

# Patient reporting in reality

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# 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**

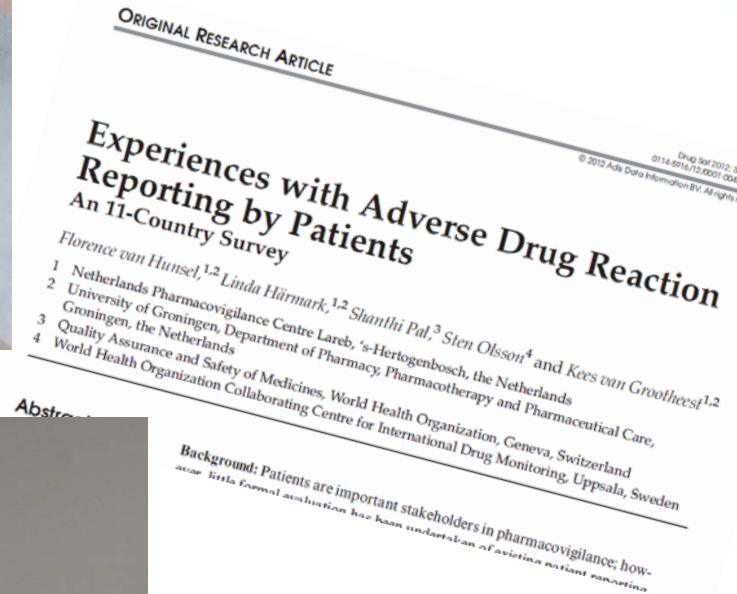
# Partners

- 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

# 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

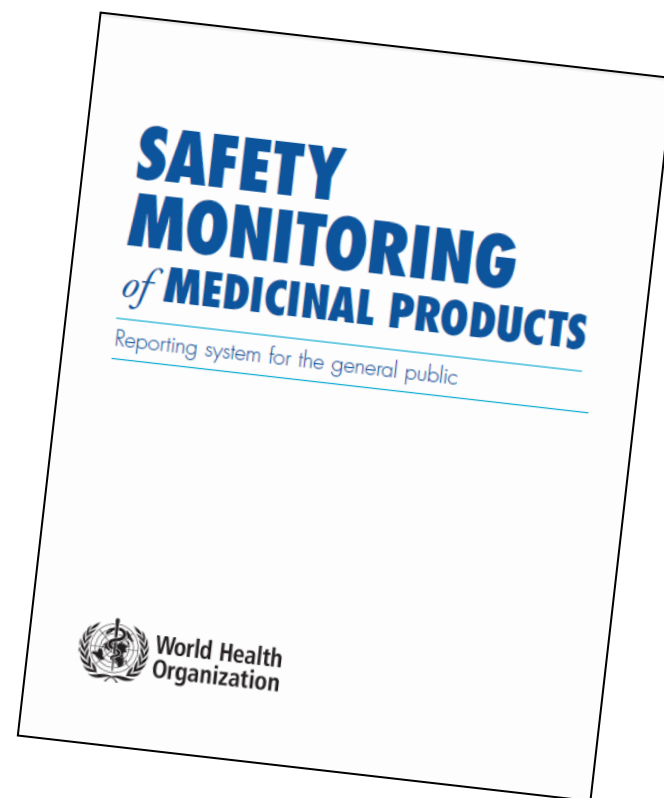


Florence van Hunsel  
Lareb

# Work Package 2

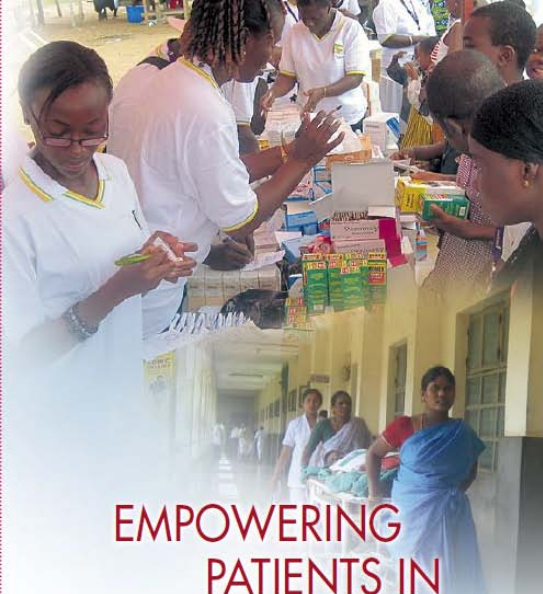
## *Reporting System for General Public*

