Pharmacovigilance: New Challenges for WHO

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Thanks to Dr S Pal, Dr D Tanaka
Pharmacovigilance and WHO Programme for International Drug Monitoring (PIDM)

Future of WHO PIDM

Challenges
WHO PROGRAMME FOR INTERNATIONAL DRUG MONITORING (PIDM)
The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems

The importance of pharmacovigilance, WHO, 2002
WHO Vision for Medicines Safety

No country left behind: worldwide pharmacovigilance (PV) for safer medicines, safer patients

No Patient harmed
The WHO Programme for Pharmacovigilance

The story begins…
History of WHO Programme for International Drug Monitoring

1960

1963 World Health Assembly Resolution 16.36:
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.
History of WHO Programme for International Drug Monitoring

1963 World Health Assembly Resolution 16.36:

1968 WHO Programme for International Drug Monitoring, pilot in ten countries

1960 1965
WHO Drug Monitoring Programme

Founding Members 1968

- Australia
- Canada
- Czechoslovakia
- Ireland
- Netherlands
- Germany
- New Zealand
- Sweden
- United Kingdom
- United States
History of WHO Programme for International Drug Monitoring

- 1960
- 1965
- 1970
- 1975

1963 World Health Assembly Resolution 16.36:

1968 WHO Programme for International Drug Monitoring, pilot in ten countries

1978 Establishment of WHO Collaborating Centre for International Drug Monitoring
WHO Collaborating Centre for International Drug Monitoring: Uppsala Monitoring Centre

- Scientific development and technical expertise
- Signal detection
- Improve visibility and status of PV globally
- Holds and maintains the WHO global database of Individual Case Safety Reports (ICSRs), VigiBase
- Provides technical support to countries and contribute to capacity building (training courses, support missions, publications)
- Provides pharmacovigilance products such as data management tools (e.g. VigiFlow)
**History of WHO Programme for International Drug Monitoring**

- **1960**: World Health Assembly Resolution 16.36
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- **1975**: 1982 Establishment of WHO Collaborating Centre for Drug Statistics and Methodology

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**World Health Organization**
WHO Collaborating Centre for Drug Statistics Methodology

- Located in Department of Pharmacology, Norwegian Institute of Public Health, Oslo, Norway
- Classify drugs according to Anatomical Therapeutic Chemical (ATC) system and establish Daily Defined Dose codes (DDDs)
- Review and revise ATCs and DDDs
- Stimulate and influence practical use of ATC codes e.g. drug utilisation research
- Provide technical support to countries
- Organize training courses in ATC/DDD methodology
- ATC/DDD toolkit to be launched soon
History of WHO Programme for International Drug Monitoring

1960
1965
1970
1975
1980
1985
1990
1995

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1995 Forty-eight countries participating in WHO PIDM
Members of WHO Programme for International Drug Monitoring 2000
History of WHO Programme for International Drug Monitoring

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History of WHO Programme for International Drug Monitoring

- 2009 Establishment of WHO Collaborating Centre for advocacy and training in Pharmacovigilance
- 2007 Establishment of Pharmacovigilance sans Frontiers (PVSF)
- 2000
- 2005
WHO Collaborating Centre for Advocacy and Training in Pharmacovigilance

- Located in Accra, Ghana.
- Advocacy for PV across Africa
- Promote integration of PV into Public Health Programmes
- Support communication and crisis management to National Pharmacovigilance Centres
- Provide technical support to National Pharmacovigilance Centres
- Fellowships, internships, workshops and support missions to countries.
- Maintains a PV toolkit
History of WHO Programme for International Drug Monitoring

2009 Establishment of WHO Collaborating Centre for advocacy and training in Pharmacovigilance

2007 Establishment of Pharmacovigilance sans Frontiers (PVSF)

2011 Establishment of WHO Collaborating Centre for strengthening pharmacovigilance practices
WHO Collaborating Centre for Strengthening Pharmacovigilance Practices

