Existing WHO work on Medicines Safety & Safe Use

Department of Essential Medicines and Health Products

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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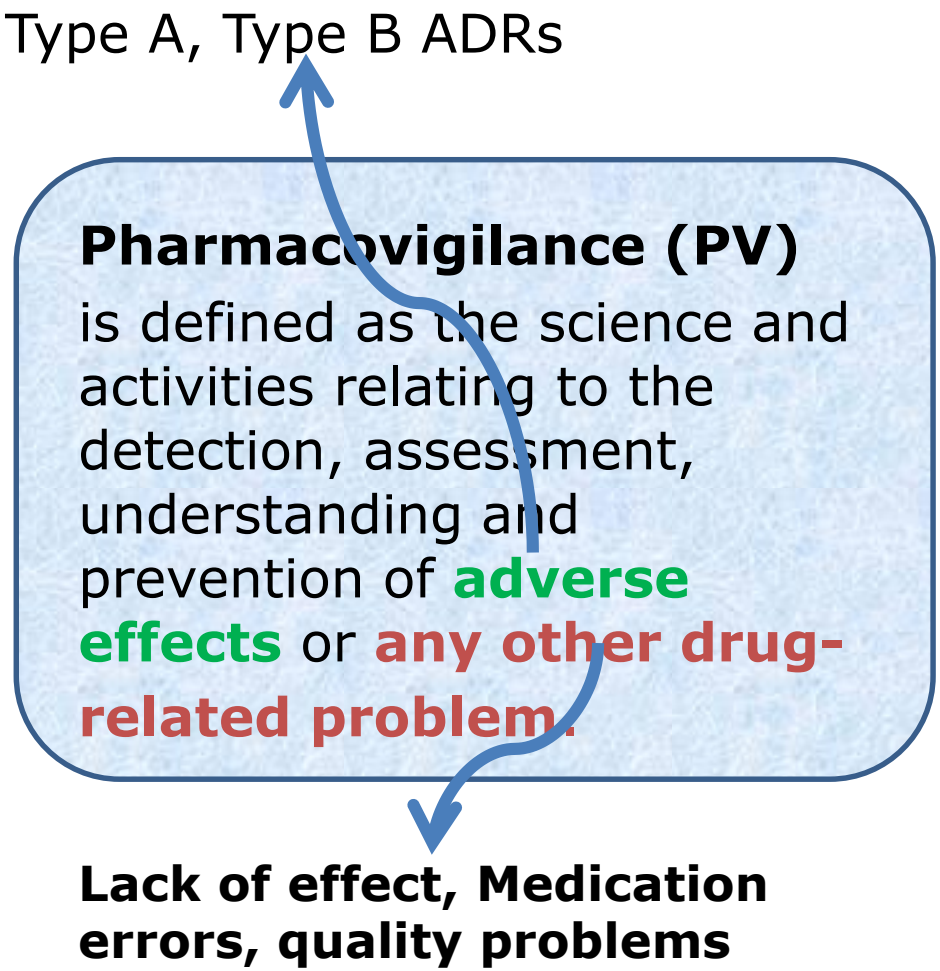
WHO definition of pharmacovigilance



WHO Programme for International Drug Monitoring (PIDM)

