WHO work on Medicines Safety: an update

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World Health Organization

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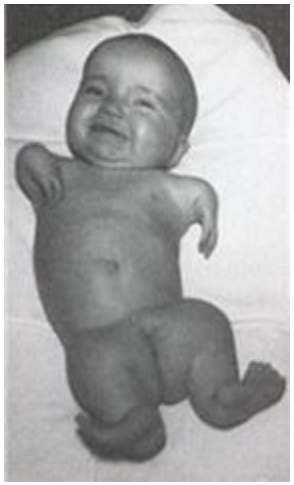
WHO Pharmacovigilance & Medicines Safety Programme

How it started



- Thalidomide 1961

- WHO Prgm. for Int. Drug Monitoring 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.

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WHO Programme for International Drug Monitoring (PIDM)

Founding members in 1968

10 Countries

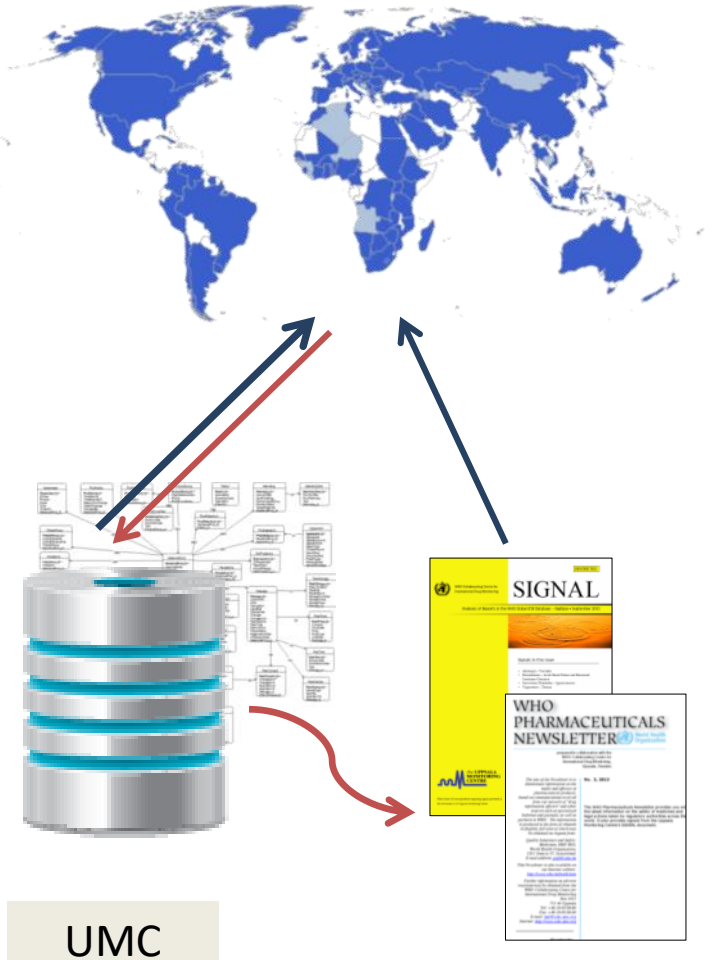
June 2018

131 Full Members
29 Associate Members

VigiBase®

the WHO global individual case safety reports (ICSR) database managed and maintained by the WHO Collaborating Centre in Uppsala

- The oldest and largest ICSR database
- Freely accessible to National Centres
- Aggregated data also accessible to the public
- Global signal detection



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Who is contributing to the ICSR/pharmacovigilance database (via national databases, to the WHO global database, Vigibase)?

- Healthcare professionals
- Industry
- General public (Patients & care-providers)
- Public health programmes and community care-providers

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Medication errors reported in the WHO Global database of Individual Case Safety Reports (Vigibase)

- Medication Error is reportable to PV database
- All MEs can be reported, whether or not they lead to patient harm
- Standardised MedDRA Query (SMQ)
  - Medication errors broad SMQ
- Over 18 million safety reports and growing
  - 934 888 reports of Medication Error (June 2018)
  - ~ 5% of all ICSRs in database

