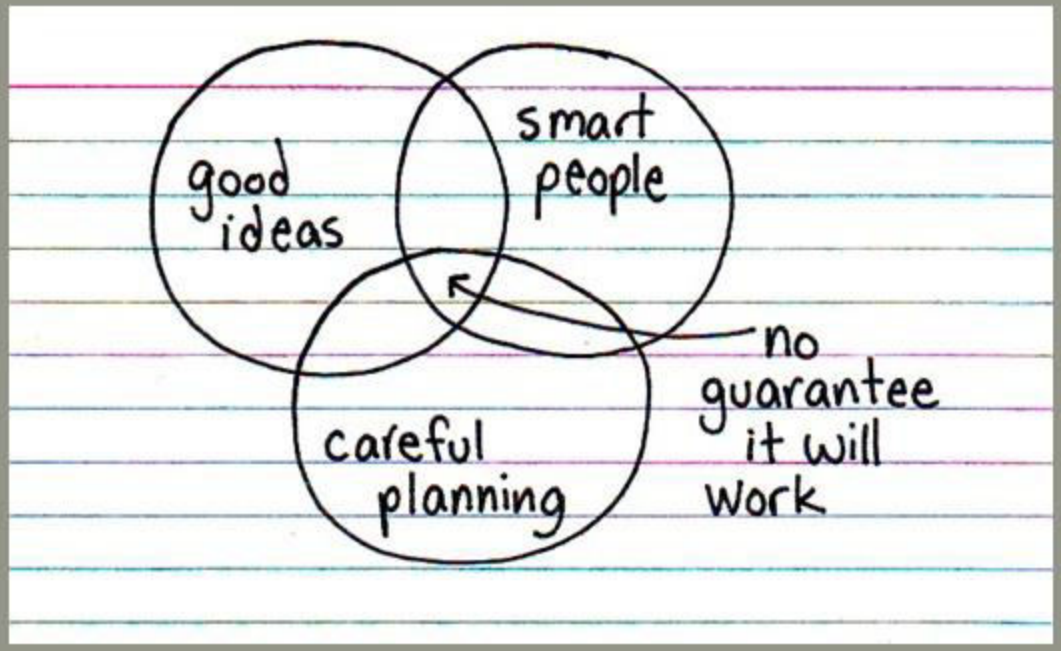
# Haemovigilance: Concepts and frameworks

Erica Wood, Jo Wiersum, Linley Bielby, Lisa Stevenson

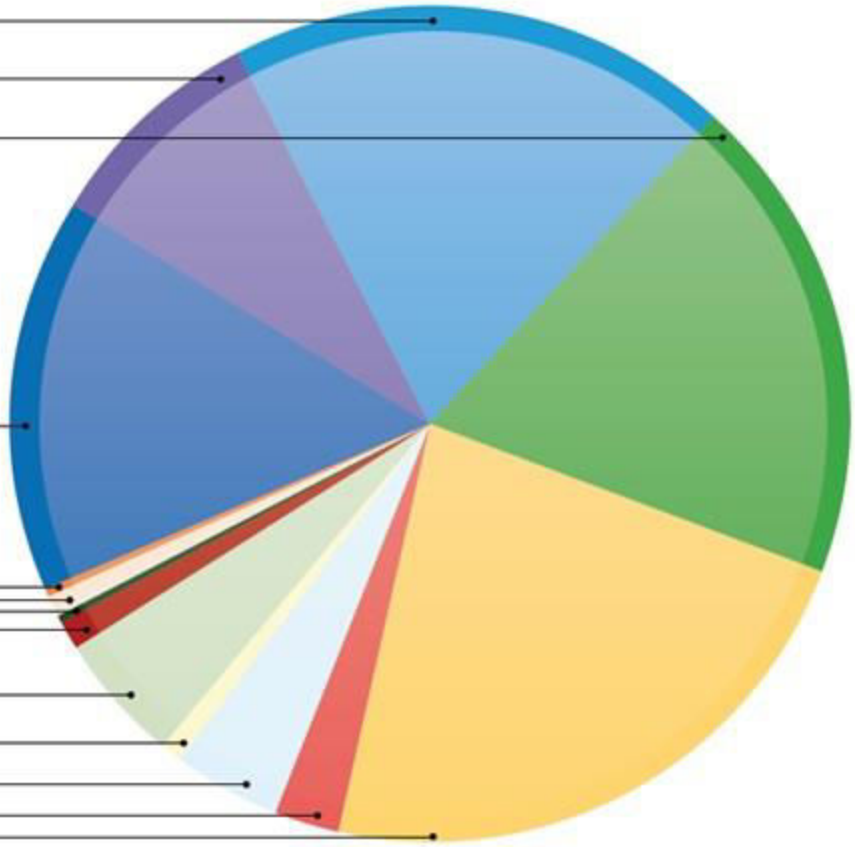


# Hospital transfusion practice: Processes and communication

Handling and storage errors
Avoidable, delayed or under-transfusions
RhD immunoglobulin
Incorrect blood component transfused

**Figure 4.1:**
**Cases reviewed in 2012**

| | | | |
|---|---|---|---|
| HSE | 316 | 19.2% |
| ADU | 145 | 8.8% |
| Anti-D | 313 | 19.0% |
| IBCT | 252 | 15.3% |
| TA-GvHD | 1 | 0.1% |
| TTI | 3 | 0.2% |
| PTP | 1 | 0.1% |
| CS | 11 | 0.7% |
| UCT | 8 | 0.5% |
| TAD | 19 | 1.2% |
| TACO | 82 | 5.0% |
| TRALI | 11 | 0.7% |
| ALLO | 69 | 4.2% |
| HTR | 42 | 2.6% |
| ATR | 372 | 22.6% |
| **TOTAL** | **1645** | **100.0%** |



☒ = *The number of cases for TA-GvHD and PTP are too small to be represented on this Figure 4.1.*

IHN International Haemovigilance Network

"A set of surveillance procedures covering the whole transfusion chain (from the collection of blood and its components to the follow-up of recipients), intended to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products, and to prevent their occurrence or recurrence."

# What is HV?

- Mandated by law in many countries
- Different models:
  - Mode of participation
  - Operating agency
  - Confirmed/all, ‘near miss’ etc
  - Scope (V2V or recipients only, biovigilance)


“Vein to vein”

# HV: scope and links

- Blood and components
  - "Manufactured" conventional components: allogeneic, autologous, directed
  - Cell salvage
- Fractionated plasma products (pharmacovigilance)
- Cellular therapies, tissues and organs (biovigilance)
- Related products:
  - ESAs, rVIIa, antifibrinolytics, topical agents etc

# Other (difficult) areas

- Delayed reactions
- Inappropriate clinical decision-making
- Failure of expected benefit
- Product wastage
- Complications of procedures (e.g. IV access-related complications of therapeutic plasma exchange)

# Why are we trying to do this?

## Improve clinical management & outcomes:

- Develop guidelines and protocols for identification, investigation, management
  - Donors
  - Patients

## Education:

- Clinical and lab staff (hospitals & BTS)
- Patients and donors
- Community

# Why are we trying to do this?

## Classify reactions:

- Monitor, report, bench-mark

## Facilitate reporting and monitoring:

- Internal institutional, including audit
- HV programs
- Health authorities
- Others (public, funders, insurers etc)
- Evaluate introduction of preventive/corrective measures

# Practice improvement, not punishment

- Understand events to prevent occurrence/recurrence
- Not intended to blame or punish
- Need careful case description and in some cases RCA
- Need open discussion with staff involved
- In many countries “open disclosure” to patient mandatory
- Culture of trust, openness – time and persistence
- Staff also affected by event, need support

# Nurses ignored warning on wrong blood, court told

Claire O'Rourke

An elderly woman received a transfusion of incompatible blood and died after hospital staff ignored warnings from relatives, a court has been told.

The NSW Coroners Court heard that Mrs Antonina Malarbi, 68, of Gymea, died in the intensive care unit at St George Public Hospital on May 29 last year. She had been in a motor accident at Sylvania.

A coronial investigator, Detective Senior Constable Michael O'Rourke, said nurses involved in the administration of the incompatible blood "failed to observe existing protocols" at the hospital regarding blood transfusions.

Mrs Malarbi's death is one of three cases of incompatible blood transfusions before the Chief Magistrate, Ms Patricia Staunton, with findings and recommendations to be made on October 5.

