Patient reporting in reality

Magnus Wallberg
Sten Olsson

Monitoring Medicines
Broad objectives

1. Support and strengthen patient reporting
2. Expand the role and scope of PV centres in analysing medication errors
3. Promote better and broader use of existing PV data identifying dependence potential and substandard quality
4. Develop additional PV methods to complement spontaneous reporting systems for Public Health Programmes. (Targeted Spontaneous Reporting and Cohort Event Monitoring)
5. Develop a learning tool for ARV-adverse event management

Partners

- Uppsala Monitoring Centre, Sweden
- World Health Organization
- Medical Products Agency, Sweden
- Lareb foundation, the Netherlands
- National Patient Safety Agency, UK
- National Antipoison & Pharmacovigilance Centre, Morocco
- Copenhagen HIV Centre, Denmark
- Elliot Brown Consulting Ltd, UK
- Zuellig Family Foundation, Philippines
- University of Ghana Medical School
- Pharmacy & Poisons Board, Kenya

MONITORING MEDICINES

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

Activities

- Work Package 1 – 4
  - Develop guidelines and tools for direct patient reporting of drug related problems
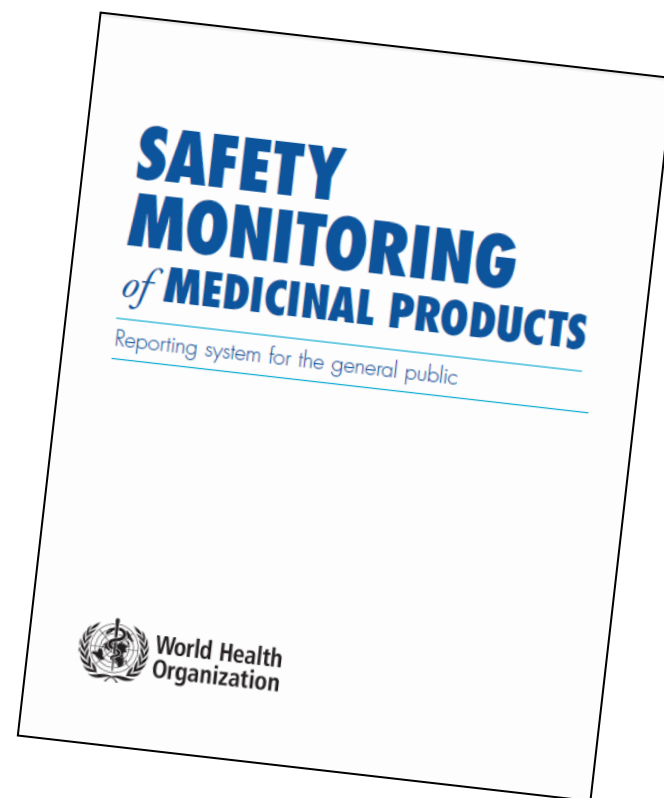 - Carry out training for patient organizations

