

# Update from the Pharmacovigilance Workstream

Shanthi Pal, Alex Dodoo, Serge Xueref  
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WHO Collaborating Centre for Advocacy & Training in Pharmacovigilance, University of Ghana Medical School



# History

- The PV workstream (created in 2009) used to be part of the PSM Working Group
- Opinions were divided as to whether PV belonged to the PSM-WG or the CMWG
- After consultations, PV Workstream moved to the CMWG in 2012



# Terms of Reference of PV Workstream

- To facilitate and guide the various international and in-country efforts in pharmacovigilance of antimalarials on behalf of RBM's CMWG
- To create a central repository of all independent ***malaria-focused*** pharmacovigilance activities
- To work with all partners including the WHO on resource mobilization for PV
- To assist countries in the implementation of PV programmes
- To contribute to the advocacy process for PV in malaria-endemic countries

– *\*\*Malaria has often been the entry-point for PV in most malaria endemic countries*



# Activity update (up to 2012)

- Provided support to countries (PRs) in completing GF proposals
- Hosted an RBM PV advocacy event at ISoP 2010 in Accra, Ghana
- Facilitated the incorporation of specific PV questions into GF applications
- Provided guidance on PV to AMFm countries
- Published an assessment of ADR reporting to antimalarials
- Developed the PV Toolkit ([www.pvtoolkit.org](http://www.pvtoolkit.org)) and the malaria PV toolkit



RESEARCH

Open Access

# Assessment of global reporting of adverse drug reactions for anti-malarials, including artemisinin-based combination therapy, to the WHO Programme for International Drug Monitoring

Andrea Kuemmerle<sup>1,2,3</sup>, Alex NO Dodoo<sup>4</sup>, Sten Olsson<sup>5</sup>, Jan Van Erps<sup>6</sup>, Christian Burri<sup>1,2</sup>, Paul S Lalvani<sup>7\*</sup>

## Abstract

**Background:** In spite of enhanced control efforts, malaria remains a major public health problem causing close to a million deaths annually. With support from several donors, large amounts of artemisinin-based combination therapy (ACT) are being deployed in endemic countries raising safety concerns as little is known about the use of ACT in several of the settings where they are deployed. This project was undertaken to profile the provenance of the pharmacovigilance reporting of all anti-malarials, including ACT to the WHO adverse drug reaction (ADR)



# The Pharmacovigilance Toolkit

## [www.pvtoolkit.org](http://www.pvtoolkit.org)

- A collection of resources and information needed for the practice of pharmacovigilance
- Main aim is to ensure that PV practitioners in low- and middle-income countries get access to information on PV from a trusted source
- Toolkit contents endorsed by the WHO Advisory Committee on the Safety of Medicinal Products
- Web-based (but USB versions are also available)





# Pharmacovigilance Toolkit



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## 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.

Development of the PV Toolkit was supported by a generous grant from the Global Fund.

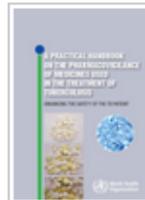
## What's New?

### 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 ...

### Safety Monitoring of Medicinal Products - Reporting system for the general public



# Going Forward

- Most of the activities conducted had been in an era of just two ACTs for most malaria-endemic countries in Africa (AA+AsAq)
- We now have an era of multiple ACTs
- Malaria landscape is rapidly changing and need for PV is increasing
- Several malaria endemic countries are now members of the WHO Programme for International Drug Monitoring



# ECSC Priorities

- **Promote adoption of T3 (Test. Treat. Track.)**
  - 6. Map malaria pharmacovigilance activities in all malaria endemic countries
  - 7. Update the pharmacovigilance malaria toolkit



# Mapping Malaria PV Activities

- In collaboration with WHO, national PV Centres and national malaria control programmes
  - Activities from EDCTP, MMV, INESS, research institutions, ongoing work on RTSS etc all to be mapped to ensure that safety studies are harmonised and standardised and that data is shared real-time
- Will be part of the work of the WHO-CC for Advocacy and Training in PV in Accra Ghana to provide country PV situations in real time



# Updating Malaria PV Toolkit

- Toolkit reviewed and accessed
- Comments include
  - Need for more tools
  - Need for regular updates
  - Need for active promotion on the existence of the toolkit
  - Re-writing of sections of the malaria PV toolkit
  - Re-writing of aspects relating to the Global Fund
  - Inclusion of missing chapters
- Toolkits Manager recruited by WHO-CC to lead this full time



# Building capacity for PV

- Not a PV Workstream activity directly but allied to capacity building in Africa in general
- 4-week “Pharmacovigilance Fellowship” at the WHO Collaborating Centre for Advocacy and Training in PV, Accra, Ghana
- Theory, Hands-on Practice, Field Visit (Hospital, Research Sites, Industry, NRA), Work Plan Development
- Starting June 2013



# Conclusion

- PV Workstream aims to let patient safety issues play a key role in case management
- PV-WS will provide the tools and expertise to RBM and countries to ensure the practiced of sound PV
- Data sharing to be encouraged especially the reporting of ADRs to ACTs
- New methods to be explored



# Thank You!!!!!!

## Contact Details

- **Email:**
  - [alex.dodoo@umcafrica.org](mailto:alex.dodoo@umcafrica.org)
  - [alexooo@yahoo.com](mailto:alexooo@yahoo.com)
- **Skype ID**
  - alexdodoo