- Located in the Centre anti poison et de Pharmacovigilance in Rabat, Morocco
- Build capacity in Arabic speaking and Francophone countries
- Organize training courses and workshops
- Involved in projects such as integrated pharmacovigilance systems and patient safety.
Growth of Pharmacovigilance in Africa

Growth of pharmacovigilance in Africa between 1995 and 2010

World Health Organization
History of WHO Programme for International Drug Monitoring

2009 Establishment of WHO Collaborating Centre for advocacy and training in Pharmacovigilance

2007 Establishment of Pharmacovigilance sans Frontiers (PVSF)

2013 Establishment of WHO Collaborating Centre for Pharmacovigilance in Education and Patient Reporting

2011 Establishment of WHO Collaborating Centre for strengthening pharmacovigilance practices
WHO Collaborating Centre for Pharmacovigilance in Education and Patient Reporting

- Located in ’S-Hertogenbosch in the Netherlands
- Work on developing and maintaining the core pharmacovigilance curriculum in university programmes
- Promote PV curriculum
- Patient reporting systems
- Provide training in handling patient reports
- Promote research in pharmacovigilance using different data sources
History of WHO Programme for International Drug Monitoring

- **2009** Establishment of WHO Collaborating Centre for advocacy and training in Pharmacovigilance
- **2013** Establishment of WHO Collaborating Centre for Pharmacovigilance in Education and Patient Reporting
- **2000**
- **2005**
- **2010**
- **2015**

Growth of Programme to 153 participating countries

- **2007** Establishment of Pharmacovigilance sans Frontiers (PVSF)
- **2011** Establishment of WHO Collaborating Centre for strengthening pharmacovigilance practices

World Health Organization
Members of the WHO Programme for International Drug Monitoring
1968-2015

153 Members
125 full members
The WHO global ICSR database: VigiBase®

- The oldest and largest Individual Case Safety Reports (ICSRs) database
- Freely accessible to National Centres
- Global + country-specific signal detection
September 2016

- One hundred and twenty five countries contributing to database
- Over 14 million reports of suspected adverse drug reactions known as Individual Case Safety Reports
Total Number of Individual Case Safety Reports (ICSRs) in VigiBase

- **Region of Americas**
- **European Region**
- **Western Pacific Region**
- **South-East Asia Region**
- **African Region**
- **Eastern Mediterranean Region**
Quiz

1) How many countries founded the WHO Programme for International Drug Monitoring in 1968?
   10

2) How many countries are members of the WHO PIDM now?
   153 (125 full, 28 associate)

3) How many of these countries are from low and middle income settings?
   96 (63%)
Quiz

- What is the name of the WHO global database for spontaneous adverse reaction reports?
  
  VigiBase

- Who maintains the database?

  WHO Collaborating Centre of International Drug Monitoring, Uppsala Monitoring Centre (UMC)
WHO and Pharmacovigilance

- Norms and standards
- Information Exchange
- Country Support
- Collaboration with various Stakeholders
- Develop indices and metrics to monitor PV systems and practice
- Integrating PV in to public health programmes
- Establish and co-ordinate a network to provide technical support in PV

World Health Organization
Normative Activities

- Publication of WHO Pharmaceuticals Newsletter
- Anatomical Therapeutic and Chemical (ATC) Classification system and Defined Daily Dose (DDD)
- Guidance from WHO Advisory Committee on Safety of Medicinal Products
- Convene annual meeting of representatives of National Pharmacovigilance Centres participating in WHO Programme for International Drug Monitoring
Policies, Guidelines and Normative Activities

Safeguard of Medicines: A guide to detecting and reporting adverse drug reactions

The SAFETY of MEDICINES IN PUBLIC HEALTH PROGRAMMES: Pharmacovigilance as essential tool

SAFETY MONITORING of MEDICINAL PRODUCTS: Reporting centre for the general public

The IMPORTANCE of PHARMACOVIGILANCE: Safety monitoring of medicinal products
WHO Advisory Committee on Safety of Medicinal Products: norms and standards