Founding members in 1968

10 Countries

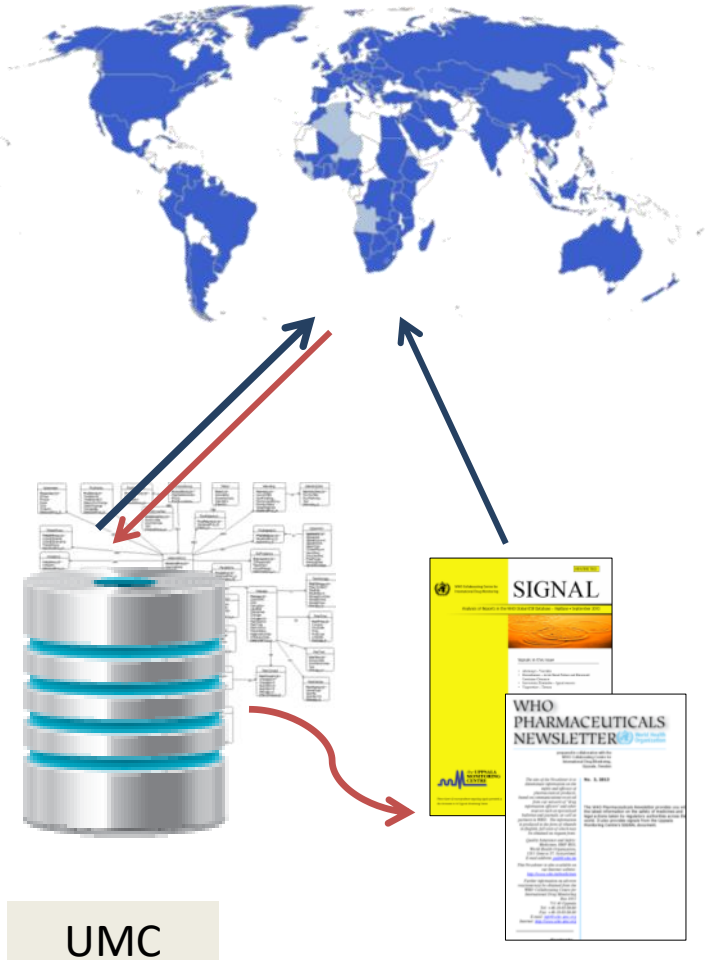
June 2018

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 17 million safety reports and growing
  - 934 888 reports of Medication Error (June 2018)
  - ~ 5% of all ICSRs in database

