Pharmacovigilance and post-registration studies capacity

Haggar Hilda Ampadu (Deputy Director)

&

Alex Dodoo (Director)

WHO Collaborating Centre for Advocacy and Training in Pharmacovigilance, Accra Ghana

EDCTP Stakeholder Meeting on Capacity Development

Berlin, Germany, 3rd July 2014

CENTRE FOR TROPICAL CLINICAL PHARMACOLOGY & THERAPEUTICS, UNIVERSITY OF GHANA MEDICAL SCHOOL

WHO COLLABORATING CENTRE FOR ADVOCACY & TRAINING IN PHARMACOVIGILANCE

Overview

- Capacity for PV and post-registration studies
- Current initiatives
- Building upon existing activities and structure
- Way forward and conclusions

Capacity for Pharmacovigilance

WHO definition for pharmacovigilance:
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

Drug = medicines, vaccines, herbals etc.
"Drug-related problems" include SSFFCs (spurious, sub-standard, fake, falsified and counterfeit medicines), rumour-induced problems, problems during mass treatment programmes

Capacity for PV

- No objective measure currently exists for measuring capacity for PV in member states
- WHO PV Indicator has been recently launched but it is yet to be fully validated
- Indicator-based Pharmacovigilance Assessment Tool (IPAT) from MSH/SIAPS has also been developed but not yet validated
- WHO's concept of "minimal capacity is thus mostly used"
- Or the number of ADR reports (Individual Case Safety Reports – ICSRs) submitted annually by the country to the WHO ICSR database – Vigibase –per million inhabitants

Minimal Capacity

- According to WHO, a country is considered to have "minimal capacity" for PV if it has the following:
  1. A National PV Centre with at least one full-time dedicated staff and in membership of the WHO Programme for International Drug Monitoring
  2. A national spontaneous reporting system
  3. A database for adverse drug reactions
  4. A Pharmacovigilance Advisory Committee
  5. A Communication Strategy

The African Situation

- Regardless of what measure is used, PV and post-registration studies (PRS) capacity in Africa is weak
- The situation is improving thanks to dedicated and continuous efforts by WHO and the WHO-CC in Accra, Morocco together with other partners
- But support is needed to ensure sustainability of the gains made so far

The WHO PV Programme

(as at 30th June 2014)

Official Members (dark blue): 118
Associate Members (light blue): 29

The status of Africa within the WHO PV Programme

(as at 30th June 2014)

Official Members (dark blue): 32
Associate Members (light blue): 5

Ass. Members

1. **Algeria**
2. **Burundi**
3. **Gambia**
4. **Guinea-Bissau**
5. **Zanzibar**

However….

- Most of the countries only joined the WHO Programme recently
  - 2009-2014: 17 members out of 32
  - 2000-2009: 10 members
  - 1992 (South Africa; Morocco) – 1999: 5
- Number of ICSRs submitted very very low
  - Less than 1% of the 9million ICSRs in Vigibase come from Africa
- WHO-CC in collaboration with WHO and UMC have been investigating and supporting…….

Reporting In Africa

Total number of ICSRs from African countries (cumulative)

	African countries
2004	6,424
2005	7,246
2006	8,401
2007	10,786
2008	11,319
2009	16,638
2010	20,895
2011	26,650
2012	41,133
2012.5	49,387
2013	55,192
2013.5	62,967
2013.667	67,710

African members of the WHO Programme

2004	8
2005	9
2007	11
2008	15
2009	18
2010	24
2011	26
2012	29
2013	31

WHO Collaborating Centre for Advocacy and Training in PV, Accra, Ghana and Capacity Development for PV in Africa

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WHO COLLABORATING CENTRE FOR ADVOCACY & TRAINING IN PHARMACOVIGILANCE

WHO-CC Terms of Reference - I

- The terms of reference of the WHO-CC
  - Training in pharmacovigilance in African countries for building and strengthening of spontaneous adverse drug reaction reporting systems
  - Advocacy for pharmacovigilance across Africa either alone or in collaboration with WHO
  - Promoting the integration of pharmacovigilance into public health programmes
  - Technical support to national pharmacovigilance centres

Terms of Reference - II

- Support in communication and crisis management to national pharmacovigilance centres
- Acquisition (from WHO, UMC) and distribution of needed literature and technical tools to national pharmacovigilance centres and governments
- Research in pharmacovigilance including cohort event monitoring of specified medicines
- Assistance in the development and maintenance of pregnancy registers

