

UPDATE ON SAFE MEDICATION PRACTICE FOR PHARMACOVIGILANCE CENTRE – FP7 PROJECT

EU Funding FP7 Project being lead by WHO and UMC

Title

Monitoring Medicines

Sub- Title

Optimizing drug safety monitoring to enhance
patient safety and achieve better health
outcomes

Overall project aims



1. support and strengthen consumer reporting of ADRs and adverse events
2. expand the role and scope of national pharmacovigilance centres to prevent medicine-related adverse events
3. promote better and broader use of existing pharmacovigilance data for patient safety
4. develop additional methods of pharmacovigilance to complement data from spontaneous reporting systems

Work Package 5



- **Organize training in RCA of subsets of national pharmacovigilance data**
- In 2006–2007 a pilot project was initiated at the Moroccan PV centre retrospective analysis of national and global reports where medication error has been reported
- RCA of events leading to the reported medication errors

Work Package 6



- **Oversee development of a guideline for national analysis of medication errors and their prevention**
- To increase the capacity of national pharmacovigilance centres to analyse reports of medication errors.
- To increase the capacity of national pharmacovigilance centres to identify preventable medication errors and take action to change the behaviour of health care providers in order to minimize their recurrence

Work Package Leaders



- WHO – Shanthi Pal
- Uppsala Monitoring Centre – Sten Olsson
- Moroccan PV Centre- Rachida Soulaymani
- NPSA – David Cousins

PV centre participants



- Brasil
- Ghana
- Iran
- Kenya
- Morocco
- Netherlands
- New Zealand
- Spain
- Switzerland
- Tunisia
- Thailand

Selection of pharmacovigilance centres	June 2010
Contact PV centres – protocol of agreement	July 2010
PV centres fully agreed	September 2010
Agree course content	October 2010
Logistics for training meeting Invitee's and facilitators Follow-up discussion	October 2010
Develop method for identifying ME within ADR	October 2010
Completion of written ME training material for PV centres	December 2010
First step – 30 adr reports 10 anticoagulants 10 NSAIDS 10 Paracetamol in paediatrics Follow-up discussion	January 2011
Distribution of written ME training materials to PV centres	January 2011
PV centres to submit education materials	February 2011
Analysis of ADR reports complete Validation of method	February 2011
Training course for PV centres	9-11th March 2011
Post training course activities by PV centre Use new method Prepare education materials	April – September 2011
Post training course support materials for PV centres	April – September 2011
Final report	June 2012

Training Course In Morocco – March 2011



Training Course Topics



- WHO World Alliance for Patient Safety
- IMSN
- Terminology of Patient Safety
- Differences between PS and Pharmacovigilance
- Detecting ME's in ADR databases
- High alert medicines and procedures
- RCA
- FMEA
- Human factors and design
- IHI quality methods
- Case Studies from PV centres
- Updating reporting forms for ME's
- ME prevention strategies

Course controversy

- Should PV centres clearly advertise that they wish to receive medication error reports and are formally providing ME services?
- Or
- Should PV centres continue to focus on ADR's not formally advertise a ME service and use the P method to identify preventable ADE's?

Post Course Activities - underway



- The P method for identifying preventable ADR's
- Delphi method to clarify understanding of medication safety and pharmacovigilance terminology

Other post course activities not yet agreed or actioned

- Opportunity for IMSN members to comment via NPSA
- What are the implications of the project outputs to IMSN members?
- Should the IMSN undertake any action?
- Review of detailed project outputs follows:

Project deliverable T5.4



- A harmonized simple protocol for carrying out RCA of reports of medication errors. The RCA protocol will describe how to analyse the "whys" and "hows" of medication errors. Morocco PV will share the RCA protocol (by email) with an expert committee consisting of Participants UMCV, WHO & NPSA and the World Alliance for Patient Safety. Morocco PV will incorporate any comments from the committee and revise the protocol as needed.

Project Deliverable 5.7



- As a follow-up, six months after training, Participants WHO & Morocco PV will contact trainees for information on the percentage of reports that relate to medication error contained in their national pharmacovigilance databases, and a brief summary of an analysis of a portion of these, to determine how many of these errors were preventable. The summary analysis of selected medication error
- reports from the 10 national centres will be collated and published on the WHO website (Participant 2 to coordinate

Project Deliverable 5.8



- WHO will coordinate development of a summary paper on preventable medication errors, the value of RCA in learning from medication errors and the role of pharmacovigilance centres in identifying preventable medication errors and in changing behaviour of health-care providers, for submission to an appropriate journal of patient safety, to raise further awareness of these issues.

