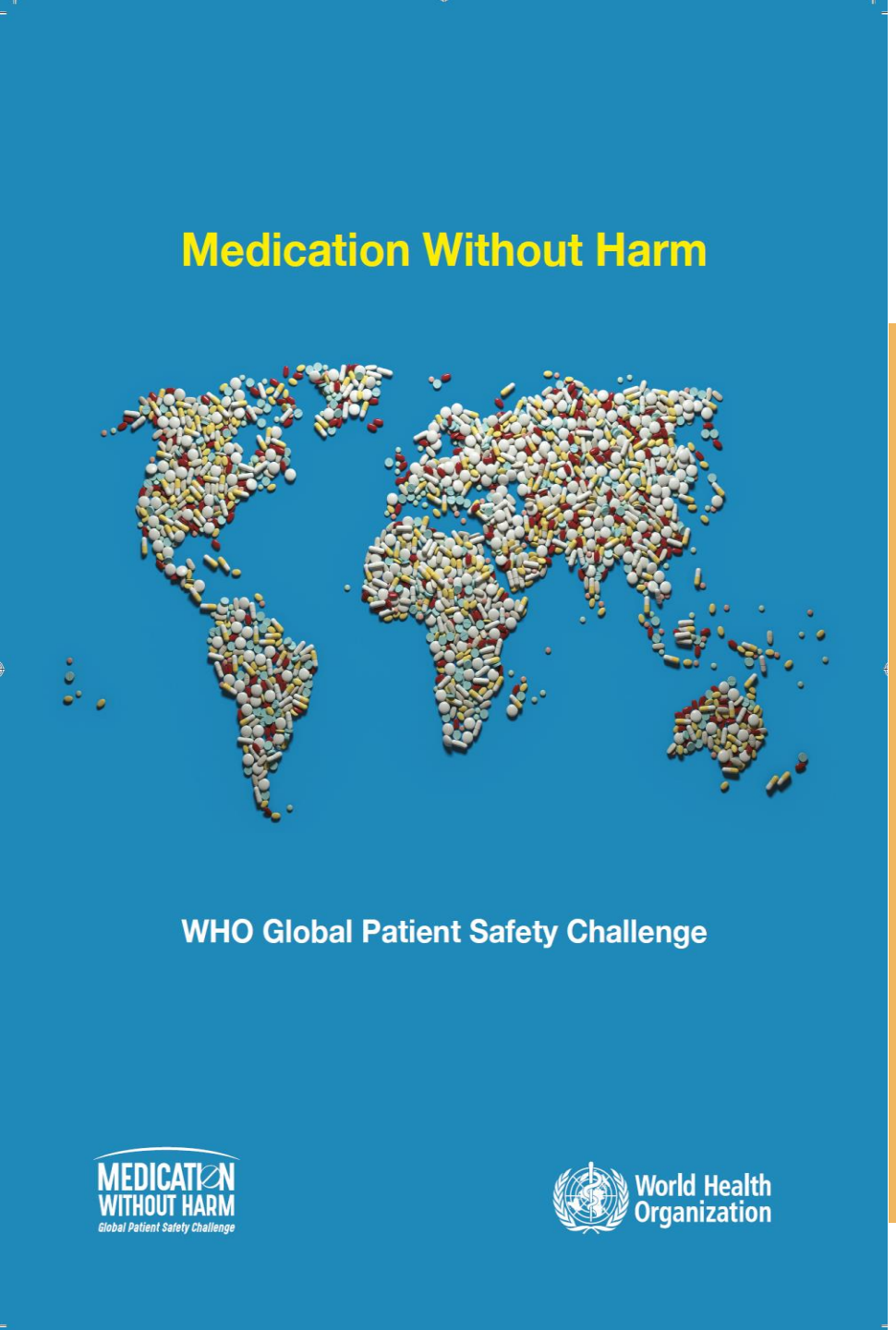


MEDICATION WITHOUT HARM
Global Patient Safety Challenge

World Health Organization

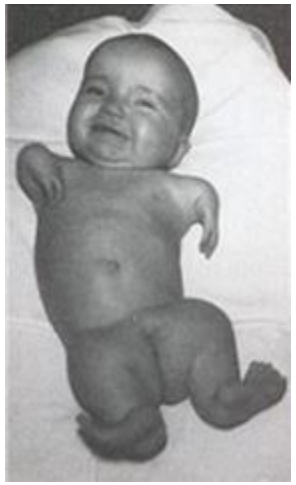
Pharmacovigilance Systems

Dr Shanti Pal
Team Lead, Pharmacovigilance
Medicines and Health Products
WHO headquarters

12 April 2022

WHO Programme for International Drug Monitoring

How it started



Thalidomide 1961

WHO Programme for International Drug Monitoring (PIDM) 1968

- World Health Assembly Resolution 16.36
- INVITES Member States to arrange for a systematic collection of information on serious adverse drug reactions observed during the development of a drug and, in particular, after its release for general use.

World Health Organization

Over 170 countries and territories are part of the WHO Programme for International Drug Monitoring (as full or associate members)

WHO Programme for International Drug Monitoring

The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

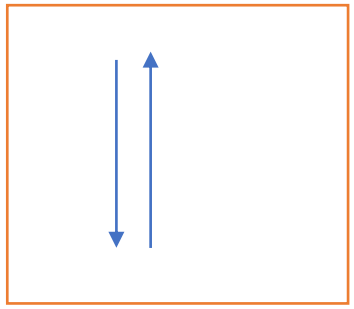
World Health Organization

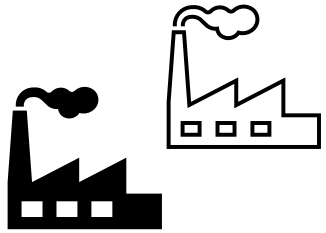
Pharmacovigilance data flow: how it works in a country

Public Health Programme (PHP)

Adverse Event (AE) observed (Dx or Vx)

