

Medicines Safety in WHO: promoting best practices in Pharmacovigilance

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How it started

- Thalidomide 1961



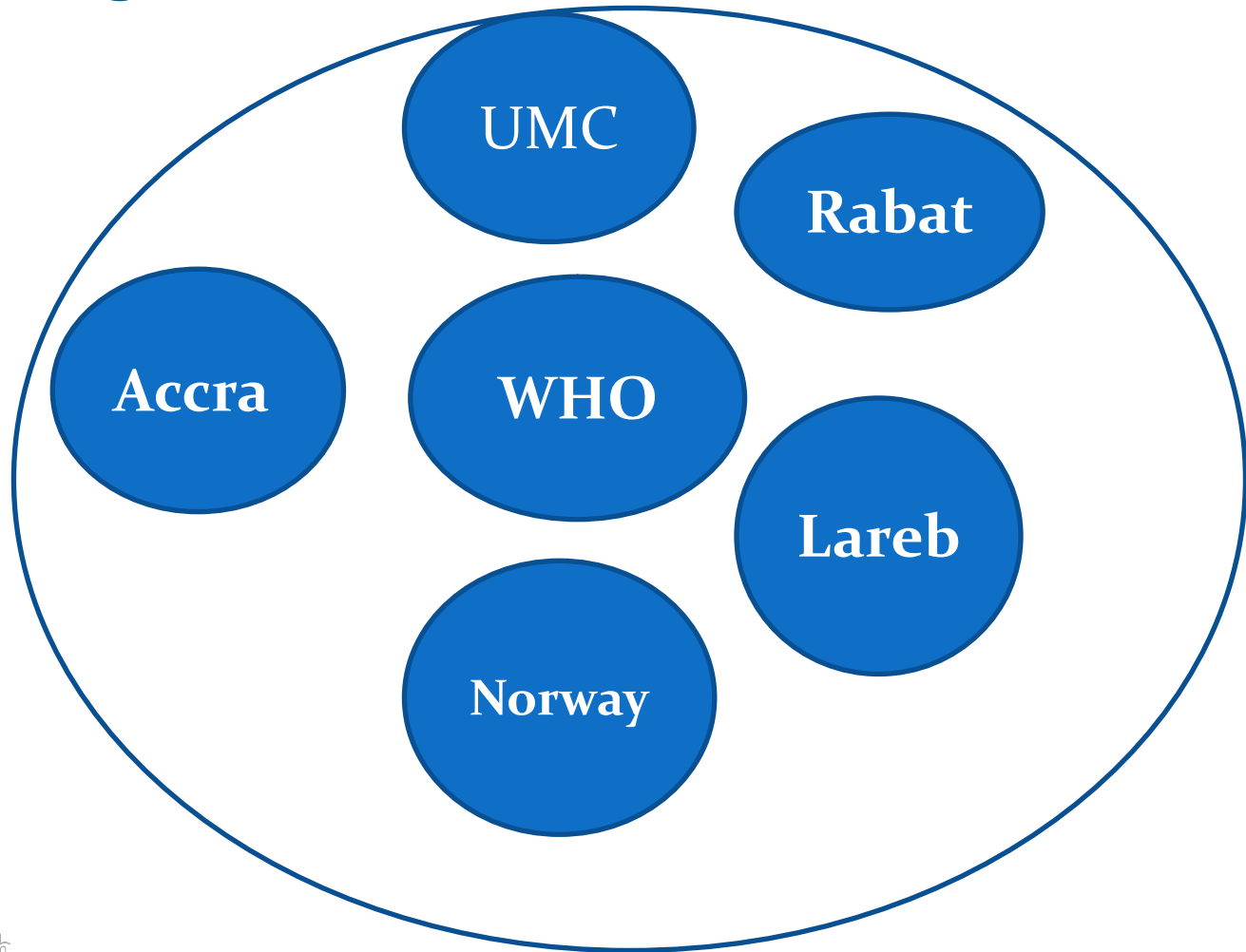
- WHO Prgm. for Int. Drug Monitoring 1968

16th World Health Assembly 1963

Assembly Resolution 16.36 - Clinical and Pharmacological Evaluation of Drugs

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.