Project Deliverable 6.1

- One year after the training meeting, WHO will issue a one-month contract to each of the 10 national pharmacovigilance centres:
- ***To undertake a full analysis of all reports of medication errors in their national database and submit a report that includes:***
- Number of ME's
- *Classes of medicines frequently associated with ME*
- *reasons why those medication errors occurred and how they may be prevented*
- *ME activities to prevent ME's*
- *what should be done to ensure reporting of ME's*

Project Deliverable 6.2

- WHO will forward the reports to participants UMC, Morocco PV and NPSA and the World Alliance for Patient Safety who will study the reports and summarize the 10 national centres' collective experience to prepare a guideline to help national centres:
- work with the World Alliance for Patient Safety
- solicit forwarding of reports of medication errors to national pharmacovigilance databases
- analyse reports of medication errors
- identify those classes of drugs that are most often incorrectly prescribed, dispensed, or incorrectly administered
- deepen understanding of the reasons for the frequent errors associated with some medications
- undertake training of health care professionals aimed at reducing the occurrence of preventable medication errors.

Project Deliverable 6.3



- UMC and WHO will edit the guideline and publish it as a draft guideline (15 copies). They will appoint an expert committee to review the guideline. The expert committee will consist of 8 members (Participants Morocco, NPSA and others). The expert committee will meet in Geneva for two days and review the guideline.

Project Deliverables 6.4 & 6.5



- WHO will edit, finalize and print the guideline (200 copies) and distribute to all national pharmacovigilance centres.
- UMC and WHO will organize a working group session at the (next) annual meeting of the national pharmacovigilance centres to discuss practical use of the guideline. The centres will share their experience in using the guide. The number of reports of medication errors in the national centres' database will be used as an indicator of implementation of the guideline.

NPSA Proposed Contents

WHO Guideline vs 1 10.8.2011

- **1. General introduction**
 - **Guideline objectives**
 - **Why are reporting and learning systems for medication errors required?**
 - **The WHO Alliance for Patient Safety**
 - **WHO Pharmacovigilance**
 - **Organisations who are already providing reporting and learning systems for medication errors - IMSN**
 - **Glossary**

NPSA Proposed Contents

WHO Guideline vs 1 10.8.2011

2. Identifying, and reporting medication errors

- ▣ What organisations should operate medication error reporting systems?**
- ▣ Methods for collecting medication error reports**
- ▣ Medication error reporting systems**
- ▣ Adverse drug reaction monitoring systems**
- ▣ The P method for identifying preventable adverse drug reaction reports**

NPSA Proposed Contents

WHO Guideline vs 1 10.8.2011

3. Classifying medication incident reports

Using the WHO International classification for patient safety

- Incident characteristics
- Patient factors
- Detection
- Contributing factors
- Staff and patient factors
- Work and environmental factors
- External factors
- Mitigating factors
- Patient and organisational outcomes
- Ameliating actions
- Medicine product (s)
- Medication use process
- Medication problem



Exemplar medication error reporting form

See attached

NPSA Proposed Contents

WHO Guideline vs 1 10.8.2011

- 4. Analysing medication error reports
 - Human error, human factors and systems
 - Identifying contributory factors
 - Identifying root causes
 - Exemplar analyses



Exemplar medication error analysis form

See attached

NPSA Proposed Contents

WHO Guideline vs 1 10.8.2011

5. Strategies to manage and minimise harms:

- Facilitate correct actions.
- Make wrong actions more difficult.
- Make it easier to discover errors that occur.
- Make it possible to reverse or undo incorrect actions.

NPSA Proposed Contents

WHO Guideline vs 1 10.8.2011

□ **Design safety strategies around the following principles**

- Clarify / simplify tasks, processes, protocols, medicine products, devices and responsibilities.
- Standardise processes and equipment where relevant.
- Design tasks and processes to minimise dependency on short-term memory and attention span.
- Ensure that essential information is available and well communicated
- Use protocols and checklists wisely; resist reliance on policies and protocols as task aids.
- Empower patients and carers to help identify and minimise errors.
- Make full use of the multidisciplinary team and do not focus strategies solely on prescribers
- Education and training need to be combined with other strategies.



Questions and discussion