

Medication Without Harm



WHO Global Patient Safety Challenge

The role of the health and care workers in reducing medication errors and medication-related harm

Pharmacists

Ms Zuzana KUSYNOVÁ

Lead for Policy, Practice and Compliance
International Pharmaceutical Federation
(FIP)

15 September 2022



The role of pharmacists in reducing medication errors and medication-related harm

Zuzana Kusynová

Lead for Policy, Practice and Compliance

ADVANCING
PHARMACY
WORLDWIDE



FIP's commitment

Long term partnership with WHO



Patient safety

FIP's commitment to patient safety & recommendations for:

- *Practicing pharmacists*
- *Pharmaceutical scientists*
- *National pharmacy organisations*
- *Industry partners*
- *Academia and educators*

Adopted by 140+ pharmacy organisations around the globe



Patient and Medication Safety

Recommendations

Minimising avoidable harm:

- ✓ Using the evidence to implement just culture
- ✓ Collaborating with other health professional associations to implement interprofessional strategies to foster close working relationships
- ✓ Developing educational tools to support appropriate pharmacist workforce development and safety culture
- ✓ Developing new services and health programmes while securing appropriate remuneration models
- ✓ Advocating for access to patient medication history
- ✓ Empowering and engaging patients to 'Know, Check, Ask' about their medications
- ✓ Advocating locally and globally for the importance of pharmacists in patient safety

Pharmacists can improve patient safety by promoting patient engagement, interprofessional collaboration and a safety culture to reduce avoidable harm caused by medication errors

Patient and Medication Safety

Recommendations

Minimising avoidable harm

- ✓ Using the evidence to implement
- ✓ Collaborating with other health professionals and associations to implement interprofessional strategies to foster close working relationships
- ✓ Developing educational tools to support appropriate pharmacist workforce and safety culture

Pharmacists can improve patient safety and a safety culture



Implementing new services and health programmes
Securing appropriate remuneration models

Working for access to patient medication

Informing and engaging patients to 'Know, Ask' about their medications

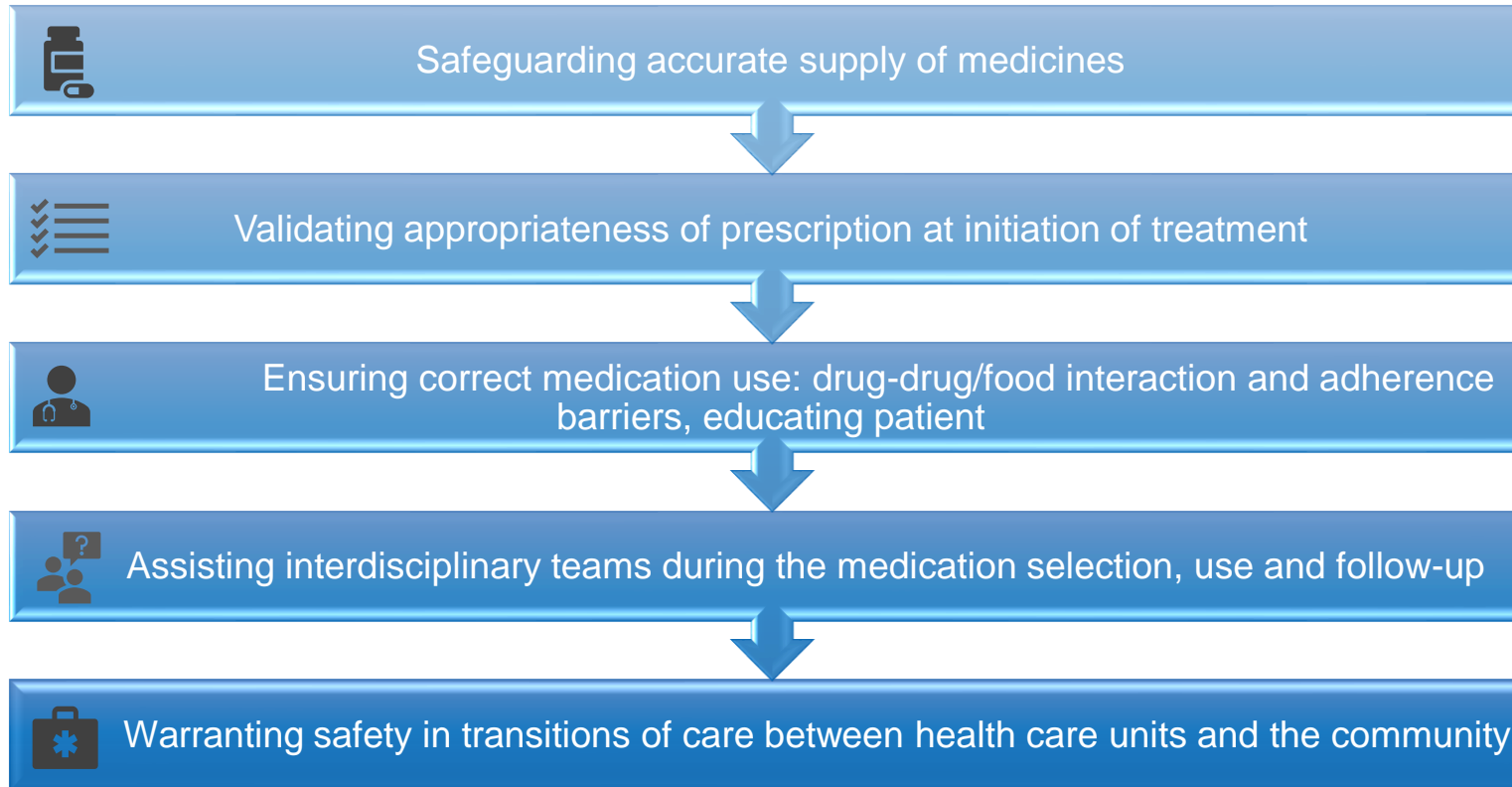
Working locally and globally for the importance of pharmacists in patient safety

Improving patient management, interprofessional collaboration
Reducing harm caused by medication errors

Minimising preventable harm

Pharmacists' role

Pharmacists are well-positioned to minimise safety risks related to the entire medication use process by:

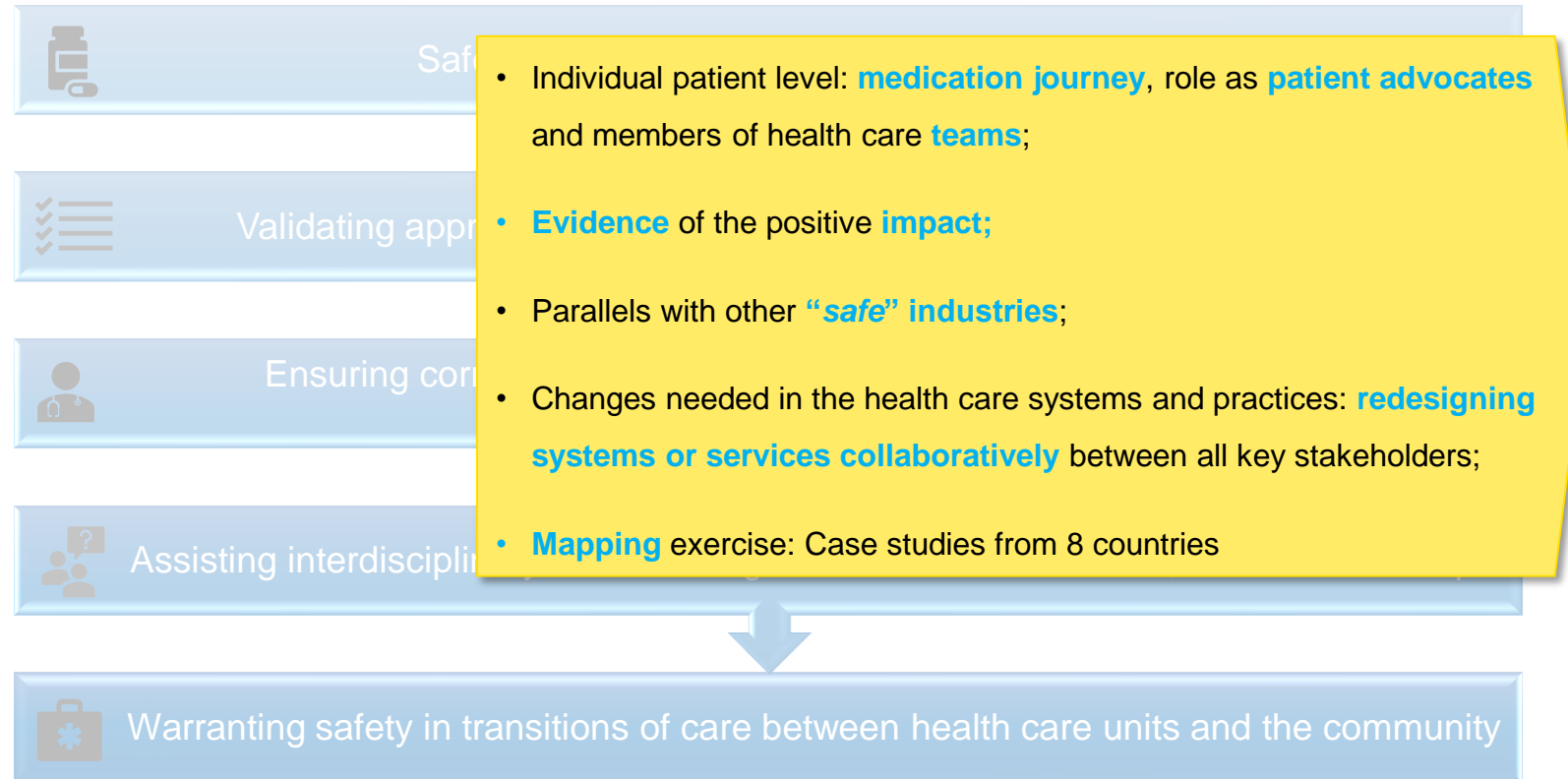


FIP Reference Document on Patient and Medication Safety.
Available from: fip.org/publications

Minimising preventable harm

Pharmacists' role

Pharmacists are well-positioned to minimise safety risks related to the entire medication use process by:



Promoting a Safety Culture

Why is healthcare hesitant to report adverse events?