While at her bedside, Mrs Malarbi's daughters, Mrs Connie Barbaro and Mrs Grace Compton, noticed two nurses preparing a unit of blood that carried an orange sticker marked "A positive".

"When I saw this I was taken aback, because I was under the impression that Mum's blood type was O positive," Mrs Compton said in her statement.

The daughters questioned clinical nurse specialist Kate Curtis and registered nurse Lara Angonese and were assured their mother had A positive blood. But the daughters were correct.

They said that they saw the nurses smiling and giggling after responding to their questions, which the nurses denied.

Nurse Kate Curtis, above, Grace Compton and her husband Neil, right, and Antonina Malarbi. Photos: Edwina Pickles


"From the response that she gave us I got the impression that the nurse thought that [we] were questioning her ability and telling her how to do her job," Mrs Compton said in her statement.

Mrs Barbaro searched for other hospital staff, but could not find anyone with whom to raise her concerns. She then began to doubt herself "because the nurses reassured me that there was no problem and I assumed they should know".

"I have felt great feelings of guilt that I should have insisted to the nurses, but the assurances I received at the time made me turn around and question myself."

Nurse Curtis had checked the unit of A-positive blood with nurse Jennifer Ryan, against the order sheet. But Mrs Malarbi's wristband was not checked, a requirement of hospital protocols.

After she received the blood about 5 pm, Mrs Malarbi's condition deteriorated. The error was not detected until 9.30 pm.

Mrs Malarbi died at 11.15 pm from the combined effects of multiple injuries from the car accident and the incompatible blood transfusion, Detective O'Rourke said.

The hearing continues.

Every healthcare accident has at least two victims, both of whom require support.

Stainsby, BJH 2005

Scan, LS

# Structure and governance

- Who operates the system?
  - Health authority: MoH, regulator
  - Blood service
  - Professional body
  - Centrally: single national ‘office’ vs regional with national coordination vs other
- Consider local blood sector/healthcare context

# Structure and governance

- Need clear structures and roles
- Oversight vs operation
- Link with national health policy priorities
- Resources
- Protection/indemnity
- Review and analysis
- Link with/expand other incident reporting system (sentinel events, biovigilance)?

# National Institute of Biologicals

Ministry of Health and Family Welfare, Government of India

http://nib.gov.in




- Governance
- Infrastructure
- Laboratories
- Monographs
- Sample Tracking
- Inventory Module
- Tenders NEW!
- Collaboration NEW!
- Proficiency Testing
- Haemovigilance Programme NEW!
- RTI
- Suppliers Log
- Reports/ Publications NEW!
- Daily Dispatch Reports UPDATED
- ARCHIVE NEW!
- Download NEW!


## Haemovigilance Programme

## National Institute of Biologicals & Indian Pharmacopoeia Commission Collaboration

Haemovigilance is a continuous process of data collection and analysis of Transfusion-related Adverse Reactions in order to investigate their causes and outcomes, and prevent their occurrence or recurrence.

Indian Pharmacopoeia Commission in collaboration with National Institute of Biologicals has launched a Haemovigilance Programme of India (HvPI) including Haemovigilance across the country under its Pharmacovigilance Programme of India (PvPI) with following Terms of References:

1. To track Adverse Reactions/ Events and incidence associated with Biologicals, Blood Transfusion and Blood Product Administration (Haemovigilance) as well as tissue organ and cell therapy transplantation.

2. To help identify trends, recommend best practices and interventions required to improve patient care and safety, while reducing overall cost of the healthcare system.

Haemovigilance Programme was launched on 10th Dec 2012 in already enrolled 60 Medical College under PvPI as an integral part of Pharmacovigilance Programme of India NIB is the Coordinating Centre, for HvPI to collate & analyze data with respect to Biologicals & Haemovigilance.

A Core Group & Advisory Committee in this regard have already been constituted and first meeting of advisory committee was held on 29th Nov, 2012 to finalize Haemovigilance Transfusion Reaction Reporting Form (TRRF) & Guidance Document. The committee also discussed the modalities & roadmap for implementation of other Terms of References.

**All Correspondence w.r.t Haemovigilance may be addressed to Ms. Akanksha Bisht, Member Secretary, HvPI at: haemovigilance@nib.gov.in**


Guidance Document For Reporting Serious Adverse Reactions in Blood Transfusion Service

Transfusion Reactions Reporting Form (TRRF) For Blood & Blood Products

Medical Colleges/Institute/Hospital / Blood Bank Enrolled under Haemovigilance Programme of India

Newsletter / Publication NEW!

Orders - Haemovigilance

Meetings- Haemovigilance

NEW! Training Programme

*Haemo-Vigil Software* NEW!

Haemo-Vigil Software Manual NEW

Any Queries / Suggestions kindly mail us : haemovigilance@nib.gov.in

Photo Gallery - Haemovigilance


Updates

# NHSN
National Healthcare Safety Network

## Components and Modules

**Component Patient Safety**

***Events Modules***
- *Device Associated*
- *Procedure Assoc.*
- *Medication Assoc.*
- *MDRO and CDAD*
- *High Risk Inpatient Influenza Vaccination*

