Medicines Safety in WHO: promoting best practices in Pharmacovigilance

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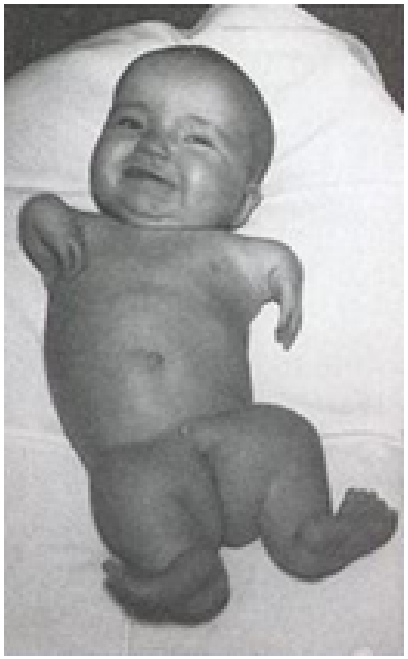
WHO

World Health Organization

How it started



- Thalidomide 1961

- WHO Prgm. for Int. Drug Monitoring 1968

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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.

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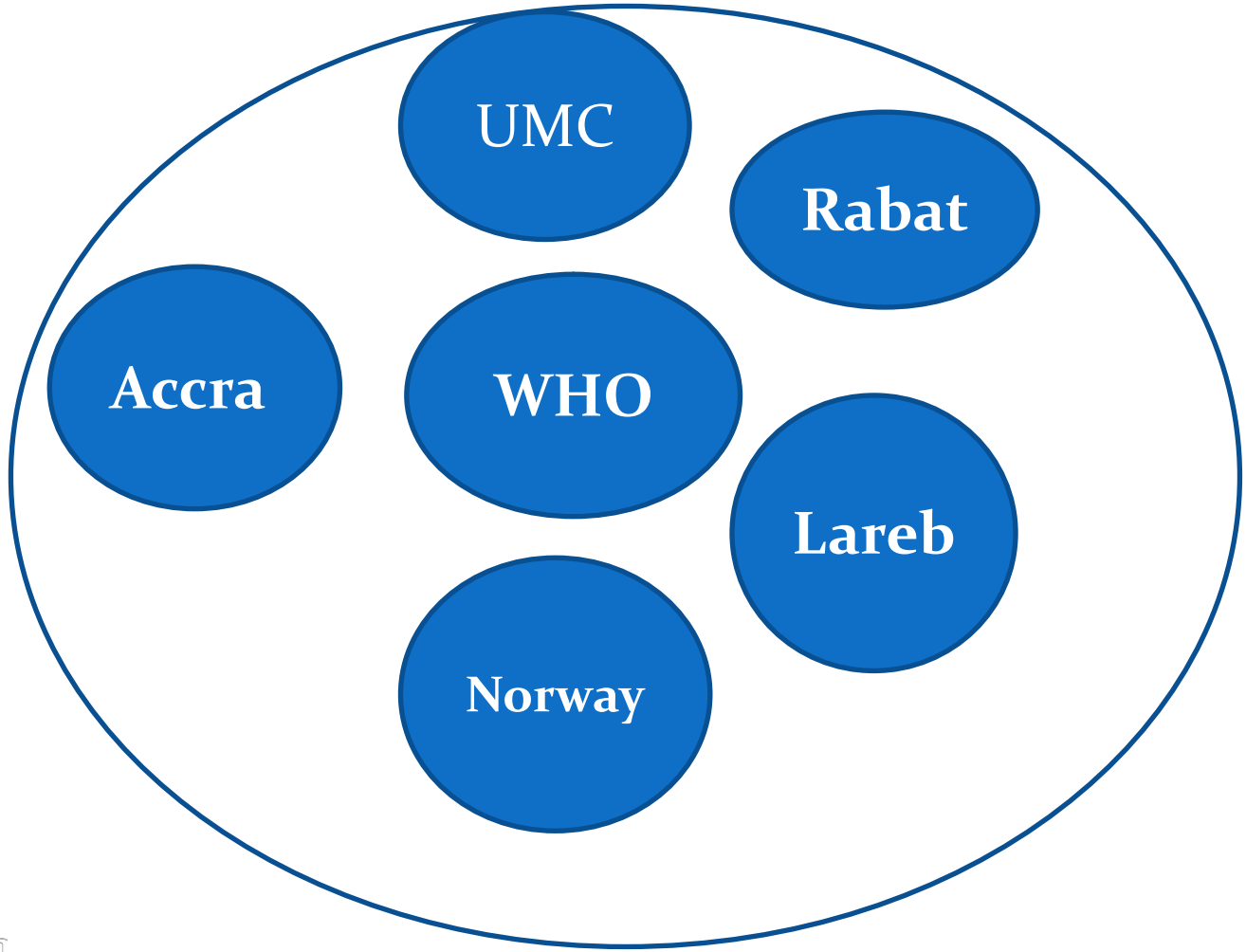
WHO Medicines Safety Programme and its Collaborating Centres