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






# Seminar at World Health Assembly 65 24 May 2012





**EMPOWERING  
PATIENTS IN  
PHARMACOVIGILANCE**

*If we don't count on patients,  
patient-care will not count*

**MONITORING  
MEDICINES**

 the UPPSALA  
MONITORING  
CENTRE

 World Health  
Organization

 EUROPEAN  
COMMISSION



# 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

# 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

# General requirements

- Challenge
  - Build a patient reporting system
  - Easy to operate for patients
    - Should operate on smart-phones but not optimized for it
  - Get enough data for analysis work at the NCA
  - International standard, E2b
  - Mandatory fields
  - Error checks
  - Useable around the world
    - Easy translation and adjustable to varying requirements

To improve quality but without making data entry more difficult

# 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)

**Primary reporting**

Reporter Report Summary Finished

\* = Mandatory field

**Reporter**

Email \*

Reporter

**User of the medicine**

Initials \*

Sex \* Male  Female

Weight  kg

Date of birth \*    or Age

Country where the reaction(s) started

**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

**Did the reaction lead to any of the following**

*Tick those that apply or leave blank*

Results in death
  Life threatening
  Disabling/Incapacitating
  Caused/prolonged hospitalization
  Congenital anomaly/birth defect
  Lead to other medical condition

**Patient reporting E2B**

Reporter Report Summary Finished

\* = Mandatory field

**Reporter**

Email \*

Reporter

**User of the medicine**

Initials \*

Sex \* Male  Female

Weight  kg

Date of birth \*    or Age

Country where the reaction(s) started

**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.

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0 of 20000

**Did the reaction lead to any of the following**

*Tick those that apply or leave blank*

Results in death
  Life threatening
  Disabling/Incapacitating
  Caused/prolonged hospitalization
  Congenital anomaly/birth defect
  Lead to other medical condition

# 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

# Example (integration in external system)

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

Unserer Kompetenz – für Ihr Vertrauen in Heilmittel

telinstitut

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

edic Bewilligungen Zulassungen Marktüberwachung Recht Heilmitteldaten

### Patient reporting E2B

Reporter Report Summary Finished

\* = Mandatory field

#### Reporter

Email \*

Reporter

#### User of the medicine

Initials \*

Sex \* Male  Female

Weight  kg

Date of birth \*    or Age

Country where the reaction(s) started

#### 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...)

The image displays two overlapping screenshots of a web form. The left screenshot shows the 'Reporter' step of a process with tabs for 'Reporter', 'Report', 'Summary', and 'Finished'. It includes a header 'Reporter - Demo country 3' and fields for 'Email \*', 'Language \*' (set to English), and 'Reporter' (set to 'User of the medicine'). A CAPTCHA image with the text 'VQK6N9' is shown, with a text input field below it labeled 'Type the characters exactly as in the image \*'. A 'Next page' button is highlighted with a green box.

The right screenshot shows the 'Report' step with tabs for 'Report', 'Summary', and 'Finished'. It includes a header 'Demo country E2B' and fields for 'Language \*' (set to English) and 'Reporter' (set to 'User of the medicine'). A CAPTCHA image with the text 'QEGBDG' is shown, with a text input field below it labeled 'Type the characters exactly as in the image \*'. At the bottom, there is a checkbox for 'Click [here](#) for Terms and Conditions' and a 'Next page' button, both highlighted with a green box.



# Flow of functionality

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



# This is NOT the first page

**Primary** <http://paniflow.who-umc.org/PrimaryReporting/Reporting/Reporter?OrganizationID=demo1>

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=demo2>

# Reporter page

The image shows a web form titled "Reporter page" with a progress bar at the top containing steps: Reporter, Report, Summary, Finish, and a partially visible "inished" step. The form fields include:

- Reporter**: A dropdown menu with "User of the medicine" selected.
- Language \***: A dropdown menu with "English" selected.
- Reporter ?**: A text input field containing "wallberg@who-umc.org".
- Captcha**: An image showing the number "696859" in blue and red, with a text input field below it for typing the characters.
- Terms and Conditions**: A checkbox that is checked, with the text "Click [here](#) for Terms and Conditions".
- Next page**: A button to proceed to the next step.