"Blame Culture"

- *Individuals responsible blamed & suffer consequences → encourages covering up of errors in fear of retribution.*



Healthcare culture
needs to shift

"Safety/Just Culture"

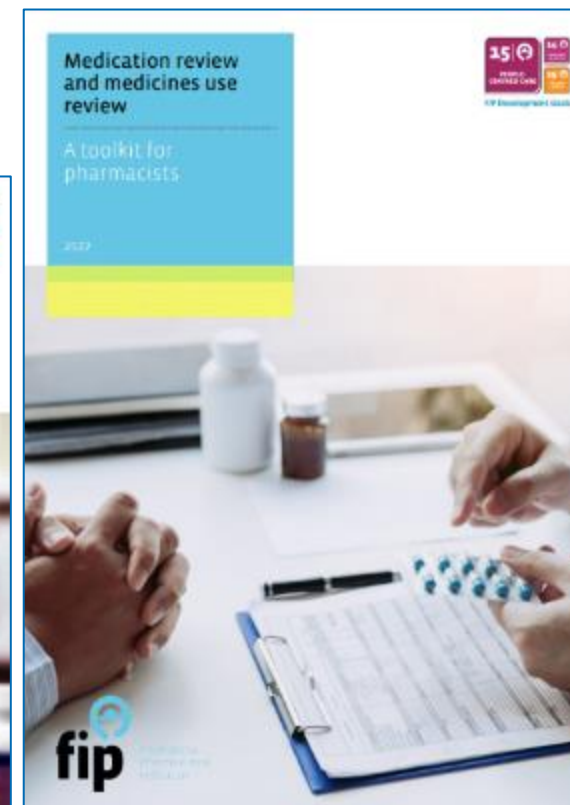
- *Focuses on identifying system flaws that can be resolved*
- *The goal is promoting patient safety*
- *An integrated pattern of individual and organizational behavior*



FIP digital events on patient safety

FIP Resources

Toolkits for practitioners



Conclusions

Commitment of pharmacists

- Pharmacists are in a unique position to address the challenges related to medication use.
- They are well-positioned to minimise safety risks related to the entire medication use process.
- Pharmacists can improve patient safety by promoting patient engagement, interprofessional collaboration and a safety culture to reduce avoidable harm caused by medication errors
- FIP is representing voices of over 4 million pharmacists around the globe – visible commitment through collaboration with partners, and at supporting pharmacists both at individual and systems/policy level

#WPSD2022



Questions?

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WHO Global Patient Safety Challenge



Message on World Patient Safety Day 2022 from the WHO Regional Office for the Eastern Mediterranean

Dr Ahmed AL-MANDHARI

WHO Regional Director for
Eastern Mediterranean

15 September 2022



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WHO Global Patient Safety Challenge

Session 3

Medication safety: medicines as products

Chair: Dr Shanthi PAL

Team Lead

Pharmacovigilance, Regulation and Prequalification
department

WHO headquarters, Geneva



15 September 2022

Medication Without Harm



WHO Global Patient Safety Challenge

Naming, labelling and packaging solutions to avoid LASA errors

Prof Hisham S. AL JADHEY

Executive President

Saudi Food & Drug Authority

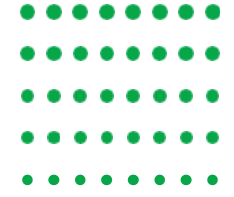
Saudi Arabia

15 September 2022





Kingdom of Saudi Arabia
Saudi Food & Drug Authority



SFDA Naming, Labelling and Packaging Solutions to Avoid Medication Errors

Prof. Hisham Aljadhey
Executive President of Saudi Food & Drug
Authority (SFDA) Saudi Food and Drug Authority



Outline

- **Medication Error Definition**
- **Medication Errors Department Activities in Medication Naming, Labelling and Packaging to Avoid Medication Errors**
- **Pre-Registration**
- **Post-Registration**



The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP)

Medication Error Definition

“A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing, order communication, product labeling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use.”



Product-related Evaluation



**Invented
Names
Evaluation**



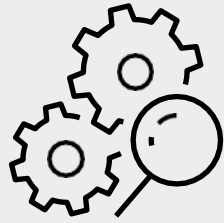
**Product
labels/
labeling**



**Product
packaging**



**Postmarket
Pharmacovigilance**



Medication Error Department Scope of Services





WHO Global Patient Safety Challenge





Role of SFDA

in preventing Medication Errors

■ Pre-Registration



Naming
Evaluation



Packaging
Evaluation

■ Post-Registration



Variation
Requests



Reporting



Published
Reports



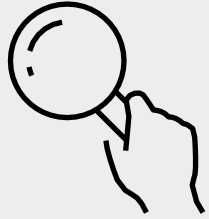
Pre- Registration Activities





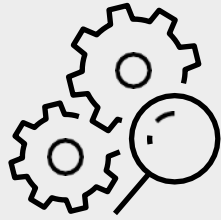
Naming Evaluation

- **SFDA Guidance for Naming of Medicinal Products**
 - Assessment for any error-prone attributes
 - Best practices for invented names design
 - Misleading/promotional concerns
 - Medicinal characteristics-related attributes
 - Name similarity evaluation including generic names
- **International Nonproprietary Names (INN) Stem Book 2018 (WHO)/United States Adopted Names (USAN) approved stems**



Naming Evaluation Name Similarity

- Saudi Naming Registration (SNR)/SFDA Drugs List
- Phonetic and Orthographic Computer Analysis (POCA)
- WHODrug Insight
- Martindale: The Complete Drug Reference
- Micromedex
- Lexicomp



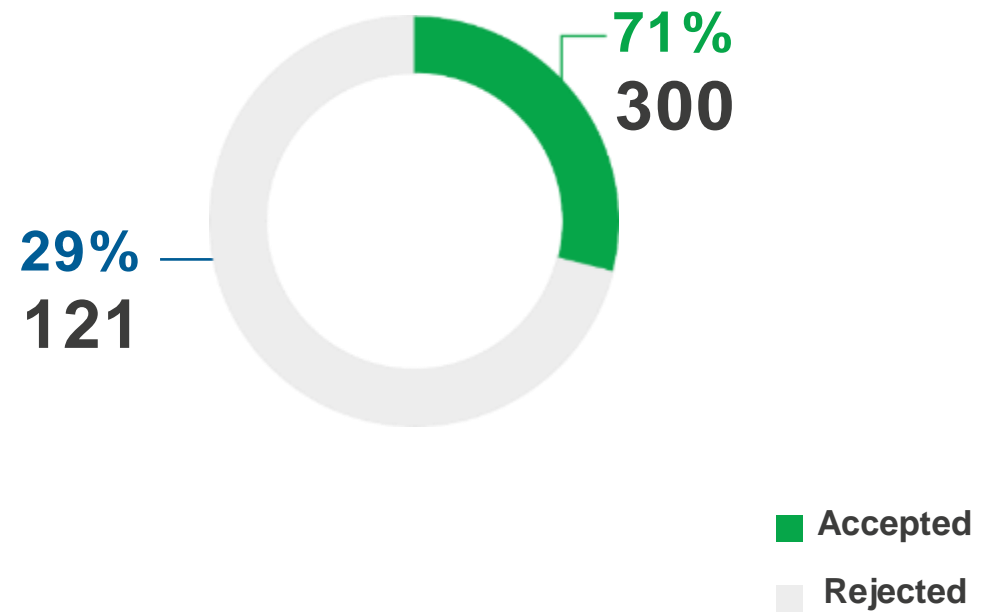
Name Similarity Evaluation: A Look at Product Characteristics

- **Active ingredient**
- **Strength**
- **Dosage form**
- **Route(s) of administration**
- **Indication**
- **Frequency**



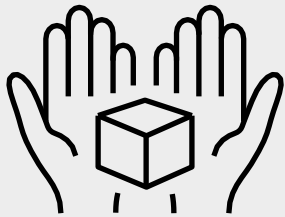
Acceptance vs. Rejection Rate

of Proposed Invented Names (Calendar Year 2021)



Safety Concerns Associated with Rejected Proposed Invented Names

| | |
|---|-------------------|
| Name Similarity | 73 (47.7%) |
| Incorporation of International Nonproprietary Names Stem | 24 (15.7%) |
| Promotional/Misleading Names | 15 (9.8%) |
| Inappropriate Use of Qualifiers | 13 (8.5%) |
| Inappropriate Use of Company Name | 8 (5.2%) |
| Inclusion of Dosage form/Frequency/Strength | 6 (3.9%) |
| Use of Abbreviations | 5 (3.3%) |
| Name Discrepancies in Submitted Files | 4 (2.6%) |
| Indication Derived Names | 3 (2.0%) |
| Use of Ambiguous Numbers | 2 (1.3%) |