RCORE designation – May 2014

NEPAD
TRANSFORMING AFRICA

Ref: RCORE/01/2014
Date: 02 May 2014

Prof Alex Dodoo
Director, Centre for Tropical Clinical Pharmacology & Therapeutics
Director, WHO Collab. Centre for Advocacy and Training in Pharmacovigilance
University of Ghana Medical School
P. O. Box 4236, Accra, Ghana: Tel/Fax: +233-302-668219

Dear Prof. Dodoo,

Re: **Application for designation as a Regional Centre of Regulatory Excellence**

Following review of your application, I am happy to inform you that your institution has been approved for designation as a ***Regional Centre of Regulatory Excellence (RCORE) in Pharmacovigilance.***

2013/2014 Activities-I

Country Visits

The following countries were visited for strengthening in PV and Regulatory Activities

- 2013
  - Eritrea, Liberia; Rwanda; Kenya, Guinea; Uganda, Angola; South Africa, Togo
- 2014
  - Mauritius, Namibia, Mauritania, Burundi, Tanzania and counting….
  - Scheduled: Zanzibar(Jul26-Aug 1), Djibouti (September)

Our Flagship 4 week Pharmacovigilance Fellowship Course

Pharmacovigilance Fellowship

- 4-week training in the theory and practice in PV
- Includes hands-on sessions on tools used in PV
- Field trips to the Ghana National PV centre, hospitals, research institutions and rural field stations

4 courses so far:

17th June – 12th July, 2013

16th September – 11th October, 2013

2nd June – 28th June 2014

14 July- 8th August 2014

31 participants from 24 African countries

Modules include but not limited to;

- Developing an ADR reporting culture
- PV methods
- Regulatory aspects of PV
- Mechanism of ADRs
- Causality Assessment
- Research in PV
- Statistics and bioinformatics
- Data management

Our Yearly Data Management Course

2013 Activities-II

- **Communication and Crisis Management**
  - Providing support to countries in effective Communication & Crisis Management
  - Support to Ghana (Ministry of Health) in developing a manual for Communication and Crisis Management for Public Health Programs in collaboration with the WHO Ghana Country Office

2013 Activities-III

Support in Risk Management Plans

- Support to the National Drug Authority (Uganda) in the development of an enterprise risk management plan.

- Assistance in providing framework for developing risk management plans

- Support in providing tools for data collection for a risk register

2013 Activities - IV

Toolkits

- Pharmacovigilance toolkit (www.pvtoolkit.org)
- Vaccine Pharmacovigilance Toolkit (under development – www.vaccinepvtoolkit.org)
- Malaria Pharmacovigilance Toolkit (http://pvtoolkit.org/malaria-pv-toolkit/)
  - under revision with new sections and areas