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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)**

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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.

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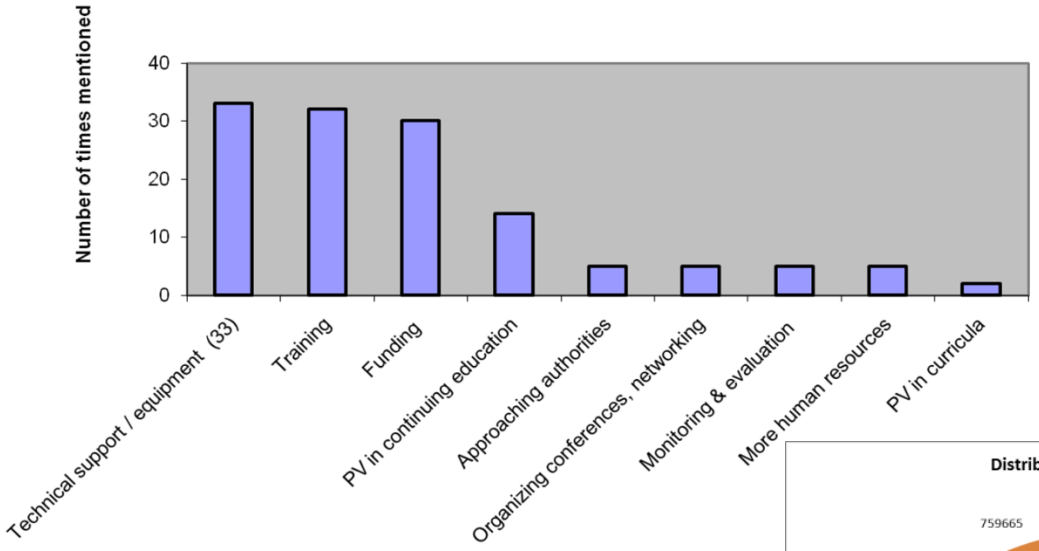
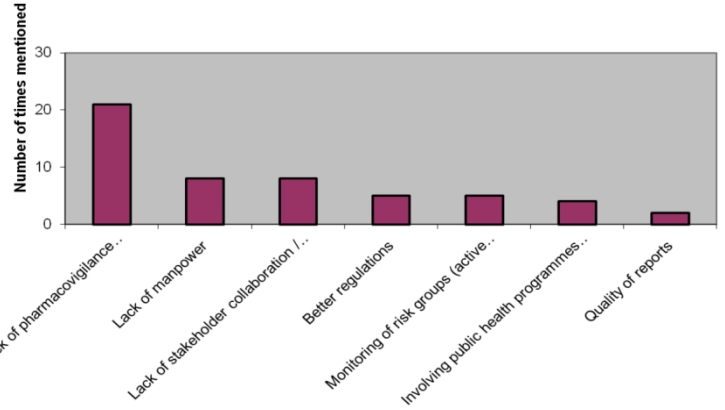
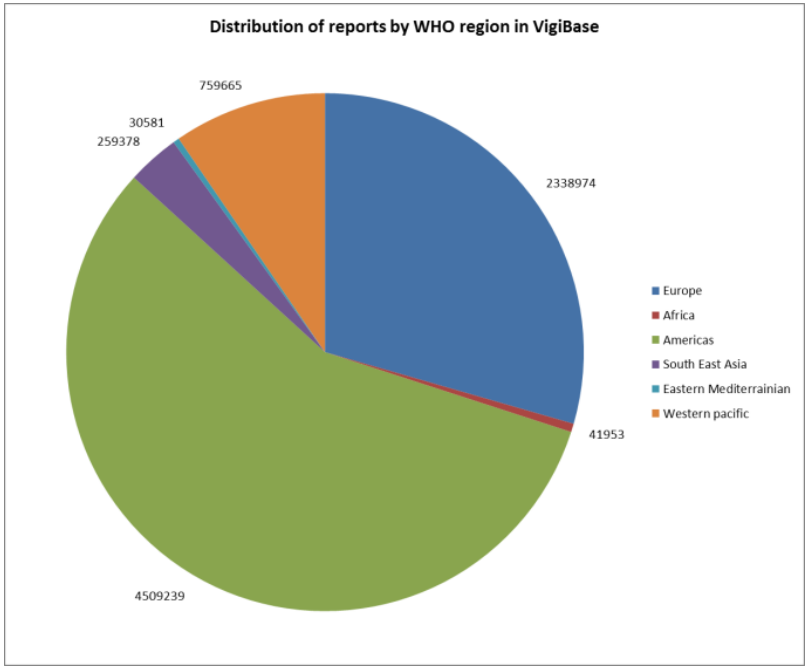
WHO Strategies for advancing pharmacovigilance