Annotations in yellow boxes with arrows pointing to specific form elements:

- Top right: "An e-mail is required to make sure it is a 'real' patient. This is also needed for follow up and feedback" (points to the email field).
- Left side: "A 'captcha' is needed to make sure that a 'human' is doing the data entry" (points to the captcha image).
- Right side: "The reporting system is available also for others then the actual patient" (points to the Reporter dropdown).
- Bottom right: "Some NCAs will need a caveat document" (points to the "Next page" button).

# Report page

Reporter

Report

Summary

Finished

## Reporter

Email \*

Reporter ?

## User of the medicine

Initials \*

Sex \* Male  Female

Weight ?  kg

Date of birth \* ?    or Age at time of reaction

Country where the reaction(s) started ?

## Describe what happened

\* Describe what happened in your own words, any symptoms or side effects you suspect were caused by your medicine, 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 Reactions/Symptoms section below.

0 of 20000

...

[Add details for reactions/symptoms](#)

### Did the reaction(s) lead to any of the following

Tick those that apply or leave blank

- Caused/prolonged hospitalization ?  Life threatening
- Disabling/incapacitating  Results in death
- Congenital anomaly/birth defect  Other medically important condition

## Medicines

Enter the name and details for each medicine you were taking before the reaction occurred. Click on "Add another medicine" for each new medicine you need to describe. Please also describe any herbal preparations, recreational drugs or other alternative medicines you were taking.

1 Name on medicine \* ?  Medicine producer ?   Probably causing the reaction ?

Strength ?  Dosage ?

Route  Place where medicine was obtained ?

Start date ?    End date ?    or Duration

Reason for taking the medicine ?  0 of 250

What else did you do ? ?  0 of 90 Action taken with medicine

Has the medicine caused a similar reaction before? Yes  No  Unknown  [Clear](#)

[Add another medicine](#) Add information on all medicines, one by one. Please do not forget about "over the counter" medicines, herbal preparations, recreational drugs or other alternative medicines.

## Additional information

Please give a short description of your medical history. This is important since some reactions only appear with a combination of previous or ongoing disease, special diets, recreational drugs, smoking habits, alcohol intake or allergies. You can also enter other comments you feel are important.

Current and previous illnesses 0 of 10000

...

Additional comments 0 of 500

...

[Next page](#)

# Summary page

Reporter

Report

Summary

Finished

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
	<b>Strength and Dosage</b>		
	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.

## Patient reporting E2B



Thank you for submitting your report!

Use this link to view the created report: <http://localhost/PrimaryReporting/Reporting/ViewReport?reportID=755a7fb4-5475-4fc5-8bca-a8af284f2771>