**Component Healthcare Personnel Safety**

***Modules***
- *Blood/Body Fluid Exposure*
- *Vaccine*

**Component Biovigilance**

***Modules***
- *Hemovigilance - patients*

**Component Research and Development**

*eSurveillance*
- *HL7 Messages*
- *HL7 CDA*

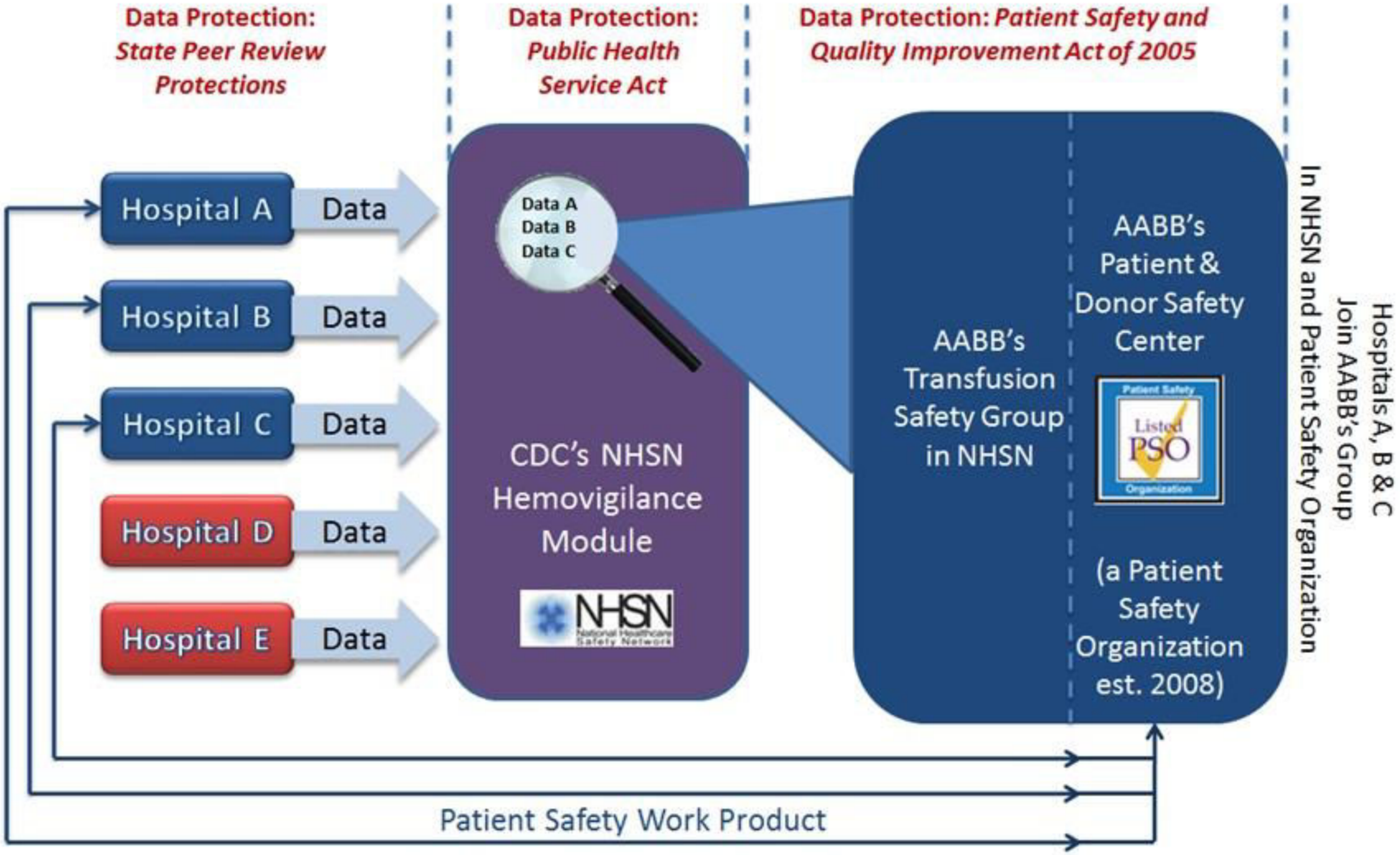
*Prevention research*

**>2,500 participating hospitals**
**Mandatory in 22 states**

Slide: Sue Stramer, AABB

U.S. Biovigilance Network

# AABB's Patient and Donor Safety Center Data Protection Diagram




**Data Protection: *HIPAA and the Patient Safety Act***

*Note: Reports, benchmarking, analysis, etc. cannot be returned to participating facility without the HIPAA Business Agreement and AABB's Participation & Confidentiality Agreement in place.*



Slide: Sue Stramer, AABB

# Who needs to be involved?

How will they be involved?

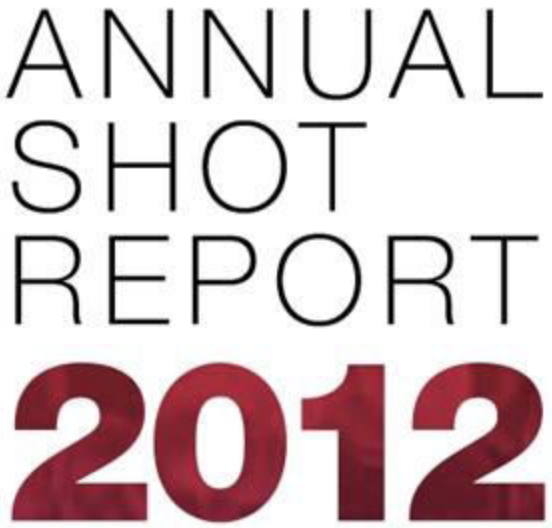
- Clinical and laboratory staff
- Health authorities
- Blood services
- Patients and broader community are ultimate stakeholders
- Other interested parties: media, lawyers, insurers, etc

# Engaging healthcare professionals and others

- "Transfusionists" = easy
- Others: surgeons, anaesthetists, obstetricians, internal medicine, ICU
- What channels:
  - Special societies and professional organisations
  - Educational/training organisations
  - Patient representative/s

Davis, Vincent, Murphy, TMR 2013

# Government and professional endorsement




**Affiliated to the Royal College of Pathologists**

**The Steering Group includes members representing the following professional bodies:**

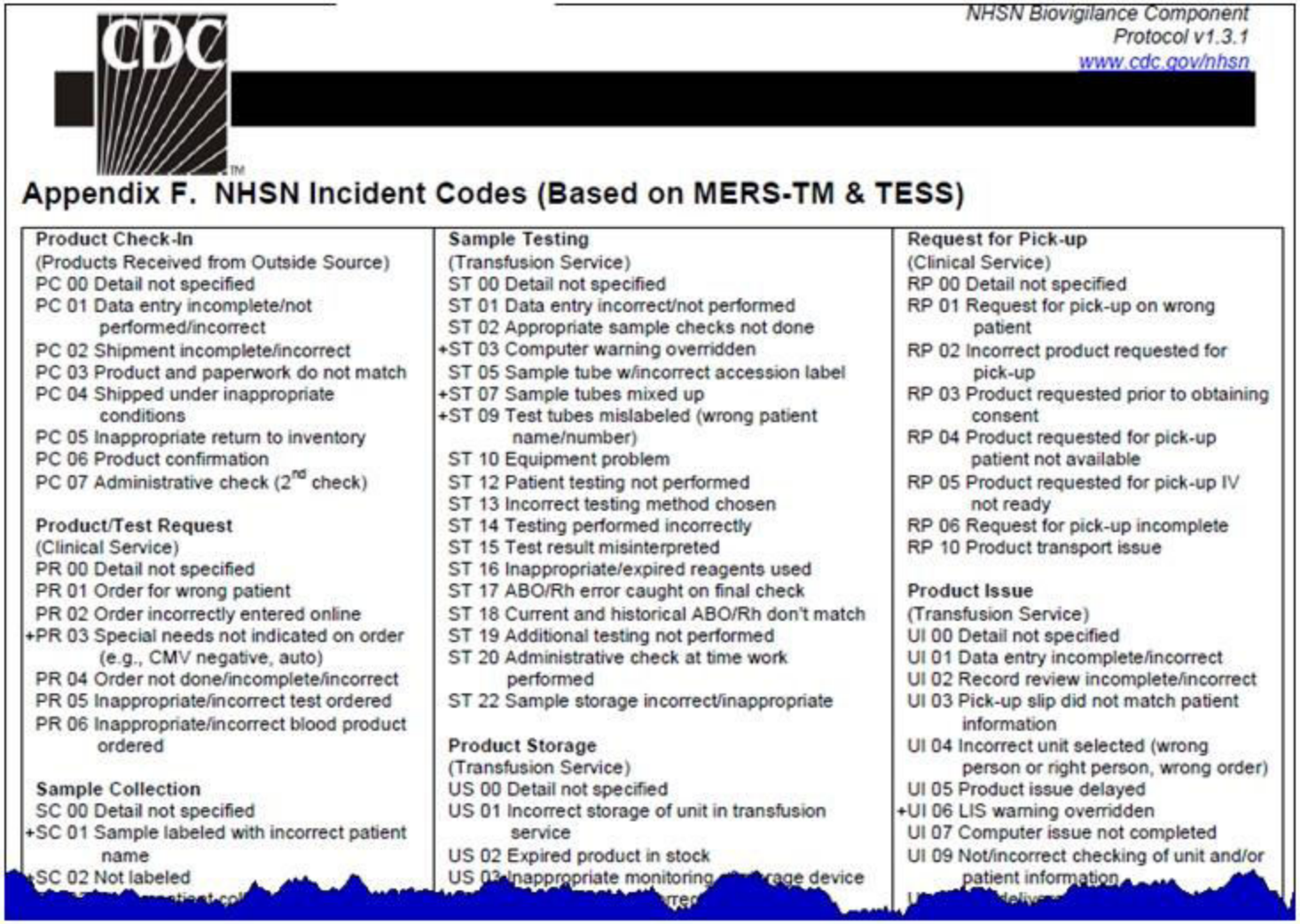
British Blood Transfusion Society
British Society for Haematology
British Society of Gastroenterology
British Committee for Standards in Haematology
Faculty of Public Health
Institute of Biomedical Science
Public Health England
(formerly the Health Protection Agency)
NHS Confederation
Royal College of Anaesthetists
Royal College of Nursing
Royal College of Midwives
Royal College of Obstetricians and Gynaecologists
Royal College of Physicians
Royal College of Surgeons
Royal College of Paediatrics and Child Health
Intensive Care Society
Faculty of Intensive Care Medicine
The College of Emergency Medicine
Defence Medical Services
UK Forum

www.shot-uk.org

# Consistent reporting

- Essential for comparisons of results
  - Over time, and with other settings or programs
  - Benchmarking
- Case definitions: develop or adapt 
- Case report forms: electronic, paper or both
- Mechanism for submitting and collating reports

# Incident Codes



NHSN Biovigilance Component
Protocol v1.3.1
www.cdc.gov/nhsn

## Appendix F. NHSN Incident Codes (Based on MERS-TM & TESS)

**Product Check-In**
(Products Received from Outside Source)
PC 00 Detail not specified
PC 01 Data entry incomplete/not performed/incorrect
PC 02 Shipment incomplete/incorrect
PC 03 Product and paperwork do not match
PC 04 Shipped under inappropriate conditions
PC 05 Inappropriate return to inventory
PC 06 Product confirmation
PC 07 Administrative check (2nd check)