Packaging Evaluation

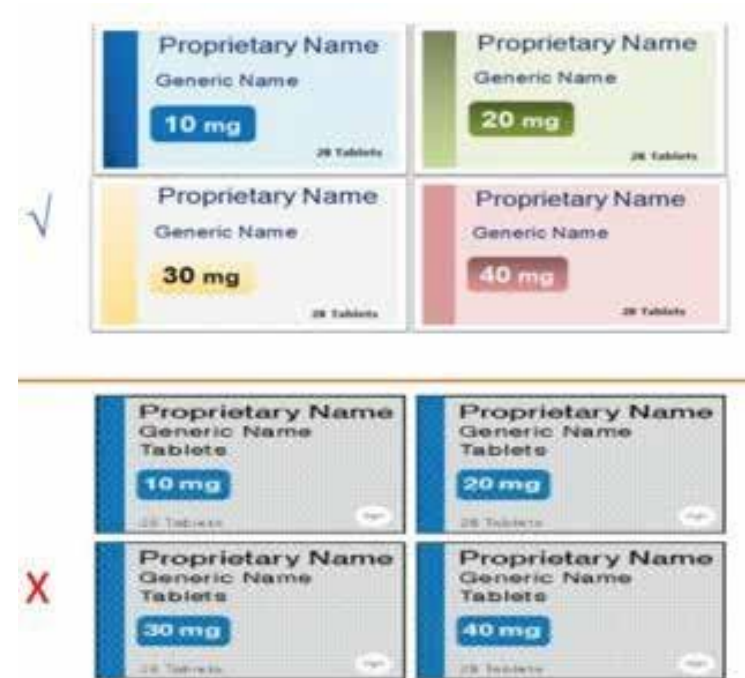
- **SFDA Guidance for Graphic Design
of Medication Packaging**
- **Artwork Catalogue**
- **Country of origin packaging**

Naming Evaluation Look-Alike Names and Tall Man Lettering

| Prescribed | Given | Adverse Drug Event (ADE) |
|----------------|----------------|--|
| Morphine | HYDROmorphone | Respiratory Arrest, Death |
| ChlorproMAZINE | ChlorproPAMIDE | Anoxic Brain damage from sustained hypoglycemia |

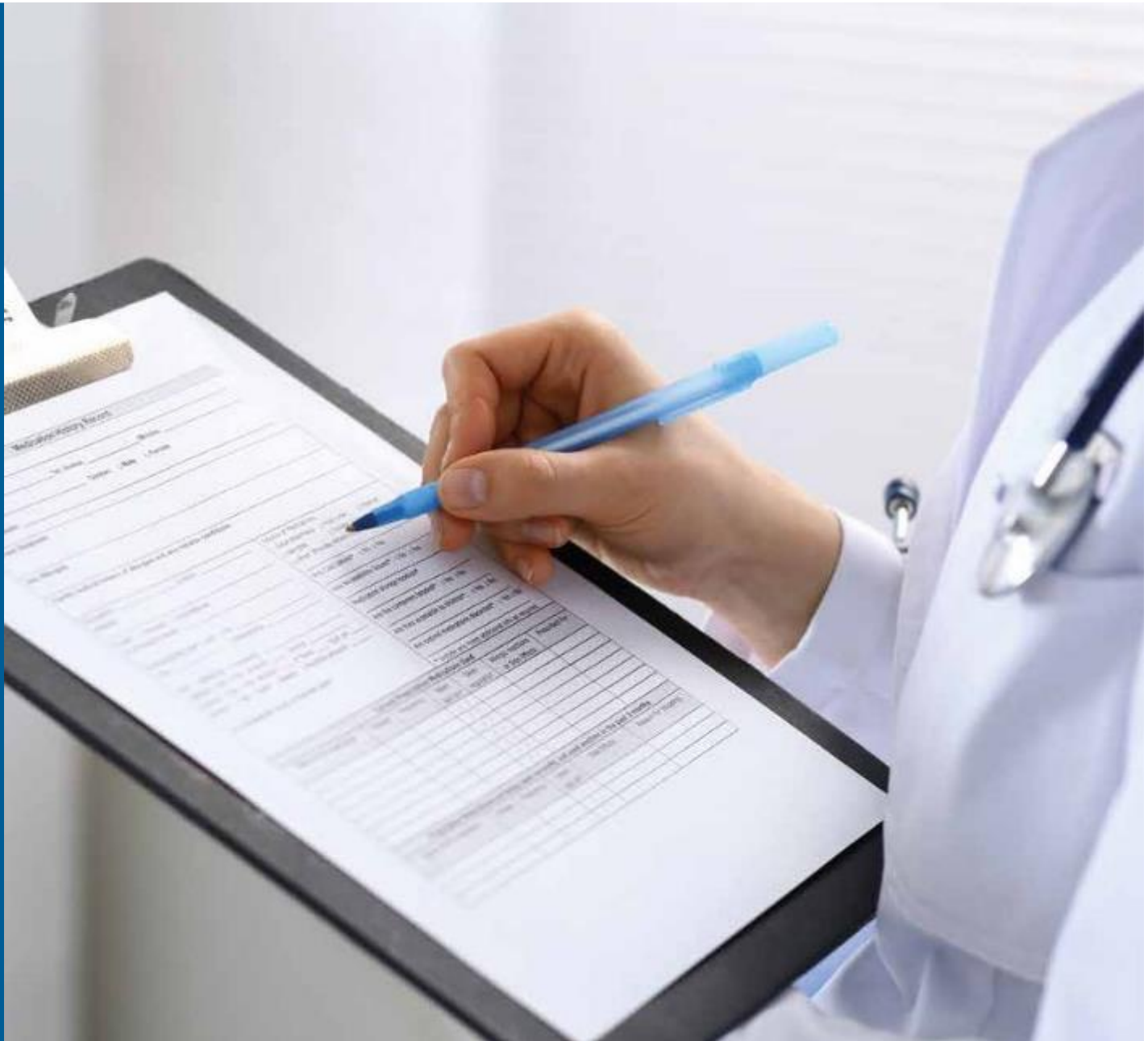
Packaging Evaluation Cont.'

Color Differentiation among different strengths





Post- Registration Activities Reporting





Importance of Med Error Reporting

Providing knowledge & updates of medication errors to boost activities in both pre & post marketing



How to Report



SFDA Call center
19999



بالأهم نهتم

     Saudi_FDA | www.sfda.gov.sa

Medication Without Harm



WHO Global Patient Safety Challenge

The safety of opioid medications: practical action at a system level

Mr Ewan MAULE

Director of Medicines and Pharmacy
North-East and North Cumbria
Integrated Care Board
UK

15 September 2022



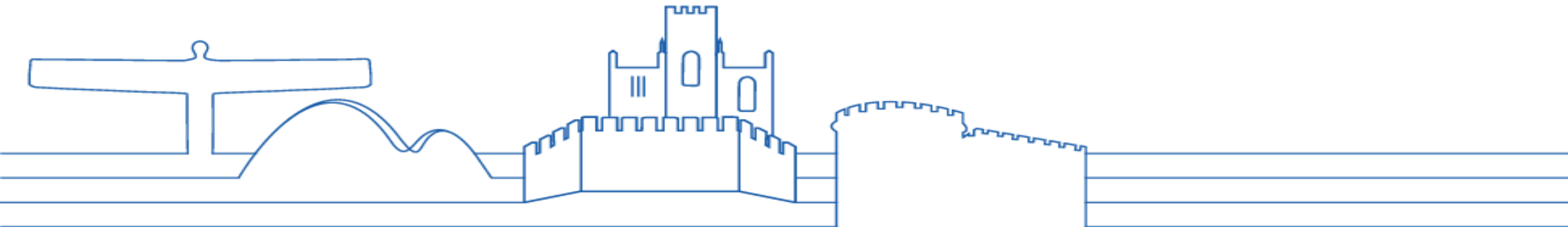
North East & North Cumbria

Tackling the opioid crisis: one region's experience

Ewan Maule

Director of Medicines and Pharmacy

WHO World Patient Safety Day Sept 2022



Global scale of the opioid crisis

Worldwide, about 0.5 million deaths are attributable to drug use, both prescribed and illicit

More than 70% of these deaths are related to opioids

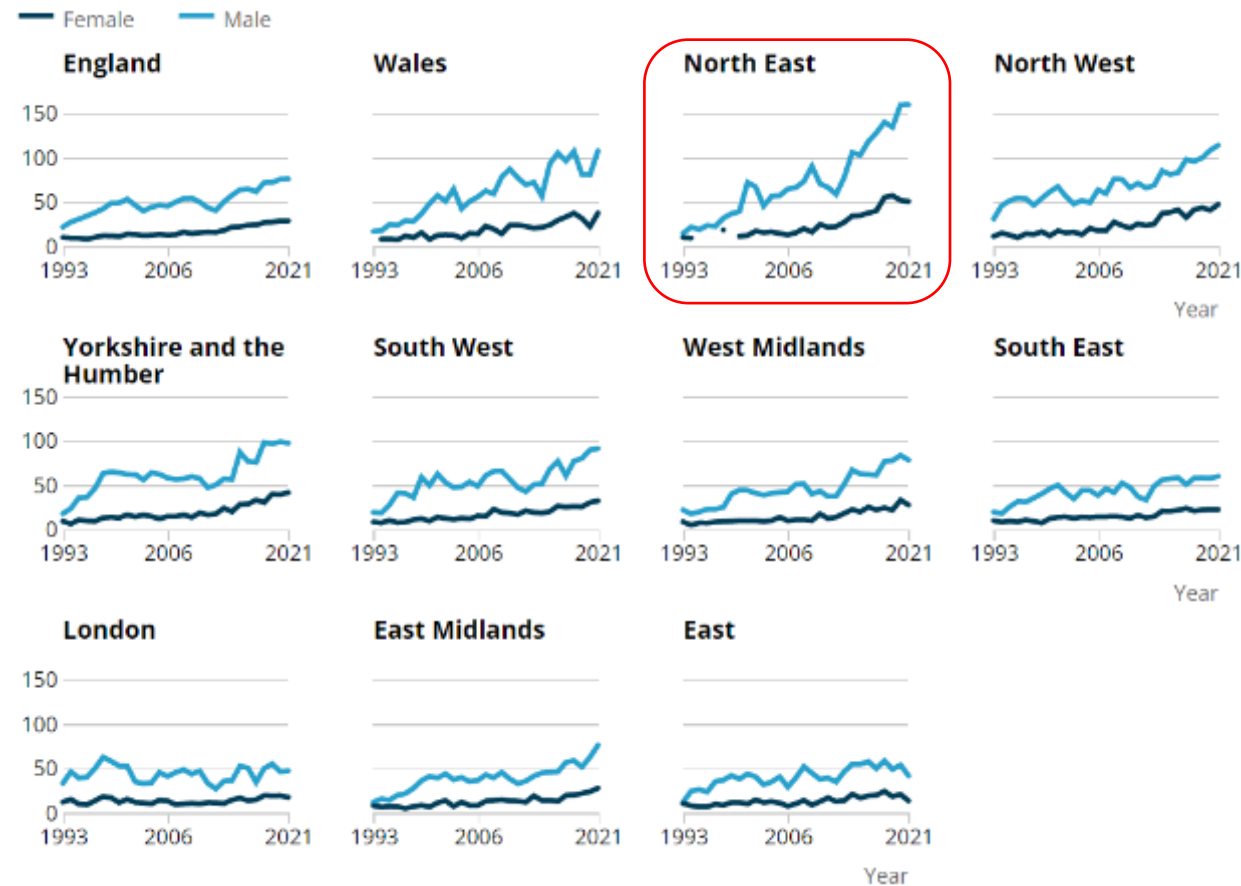
*'The epidemic of **opioid addiction** and its consequences touch every community, every demographic and every single one of us in some way.'*