AE is reported





Sometimes the report is sent to the PHP or the national pharmacovigilance centre

National Pharmacovigilance Centre

WHO global database of Individual Case Safety Reports, VigiBase

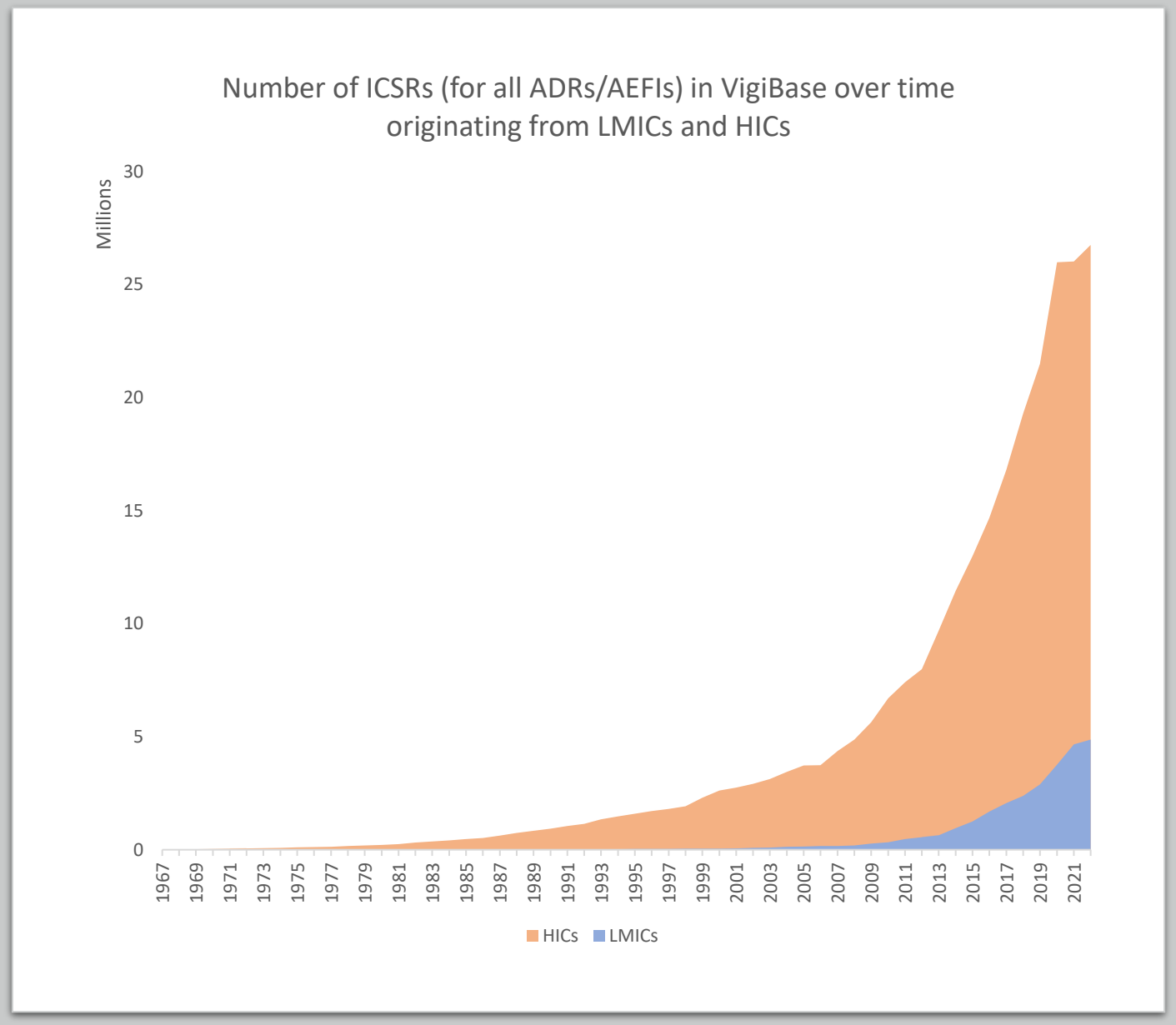
National Regulatory Authority

Regulatory decisions

World Health Organization

VigiBase: WHO global database of individual case safety reports

- Contains over 30 million reports of adverse drug reactions/adverse events following immunization
- Currently 152 countries and territories contribute to the database



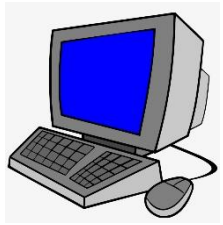
World Health Organization

How reports of medication errors reach the WHO database of Individual Case Safety Reports, VigiBase