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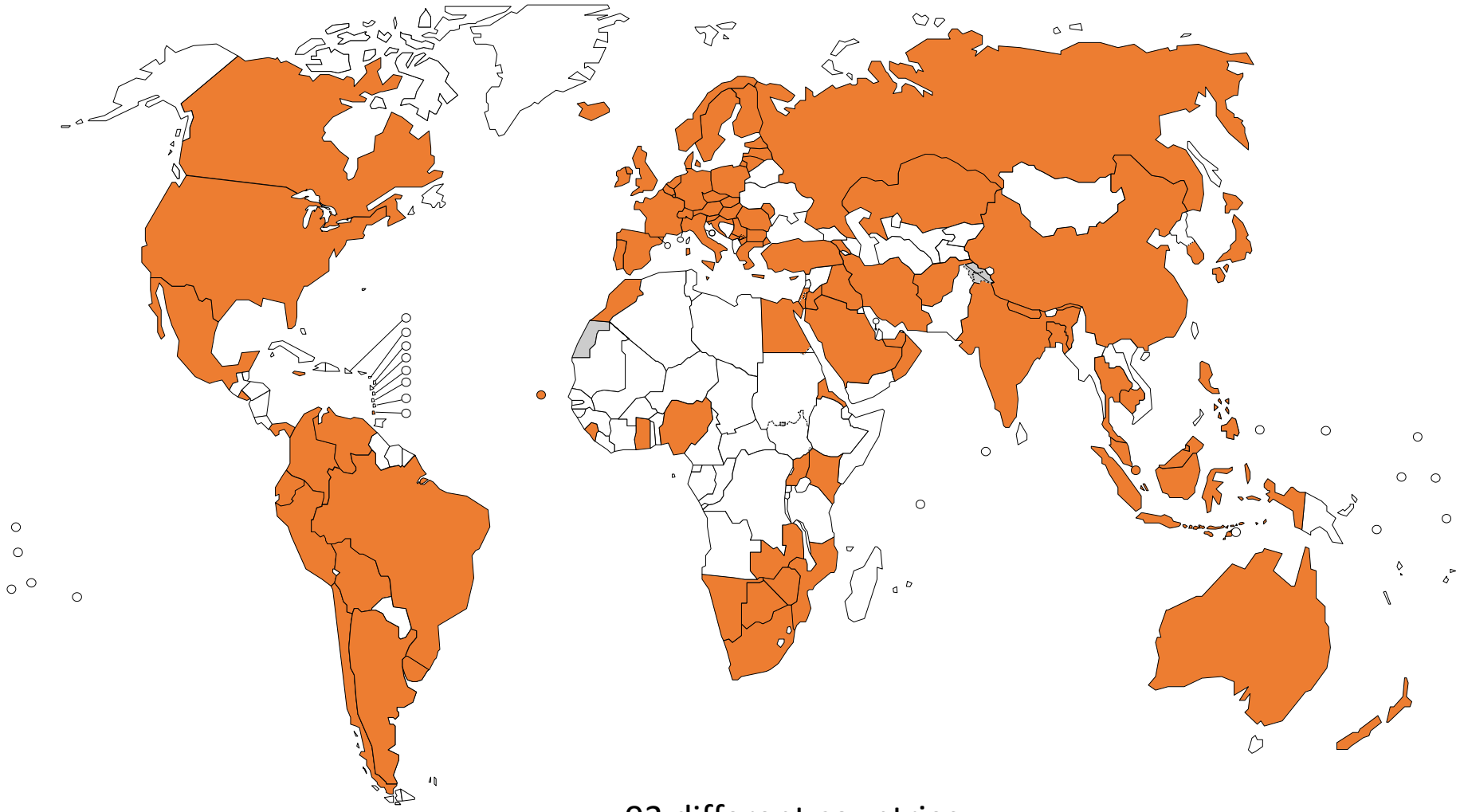