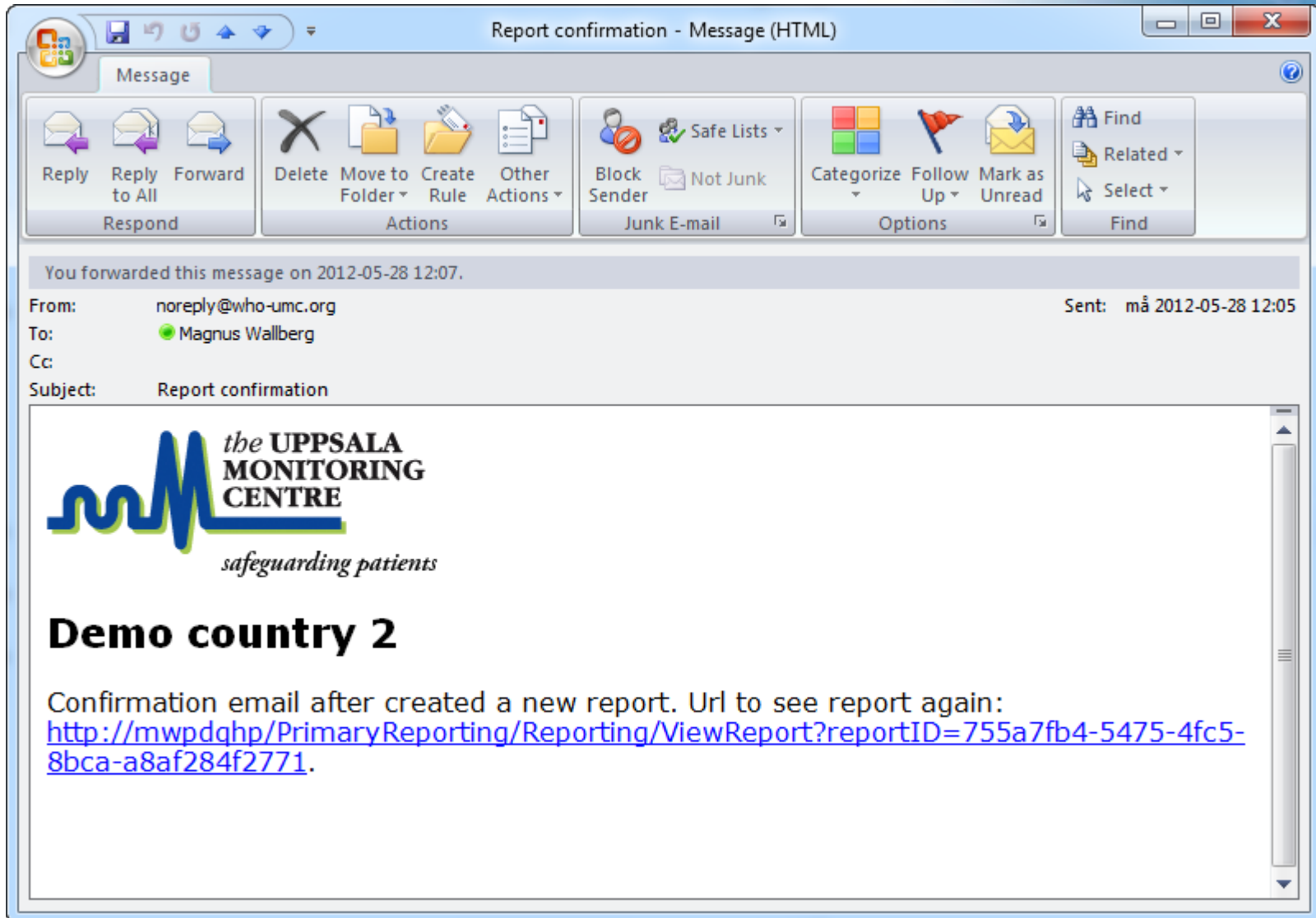
Please close the browser window to prevent someone else reading your report.

 [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

# View previously sent report

Opera

View Report

Web mwpdqhp/PrimaryReporting/Reporting/ViewReport

Search with Google

## Patient reporting E2B

[Print the report](#)

Created: 28 05 2012 12:04:57, Report reference: **dbd07209-988e-45b2-a98d-547604503a03**

### 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...

Zoom (100%) Downloading...

# 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”

# 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.





# 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...

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

**MONITORING MEDICINES**

Uppsala Monitoring Centre World Health Organization European Union

**Patient reporting**

Reporter Report Summary Finished

Before creating the report we need some basic information about you. Please provide the information prompted below and then click the Next button.

\* = Mandatory field

Reporter - Demo country 2

Email \*

Language \* English

Reporter User of the medicine

MUDFYR

Type the characters exactly as in the image \*

Click [here](#) for Terms and Conditions Next page

# "Complete" report flow



Reporter

Introduction DMO E2B  
\* - Mandatory field

Reporter - Demo country E2B

Email \*

Language \* English

Reporter \* User of the medicine \*

Type the characters exactly as in the image \*

[Click here for Terms and Conditions](#) [Next page](#)

Reporter

Email \* magnus.wallberg@who-umc.org

Reporter User of the medicine

User of the medicine

Initials \*

Sex \* Male  Female

Weight (kg) kg

Date of birth \*  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.

8 of 2000

Did the reaction lead to any of the following

Tick those that apply or leave blank

Results in death  Life threatening

Disabling/incapacitating  Caused/prolonged hospitalization

Congenital anomaly/birth defect  Lead to other medical condition



Patient reporting E2B

Reporter Report Summary Finished

Thank you for submitting your report!

Please close the browser window to prevent someone else to read your report.

[Print the report](#)

Reporter

Email magnus.wallberg@who-umc.org

Reporter User of the medicine

User of the medicine

Initials WW

Sex Male

Weight 70 kg

Date of birth 2802-1980

Age

Country where the reaction(s) started United Kingdom

Describe what happened

I suffered from a...