**Product/Test Request**
(Clinical Service)
PR 00 Detail not specified
PR 01 Order for wrong patient
PR 02 Order incorrectly entered online
+PR 03 Special needs not indicated on order (e.g., CMV negative, auto)
PR 04 Order not done/incomplete/incorrect
PR 05 Inappropriate/incorrect test ordered
PR 06 Inappropriate/incorrect blood product ordered

**Sample Collection**
SC 00 Detail not specified
+SC 01 Sample labeled with incorrect patient name
+SC 02 Not labeled

**Sample Testing**
(Transfusion Service)
ST 00 Detail not specified
ST 01 Data entry incorrect/not performed
ST 02 Appropriate sample checks not done
+ST 03 Computer warning overridden
ST 05 Sample tube w/incorrect accession label
+ST 07 Sample tubes mixed up
+ST 09 Test tubes mislabeled (wrong patient name/number)
ST 10 Equipment problem
ST 12 Patient testing not performed
ST 13 Incorrect testing method chosen
ST 14 Testing performed incorrectly
ST 15 Test result misinterpreted
ST 16 Inappropriate/expired reagents used
ST 17 ABO/Rh error caught on final check
ST 18 Current and historical ABO/Rh don't match
ST 19 Additional testing not performed
ST 20 Administrative check at time work performed
ST 22 Sample storage incorrect/inappropriate

**Product Storage**
(Transfusion Service)
US 00 Detail not specified
US 01 Incorrect storage of unit in transfusion service
US 02 Expired product in stock
US 03 Inappropriate monitoring of storage device

**Request for Pick-up**
(Clinical Service)
RP 00 Detail not specified
RP 01 Request for pick-up on wrong patient
RP 02 Incorrect product requested for pick-up
RP 03 Product requested prior to obtaining consent
RP 04 Product requested for pick-up patient not available
RP 05 Product requested for pick-up IV not ready
RP 06 Request for pick-up incomplete
RP 10 Product transport issue

**Product Issue**
(Transfusion Service)
UI 00 Detail not specified
UI 01 Data entry incomplete/incorrect
UI 02 Record review incomplete/incorrect
UI 03 Pick-up slip did not match patient information
UI 04 Incorrect unit selected (wrong person or right person, wrong order)
UI 05 Product issue delayed
+UI 06 LIS warning overridden
UI 07 Computer issue not completed
UI 09 Not/incorrect checking of unit and/or patient information

Slide: Sue Stramer, AABB

U.S. Biovigilance Network

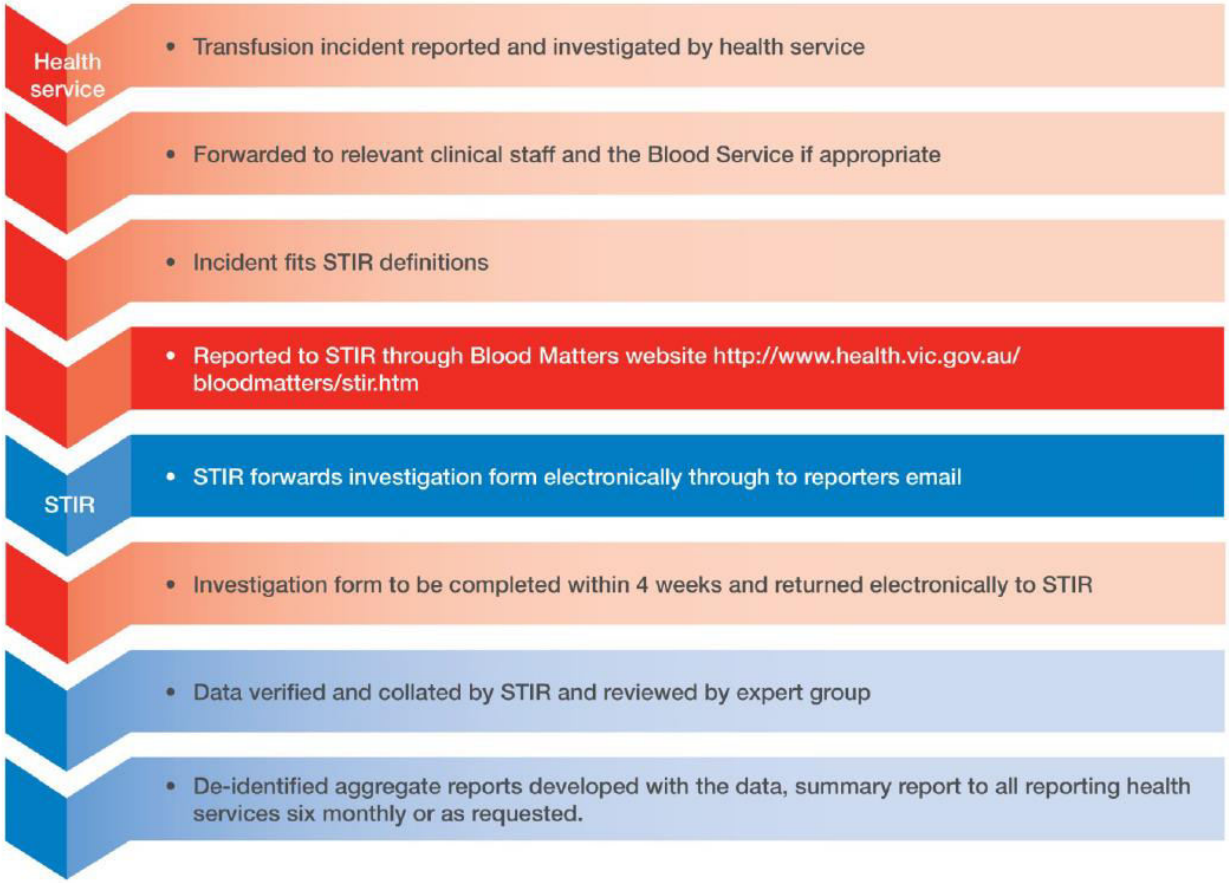
health

Blood Matters: Serious Transfusion Incident Reporting guide

Revised 2013

Victoria

# Serious Transfusion Incident reporting flowchart




www.health.vic.gov.au/bloodmatters/stir.htm

State Government of Victoria, Australia

Department of Human Services

# Serious Transfusion Incident Report (STIR)

The * symbol indicates required information.

Any data submitted using this electronic form via the Internet is secure and will be encrypted using SSL (Secure Sockets Layer)

**The Serious Transfusion Incidents Reporting (STIR) system is a central reporting system for serious adverse events with transfusion of blood or blood components including near-miss incidents**

**Please use this form to report serious incidents with transfusion of fresh blood and blood components.**

**Confidentiality of data is fundamental to the success of this scheme. We have not requested unique patient indentification details. We will contact you to obtain additional details if necessary.**

**Key details of incident**

* Hospital code
* Patient details ◯ Male ◯ Female
* Age
* Description of Age -SELECT-

**Details of product -including autologous**

* Please tick (you may check more than one box) ☐ Red Cells ☐ Platelets ☐ Fresh frozen plasma ☐ Cryoprecipitate ☐ Other

Other (please specify)

* Date of Implicated Transfusion or date of sample (dd/mm/yyyy)
* Time of implicated transfusion or time of sample (hh:mm - based upon a 24 hour clock i.e. 08:35 or 21:58)

**Nature of Incident**

| | | |
|---|---|---|
| 1. Incorrect Blood component transfused | Category of Incident | -SELECT- |
| 2. Acute transfusion reaction (including anaphylaxis) | Category of Incident | -SELECT- |
| 3. Delayed transfusion reaction | Category of Incident | -SELECT- |
| 4. Transfusion-associated circulatory overload (TACO) | Category of Incident | -SELECT- |

Detailed, incident-specific follow up form

# What information to collect?

- What is “just right”?
- Too much information: time-consuming, and not always possible
- Too little: inadequate for analysis