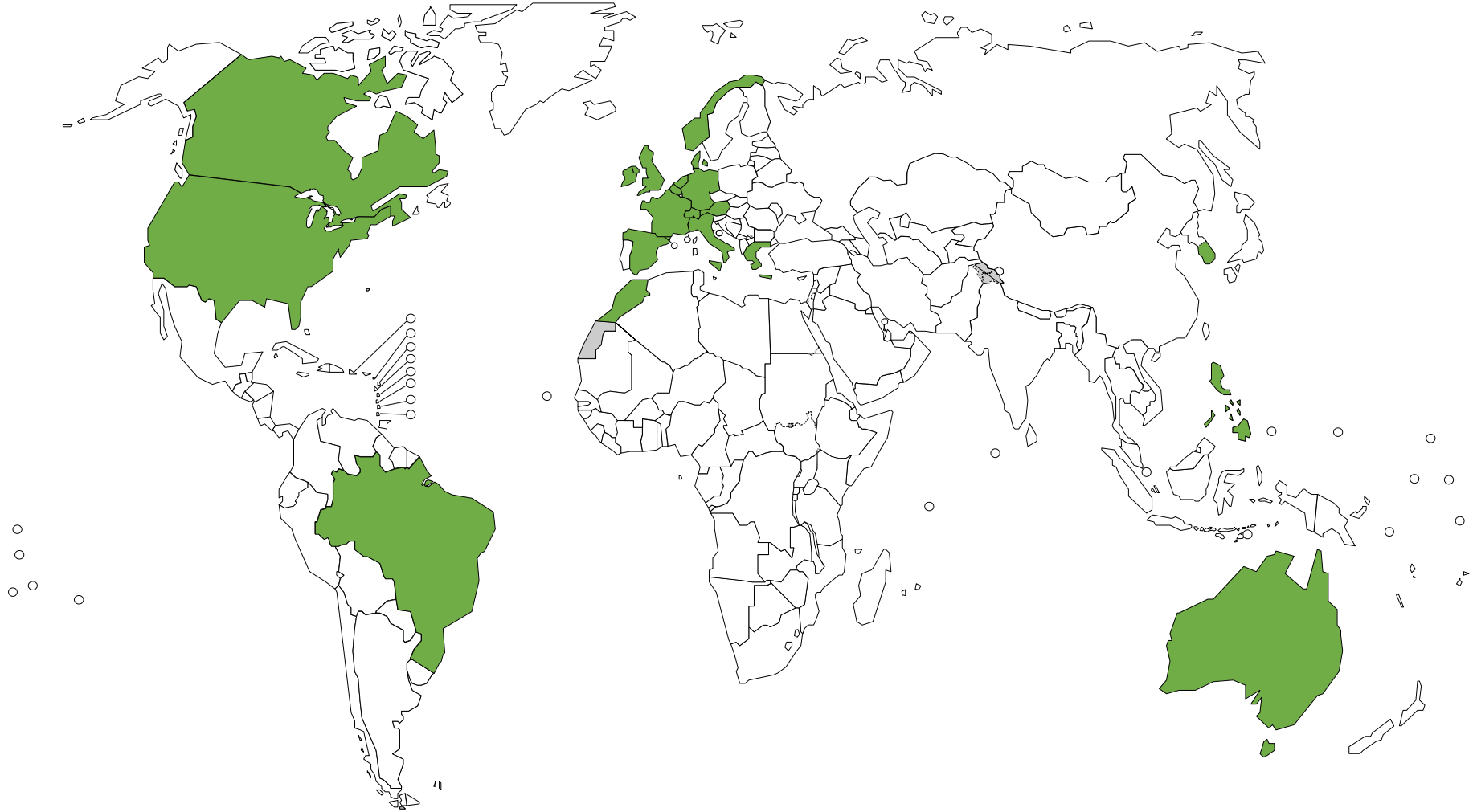
ME Reporting countries
June 2018