- John Suthers – Colorado Attorney General

How a patient can suffer avoidable harm from opioids

- Faye, a 28 year old woman, sustained a back injury lifting a heavy object at home
- Two years later she had surgery to try to resolve the problem
- Oxycodone was given post operatively as 80mg a day (morphine equivalent 160mg)
- Faye's continuing chronic pain was treated with higher and higher doses of oxycodone
- Four years on from the original injury Faye was taking a cocktail of drugs including
 - oxycodone, gabapentin, amitriptyline, sertraline, diclofenac and paracetamol
- She developed a range of symptoms including huge weight gain, sleep apnoea and depression
- A late stage introduction of cognitive behavioural therapy brought some improvement, but she tragically died with a respiratory arrest at the age of 32 years

Opioid deaths in the North East of England are higher and rising faster than the rest of the country



1. <https://www.who.int/initiatives/medication-without-harm>
 2. <https://jamanetwork.com/journals/jama/fullarticle/2757570>

A single agency approach to opioid harm will not work



A public facing campaign to tackle opioid harm



Progress with the opioid harm reduction programme over five years

30% reduction in overall opioid use

50% reduction in high dose opioid use

It may be a crisis, but lives can be and are being saved

- *It's taken me five years to get to where I am now. I understand I can live with some pain in my life. I **was looking for the magic pill that does not exist.** By accepting that the painkillers were doing more harm than good, that they were actually at the root of many of my problems, I am now in a much better place.*
- *I've lost 8 ½ stone. I walk most days. Everything starts to hurt more when I stay still, so the solution is to be more active. I'm a better mum because I'm present. I'm much more social, I love listening to music and when my restless legs kick in, well, **I turn up the music and have a dance instead of turning to pills that stopped working a long time ago.***

Louise Trewern

@Loulouscorpio



Medication Without Harm



WHO Global Patient Safety Challenge

Product quality and Safety: scale of the problem and solutions – substandard and falsified medical products

Mr Rutendo KUWANA

Team Lead

Regulation and Safety

WHO headquarters

Geneva

15 September 2022



World Patient Safety Day 2022 Global Virtual Event



"Medication Without Harm"

Product quality and safety: scale of the problem and solutions for substandard and falsified medical products

15 September 2022

Rutendo KUWANA

Tedros Adhanom Ghebreyesus -

Director General, WHO

26 March 2021



*"Some falsified products are also being sold as vaccines on the **internet**, especially on the **dark web**.....we are aware of other reports of corruption and re-use of **empty vaccine vials**. We urge the secure disposal or destruction of used and empty vaccine vials to prevent them from being reused by criminal groups.*

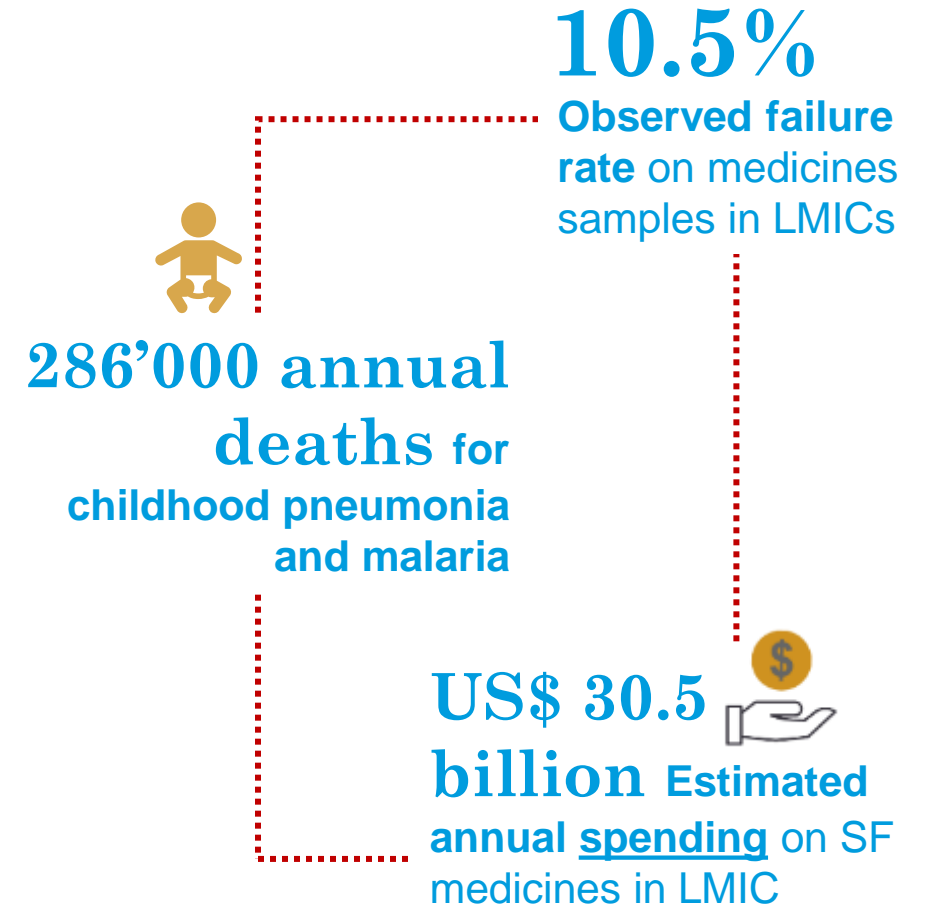
And we urge all people not to buy vaccines outside government-run vaccination programmes. Any vaccine bought outside these programmes may be substandard or falsified, with the potential to cause serious harm.

*WHO regularly issues **global medical product alerts on substandard and falsified products**, and we will do so when and if necessary for COVID-19 vaccines and therapeutics.*

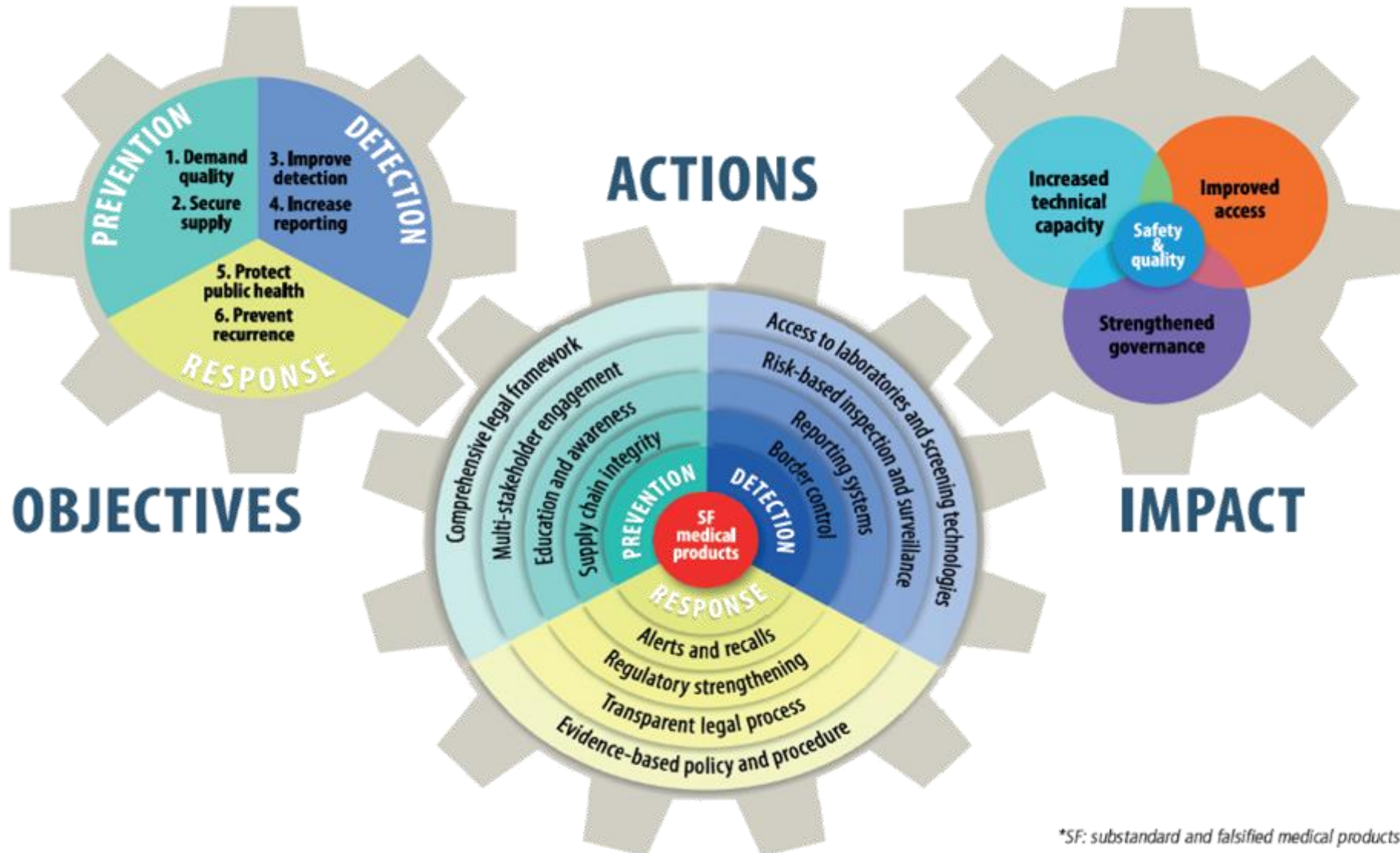
*We urge all countries and individuals to pay careful attention to this issue. Any suspicious sale of vaccines should be reported to national authorities, who will report it to WHO. **Information flow is essential to map global threats and protect confidence in vaccines**"*

SF medical products – scale of the problem

- Undermine all global public health investments through treatment failure or harm to patients
- Antimicrobial resistance
- Damage trust in public systems
- Increase out-of-pocket spending
- Increase morbidity and mortality
- lost income and increased poverty, etc.