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

Challenges to PV in LMIC







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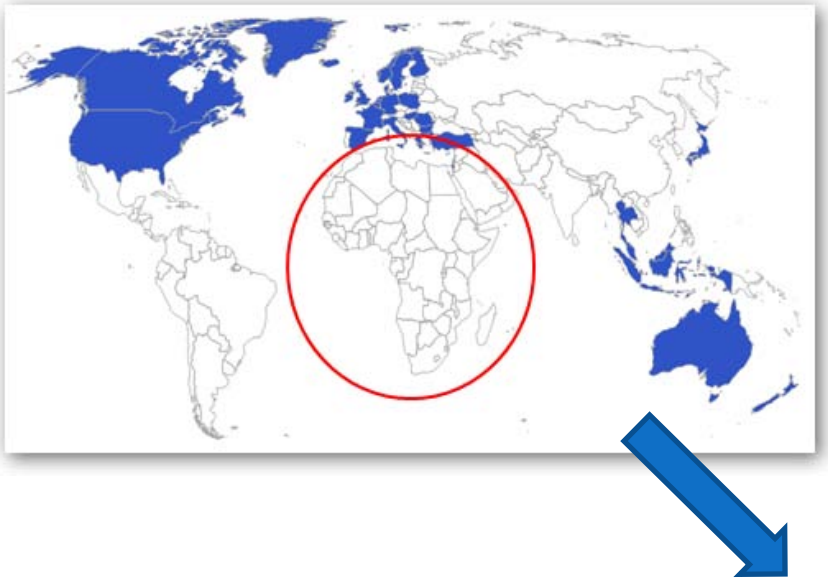
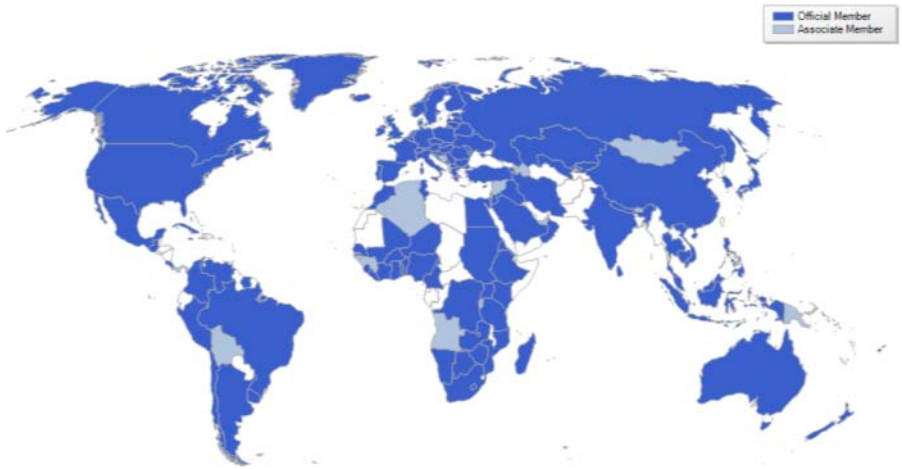
WHO Solutions:
First build PV systems