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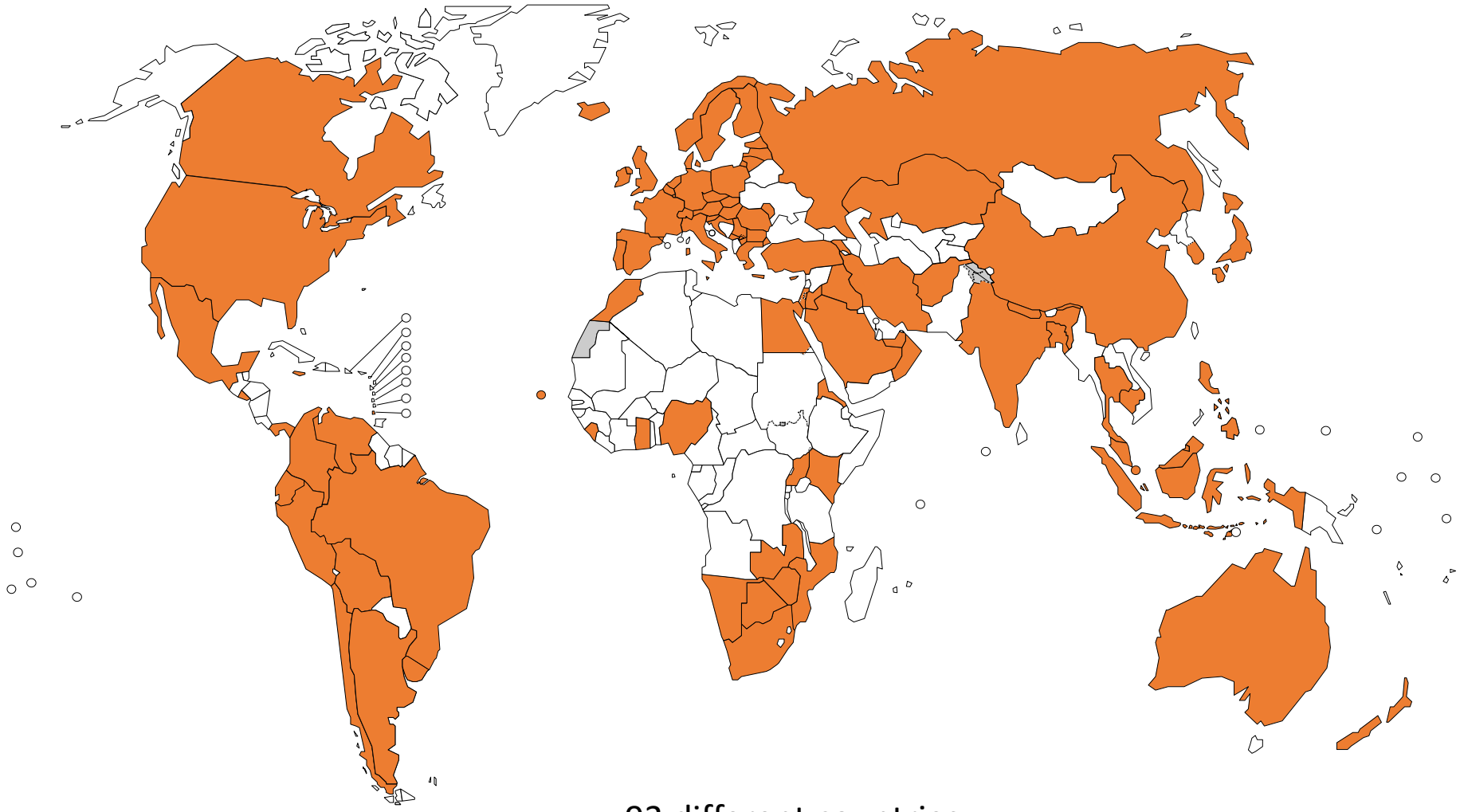