HSE
ADU
RBRP
WCT
SRNM
TRALI
TAD
TACO
ALLO
HTR
ATR

Fig 2.3a – All events in haematology

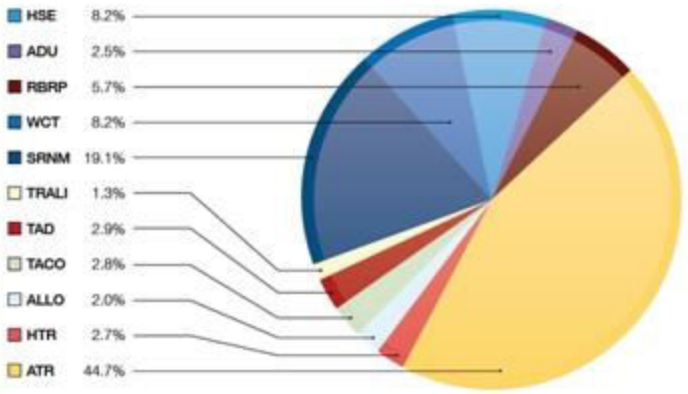



Fig 2.3b – All events in emergency medicine

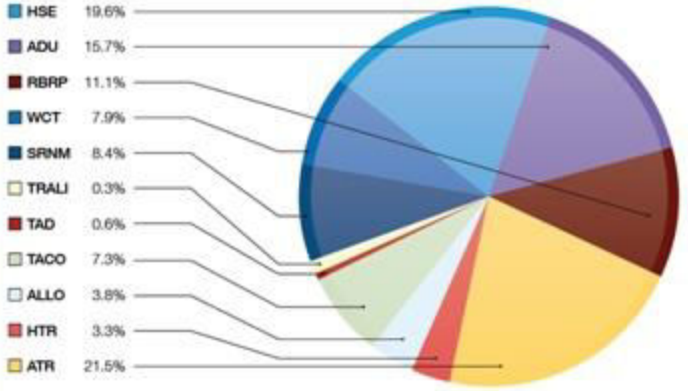
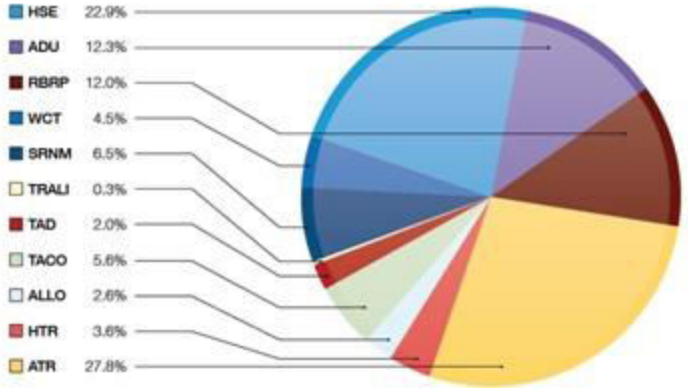



Fig 2.3c – All events in general medicine



# Case validation

Will validation be performed? If so, by:

- Hospital – access to all available information but not necessarily independent or have expertise
- Expert group (independent, but remote in time and place from actual event)?

# Resources

- People
- Data: reports, denominators etc
- IT/data management
- Money
- Permission/support/endorsement/promotion

# People: roles and responsibilities

Hospitals/other clinical settings:

- Medical oversight
- Transfusion safety officers, TP/TN
- Transfusion committee
- Quality managers
- Executive management



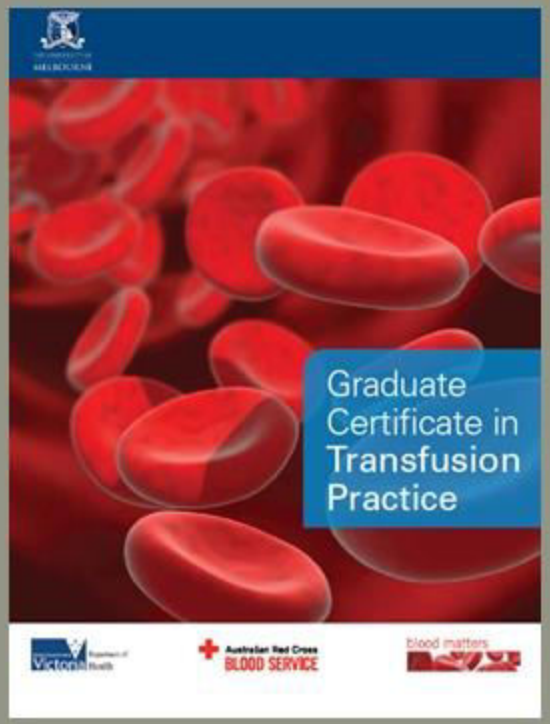
# People: roles and responsibilities

In the HV program

- Program management
- Transfusion content knowledge
  - Manage reporting process
  - Data analysis
  - Expert group – range of clinical experience
- Data management, analysis and reporting

# What else do we need?

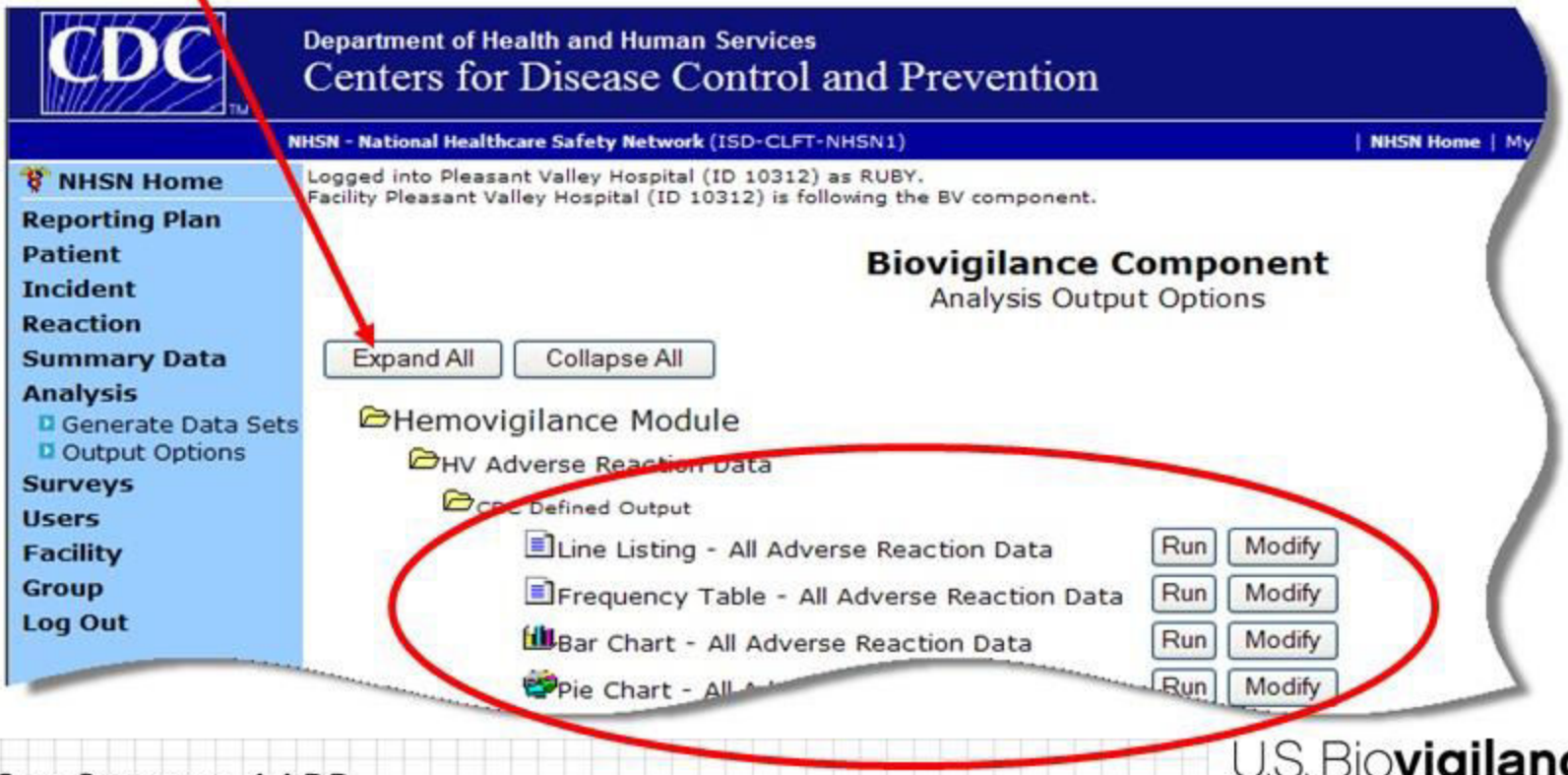
- Authority and responsibility
- Dedicated time
- Education, training, experience
  - Transfusion content
  - Quality and safety: e.g. clinical audit
  - Project management
  - Data and database management
  - Privacy, security etc
  - Analysis and reporting




www.health.vic.gov.au/bloodmatters/cert.htm

# US Hemovigilance: Analysis

- **Analysis output options available in NHSN**
  - Reports are "canned" with pre-defined variables but can be modified by the user