A holistic strategy to address a cross cutting issue



**SF: substandard and falsified medical products*

WHO's dual approach

Political, operational
and technical
response

Influence change in health and governance systems

Technical and operational support to countries to prevent-detect-respond to SF medical products

Various services e.g. global medical product alerts based on reports and analysis of the global surveillance & monitoring system

Facilitate effective collaboration through the Member State mechanism

Provide validated evidence base to guide policy and regulatory capacity building

The Global Surveillance and Monitoring System for substandard / falsified (SF) medical products

What is in it?

- Confirmed or suspected Falsified medical products
- Unexpected Adverse Reactions caused by medical products – including lack of efficacy
- Stolen medical products or products removed from the regulated supply chain

Why report?

- Product and batch may have already been reported by another Country
- The product may pose a risk to public health, perhaps in another country or region
- The product may have already undergone laboratory analysis - which can be shared
- Another country may be investigating the origin of the product and have helpful information

WHO Member State Mechanism

Established by World Health Assembly [Resolution 65.19](#) to address SF medical products

Led by a [Steering Committee](#) chaired by Australia and supported by 11 Vice Chairs from all WHO Regions

WHO Member States agree on a [2-year workplan](#); current prioritized activities are for 2022-2023 and include work on:

- Regulatory capacity-building for prevention, detection and response
- Global networks
- Detection technologies and traceability
- Competencies and good governance
- Risk communication
- Impact and awareness
- Internet distribution and sale
- Informal markets

“The goal of the Member State Mechanism is to protect public health and promote access to affordable, safe, efficacious, and quality medical products, and to promote through effective collaboration among Member States and the Secretariat, the prevention and control of substandard and falsified medical products and associated activities.”





Rutendo KUWANA
Team Lead
WHO ISF Medical Products Team

rapidalert@who.int

Medication Without Harm



WHO Global Patient Safety Challenge

Message on World Patient Safety Day 2022 from the WHO Regional Office for Africa

Dr Matshidiso MOETI

WHO Regional Director for Africa

15 September 2022



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WHO Global Patient Safety Challenge

BREAK

Medication Without Harm



WHO Global Patient Safety Challenge

Session 4

Medication safety: systems and practices

Chair: Mr Frank FEDERICO

Faculty for Institute for Healthcare Improvement (IHI)
Senior Safety Expert

15 September 2022



Medication Without Harm



WHO Global Patient Safety Challenge

Reducing patient harm through safe medication use process – focusing on prescribing, administration and monitoring

Ms Carolyn HOFFMAN

Chief Executive Officer
Institute for Safe Medication Practices
Canada (ISMP-Canada)

15 September 2022



Preventable Harm from Medications



“Medications are the most widely utilized interventions in health care, and medication-related harm constitutes the greatest proportion of the total preventable harm due to unsafe care, let alone the economic and psychological burden imposed by such harm.”

World Health Organization, 2022

April 2012 feature article:
<https://thewalrus.ca/the-errors-of-their-ways/>

A complex system...



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“Just telling doctors and nurses to be more careful won’t do much. We need to change the systems that allow errors to happen.”

Dr. James Bagian
Anesthesiologist and Astronaut

5 Stages of Medication Use



Prescribing



Order Entry or
Transcribing



Dispensing

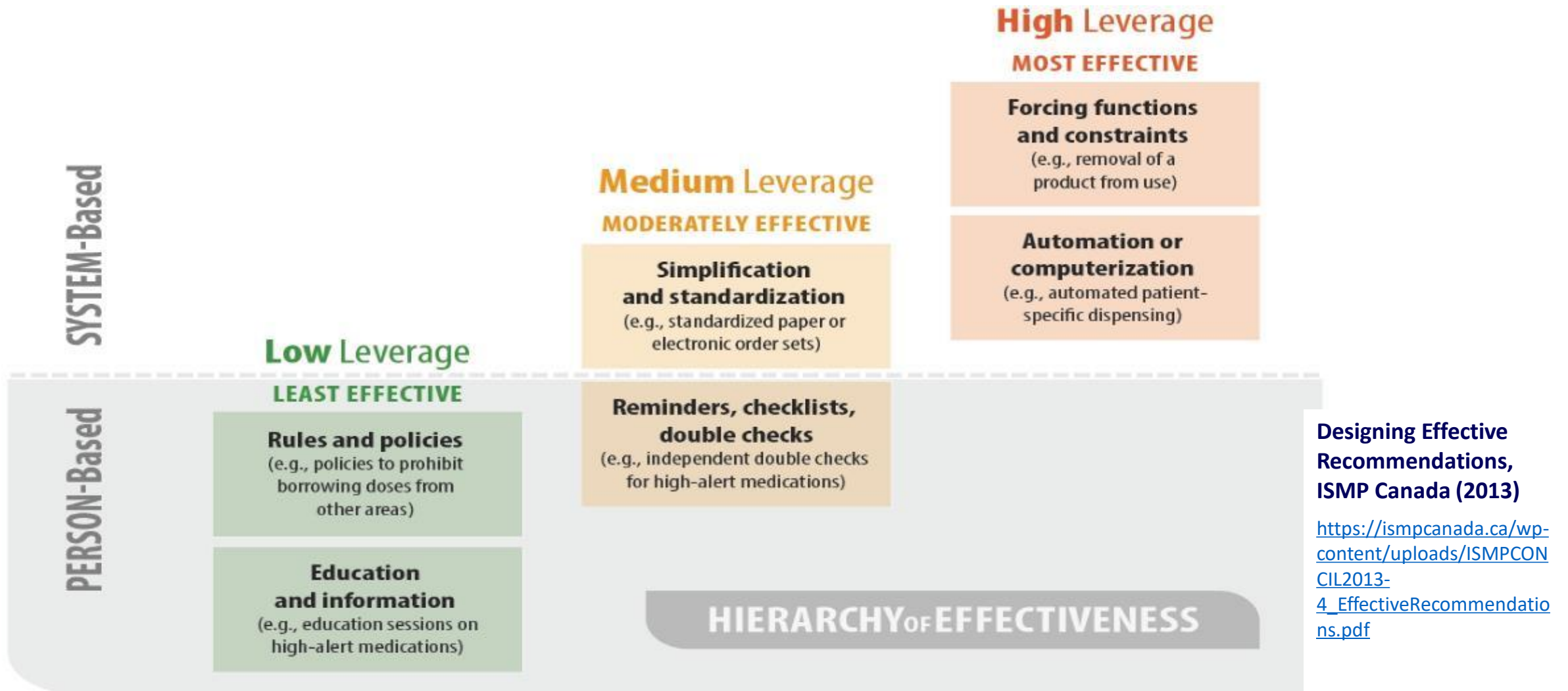


Administration



Monitoring

The Hierarchy of Intervention Effectiveness



Reduce the risk of prescribing errors



Prescribing

- Have essential patient information (e.g. age, weight, allergies, lab results)
- Use clinical decision support resources to inform evidence-based decisions
- Use computerized prescriber order entry
- Engage the patient/family so they can KNOW about their medications, CHECK for accurate dispensing / administration, monitor for ongoing safety, and ASK questions

Remember that abbreviations, symbols and dose designations can be error prone – comply with ‘Do Not Use’ lists

ISMP Canada - <https://ismpcanada.ca/resource/do-not-use-list/>

ISMP - <https://www.ismp.org/recommendations/error-prone-abbreviations-list>

Reduce the risk of administration errors



Administration

- Practitioners at the bedside play a key role in preventing errors
- Implement TALLman lettering for medications that may be confused, particularly look-alike/sound-alike (LASA) meds
- Implement independent double-checks for high-alert medications
- Verify the correct patient with 2 patient identifiers
- Use barcode-assisted medication administration technology
- Engage the patient/family in verifying medications so they can be a partner in their safety

Reduce the risk of monitoring errors



Monitoring

- Ensure all healthcare providers on the team know:
 - what measures will be taken to monitor the patient following administration of high-risk medications, and
 - what assessment results will trigger required action (e.g. blood glucose testing, sedation monitoring, INR monitoring)
- Integrate monitoring protocols into workflow design and health record documentation
- Engage the patient and family in the monitoring plan and results so they can be a partner in their safety

Reduce errors across all stages of medication use

- ✓ Use standardized order sets and standardized concentrations of medications wherever possible and integrate across prescriber and pharmacy systems, IV pump libraries, and monitoring records
- ✓ Make errors visible, use a systems approach to analyzing errors locally, integrate learning from others, and take action



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Thank you!