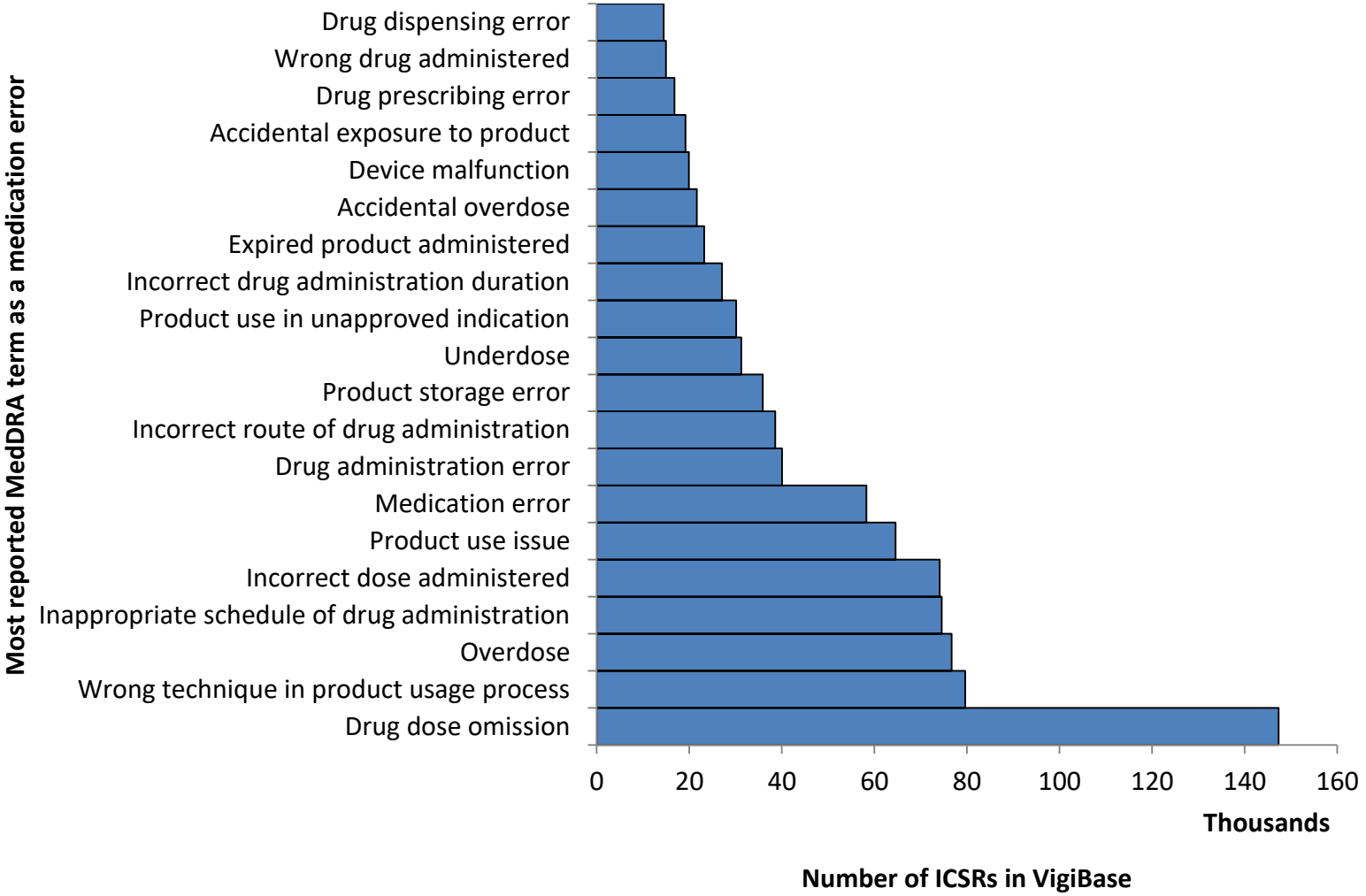


93 different countries

Top 20 ME reporting countries June 2018



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



Top reported MedDRA term for medication errors in each region

Region	Top three reported medication error
Americas	Drug omission Wrong technique in product process Incorrect dose administered
Europe	Overdose Medication error Product in unapproved indication
Eastern Mediterranean	Medication error Incorrect dose administered Inappropriate schedule of drug administration
Western Pacific	Inappropriate schedule of drug administration Medication error Overdose
South-East Asia	Inappropriate schedule of drug administration Medication error overdose
Africa	Overdose Drug administration error Medication error

Reporters

Region	Top three reported medication error
Western Pacific Last 1000 ICSRs (June 2018)	Other Health Professional (79%) Consumer/non health professional (43%) Physician (23%) Pharmacist (14%) Lawyer (1%) Other reporters are not clearly specified
Europe Last 1000 ICSRs (June 2018)	Consumer/non health professional (41%) Physician (21%) Pharmacist (15%) Other Health Professional (14%) Other reporters are not clearly specified
Americas Last 1000 ICSRs (June 2018)	Consumer/non health professional (64%) Physician (13%) Other Health Professional (11%) Pharmacist (10%) Lawyer (<1%) Other reporters are not clearly specified

Please note that many ICSRs do no clearly specify reporters, thus compromising the accuracy of these estimates