WHO Medicines Safety Programme and its Collaborating Centres



Roles and Responsibilities

WHO

- **Policies and strategies for medicines safety and PV**
- **Guidelines, norms and standards**
- **Exchange of information**
- **Training and capacity building**
- **Collaborations: public health programmes**
- **Dialogue with donors**

WHO Collaborating Centres

- **Tools and technologies**
- **Research and Innovation**
- **Implementation / proof of concept**
- **Everyday technical support**
- **Training and capacity building**
- **Exchange of information**
- **Signal detection, communication (UMC)**

Advisory Committee on Safety of Medicinal Products (ACSoMP)

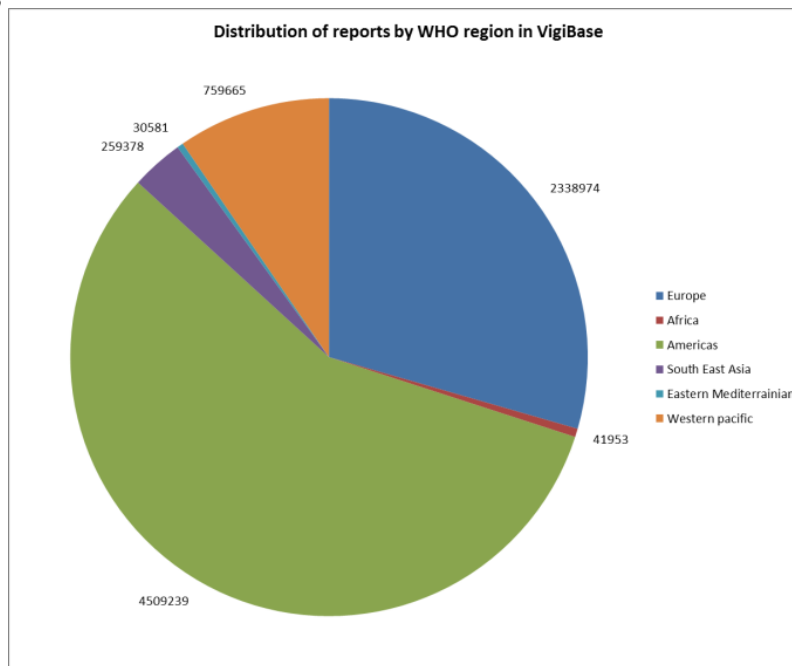
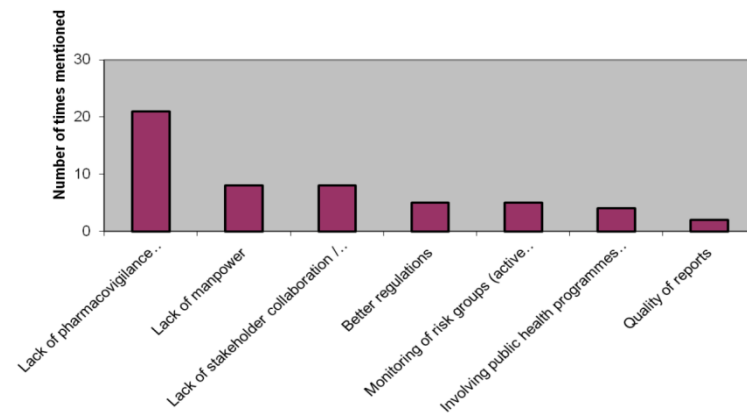
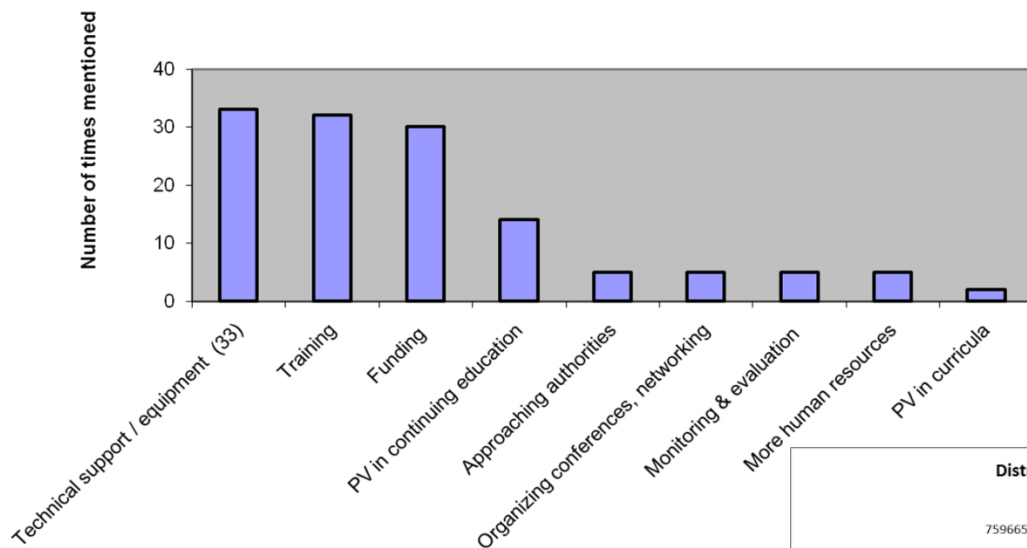
The Advisory Committee on Safety of Medicinal Products provides advice on pharmacovigilance policy and issues related to the safety and effectiveness of medicinal products