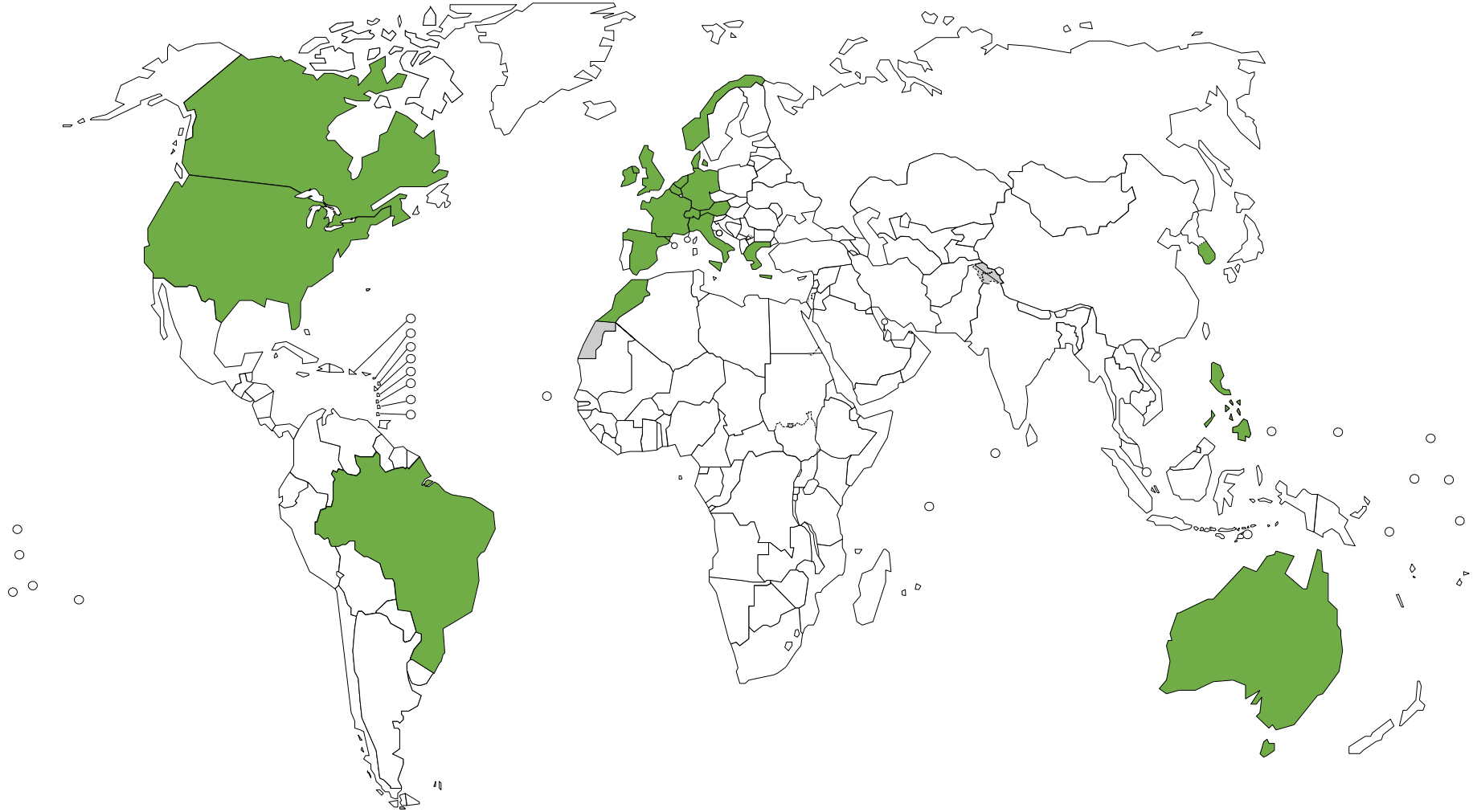
ME Reporting countries
June 2018