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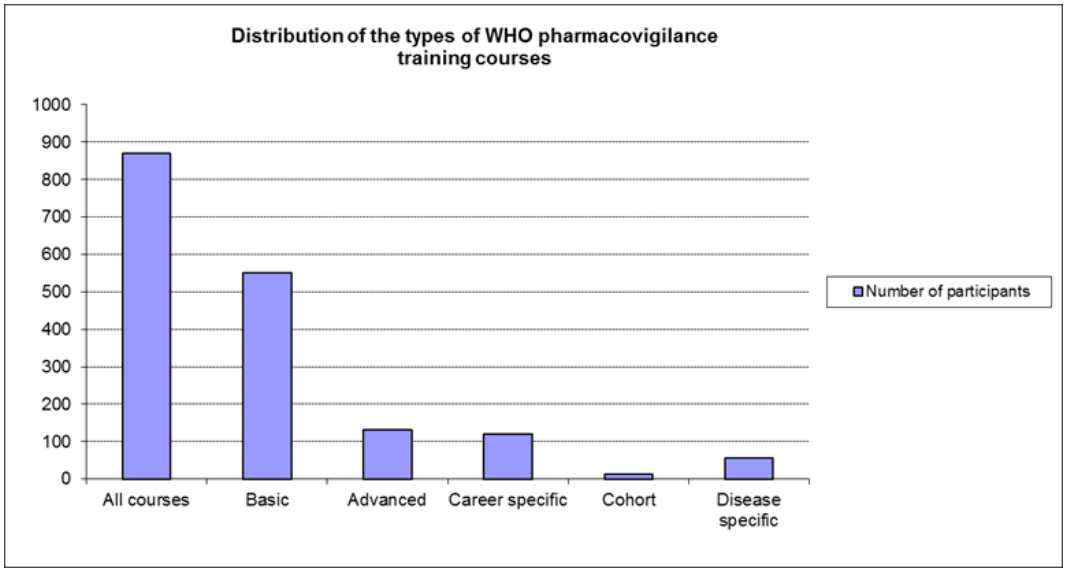
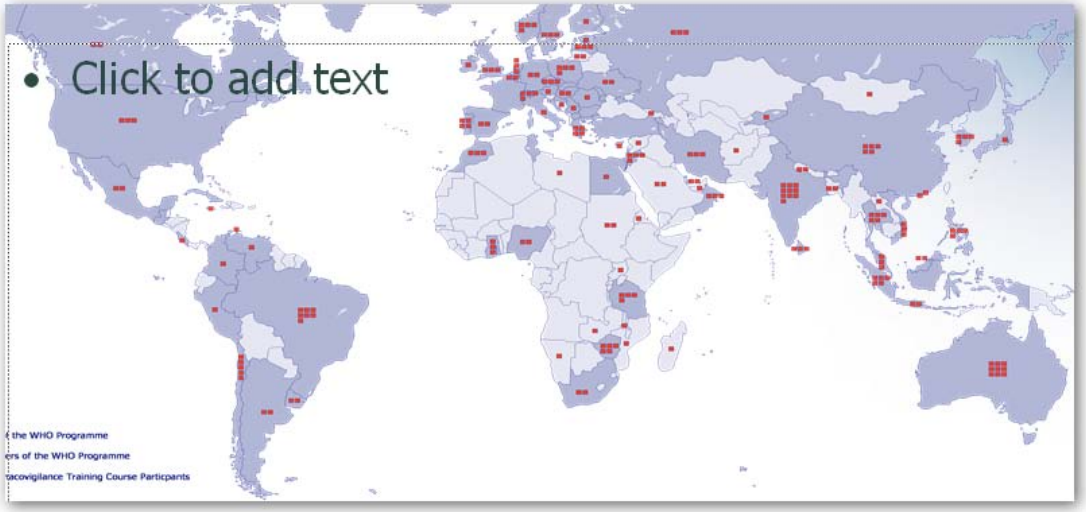
Building capacity for PV in LMIC