Slide: Sue Stramer, AABB

U.S. Biovigilance Network

# How will the information be used?

- Health policy development
- Clinical practice standards and guidelines
- Education and training for healthcare staff
- Reports to the community
- Sharing experience and reports can provide valuable feedback locally and nationally
- Target priority areas
- Develop and implement better systems

# Many challenges

- Getting everyone on board
- Measuring participation and progress
- Funding and support for
  - HV program
  - Implementation (e.g. IT)

# What and how?

- No ‘one size fits all’
- Have a plan, review, revise
- Can start small
  - better to start than not
  - it takes time
- Learn and borrow from other systems
- Share results
- Integrate with other activities

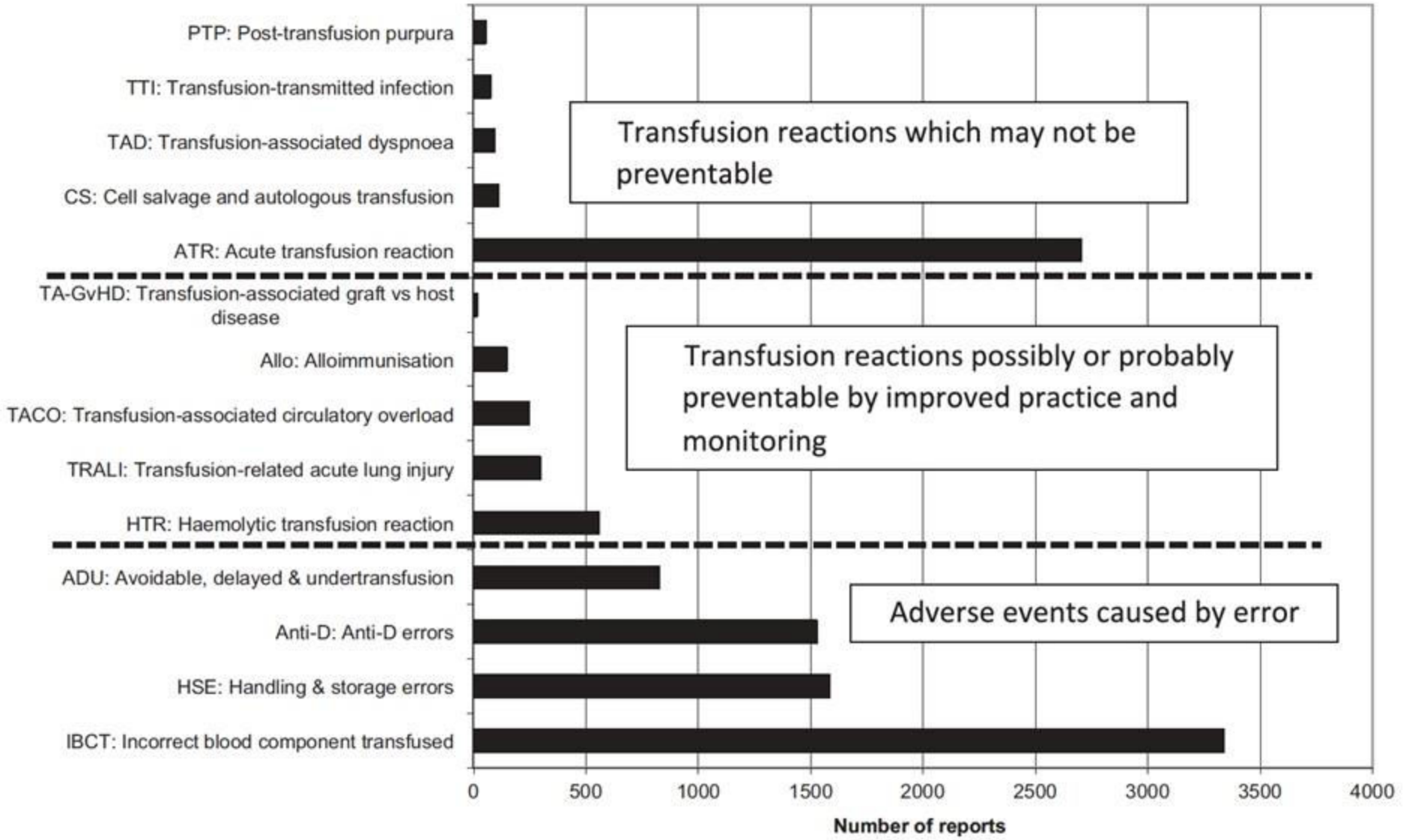
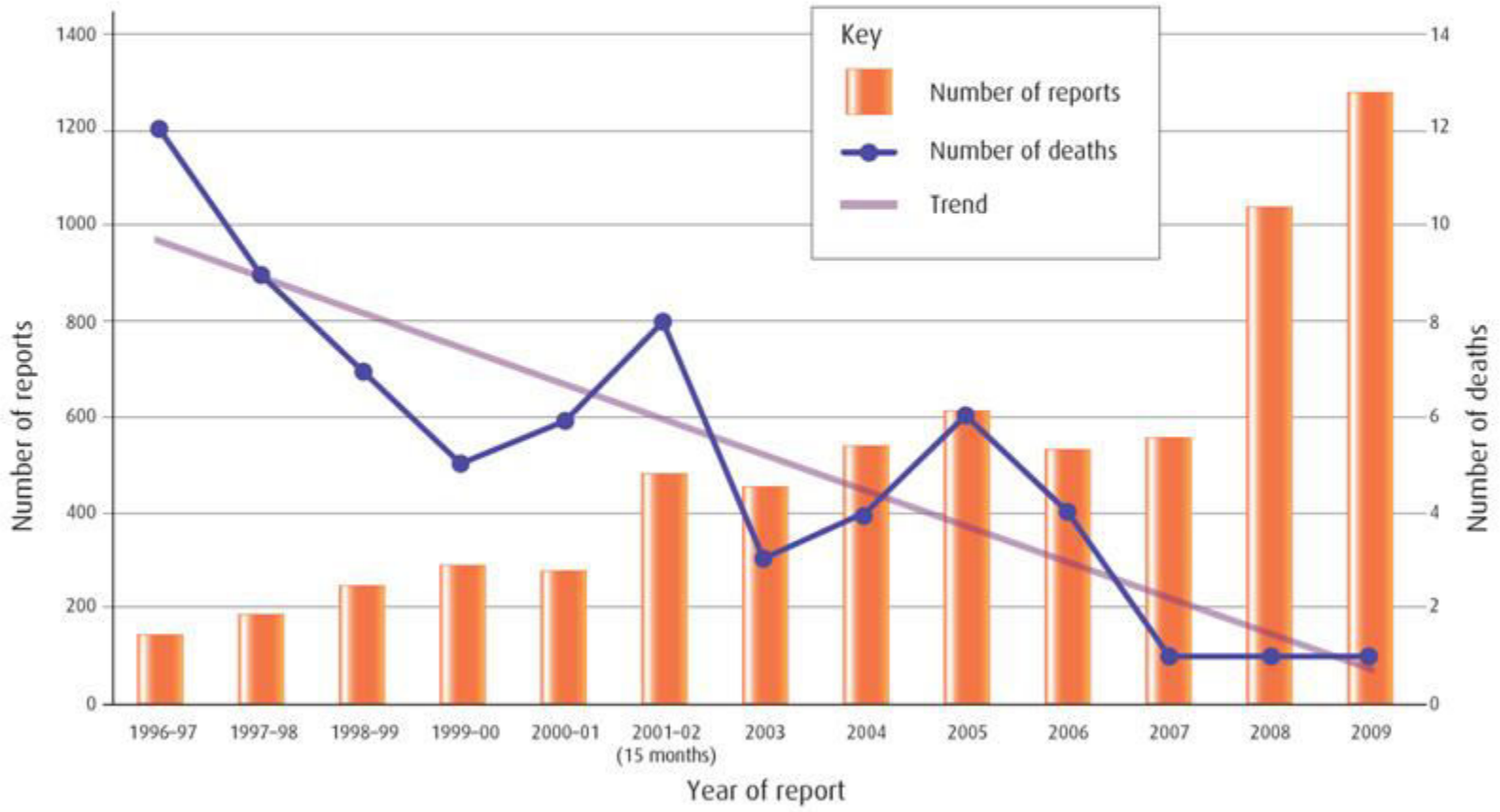



Fig 1. Cumulative data for SHOT categories 1996/7 to 2012, n 11570. Reported events can be divided into three groups: those caused by error that should be preventable, those caused by unpredictable reactions, and an intermediate group of complications that may be preventable by better pretransfusion assessment and monitoring.