- to the relevant Assistant Director-General in WHO and through him / her
 - to the Collaborating Centres for Medicines Safety Programme and,
 - to the Member States of WHO.

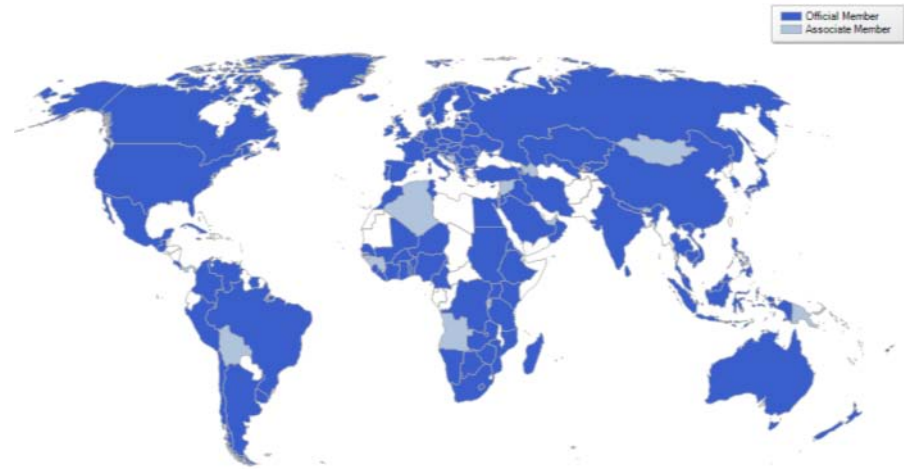
WHO Strategies for advancing pharmacovigilance