Carolyn Hoffman, CEO

Carolyn.hoffman@ismpcanada.ca



ZERO Preventable Harm From Medications
Institute for Safe Medication Practices Canada

Medication Without Harm



WHO Global Patient Safety Challenge

Challenges of reducing medication errors in primary, ambulatory, residential and home care

Prof Jose M VALDERAS

Chairman, WONCA Working Party
In Quality & Safety

15 September 2022

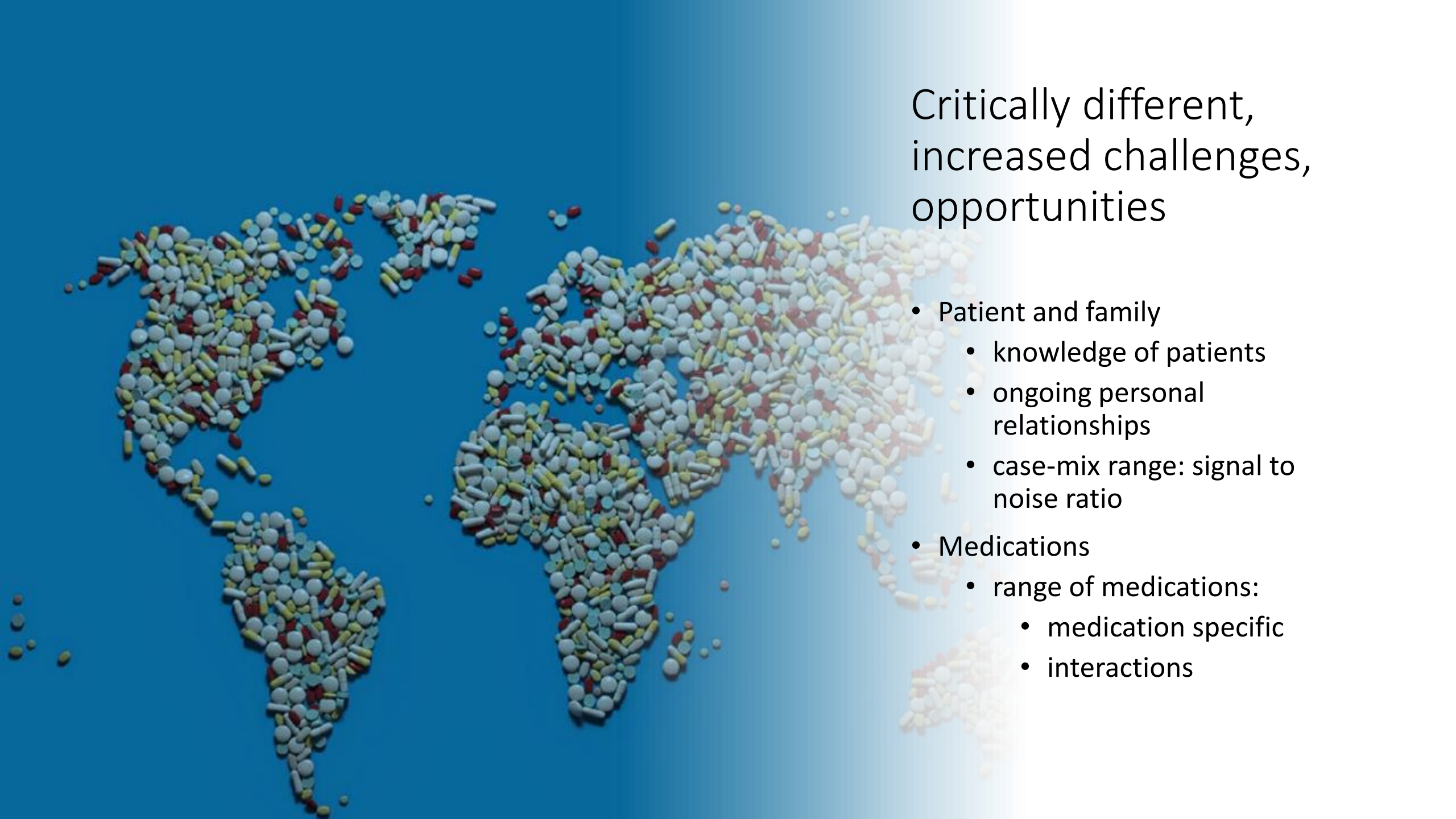




Critically different, increased challenges, opportunities

- Professional roles and scope of practice:
 - continuous (rather than episodic)
 - whole person oriented (rather than disease/problem oriented)
 - comprehensiveness
 - critical role in care coordination
 - high risk situations
 - polypharmacy
 - transitions
- Setting
 - less technology intensive
 - interface with multiple different settings
 - range of arrangements:
 - less hierarchized
 - less standardised (across settings)



A world map is formed by a dense collection of various pills and capsules in white, yellow, red, and blue. The map is centered on a blue background that has a light blue gradient on the right side where the text is located.

Critically different,
increased challenges,
opportunities

- Patient and family
 - knowledge of patients
 - ongoing personal relationships
 - case-mix range: signal to noise ratio
- Medications
 - range of medications:
 - medication specific
 - interactions

High risk situations

Specific groups

- young children
- frail patients and those with cognitive impairment
- those living alone

Specific medications

- Antibiotics
- Insulin
- Narcotics
- Heparin and anticoagulants

Tools and technologies

- high-alert medications

Patient and family empowerment

Polypharmacy

Integrating care as provided by multiple specialists and settings

Increased uncertainty about risks and benefits

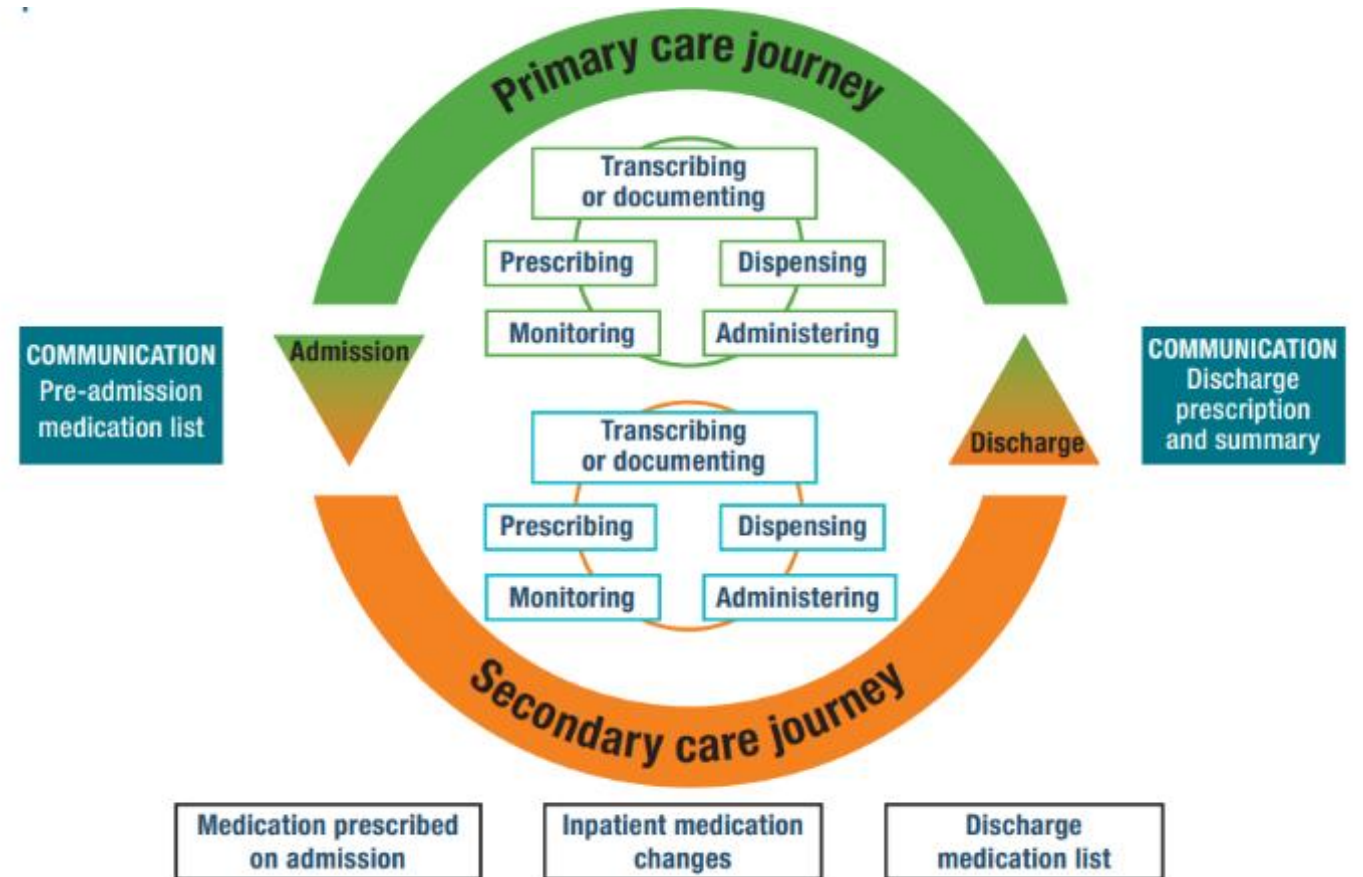
Medication history

Medication reviews

Tools and technologies

Patient and family empowerment

Transitions of care



Transitions of care

Multiple interfaces

Multiple multidisciplinary teams

Medication reconciliation

Tools and technologies

Patient and family empowerment

Key role of Family Medicine

- At the intersection of high risk, polypharmacy and transitions
- Whole patient orientation and life course approach
 - Not just about the condition or the indication or the strength of evidence for a given pharmacological treatment
 - “Will THESE medications help THIS patient?”
- Partner with patients and families

Key role for Primary Care

- Need for settings and level specific evidence
- High quality primary care as a pre-requisite
- Monitoring of medication safety in primary care
 - OECD PaRIS Project



