



## **Working Group**

**Surveillance of Adverse Reactions/Events (STARE)  
Associated with Blood Donation and Transfusion  
and of Medical Devices and Traceability**

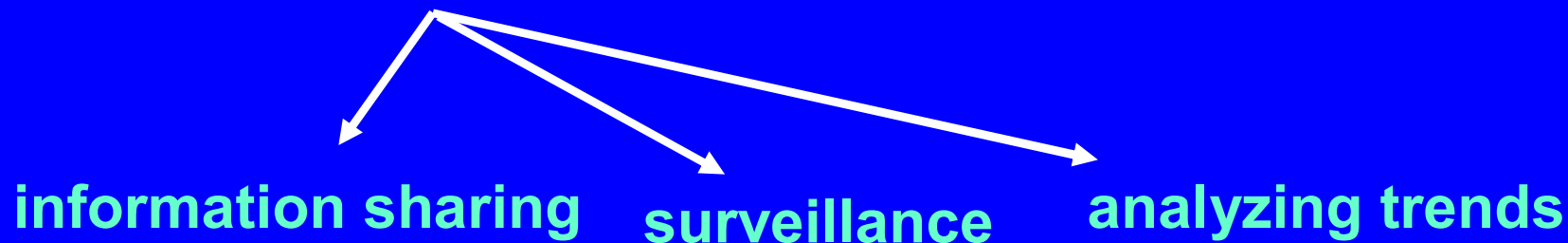
***An Initiative for the Construction of an  
International Haemovigilance Database***

***C. Politis, C. Richardson,***

***J. Jorgensen, P. Robillard, J. Wiersum***

## Background / Aim

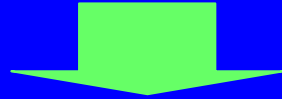
- **Proposal** from the working group on surveillance that was **mandated** by the EHN annual general meeting, Frankfurt, Feb 28<sup>th</sup> 2008
- **Objective** to establish an international haemovigilance database for the purposes of



on  
adverse reactions and adverse events associated  
with the donation–transfusion chain

- *to improve safety and effectiveness of the clinical use of blood and*
- *to promote optimal safety for donors and transfusion recipients*

# Use of database



International, beyond the EU and Europe

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## Collection of data

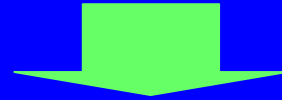
Aggregated national data or  
regional data where appropriate

Confidential, only anonymised (coded)  
data are published

**STARE:** a new initiative of EHN, in line however with its earlier  
work (*acknowledgement to J.C. Faber*)

# Goals of database

Contribution to international scientific efforts aiming at



- preventing and correcting errors and mistakes
- benchmarking for countries
- reliable data
- education
- risk assessment
- root cause analysis remains a national rather than international concern

# Participation

## **EHN is seeking collaboration with**

- Relevant Intergovernmental Organizations
- International Scientific Bodies
- Haemovigilance Networks
- Other Interested Parties (*e.g. the Global Steering Committee on Haemovigilance of the ISBT, the Public Health Agency of Canada and Health Canada*)

**If a joint activity with ISBT is established, data may be requested from beyond the EHN membership**

*In the meantime, for purposes of information sharing, other non-EHN countries or regions with systematically collected data may be allowed to contribute to the database.*

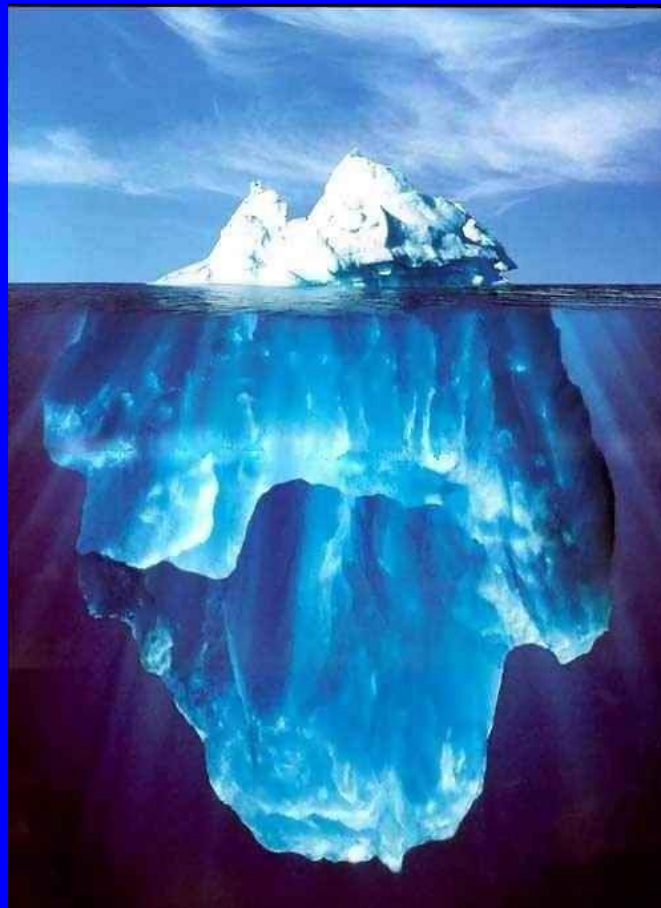
# The philosophy of STARE

## Haemovigilance

- Should not be restricted only to serious adverse reactions / events related to the quality and safety of the transfused blood products  
*(EU Directives 2002 /98/EC and 2005/61/EC and the Guide of the Council of Europe)*
- Nor should it be limited simply to meeting administrative requirements related to quality systems in transfusion