Medication error

Patient harm due to medication error

Report medication error



Submit to national pharmacovigilance centre

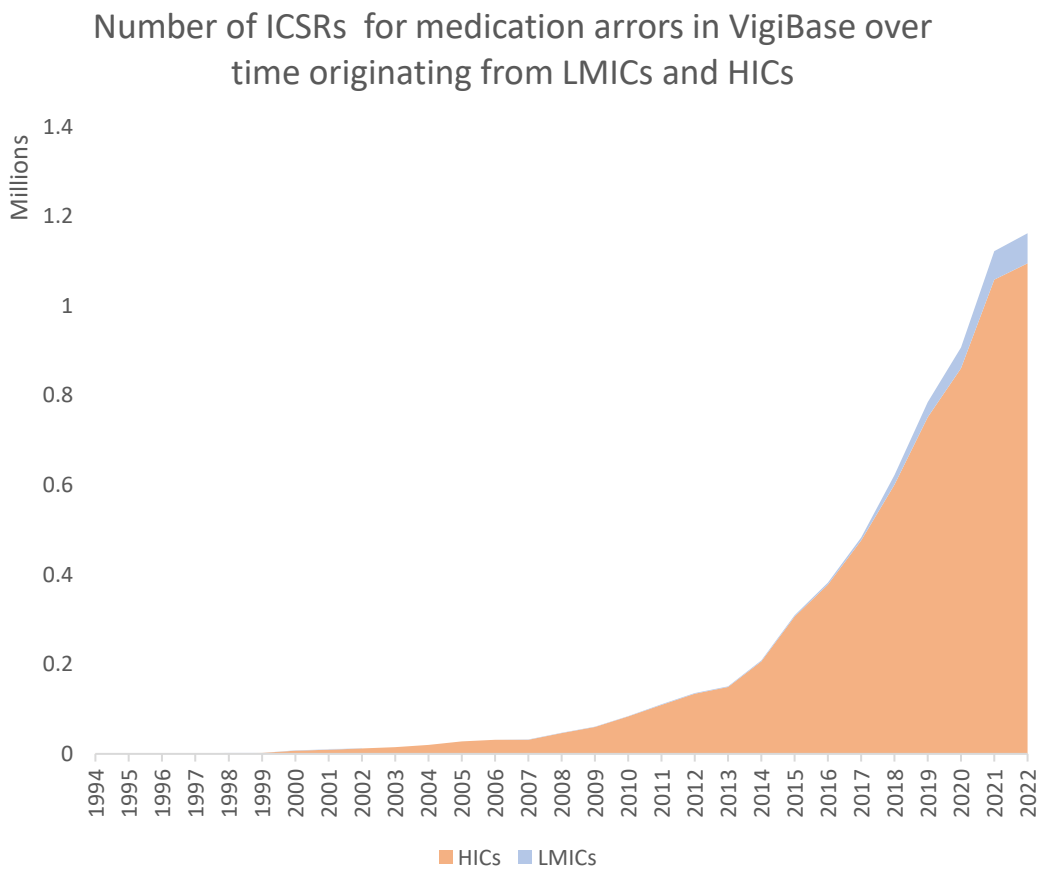
Medication error is coded

Submit to WHO global database of Individual Case Safety Reports

Near miss

World Health Organization

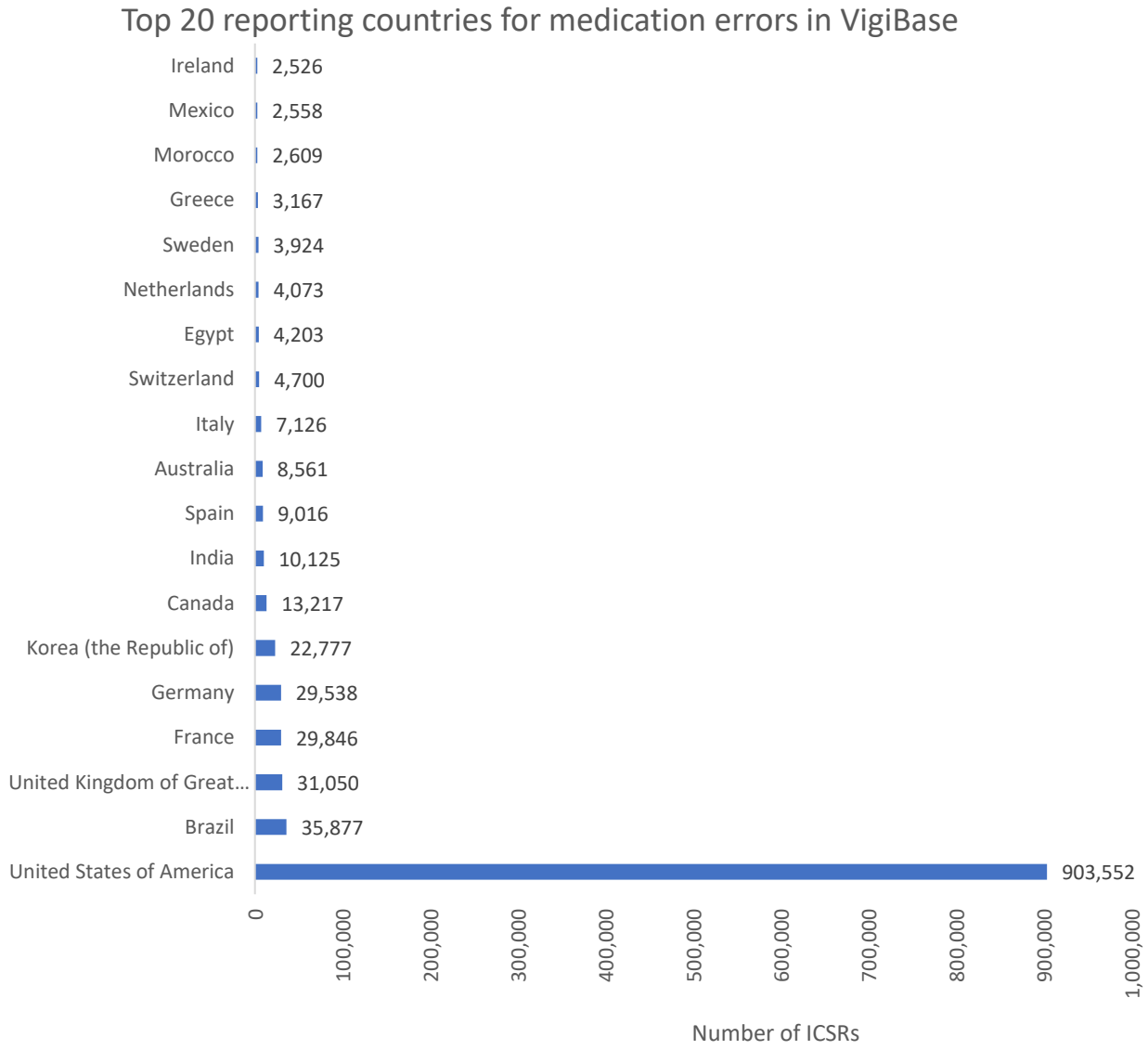
Number of ICSRs with a medication error in VigiBase



- A total of 1,162,041 ICSRs reporting a medication error in VigiBase (4% of all ICSRs)
- Reports originate from 107 countries
- 6% of ICSRs for medication errors originate from LMICs

World Health Organization

Reports of medication errors in VigiBase: Originating countries – top reporting countries