UMC PV courses



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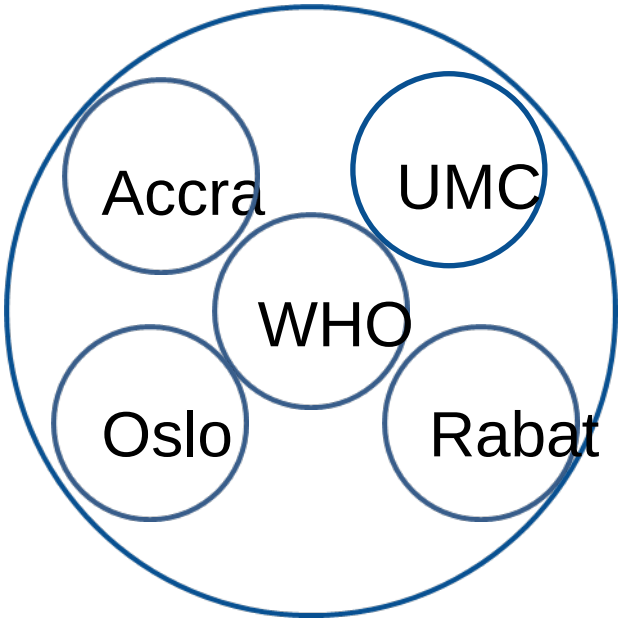
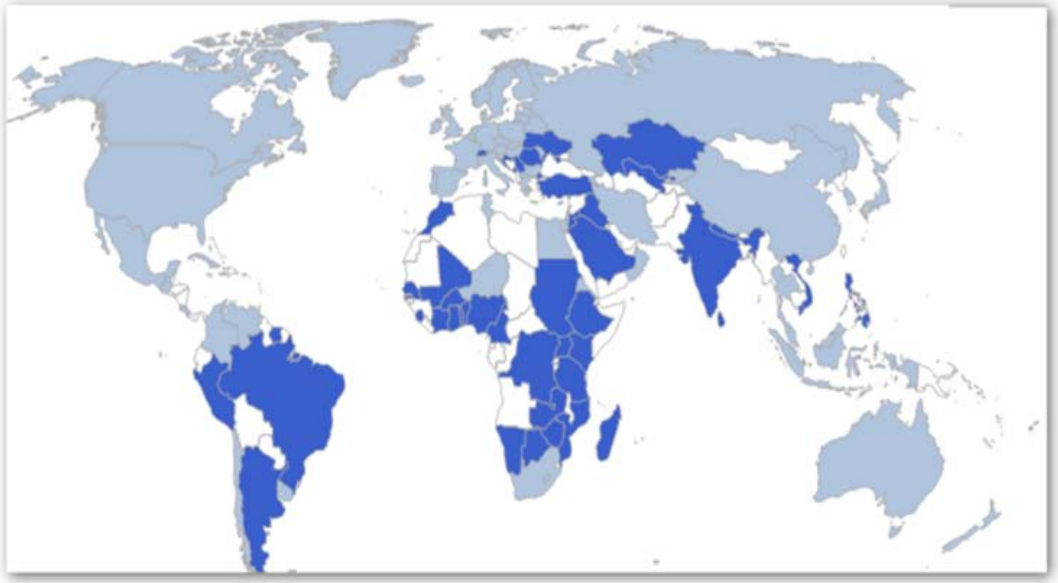
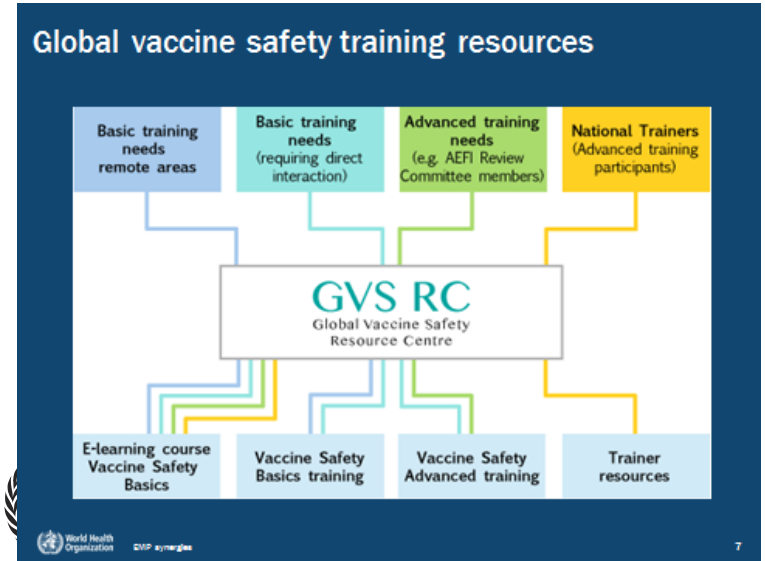
Next, support those systems