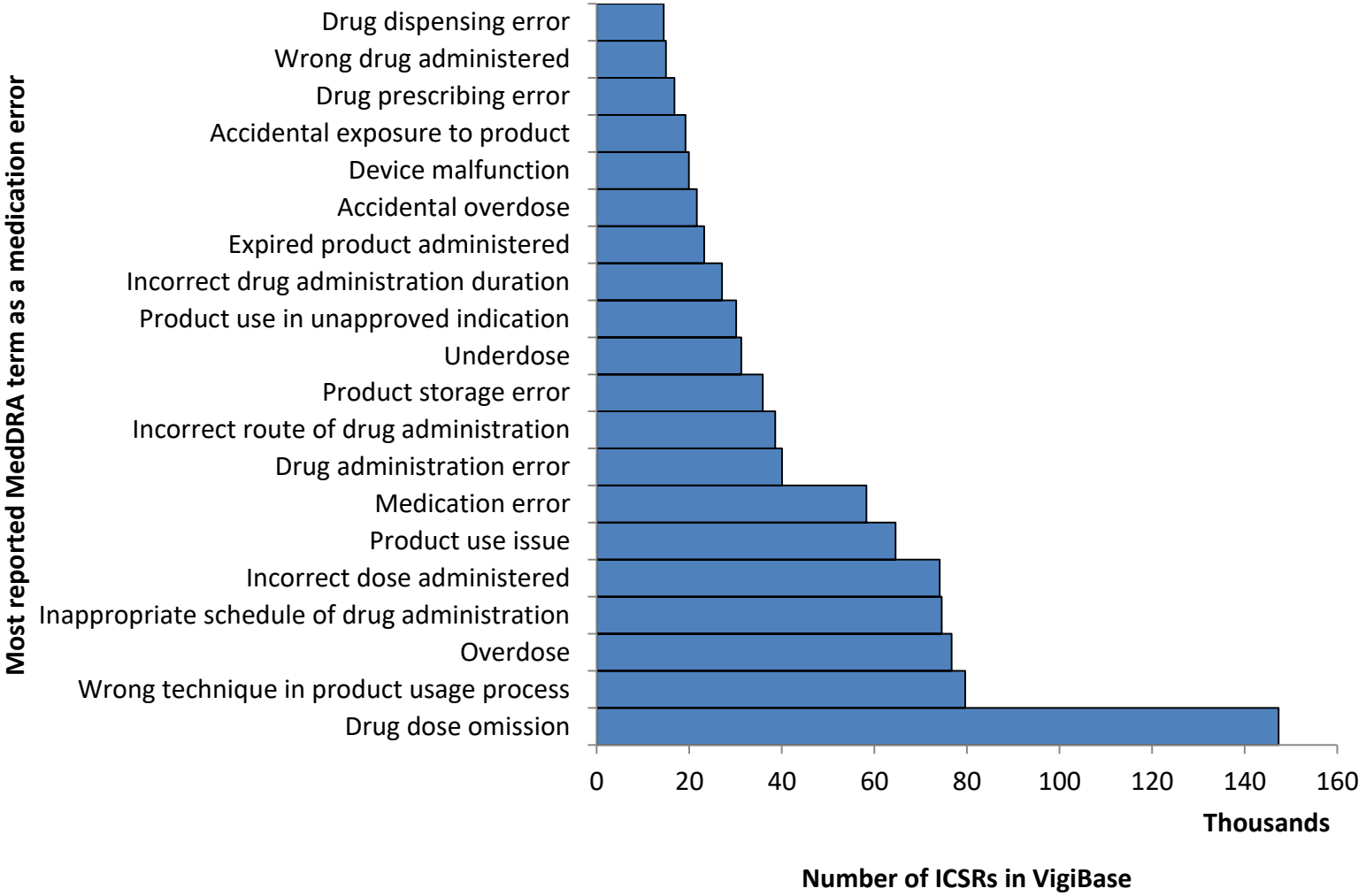


93 different countries

Top 20 ME reporting countries June 2018



Top reported MedDRA terms related to medication errors (1968-June 2018)

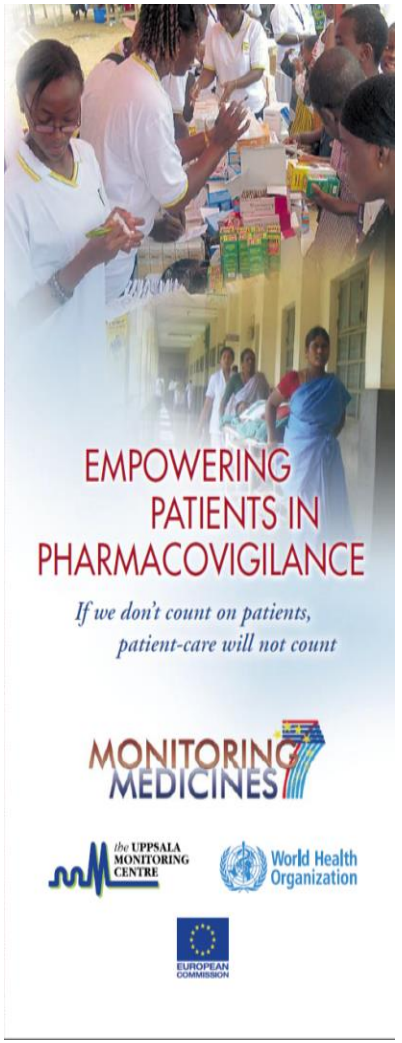


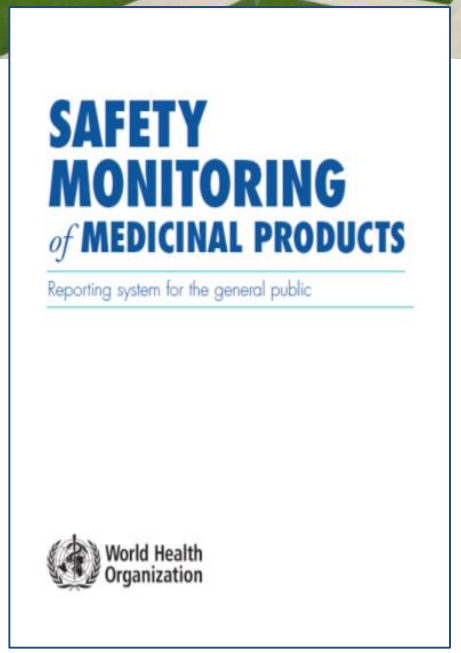
Example of signals published for medication errors