Bolton-Maggs and Cohen, BJH 2013

# HV does work

Figure 1
Total reports and total deaths definitely due to transfusion between 1996 and 2009




www.shotuk.org

# ISBT working party on haemovigilance

Chair: Dr Jo Wiersum, NL

Open to individual members of ISBT with interest in HV

Donor and recipient HV

Next meeting:
ISBT congress, Seoul 2014

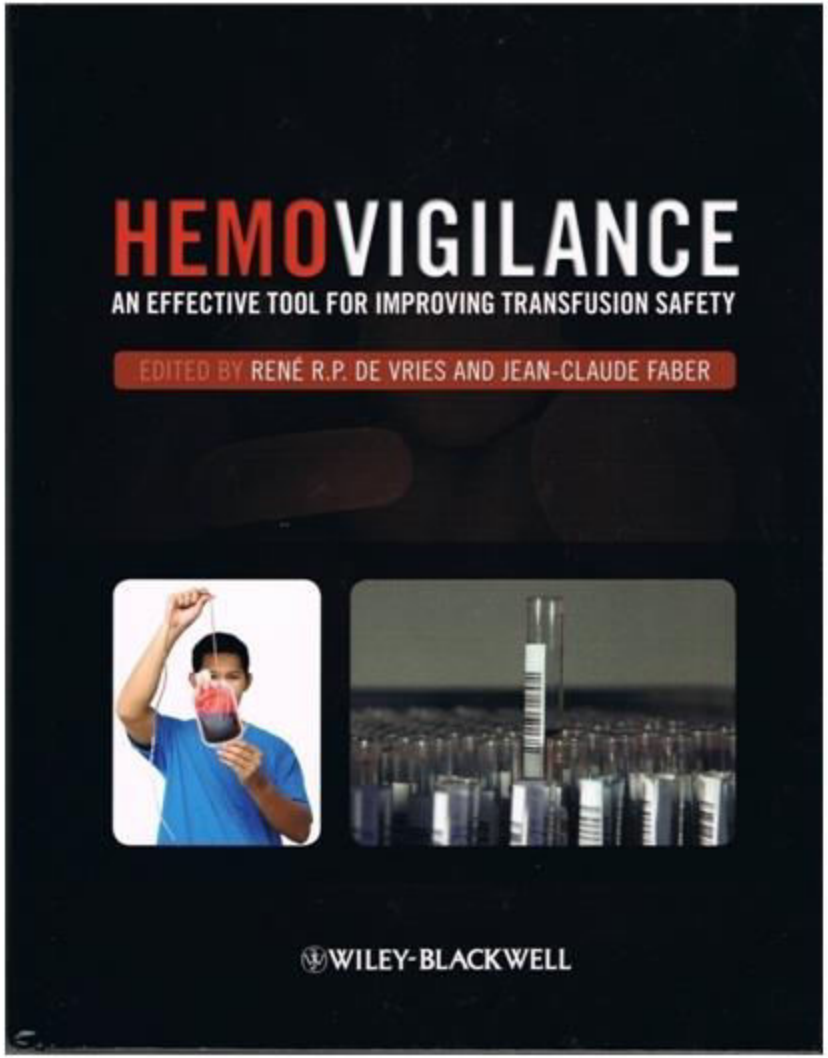
IHN International Haemovigilance Network

- International network of HV systems
- Educate, collaborate, share experience, benchmark
- International database (ISTARE)
- Definitions (with ISBT)
- Award and medal



16th Annual IHS
5-7 March 2014

IHN International Haemovigilance Network



IHN International Haemovigilance Network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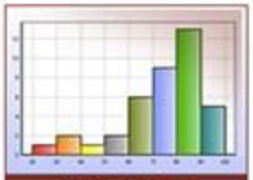
## Welcome to the International Haemovigilance Network


IHN Members Area


IHN Symposium


Resource Library


Donor Vigilance Database

ISTARE


National & International Haemovigilance Systems

The International Haemovigilance Network was formed in 2009 from the European Haemovigilance Network which itself was founded in 1998.

The membership of the network consists of national, operational haemovigilance systems. These organisations join the group on behalf of their country, with a nominated

### Latest News

**IHN Award**

IHN Award 2013 goes to Constantina Politis

View more...

**IHS XVI Barcelona 5-7 March 2014**

Registration details and travel fellowships

View more...

**IHN Medal**

Dr Paul Strengers

# National Healthcare Safety Network (NHSN)

NHSN
About NHSN
Enroll Here
Materials for Enrolled Facilities
Acute Care Hospitals/Facilities
Surveillance for Antimicrobial Use and Antimicrobial Resistance
Surveillance for CAUTI
Surveillance for *C. difficile* and MRSA Infections
Surveillance for CLABSI
Validation Guidance and Toolkit; Validation for 2012 CLABSI in ICUs
Surveillance for CLIP Adherence
Surveillance for SSI Events
Surveillance for VAE
Surveillance for VAP Events
Surveillance for Healthcare Personnel

NHSN > Materials for Enrolled Facilities > Acute Care Hospitals/Facilities

Email page link
Print page
Recommend Tweet Share

## Blood Safety Surveillance

### Resources for NHSN Users Already Enrolled

#### Training

- Facility Enrollment or Component Activation [PDF - 1.49 MB]
  **Audience:** Facilities interested in participating in the Hemovigilance Module.
- Surveillance Requirements and Data Reporting [PDF - 987 KB]
  **Audience:** Facilities participating in the Hemovigilance Module.
- Incident Reporting [PDF - 1.60 MB]
  **Audience:** Hemovigilance Module users that will be collecting and entering data on incidents related to blood transfusion.
- Adverse Reaction and Denominator Reporting [PDF - 1.18 MB]
  **Audience:** Hemovigilance Module users that will be collecting and entering data on blood transfusion recipient adverse reactions.
- Hemovigilance Module: Introduction to Analysis [PDF - 1.04 MB]
  **Audience:** Blood transfusion services personnel collecting and/or entering information on blood transfusion recipient

### Webinar Registration

The NHSN Biovigilance Component Team will be conducting a training webinar for the Hemovigilance Module.
**Date: Thursday, December 5, 2013**
**Time: 2:00 – 3:00 pm ET**
Registration deadline December 3, 2013

**Go to registration ››**

### On this Page



### New Users - Start Here

Step 1: Enroll into NHSN

NHSN Login
Continuing Educ Opportunities

Get email upda
To receive email updates about this page, enter your e address:
What's this?