Countries using Vigiflow data management systems







Challenges to PV in public health programmes

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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

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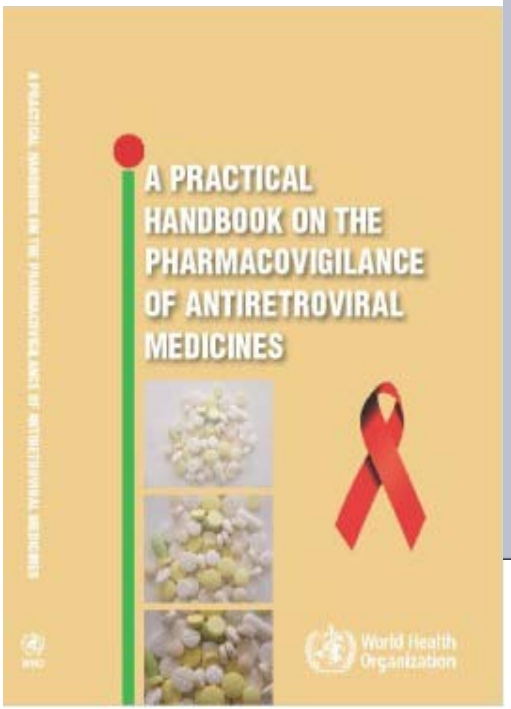
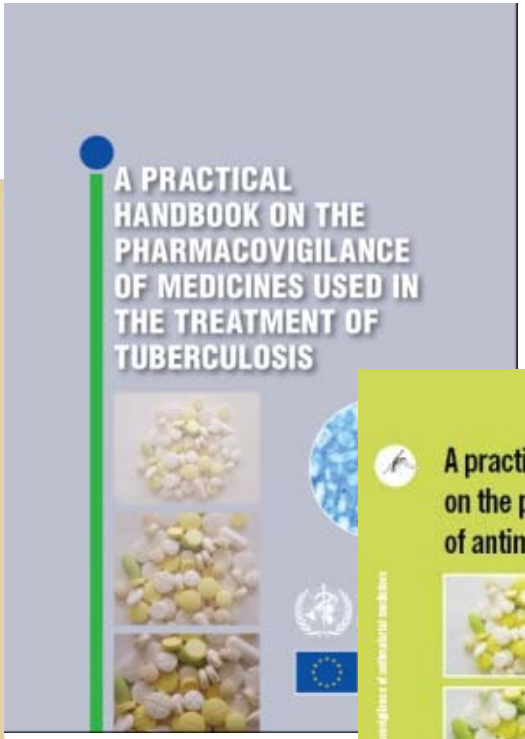
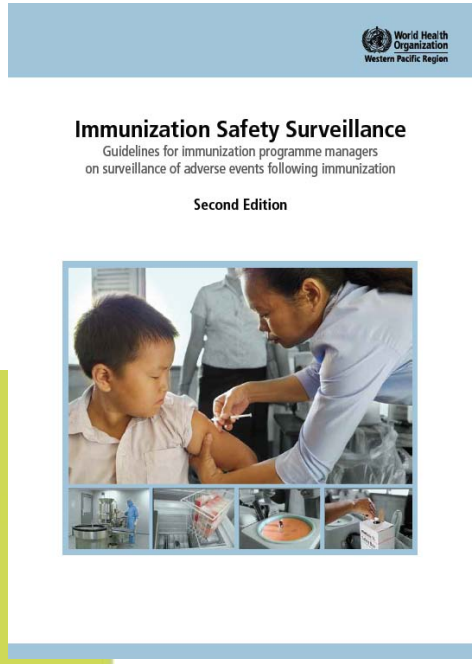
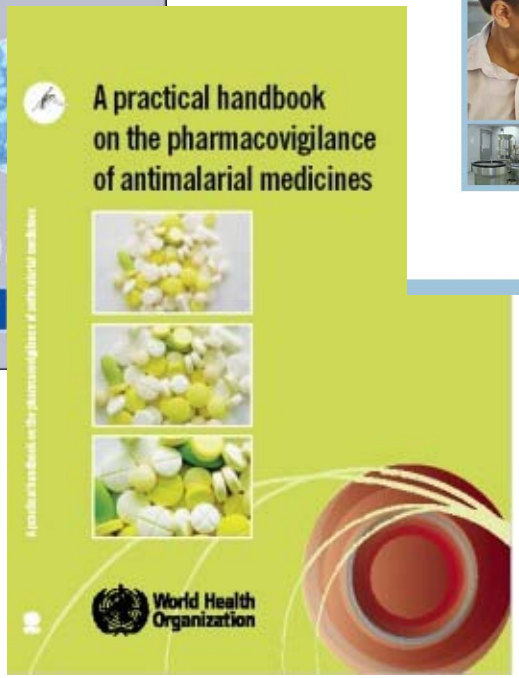
WHO solutions for pharmacovigilance in public health programmes