- ACSoMP
- Constituted in 2003
- High level group of experts
- Composed of 12 members from all 6 WHO regions

12th WHO Safety Advisory Committee meeting, 2015, Geneva
Chairs: Dr Gerald Dal Pan, US FDA and Dr June Raine, MHRA, UK
Contents:

- Regulatory matters
- Safety of medicines
- Signal
- Feature

Open Access to the WHO Global Medicines Safety

http://www.vigiaccess.org/
Country Support
Establishing and Co-ordinating a Network

Disease Programmes
- Malaria
- Neglected Tropical Diseases
- Patient Safety

National Pharmacovigilance Centres
- Convene annual meeting for National Pharmacovigilance Centres who are members of the WHO Programme for International Drug Monitoring

Other WHO Offices
- Six regional offices
- Over 100 country offices
FUTURE OF PV AND WHO PIDM
Priorities for the future

- Signal detection using other data sources (electronic health records, social media)
- Integration of PV into Public Health programmes
- Pro-active and active surveillance methods for new medicines
- Making use of technology for reporting
- Patient reporting
- Medication errors
- Emergency response (e.g. Ebola)
- Regulatory framework
- Integrated vigilance systems
New Products

- More than 300 products in the pipeline for neglected diseases, HIV AIDS, TB and malaria

- At least half of them will be launched in the coming years in those very settings where there is little or no capacity for post approval monitoring
PV is at the heart of Public Health Programmes (PHPs)

PV contributes to:

- prevent unnecessary harm
- improve clinical practice
- promote rational use of drugs
- support research and education
In most settings PV and PHPs operate in isolation, as independent vertical programmes.

- PV could often remain to be incorrectly perceived as a luxury discipline.
- PHPs would not be neither aware of or trained in the need to detect and report AE.
- PHPs would not always collaborate with PV centres, sometime even not be aware of PV centres.
- Still in general, PV might not be seen as a component of PHP.
PV in LMIC: Challenges Remain

- Lack of resources, political support
- Lack of competence
- Lack of PV systems and/or inadequate function
- Lack of communication and information exchange

WHO survey of PV systems in 55 countries
Solutions

- Improve resources and political support by introducing PV through Public Health Programs
  - Building functional PV systems
  - PV methods to monitor new products
  - Improve accessibility
  - Improve competence

- Improve information exchange, communication and decision making, by overcoming technical barriers and capacity building
Overcome technical barriers to PV in LMIC

VigiFlow

- for receiving and storing ADR reports.
- the entered reports can be extracted as XML files
- can be transferred to other (E2b)databases
- a search and statistics module is built into the system
- Easy to use and error-checking ensures accuracy.
New Products

- More than 300 products in the pipeline for neglected diseases, HIV AIDS, TB and malaria

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Moving forward

WHO Strategy

- Improve capacity to analyze local data and make decisions
  - Policies, legislation guidelines
  - Strengthening/incorporating PV in regulatory authorities

- Strengthen PV systems and functionality
  - Education
  - Patient reporting

- Improve Quality and Quantity of reports
How to prepare for launch of products that are introduced with limited data package

Pilot phase
Few products (New medicine (NCE), New vaccine, Emergency intervention)
Defined number of countries
3- surveillance approach

Spontaneous reporting throughout life of product

Targeted monitoring of specific identified concerns, anytime, but more at the beginning

Active surveillance for all unknown events in the early introduction phase
Essential elements

Principles of work sharing
Standardized methods
Agreed end-points

- Informs policy and regulation
- Strengthens system, structure, and stakeholder coordination
- Supports signal generation
- Supports risk management and communication
- Sustainable

Leverage existing infrastructure / platforms
- Existing platforms (e.g. National and Regional PV Centres, databases, WHO Programme, Vigibase)
- Ongoing initiatives (e.g. APEC, ASEAN)
- Other partners (e.g. MAH)
Thank you