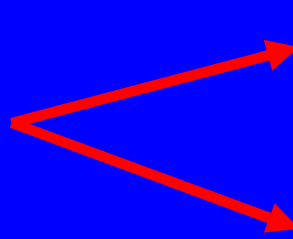
# The philosophy of STARE

*To build on the concept of avoiding the restriction of observations to only **the tip of the iceberg**.*



## Coverage (I)

Based on a scientific and holistic approach for reporting and analyzing **all** adverse reactions and events,

regardless of  *level of severity*  
*extent of harm (if any)*

that threaten the **recipient's** health status and quality of life, and also monitoring effects on the **donor's** health and well being.




## Coverage (II)

### STARE

- *Includes*
  - *errors and mistakes in the clinical area*
- *Takes note of accumulated experience in countries applying haemovigilance measures more stringent than those of the EU.*

# Adverse Reactions (All) in Patients

## Imputability levels

- 1) Possible
  - 2) Likely/ Probable
  - 3) Certain
- 
- to be included

*Levels 0 “excluded/unlikely” or unassessable are excluded*

## Severity grades *per blood product* (RBC, Platelets, Plasma, Cryoprecipitate, Others)

1) Non-severe

2) Severe

3) Life-threatening

4) Death

2) Severe

3) Life-threatening

4) Death

4) Death

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Total reactions

# Adverse Events/ Errors

- At blood establishments  
(whole blood collection, apheresis collections, processing, testing, storage, distribution, materials etc.)
- Hospital blood banks  
(storing, crossmatching, distribution, transfusion)
- Hospital clinical areas

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## Specification of adverse events

- Product defect
- Equipment failure
- Human error
- Other

*Note: EU members should attach a copy of their EU  
“serious adverse events” table*

# Errors in pre-transfusion testing

## Site of primary error

- Wrong blood group label or unit supplied by BE
- Patient sample collection error: Wrong blood/name in tube
- Wrong patient transfused (bedside error of misidentification)  
(compatibility) sample testing errors including typing error
- Wrong compatibility label
- Wrong product transfused (bedside error of misidentification)
- Total unintended ABO incompatible transfusions

## Incorrect Blood Component Transfused

(with or without reaction)

## Near Miss

# Donor Complications

Haemovigilance should have broader focus on donor complications

The Working Group proposes the continuation of EHN/ISBT data collection as started by Jan Jorgensen and Jo Wiersum

- Start with donor reactions

# Definitions

- EU 2002/98/EC and 2005/61/EC
- Council of Europe, “Guide, 14<sup>th</sup> edition, EDQM 2008”
- ISBT/EHN
- SHOT (of incorrect blood component transfused)

# What data

- Numerator data
  - on reactions, events, donors and patients
- Denominators for converting absolute numbers of reactions and events into rates
  - Units issued and distributed by blood establishment
  - Transfused units (if available)
  - Patients transfused (if available)

## What data

- Medical device defects
  - Basic general information on existence of system
- Traceability (% coverage)

*The Group is proposing that these activities be developed later*



# Working Methods

- Pilot phase

- Starting in September 2008, reporting to next annual EHN Seminar in Rome
- Participation of a few countries with established haemovigilance systems
- Collection of retrospective data, preferably covering two years

- Data collection

- By the OCP's representatives to EHN
- Submitted by a secure web-based system (when the database is fully operational)
- The location of the host, hardware and software requirements will be determined in due course
- A central body will take care of data management, analysis and dissemination (coordinating scientific committee, secretariat and epidemiological expertise are required)
- The coordinating committee has overall responsibility for the database including technical advice to data contributors, the data analyst and production of documents

# Dissemination of data

- In **anonymised** form
- Each country's data will be marked in tables and diagrams by a **code** number not by name
- The country's code will be known to its representative but not to the representatives of other countries.
- A **yearly report** will be made available publicly in whole or part on the web
- Reports to EHN, ISBT and publications in scientific journals
- A system of endorsement by the Executive of the EHN and the ISBT or other scientific organizations sharing responsibility for the database may be established
- Requests for use of the data by outside parties may be considered and will require Executive approval

# Thanks to...

- Paul Strengers, ISBT and Eurocongress for hosting the Working Group's meeting in Amsterdam