Reporters

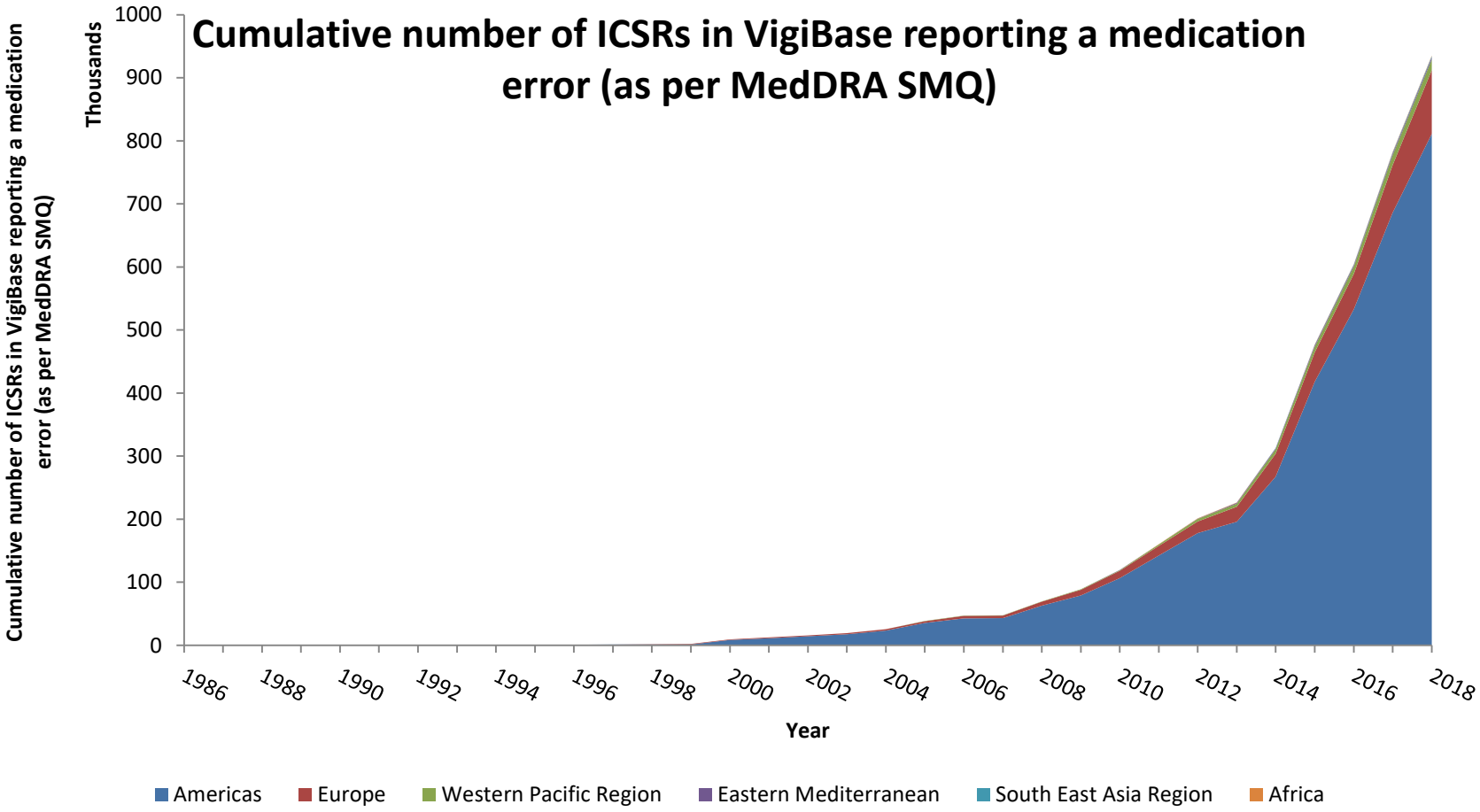
Region	Top three reported medication error
Eastern Mediterranean Year 2017	Physician (34%) Consumer/non health professional (22%) Pharmacist (19%) Other Health professional (19%) Other reporters are not clearly specified
South-East Asia Year 2017	Consumer/Non Health Professional (45%) Physician (15%) Other Health Professional (9%) Other reporters are not clearly specified
Africa Year 2017	Consumer/non health professional (39%) Other Health professional (23%) Physician (22%) Pharmacist (12%)

Please note that many ICSRs do no clearly specify reporters, thus compromising the accuracy of these estimates

Example of signals published for medication errors

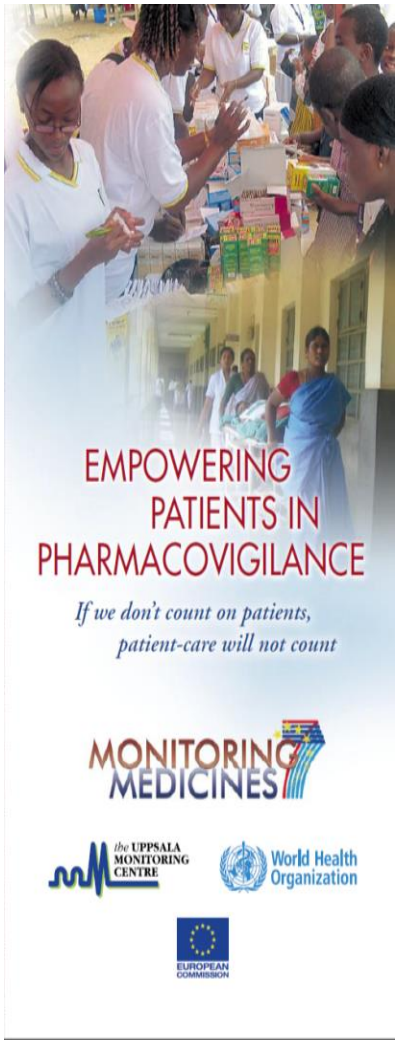
- Agomelatine: inappropriate schedule of drug administration (April 2018)
- Brivudine and 5-fluorouracil: persistence of a fatal drug-drug interaction (April 2018)
- Edoxaban: Incorrect dose administered (April 2018)
- Metamizole: Documented hypersensitivity to administered product (April 2018)
- Methotrexate: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