- Agomelatine: inappropriate schedule of drug administration (April 2018)
- Brivudine and 5-fluorouracil: persistence of a fatal drug-drug interaction (April 2018)
- Edoxaban: Incorrect dose administered (April 2018)
- Metamizole: Documented hypersensitivity to administered product (April 2018)
- Methotrexate: incorrect drug administration rate (April 2018)
- Phenprocoumon: Accidental overdose (April 2018)
- Olanzapine and accidental drug intake by children (April 2015)

MEs through patient reporting: Empowering patients in pharmacovigilance

Seminar at World Health Assembly 2012





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Can we identify Medication Errors by analysing preventable adverse drug events

OPEN ACCESS Freely available online

2012

PLoS one

Percentage of Patients with Preventable Adverse Drug Reactions and Preventability of Adverse Drug Reactions – A Meta-Analysis

Katja M. Hakkarainen[1*], Khadidja Hedna[2], Max Petzold[1,3], Staffan Hägg[4]

1 Nordic School of Public Health (NHV), Gothenburg, Sweden, **2** Laboratoire d'Enseignement et de Recherche sur le Traitement de l'Information Médicale, Université de la Méditerrané, Marseille, France, **3** Centre for Applied Biostatistics, University of Gothenburg, Gothenburg, Sweden, **4** Department of Drug Research/Clinical Pharmacology, Linköping University, Linköping, Sweden

- 2% of **outpatients** had preventable ADRs
- 52% of ADRs were preventable

- 1.6% of **inpatients** had preventable ADRs
- 45% of ADRs were preventable

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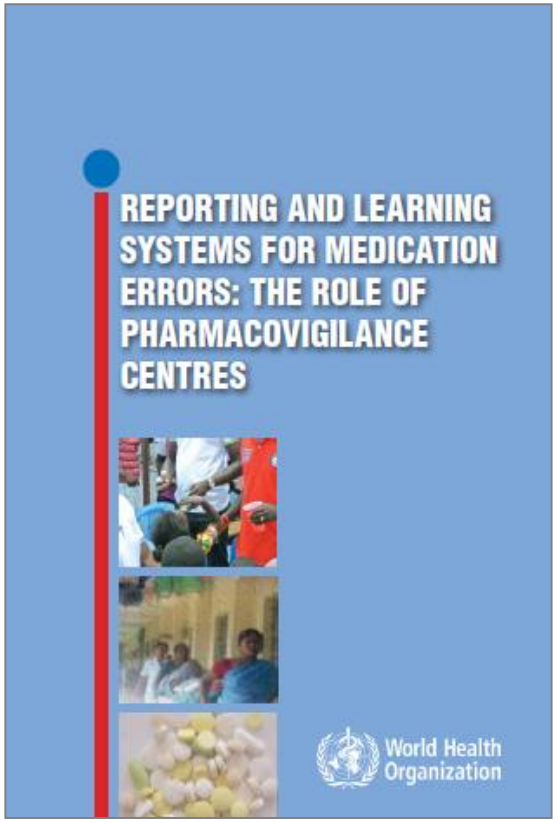
WHO, National Pharmacovigilance Centre in Morocco, Uppsala Monitoring Centre (UMC), National Patient Safety Agency (NPSA)



Other ways of detecting MEs?

Benkirane R, Soulaymani-Bencheikh R et al.

Assessment of a New Instrument for Detecting Preventable Adverse Drug Reactions. Drug Saf. 2015 Apr;38(4):383-93.

WHO Global Patient Safety Challenge

Medication Without Harm

Global Launch, 29 March 2017

Goal of the Challenge

Reduce the level of severe, avoidable harm related to medications by 50% over 5 years, globally

Strategic approaches to implement the Challenge

- Early priority actions, development programmes and global action.
- The actions planned are based on four domains of work:
- Patients and the public
- Medicines
- Health care professionals
- Systems and practices of medication

Domain 2: Medicines
Strengthen the upstream factors

Sub-domains

- **Naming, labelling and packaging**
- Quality and safety
  - **Learning from pharmacovigilance systems**
- Logistics and storage
- Right product at point of care

Sub-domain : Naming..

- The Identification of Medicinal Products (IDMP)
  - Suite of ISO standards
  - Unique alpha-numeric codes
  - Assigned to medicinal products
  - Application in the PV domain
- WHO considering the maintenance of PhPID within IDMP: pharmaceutical product identifiers
  - Global source of validated, unique PhPIDs
  - Validation and maintenance service would serve to also reduce MEs
  - Example, LASA products

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Thank you

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Safety & Vigilance

WHO

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www.who.int/medicines/en