Work Package 1
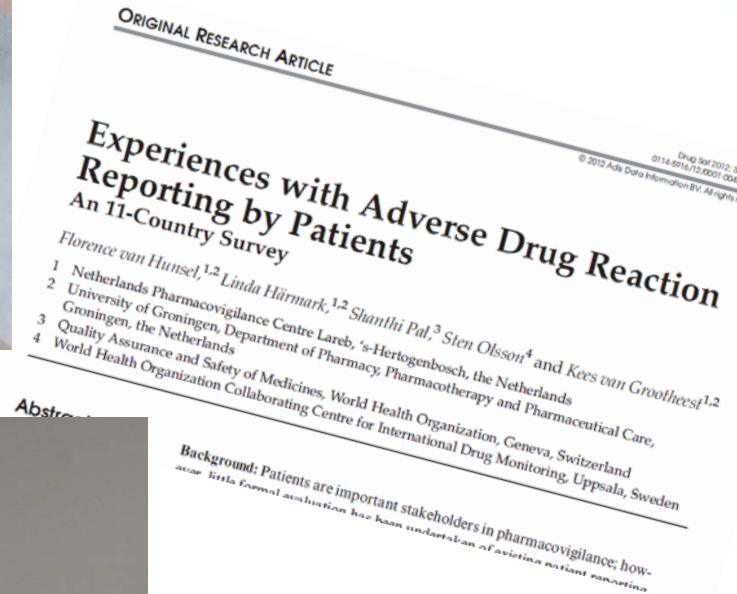
Florence van Hunsel
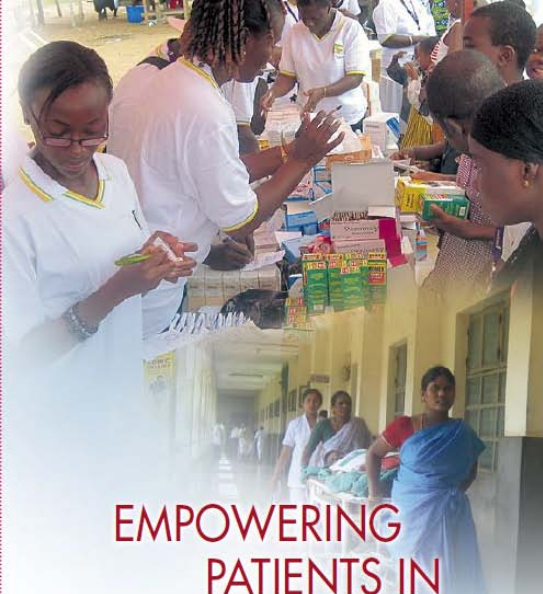Lareb

Work Package 2
Reporting System for General Public

- Process started at national centres meeting in Uppsala, 2008
- First draft by Linda Härmark and Anne Kiuru
- Included as a deliverable in Monitoring Medicines
- Published by WHO, March 2012

Seminar at
World Healh Assembly 65
24 May 2012

WHA 65

Time line

- Workshop in Uppsala, December 2010

- Original delivery date, November 2011
    - New legislation
    - 6 months prolonged delivery of the tool

- Training in Den Bosch, March 2012

- Final adjustments finalized and sent to pilot countries for translation, May 2012

Time line cont.

- Most of the work done during autumn 2011
  - Four Virtual meetings
    - October: Flow of reports
    - November: Fields
    - December: Texts
    - January: Wrap up

- Home work after each meeting

the UPPSALA MONITORING CENTRE

This presentation…

- In the rest of the presentation we will focus on the tool and the process around it, NOT the content.
  - General requirements
  - Layout
  - Adjustable functionality
  - Integration issues
  - "Work flow"

Throughout the presentation the abbreviation NCA will be used for National Competent Authority

the **UPPSALA MONITORING CENTRE**

General requirements

- Challenge
  - Build a patient reporting system
  - Easy to operate for patients
    - Should <u>operate</u> on smart-phones but <u>not optimized</u> for it
  - Get enough data for analysis work at the NCA
  - International standard, E2b
  - Mandatory fields
  - Error checks

  > To improve quality but without making data entry more difficult

  - Useable around the world
    - Easy translation and adjustable to varying requirements

Layout considerations

- The tool itself shall be as simple and straight forward as possible

  - Colour schemes, images, fonts and general appearance shall be possible to adjust to fit with the NCA using it.

Example
(different styles for different authorities)

the **UPPSALA MONITORING CENTRE**

Layout considerations II

- Focus shall be on the data entry and common web-techniques shall be used
  - The tool shall be possible to host within another web site

the UPPSALA MONITORING CENTRE

Example
(integration in external system)

This "frame" opens the actual patient reporting system within VigiFlow

Unsere Kompetenz – für Ihr Vertrauen in Heilmittel

...telinstitut

...n | Kontakt   Suchen | Erweiterte Suche   De | Fr | It | En

...medic   Bewilligungen   Zulassungen   Marktüberwachung   Recht   Heilmitteldaten

Patient reporting E2B

Reporter | **Report** | Summary | Finished

* = Mandatory field

Reporter

| Email * | magnus.wallberg@who-umc.org |
| Reporter | User of the medicine |

User of the medicine

Initials *	
Sex *	Male ○ Female ○
Weight ?	____ kg
Date of birth * ?	dd mm yyyy or Age ____
Country where the reaction(s) started	United Kingdom

Describe what happened

* Describe what happened in your own words, any symptoms or side effects you suspect were caused by your medication, and what happened since then.