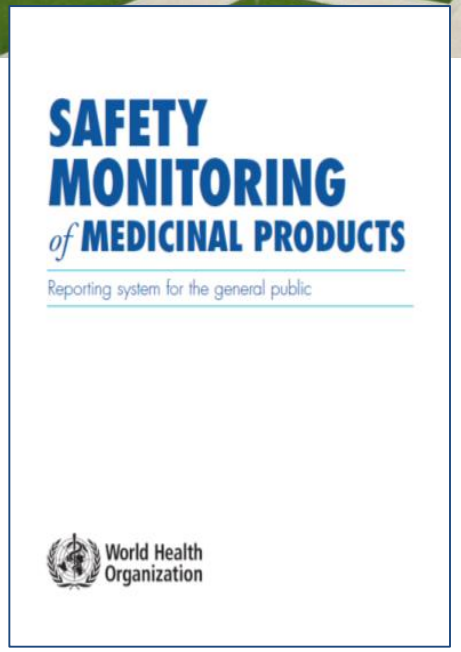
Reports for medication errors per Region



MEs through patient reporting: Empowering patients in pharmacovigilance

Seminar at World Health Assembly 2012





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WHO CC for PV in Education and Patient Reporting

Conference on Patient Reporting

Leiden, Netherlands, April 2015

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WHO Global Patient Safety Challenge