Thank you

All images from WHO documents of the Medication Without Harm series

Medication Without Harm



WHO Global Patient Safety Challenge

The Economics of Medication Safety: Improving medication safety through collective, real-time learning

Ms Katherine DE BIENASSIS

Health Policy Analyst, Health Division
The Organisation for Economic
Cooperation and Development (OECD)

15 September 2022





THE ECONOMICS OF MEDICATION SAFETY

Katherine de Bienassis, Health Policy Analyst
15 September 2022





The Economics of Medication Safety

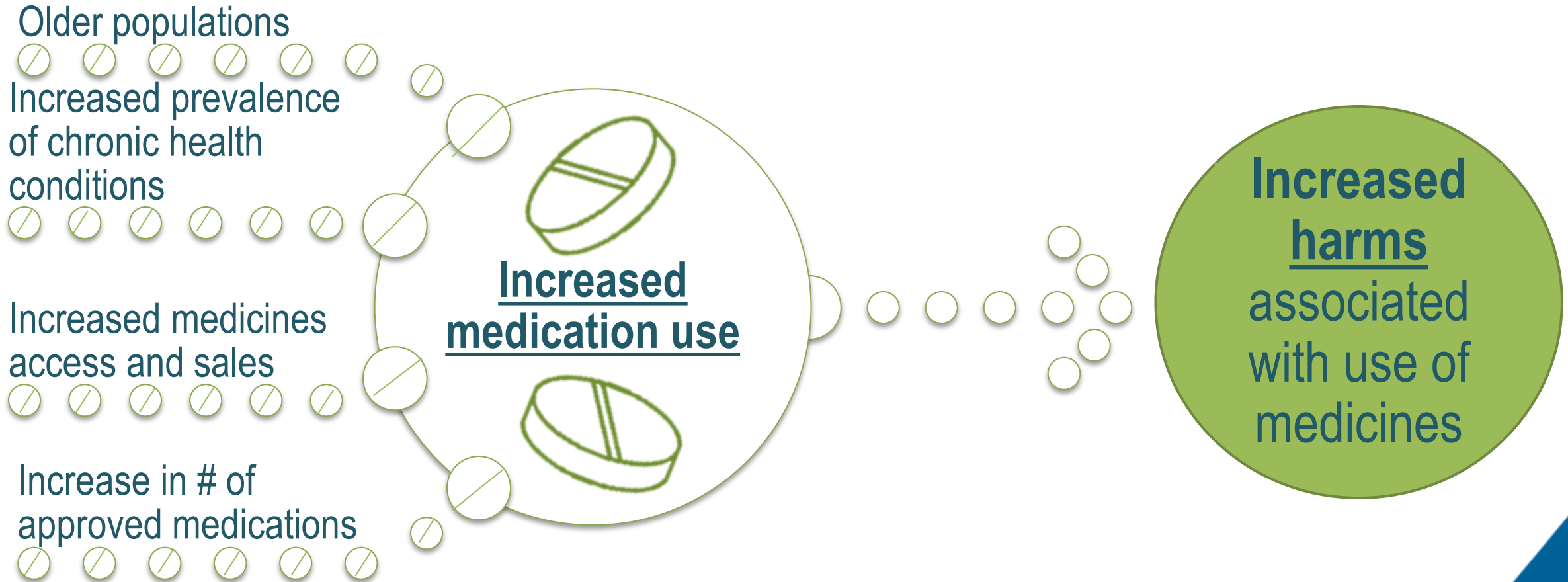
<https://doi.org/10.1787/9a933261-en>

https://www.oecd-ilibrary.org/social-issues-migration-health/the-economics-of-medication-safety_9a933261-en



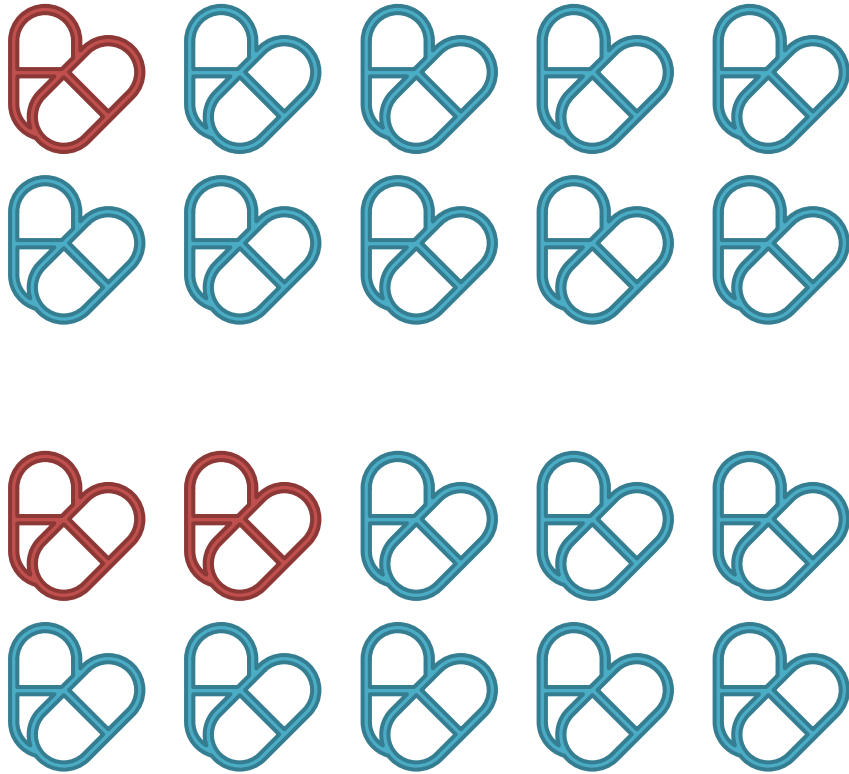


There has been **limited progress** in improving medication safety due to a number of converging factors





The scope of medication related harms

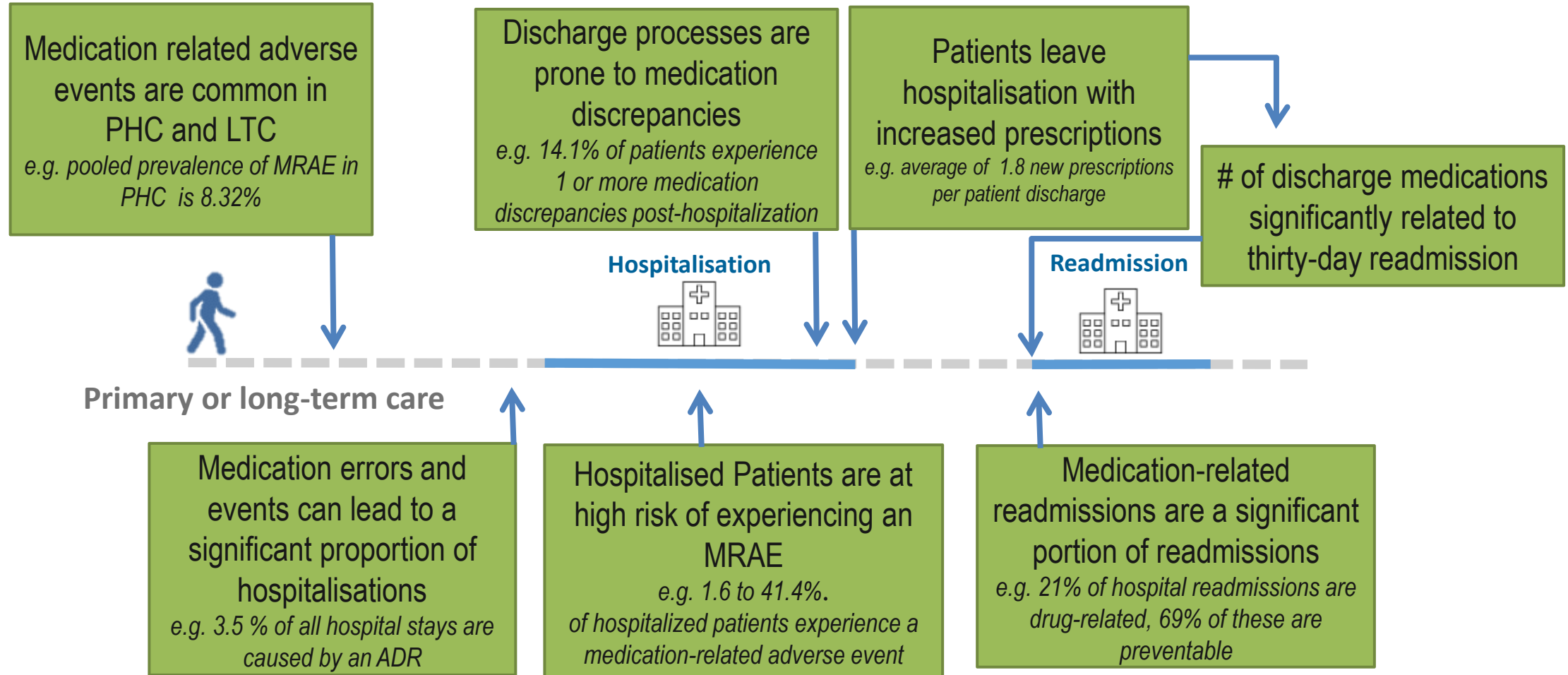


As many as **one-in-10 hospitalizations** in OECD countries may be caused by a medication-related harm and...