Other specific details about each medicine and relevant dates can be entered below, but please include enough information here to connect to the structured information below.

0 of 20000

Language considerations

- The tool shall be easy to translate to several languages
  - every NCA shall have a predefined default language
  - There should be a list of approved languages for each NCA.

- Certain texts shall be decided by each NCA like:
  - Introduction message
  - Caveat document
  - Thank you message and mail

Adjustable functionality

- Some parts of the tool needs to be adjustable due to different demands by different NCAs (more about this later…)

Flow of functionality

- The flow of functionality in the tool is very straight forward and best described with the built in navigation help

Reporter	Report	Summary	Finished
Reporter	Report	Summary	Finished
Reporter	**Report**	Summary	Finished
Reporter	Report	**Summary**	Finished
Reporter	Report	Summary	**Finished**

This is NOT the first page

Prima http://paniflow.who-umc.org/PrimaryReporting/
Reporting/Reporter?OrganizationID=demo**1**

Please choose the organisation that should be the receiver of the report.

Organisations

🇸🇪 Demo country 1

🇬🇧 Demo country 2

🇬🇧 Demo country E2B

http://paniflow.who-umc.org/PrimaryReporting/
Reporting/Reporter?OrganizationID=demo**2**

the **UPPSALA MONITORING CENTRE**

Reporter page

An e-mail is required to make sure it is a "real" patient. This is also needed for follow up and feedback

A "captcha" is needed to make sure that a "human" is doing the data entry

The reporting system is available also for others then the actual patient

Some NCAs will need a caveat document

Reporter · Report · Summary · Finished

Introduction

* =

Reporter

Email ... wallberg@who-umc.org

Language * English

Reporter ? User of the medicine

696859

Type the characters exactly as in the image *

☑ Click here for Terms and Conditions   Next page

the UPPSALA MONITORING CENTRE

Report page

Summary page

This is the summary of your report. Please verify that the information is correct.
If it's not, use the *Previous* button to change the information. To send the report, click the *Submit* button.

Reporter

Email	magnus.wallberg@who-umc.org
Reporter	User of the medicine

User of the medicine

Initials	WW
Sex	Male
Weight	80 kg
Date of birth	
Age at time of reaction	30 Year
Country where the reaction(s) started	United Kingdom

Describe what happened

I suffered from...

Medicines

1

Name on medicine	Medicine producer	Probably causing the reaction
Alvedon	Astra Zeneca	Yes

Strength and Dosage

50 mg; 1 tablet 2 times/day

Finished page

- The "Finished" page displays a "thank you" message and gives a final chance to print the report.

Confirmation e-mail

- After finishing a report a mail is sent to the patient (reporter); the mail contains:

  - A standard message from the NCA

  - A direct link to the report that shows the report as in the summary page

Confirmation e-mail
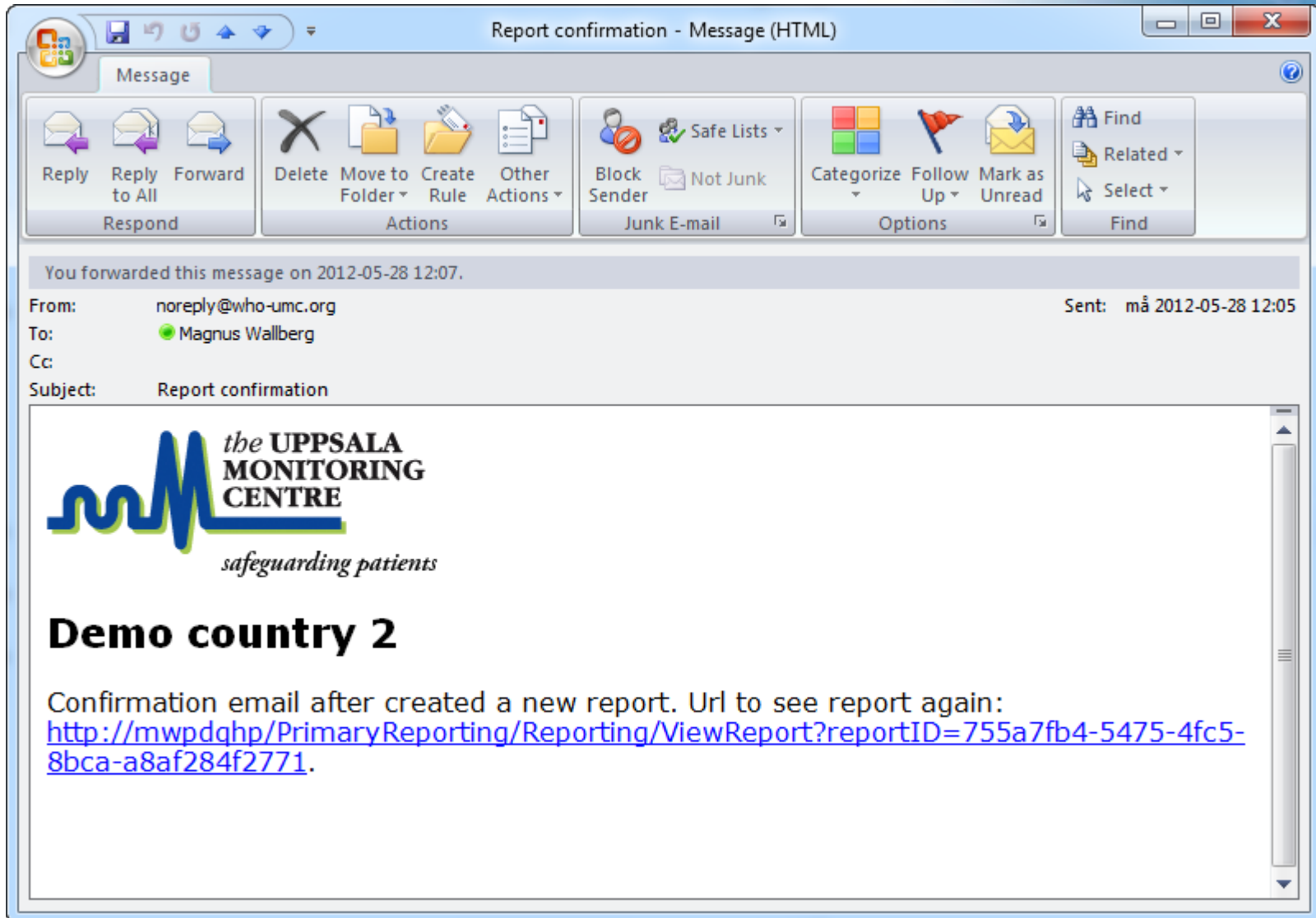
Confirmation e-mail

- The link in the e-mail *could* also provide the opportunity to give follow up information and information about report status

- The mail is one of the reasons that we require a valid e-mail address

  – However… we do not check for fake mails as of yet… it might come though

the **UPPSALA MONITORING CENTRE**

View previously sent report

When the report has been completed

- When a report has been completed it should somehow be transferred to the responsible NCA

- Why?

  – UMC will NOT analyze the patient reports directly in the patient reporting system

  – The reports must go via the "NCA" for "decoding" and assessment

  – The report will re-appear at UMC as a "normal" report after assessment by the "NCA"

the **UPPSALA MONITORING CENTRE**

Organizational settings

- Before continuing it is worth while to have a look at the settings available for an organization "NCA" in the patient reporting tool.

the **UPPSALA MONITORING CENTRE**

Organizational settings

- The available settings (currently) are:
  - Name of organisation (NCA) and address details
  - Style sheet (look and feel)
  - Available languages (and default language)
  - Logo
  - Title
  - Introduction
  - Caveat
  - Delivery method
    - Will come to that...