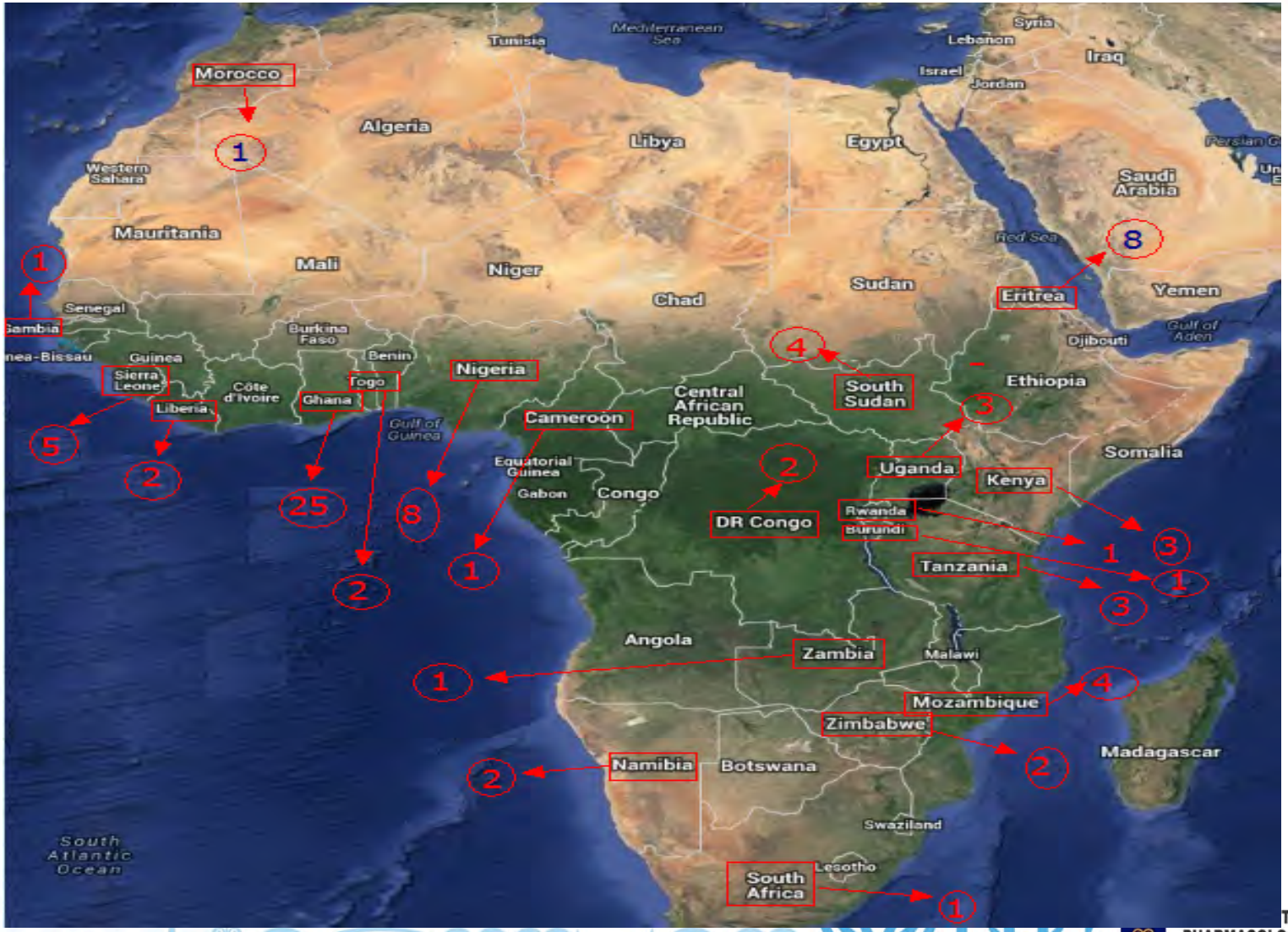
EHR for Patient Care and PV (V)

- MedSpina
  - EHR incorporating PV features
  - HL-7 framework
  - Longitudinal data collection
- Developed and being deployed in Ghana (now) and Uganda (later this year)

Meetings-ASoP Dec 3-5 2014, Host-WHO-CC, Accra (VI)

- ASoP is the African Society of Pharmacovigilance
- Formed in 2010 and accepted as a Chapter of the International Society of Pharmacovigilance (ISoP) in 2010
- A key activity is to bring ALL stakeholders in PV in Africa once a year – to meet, network, share ideas and improve PV in Africa

Number of People Trained at WHO-CC, Accra since 2013....80!!!!



Way Forward - I

- Pharmacovigilance in Africa has improved tremendously over the past 5 years in terms of NUMBERS
  - However, nearly a third of African countries still have no pharmacovigilance capacity at all
- Where PV and PRS capacity exists, the QUALITY is variable; usually very weak
- The focus now is improving **quality** and not just **quantity**

Way Forward - II

- Countries with PV activities do not want to be just data collectors
  - They now want support and training to ANALYSE their data and MAKE DECISIONS based on their data
  - Data analysis; data management skills now deemed essential
  - This calls for broader thinking into DATA CAPTURING approaches – from paper to electronic across the entire spectrum

Way Forward - III

- There is therefore the need for
  - Training of data management
  - Development of African-specific tools for data capture
    - Electronic health records should now be seriously considered for appropriate sites in Africa
  - Pharmaco-epidemiological studies need to be conceived and undertaken
  - The harmonisation efforts across the continent should consider PV as an essential component of regulatory capacity building

Way Forward - IV

- The WHO-CC in collaboration with WHO (HQ; AFRO) and partners (AMRH; AU/NEPAD; WAHO; INDEPTH; INESS) have led development of PV across Africa
- There is the need for DEDICATED support for the WHO-CC to continue this important work
- Building parallel structures etc. will not inure to the benefit of anyone
- WHO-CC is ALREADY providing the leadership and advocacy and welcomes ALL partners including the EDCTP…….

Thank you!!!