- *PV as a tool for for generating evidence to inform policies*

Challenges to PV in LMIC

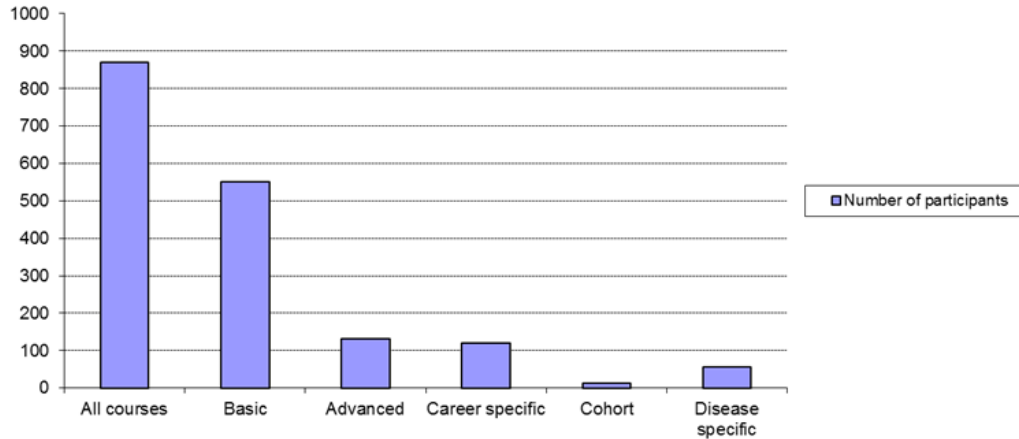


WHO Solutions: First build PV systems

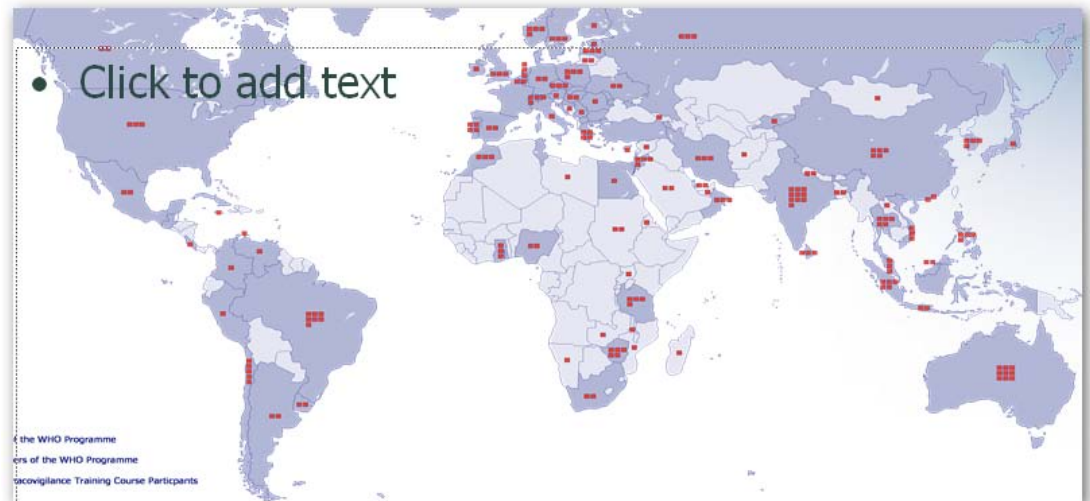


Building capacity for PV in LMIC

Distribution of the types of WHO pharmacovigilance training courses

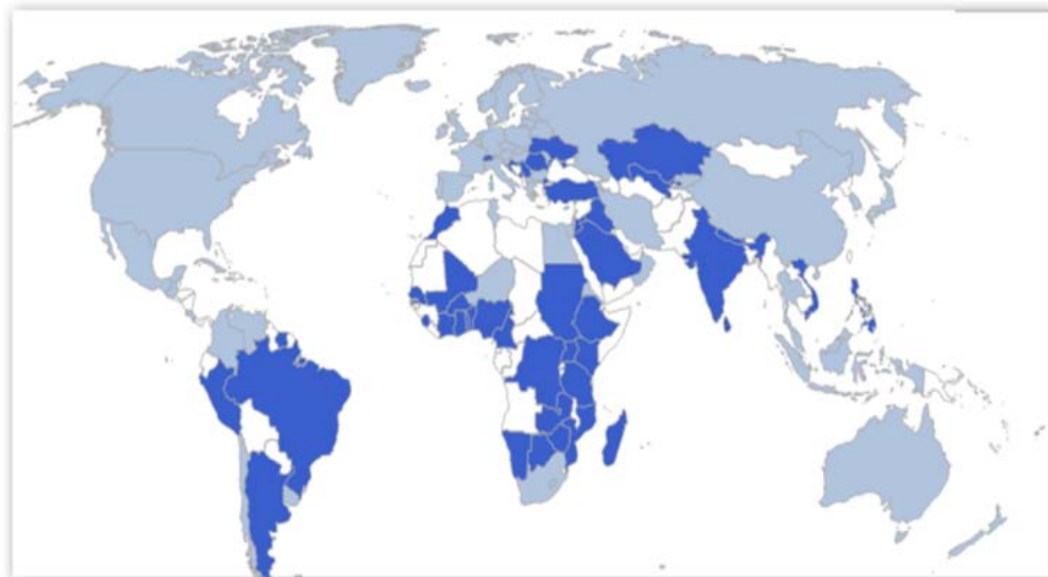
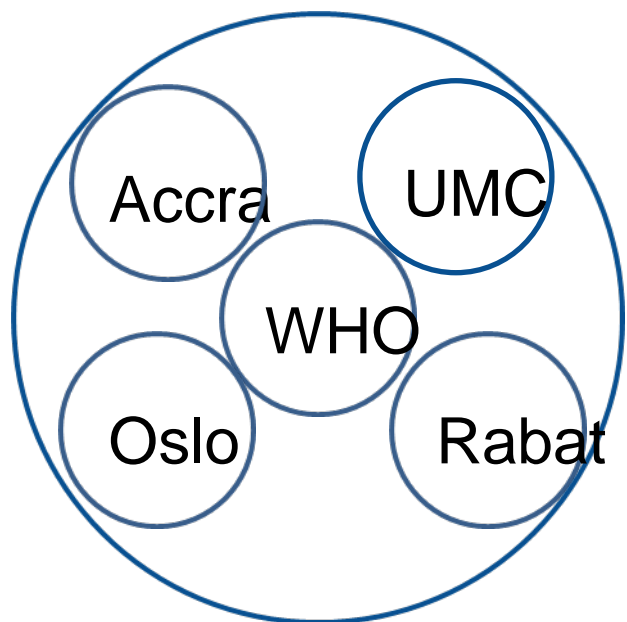