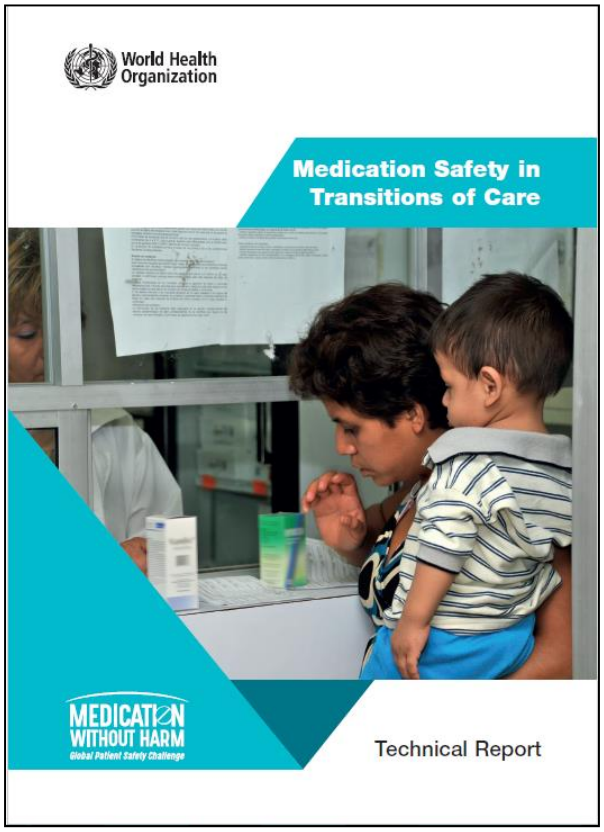
Medication Without Harm

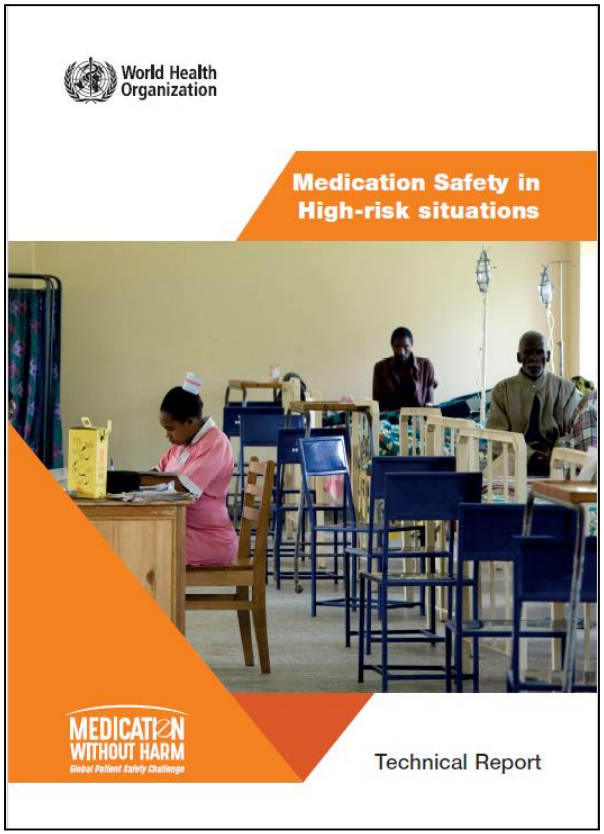
Global Launch, 29 March 2017

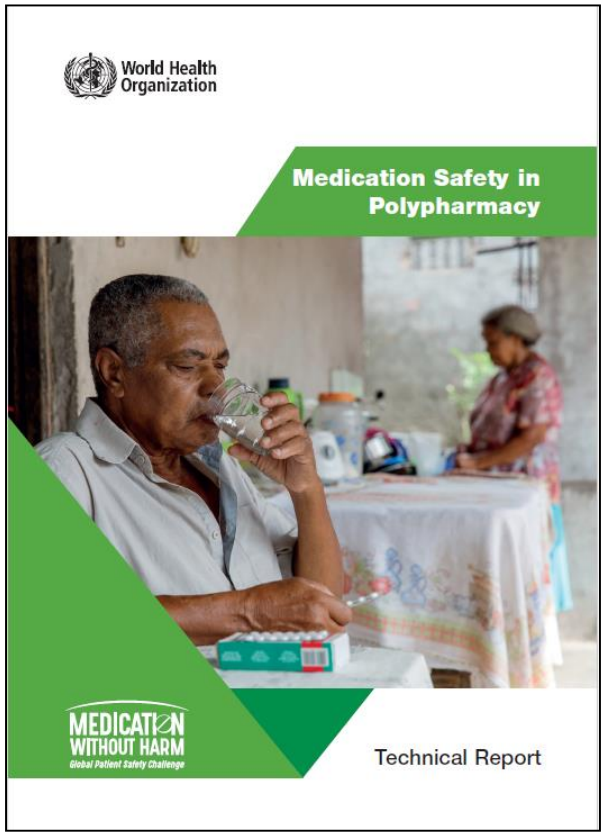
Goal of the Challenge

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

Early Priority Action







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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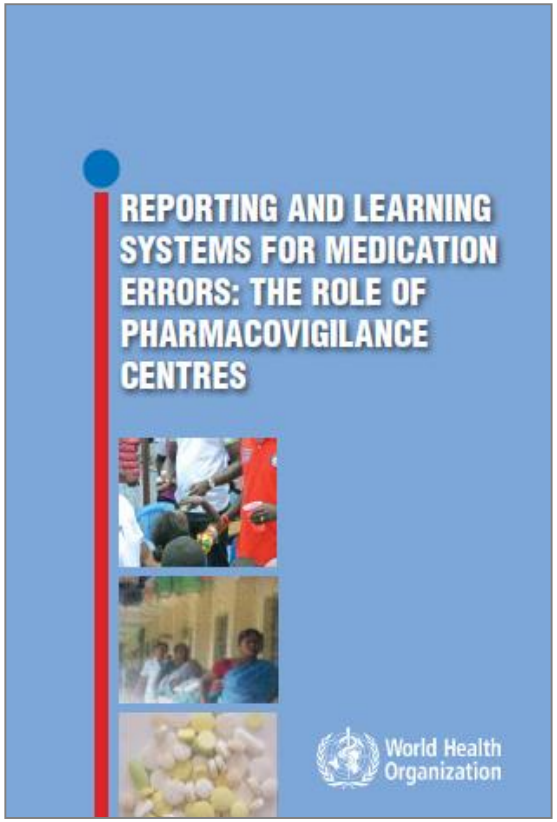
WHO Collaborating Centre for Strengthening Pharmacovigilance Systems & Practices, Rabat, Morocco



Covert 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.

Other developments

- 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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Ms Malin Jacobsson, WHO

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www.who.int/medicines/en

www.who.int/patientsafety