The reaction lead to

Caused/prolonged hospitalization

# Delivery method

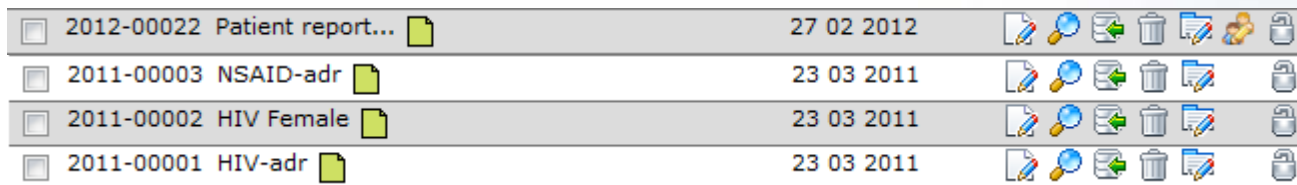
- The delivery method describe HOW the report is transferred from the patient reporting system to the NCA
- Methods can be:
  - FTP
  - Mail
  - Web services
  - ...

# 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

# 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



<input type="checkbox"/>	2012-00022 Patient report...		27 02 2012	
<input type="checkbox"/>	2011-00003 NSAID-adr		23 03 2011	
<input type="checkbox"/>	2011-00002 HIV Female		23 03 2011	
<input type="checkbox"/>	2011-00001 HIV-adr		23 03 2011	

- 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

the UPPSALA MONITORING CENTRE

report handling search and statistics tools exit  
new report send report list reports

home

back

**Patient reporting E2B**

[Print the report](#)

Created: 25 05 2012 14:00:08

**Reporter**

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

**User of the medicine**

Initials: OP  
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**

Description of what happened...

**Medicines**

1	Name on medicine	Medicine producer	Probably causing the reaction
	Alvedon	Astra	Yes
	<b>Strength and Dosage</b>		
	<b>Route</b>	<b>Place where medicine was obtained</b>	
	<b>Start date</b>	<b>End date</b>	<b>Duration</b>

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)*







A few minutes  
Depending on transfer method and receiving system



# What is missing in this picture



Reporter

Introduction DMO E2B  
\* - Mandatory field

Reporter - Demo country E2B

Email \*

Language \* English

Reporter User of the medicine



Type the characters exactly as in the image \*

[Click here for Terms and Conditions](#) [Next page](#)

Reporter

Email \* magnus.wallberg@who-umc.org

Reporter User of the medicine

User of the medicine

Initials \*

Sex \* Male Female

Weight (kg) kg

Date of birth \* 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.

8 of 2000

Did the reaction lead to any of the following

Tick those that apply or leave blank

Results in death  Life threatening

Disabling/incapacitating  Caused/prolonged hospitalization

Congenital anomaly/birth defect  Lead to other medical condition



WS  
FTP  
Mail  
...

Reporter

Email magnus.wallberg@who-umc.org

Reporter User of the medicine

User of the medicine

Initials WW

Sex Male

Weight 70 kg

Date of birth 2802-1980

Age

Country where the reaction(s) started United Kingdom

Describe what happened

I suffered from a...

The reaction lead to

Caused/prolonged hospitalization

Patient reporting E2B

Reporter Report Summary Finished

Thank you for submitting your report!

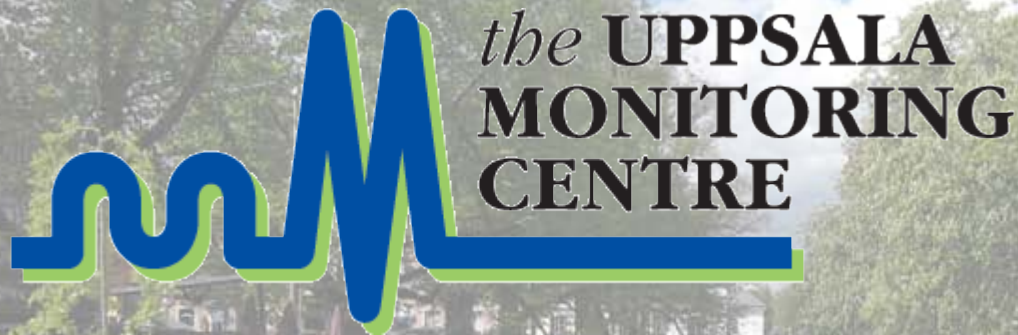
Please close the browser window to prevent someone else to read your report.

[Print the report](#)



# 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**

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