UMC PV courses



Next, support those systems

Countries using Vigiflow data management systems



Global vaccine safety training resources



Pharmacovigilance Toolkit

Home • PV Toolkit • Malaria PV Toolkit • HIV PV Toolkit • TB PV Toolkit • What's New? • Contact Us

Pharmacovigilance Toolkit

This **Pharmacovigilance (PV) Toolkit** is a collection of resources and information needed for the practice of pharmacovigilance. The main aim of its development is to ensure that PV practitioners in low- and middle-income countries get access to information on the processes and activities involved in PV from a trusted source. The Toolkit contents are endorsed by the WHO Advisory Committee on the Safety of Medicinal Products after the original text has been written and reviewed by global experts.

In addition to this website, the Toolkit is available on USB drives in a similar format to this website, for use in areas with poor internet connectivity. The Toolkit is currently available in English, and efforts are underway to have it translated into other languages, although this is dependent on availability of volunteers and/or funding. The Toolkit will be reviewed periodically to ensure that it is abreast with developments in PV.

The Toolkit Management Team is keen to have your feedback such as what you think can be added, removed or modified in order to make its use more beneficial.

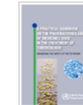
What's New?

WHO E-learning course on Vaccine Safety



This online course covers main elements of Vaccine Safety (definitions, introduction of vaccines and AEFI, surveillance, vaccine safety stakeholders and communication). It targets future WHO training participants, NRA and EPI staff in countries, and any other stakeholders working in areas related to vaccine safety. ...

A practical handbook on the pharmacovigilance of medicines used in the treatment of tuberculosis



ENHANCING THE SAFETY OF THE TB PATIENT ...