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



Medication safety is a **compounding problem**





Total cost to OECD countries > **USD 54 billion** annually;
≈ **11% of total pharmaceutical spending**

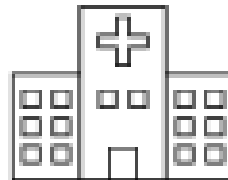
Six million hospital admissions
annually are the result of adverse
medication reactions

Costing OECD health systems
over **USD 50 billion**

Equivalent to 3% of all spending
on hospital inpatient care



Hospitalisation



Medication related harms are
experienced by an additional
**one million hospitalised
patients**, causing 3 million
avoidable hospital days

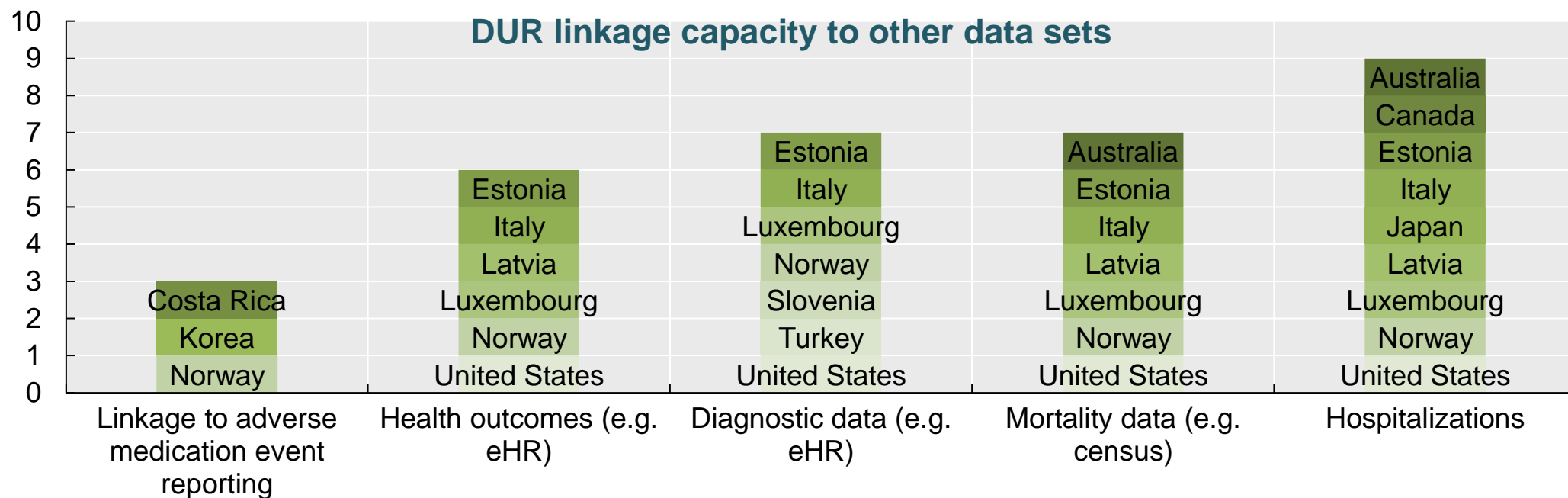
Costing an additional USD **3.4
billion.**





Scope of Drug Utilisation Review Systems in OECD Countries

70% of survived countries have systems in place to conduct **drug utilisation review on a national level**



Note: N=20 responding countries, Countries may be counted in multiple categories. In Italy data are linkable at the regional level only.

Source: OECD survey on the assessment of the adoption of systems and interventions to improve medication safety, 2022



Use of DUR data for **provider feedback, quality improvement, and policy purposes**

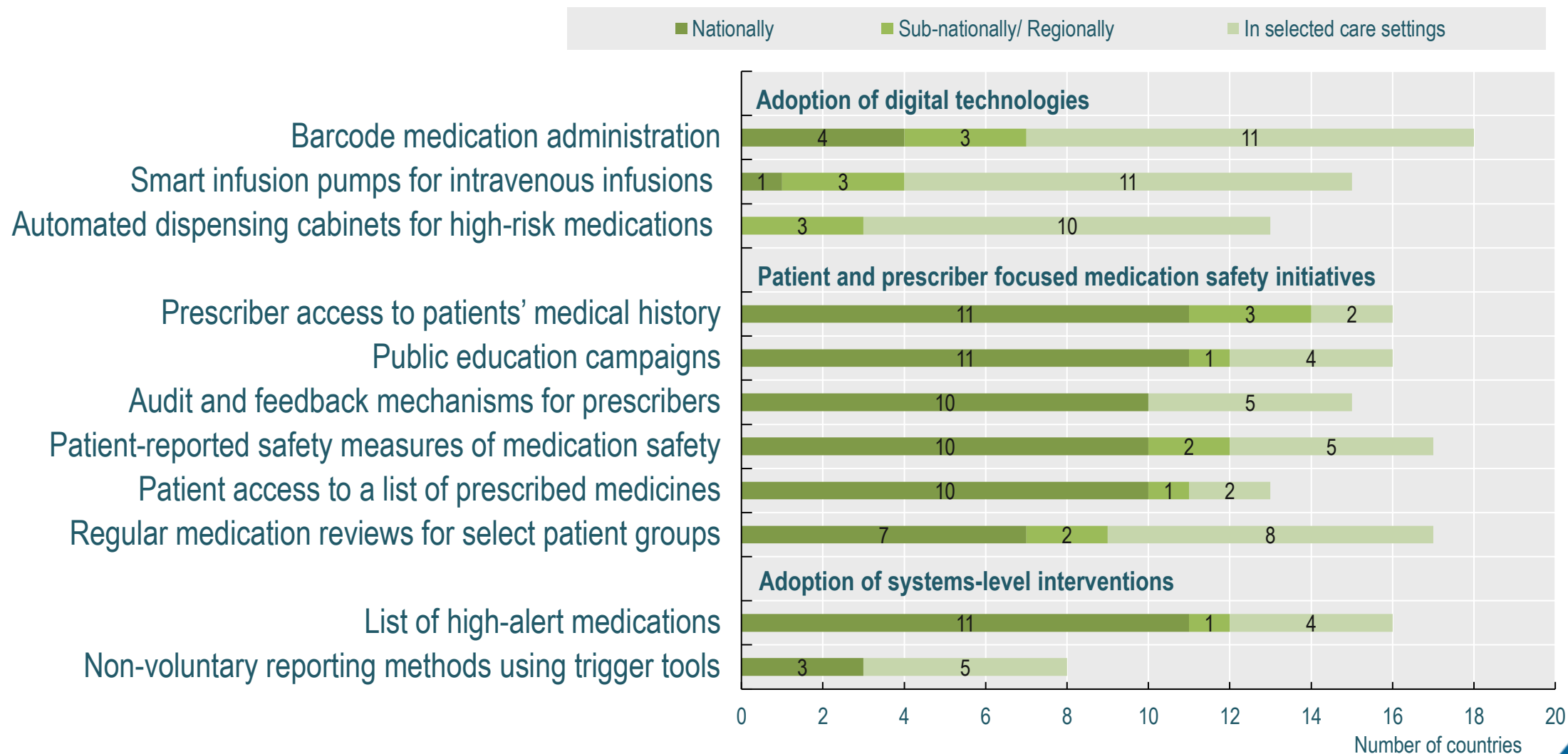
| Domain | Use of DUR data | Implementing Countries |
|--------------------------------------|--|--|
| Clinician/ prescriber feedback | Clinician-level alert system | Estonia, Republic of Korea, Netherlands, United States |
| | Practice-level prescribing | Costa Rica, Netherlands, Portugal, United States, Turkey, Luxembourg |
| | Individual clinician prescribing | Estonia, Japan, Republic of Korea, Netherlands, United States, Turkey, |
| | Real time dispensing decision support for pharmacists | Estonia, Netherlands, Republic of Korea, United States |
| | Facilitates interactions between clinicians and pharmacists/others | Estonia, Netherlands, Portugal, United States |
| Quality improvement | Local practice guidelines for prescribing | Costa Rica, Estonia, Netherlands, Portugal |
| | Professional standards | Netherlands, Portugal, Luxembourg |
| | Practice performance indicators | Estonia, Norway, Italy, Republic of Korea, Netherlands, Portugal, United States, Turkey |
| | Audit studies | Estonia, Netherlands, Portugal |
| | Structured dialogue between clinicians and pharmacists | Netherlands, Portugal, United States |
| | Linked to clinical care guideline development and evaluation | Estonia, Norway, Netherlands, Portugal, United States |
| Policy Purposes | Reimbursement coverage decisions | Estonia, Germany, Norway, Italy, Portugal, Australia, Republic of Korea, Luxembourg, Switzerland |
| | Formulary inclusion | Costa Rica, Italy, Japan, Portugal, Luxembourg |

^[1] The “rate of prevention of overlapping prescription” was implemented in 2020 as a patient safety indicator from Indicators for the Healthcare Quality Evaluation Grant initiative of Korea National Health Insurance Program. This indicator is calculated based on DUR data.

^[2] In principle, prescription of drugs with drug-drug interactions and age and pregnancy contraindications are not reimbursed (under the NHI). If these drugs were medically necessary, the reasons for prescription and dispensing must be specified on the claim, and the appropriateness of the



Digitization and medication safety initiatives by level of adoption by country





To improve medication safety, countries can:





THANK YOU AND STAY SAFE



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Message on World Patient Safety Day 2022 from the WHO Regional Office for the Americas

Dr Carissa F. ETIENNE

WHO Regional Director for Americas

15 September 2022



PANEL discussion: “Medication safety: how to get better faster”

MODERATOR



Sir Liam DONALDSON
WHO Envoy for Patient
Safety

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Message on World Patient Safety Day 2022 from the WHO Regional Office for the South-East Asia

Dr Poonam Khetrpal SINGH

WHO Regional Director for
South-East Asia

15 September 2022



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Closing session

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Message on World Patient Safety Day 2022 from WHO Director-General

Dr Tedros Adhanom GHEBREYESUS
WHO Director-General

15 September 2022



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Key messages and conclusion

Sir Liam DONALDSON

WHO Envoy for Patient
Safety



Dr Neelam DHINGRA

Unit Head
Patient Safety Flagship
WHO headquarters



15 September 2022

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Closing remarks

Dr Rudi Eggers

Director
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WHO headquarters

15 September 2022