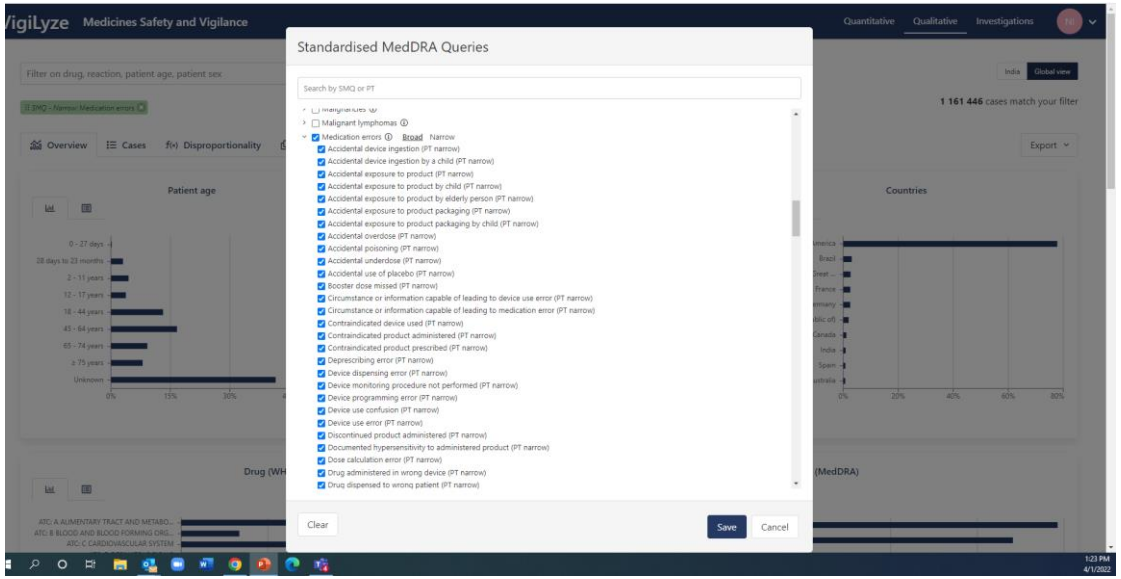
MedDRA Dictionary

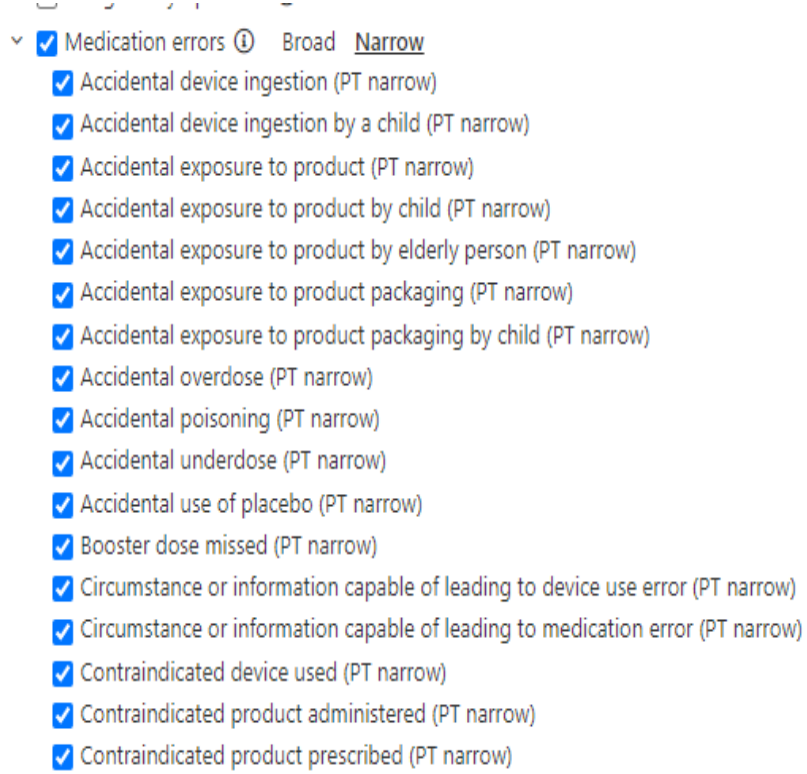
- Medical Dictionary for Regulatory Activities
- The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) developed MedDRA
- A rich and highly specific standardised medical terminology to facilitate sharing of regulatory information internationally for medical products used by humans.
- Translated in many languages
- Standardised MedDRA Queries: SMQs: validated, pre-determined sets of MedDRA terms grouped together after extensive review, testing, analysis and expert discussion. There is an SMQ related to medication errors.