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Multiple scope, multiply cost effectiveness

- 2. Make the systems do many things

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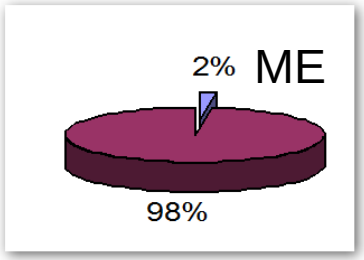
Make the PV systems do many things

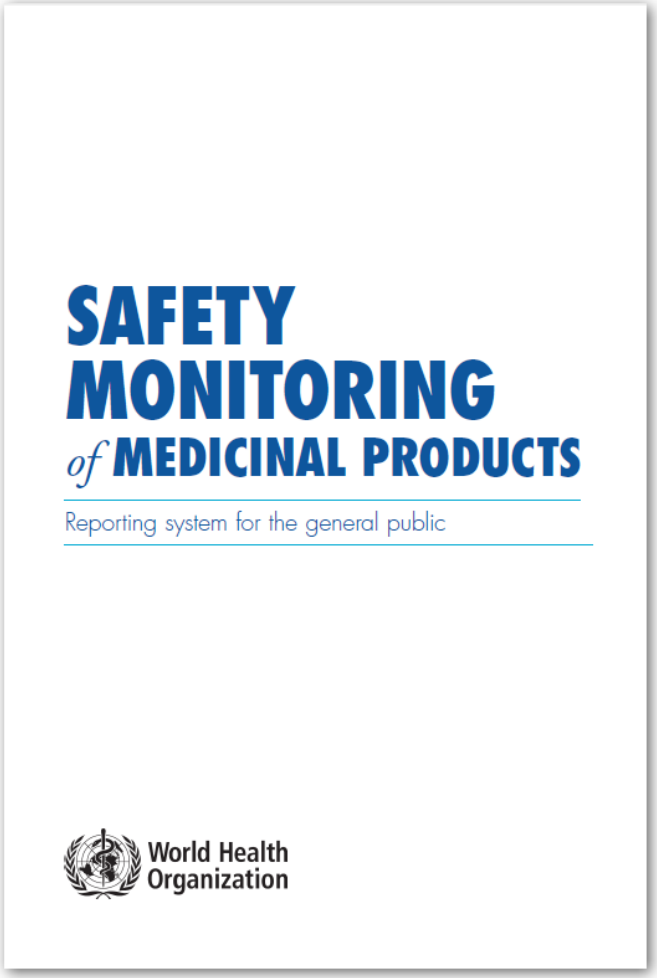
- Collect data
  - for benefit harm assessment: core purpose
  - to detect MEs, analyze root cause; propose solutions; improve quality of care



  - to detect quality issues → therapeutic ineffectiveness
  - detect dependence liability of substances → patterns of ADRs

Additional stakeholders: the full picture

- Direct patient reporting
  - WHO guidelines



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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)

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Thank you

Website

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

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