"Complete" report flow

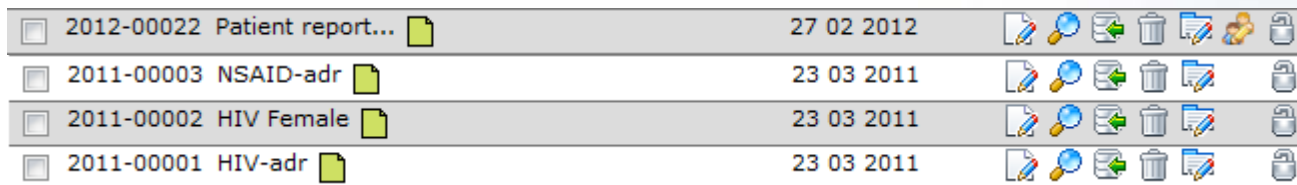the UPPSALA MONITORING CENTRE

Delivery method

- The delivery method describe HOW the report is transferred from the patient reporting system to the NCA

- Methods can be:

  – FTP

  – Mail

  – Web services

  – …

the **UPPSALA MONITORING CENTRE**

What is there today

- Today the following process is in place:
  - The report is entered by the patient
  - The report data is extracted to an E2B-XML file
    - All files for one NCA are created in a NCA specific folder *(reports from different NCAs are kept separate)*
  - Depending on delivery method set up for each NCA the files are transferred to the right destination
    - For VigiFlow countries the reports can be sent directly to VigiFlow

the **UPPSALA**
MONITORING
CENTRE

Integration with VigiFlow

- As mentioned VigiFlow supports direct and automatic submission of reports from the patient reporting system by the use of a Web Service

- However… this functionality is not installed in production yet…
  - Will be included in VigiFlow version 5.0 planned for the autumn 2012

View of the patient report in VigiFlow

This "frame" opens the actual patient reporting system within VigiFlow

In a future version the "frame" may also contain feed back and communication functionality

Live demo
(if time allows)

the **UPPSALA**
MONITORING
CENTRE

A few minutes

Depending on transfer method and receiving system

AUTHORITY

the **UPPSALA MONITORING CENTRE**

What is missing in this picture

WS
FTP
Mail
…

the UPPSALA
MONITORING
CENTRE

Communication

- A communication module is important in order to simplify:
  - Feedback from NCA to patients
  - Follow up information from patients to NCA
  - The possibility for the NCA to ask for more information if important information is missing

- The basis for a communication module has been built already but was postponed to await feedback from the pilot phase
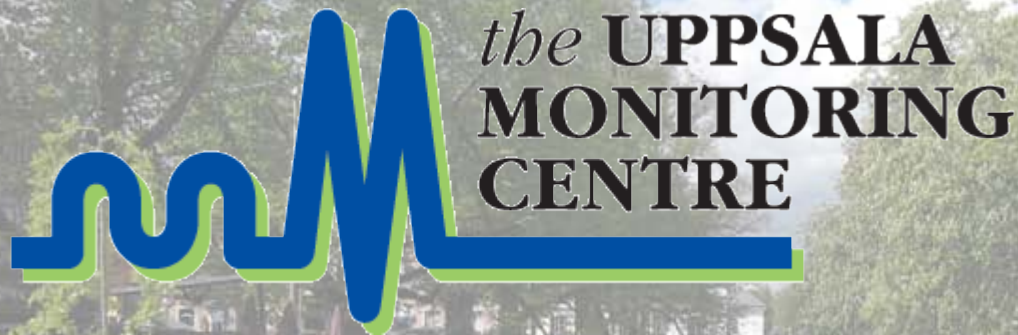
the UPPSALA MONITORING CENTRE

WHO Collaborating Centre for
International Drug Monitoring
Box 1051, SE - 751 40 Uppsala
Sweden Tel +46 18 65 60 60, Fax +46
18 65 60 88
E-mail: info@who-umc.org
Website: www.who-umc.org