World Health Organization

Standard MedDRA Queries (Narrow): Medication errors

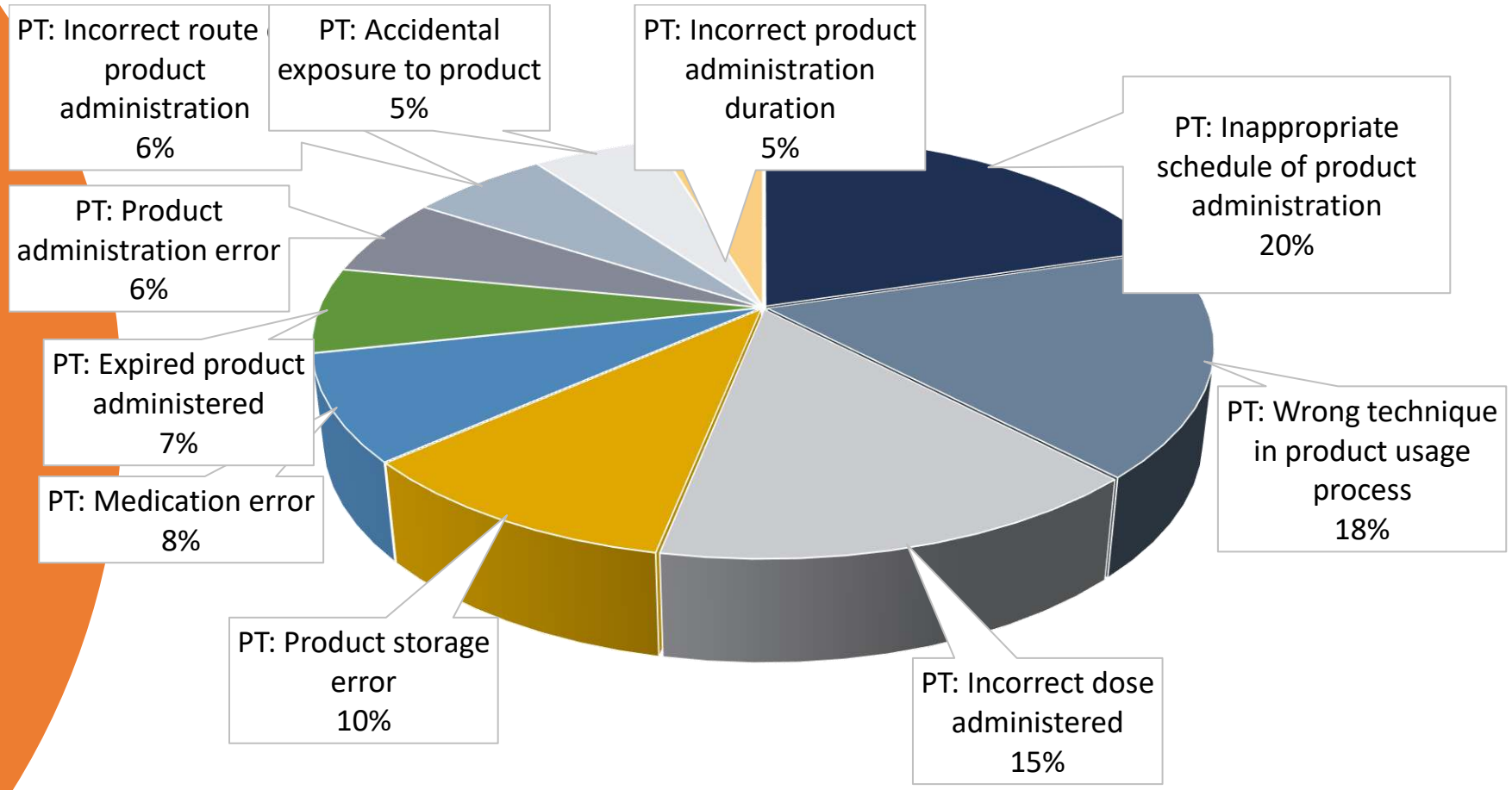
Over 90 preferred terms in Narrow SMQ for medication errors





World Health Organization

Most frequently reported Medication error, preferred MedDRA term in VigiBase



World Health Organization

Tools exist, but are we using them optimally?

- We know that many ME occur – but all are not reported to the WHO global database
- How do we link patient safety and PV databases so that
  - A global repository of MEs to help study:
    - types of medication errors
    - products prone to medication errors
    - mitigation strategies that are needed
    - the impact of the strategies: trends over time

World Health Organization

Acknowledgements

- Dr Noha Iessa
- All national PV Centres
- The WHO Collaborating Centre for International Drug Monitoring (Uppsala Monitoring Centre)

Thank you

https://www.who.int/teams/regulation-prequalification/regulation-and-safety/pharmacovigilance

World Health Organization