ICS removed methotrexate 10mg tablets completely from the local hospital's prescribing system
- Several ICSs created standardised methotrexate initiation letters from hospital specialists to GPs stating the dose of methotrexate to be prescribed in multiples of 2.5 mg tablets

5. Networking and Learning Lessons

One on one coaching was very useful to help bounce ideas to progress the work

Please continue with professional and supportive engagement and yet at the same time challenging us

Great help. As we have been working on this for a while and MedSIP support just fast tracked our work and aims

It's been useful to look at 10 CCGs rather than focusing on worst outlier which can have a negative approach

Giving benchmark reductions-helps to know how well we're heading in the right direction!

You helped us create a 'burning platform'...helped us say 'this is bigger than us'

Loved networking opportunities between CCGs to discuss progress/share tools/overcome barriers

This small forum from outside of our area is helpful to share ideas and experiences

Medicines

Creating a context for improvement: key learning and next steps

 @NatPatSIP / #MedSIP

[Future.nhs.uk/medicinessafetyimprovement/](https://future.nhs.uk/medicinessafetyimprovement/)

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inter-
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Key people
leading change

Quality and
coherence of
policy

Environmental Pressure

- This was an already known area of risk and focus in England. Open access data already existed focused on methotrexate prescribing levels
- Direct intervention from the MedSIP team helped ICSs build momentum for change.

Cooperative inter-organisational networks

- There were already pre-established and well functioning networks within the ICSs
- ICSs stated that networking sessions between ICSs helped identify barriers and potential solutions to problems.

Supportive organisational culture

- ICSs identified coaching approach from the MedSIP team, together with the use of data was integral to understanding the problem and devising a strategy to reduce prescribing.
- Medicines optimisation teams embedded in every ICS were already used to undertaking this style of work

Managerial clinical relations

- The work unearthed variations in the maturity of relationships between managers and GPs and managers and hospital clinics.
- ICS managers stated that the lack of a national driver around this issue had been a barrier to engage and influence prescribers.

Fit between change agenda and its locale

- Every team had a slightly different context, which meant that a rigid change model would have been unsuitable
- ICSs shared that receiving coaching to help them better understand the problem, enabled them to adapt their improvement strategy so that it worked for their local context

Key people leading change

- Engaging medicines management teams embedded in the ICSs meant this was a team effort, rather than individual effort
- Utilising a sustainability approach further ensured that this work was focused on overall systems and processes rather than just individuals

Simplicity and clarity of goals

- The success of this work was aided by the fact that this was a discrete intervention, with a small population of patients taking 10mg tablets in every ICS.
- The immediate availability of data enabled ICSs absolute clarity on whether they were achieving their goals

Quality and coherence of policy

- A lack of national clarity had led some ICSs struggling to engage and influence prescribers
- In most ICSs, there wasn't explicit policy around this topic. As a result of this work, most ICSs created position statements to clarify the ICSs policy.

Now what?

- > Learning from this work has been applied to the implementation of the Opioid Safety Improvement Programme:
- > Management of 'chronic non-cancer pain' requires **personalised care** and shared decision making at its core with patients requiring a mixture of **biopsychosocial support** so that they can live well with their pain.
- > Consideration of the problem from the perspective of the entire patient pathway is key:
 - simple interventions in isolation are minimally effective in reducing the burden of opioids
 - working in one part of the system often doesn't change the outcome,
 - **A whole system approach is essential** for scale and sustainability

Learning from the Methotrexate work:

Application to the Opioid safety Improvement programme



Creating a burning platform:

We have created and maintain a burning platform with the national and 7 English regional pharmacy leadership groups as well as the national Medication Safety Officers. Also creation of harm statements

Structured support to understand the problem:

A framework for a Whole Systems Approach was designed which includes:
Quality Planning: Encouraging the use of data as well as insights from local communities, service users and service providers/ commissioners in order to understand the problem and devise a strategy to reduce high-risk opioid prescribing.

Systematic approach to improvement:

Quality Improvement: Encouraging the co-design of an improvement aim, potential changes that could be made as well as support to consider measurement for continuous improvement.
Quality Control: Support for the system adopt the programme and consider how to design in sustainability from the start

Leveraging networks:

Leveraging networks of motivated stakeholders from across the local geographies that want to make changes to practice to improve pain management and opioid prescribing.

Learning between ICSs:

We are hosting quarterly national Action and Learning sessions; an opportunity for peer-to-peer coaching which helps us expose, consider and address problems that are mutually challenging then generate change ideas that teams can take back to their wider stakeholders as well as inform support requirements for the national programme. We also host informal weekly shared learning sessions for the 15 core teams

A lack of national drivers

We have worked with the pan departmental Dependence Forming Medicines Group and the Primary Care Team to ensure there are national policy drivers and financial incentives in place for primary care 2022/23- Combination of a national QI module in the QoF and incentivisation to focus SMRs on opioids and other dependence forming medicines (circa £50m).

- Innes J, Jamieson T, Dales R, et al. National quality improvement intervention to reduce high risk oral methotrexate prescribing. BMJ Open Quality 2022;**11**:e001942. doi:10.1136/ bmjoq-2022-001942
- MacKenna, B., Waler AJ., Croker., R et al (2020) Trends and variation in unsafe prescribing of methotrexate: a cohort study in English NHS primary care. Br J Gen Pract 2020; DOI: <https://doi.org/10.3399/bjgp20X710993>