Challenges to PV in public health programmes

After nine rounds of GF grants,
access to ARVs is great, but no PV

0 2,500 5,000
Kilometers

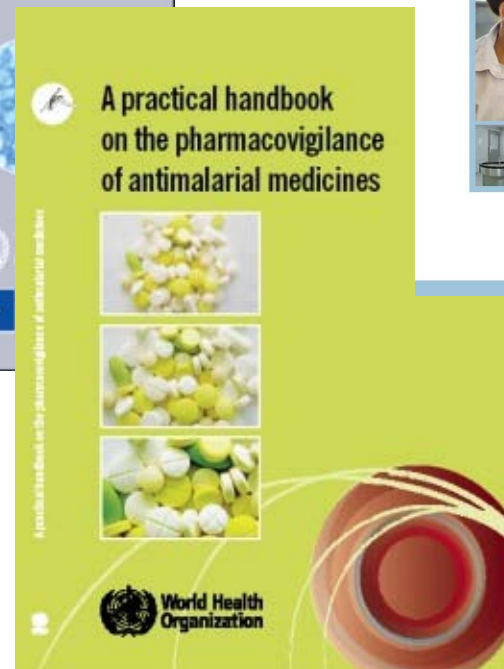
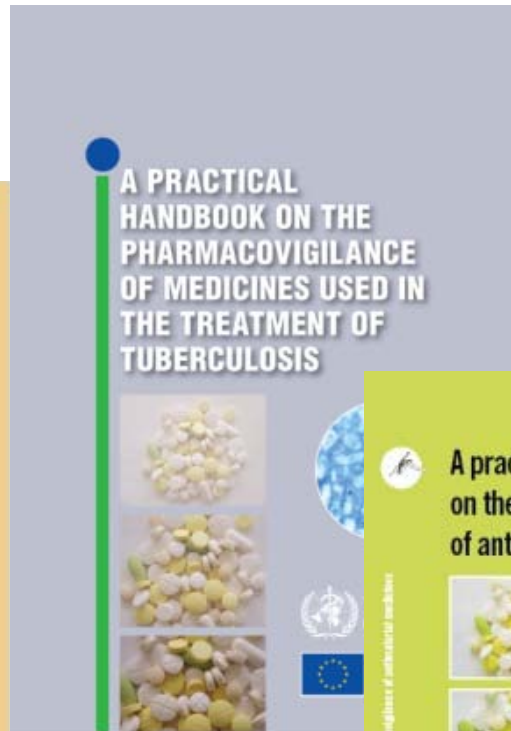
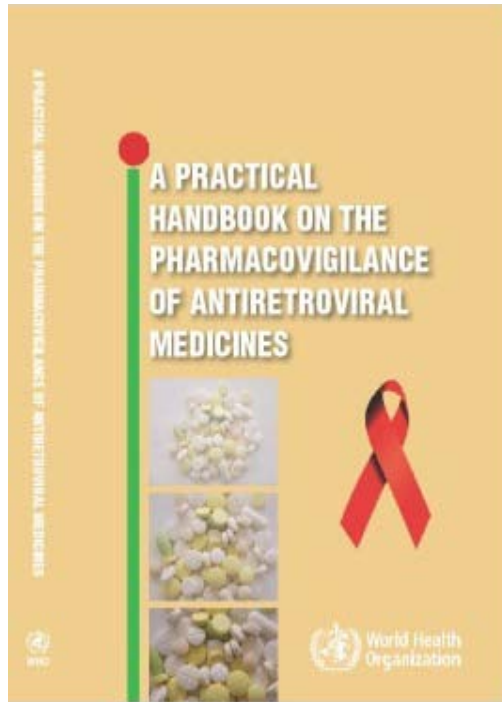
Joint WHO/Global Fund pharmacovigilance strategy

- Establish basic functions and minimum requirements of national pharmacovigilance system

[Min PV req](#)

- pharmacovigilance toolkit to support training and development
 - (www.pvtoolkit.org)
- Strong wording in Round 10 requesting countries to include PV

WHO solutions for pharmacovigilance in public health programmes



Immunization Safety Surveillance

Guidelines for immunization programme managers on surveillance of adverse events following immunization

Second Edition



Multiple scope, multiply cost effectiveness

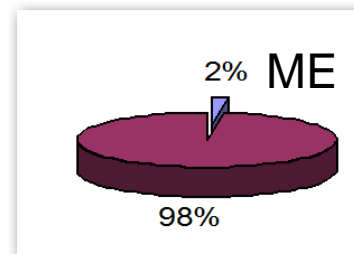
- 2. Make the systems do many things

Make the PV systems do many things

- Collect data

- for benefit harm assessment:
core purpose

- to detect MEs, analyze root cause; propose solutions; improve quality of care



- to detect quality issues → therapeutic ineffectiveness

- detect dependence liability of substances → patterns of ADRs

Additional stakeholders: the full picture

- Direct patient reporting
 - WHO guidelines

SAFETY MONITORING *of* **MEDICINAL PRODUCTS**

Reporting system for the general public



Examples of impact of WHO efforts in LMIC

- Amodiaquine-artesunate antimalarial medicine
 - Signal of Extrapyramidal symptoms from African PV data
 - Led to product information update by company
- Several LMIC now including PV in Global Fund proposals
 - Lancet, 2013
- Active surveillance (Cohort Event Monitoring) of patients on new antimalarials
 - P Bassi et al, Drug Safety, 2013

WHO Strategies for PV

As before

- Build on the strengths of the WHO Programme
 - spontaneous reporting as bed rock of PV

More than before

- Make current practices stronger
 - Focus on limitations of spontaneous reporting (quality, quantity)
 - Additional methods
 - Strengthen and sustain PV systems in LMIC

As never before

- Patients as partners; focus on p-ADRs; PV data for tracking substandard medicines, predicting dependence, biotherapeutics
- Monitoring and assessments (Structure , process, outcome)

Thank you

Website

www.who.int/medicines/areas/quality_safety/safety_efficacy/en

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