Medicines Safety in WHO: promoting best practices in Pharmacovigilance

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Essential Medicines and Health Products
WHO
How it started

- Thalidomide 1961

- WHO Prgm. for Int. Drug Monitoring 1968
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

- Accra
- WHO
- Norway
- UMC
- Rabat
- Lareb
## Roles and Responsibilities

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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.
WHO Strategies for advancing pharmacovigilance

- *PV as a tool for generating evidence to inform policies*
Challenges to PV in LMIC
WHO Solutions:
First build PV systems
Building capacity for PV in LMIC

UMC PV courses

- Click to add text
Next, support those systems

Countries using Vigiflow data management systems

Global vaccine safety training resources

Pharmacovigilance Toolkit

What's New?

WHO E-learning course on Vaccine Safety

A practical handbook on the pharmacovigilance of medicines used in the treatment of tuberculosis
After nine rounds of GF grants, access to ARVs is great, but no PV
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
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
  - detect dependence liability of substances

therapeutic ineffectiveness
patterns of ADRs
Additional stakeholders: the full picture

- Direct patient reporting
  - WHO guidelines
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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