## What's New

**15 November 2013** **Transfusion Information of transfusion-related AE/ARs and TTIs 2012 uploaded.**

9 May 2013 Transfusion Information of Transfusion-Related Acute Lung Injury uploaded.

15 October 2012 Transfusion information of transfusion-related AE/ARs and TTIs 2011 uploaded.

15 October 2012 Blood Services 2011 & 2012 (booklet about Japanese blood service) released.

## Haemovigilance Reports

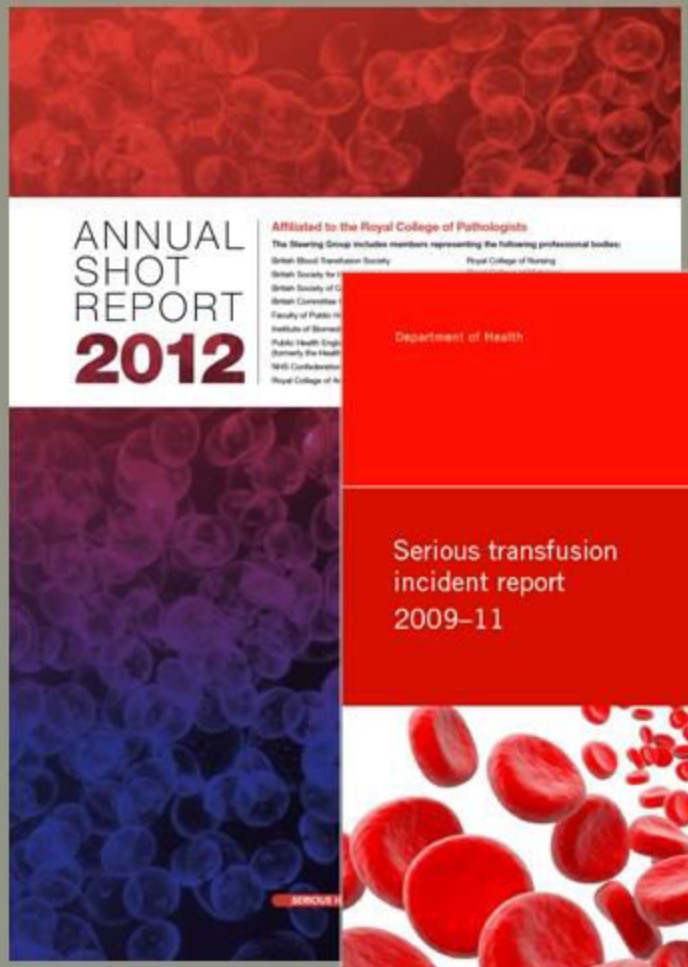
Haemovigilance Report 2008 [PDF:5000kb]

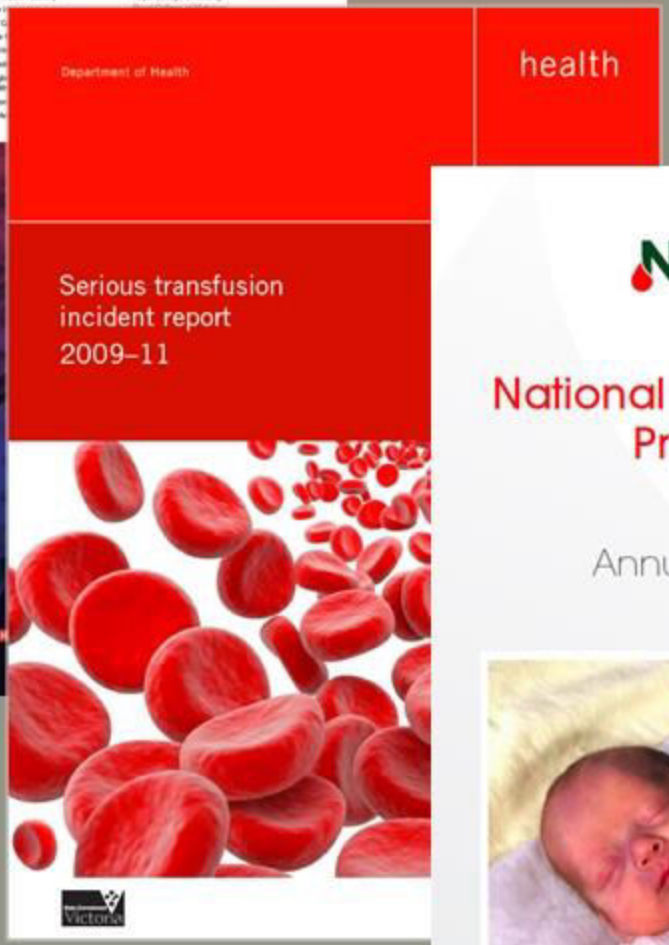
Haemovigilance Report 2007 [PDF : 2200kb]

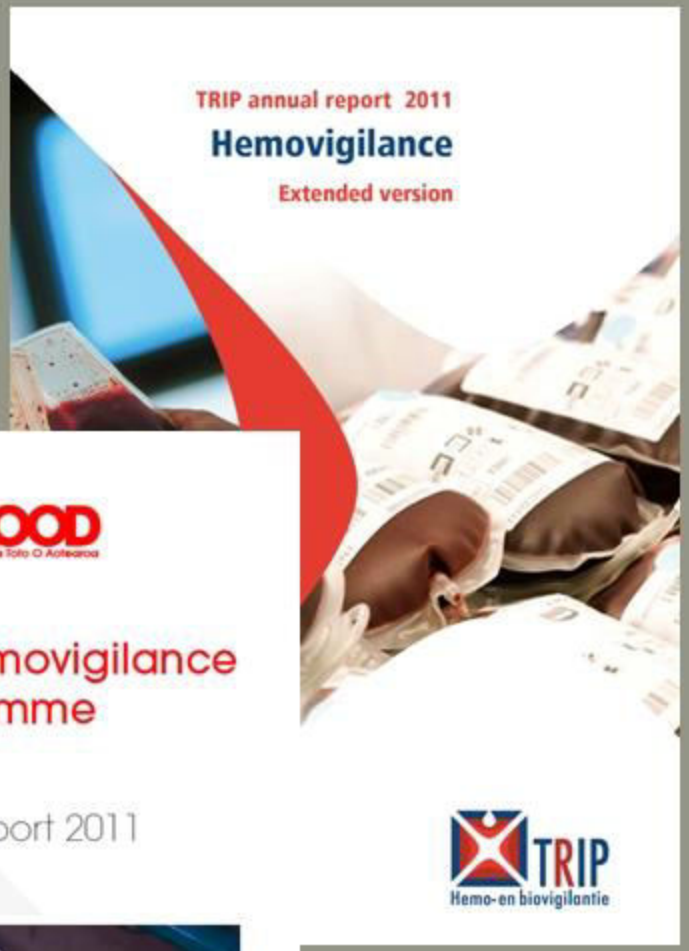
## Transfusion Information

Non-Hemolytic Transfusion Reaction Cases 2012(No.137) [PDF:1,074KB]

Transfusion Transmitted Infectious Cases 2012(No.136)


ANNUAL
SHOT
REPORT
2012
Affiliated to the Royal College of Pathologists


Department of Health
health
Serious transfusion
incident report
2009–11


TRIP annual report 2011
Hemovigilance
Extended version
TRIP
Hemo-en biovigilantie


NZBLOOD
National Haemovigilance
Programme
Annual Report 2011


The most important knowledge in the field of patient safety is how to prevent harm to patients during treatment and care. The fundamental role of patient safety reporting systems is to enhance patient safety by learning from failures of the health care system. We know that most problems are not just a series of random, unconnected one-off events. We know that health-care errors are provoked by weak systems and often have common root causes which can be generalized and corrected. Although each event is unique, there are likely to be similarities and patterns in sources of risk which may otherwise go unnoticed if incidents are not reported and analysed.

# Acknowledgements


- STIR: Linley Bielby, Lisa Stevenson, Peter Beard, Bridget Glazebrook
- IHN Board: Jo Wiersum, Paula Bolton-Maggs, Jean-Claude Faber, Martin Schipperus, Peter Tomasulo
- ISBT Working Party on HV
- Susan Stramer, AABB
- Mike Murphy, Oxford

# Definitions and tools for haemovigilance

Johanna (Jo) Wiersum-Osselton

IHN International Haemovigilance Network

TRIP Hemo- en biovigilantie

ISBT

- Introduction
- Donor complications
- TRALI
- Errors and incidents
- Denominators
- An ongoing journey, multiple stakeholders

# What is a definition for?

- Diagnosis
  - Bedside guidance
    - apply transfusion reaction protocol
    - Treatment of blood donation complication
  - Medical

- Classifying for “counting”
  - Type of reaction
  - Imputability
  - Severity
  - >Epidemiology, research, management

# Need for standardised definitions

- Essential if comparisons from different haemovigilance systems are to be made.
- These definitions should be simple yet precise enough to be able to classify most adverse transfusion events for purposes of surveillance.
- Surveillance definitions are not intended as strict diagnostic criteria.

Preamble of ISBT/IHN definitions, 2011

# History

- European hemovigilance network, from 2004:
  - Draft definitions for adverse transfusion events - >heated debates, multiple rounds of corrections!
  - Draft definitions for donor complications
- ISBT haemovigilance working party, from 2005
- Activity on definitions merged between EHN (later IHN) and ISBT, approx. 2008

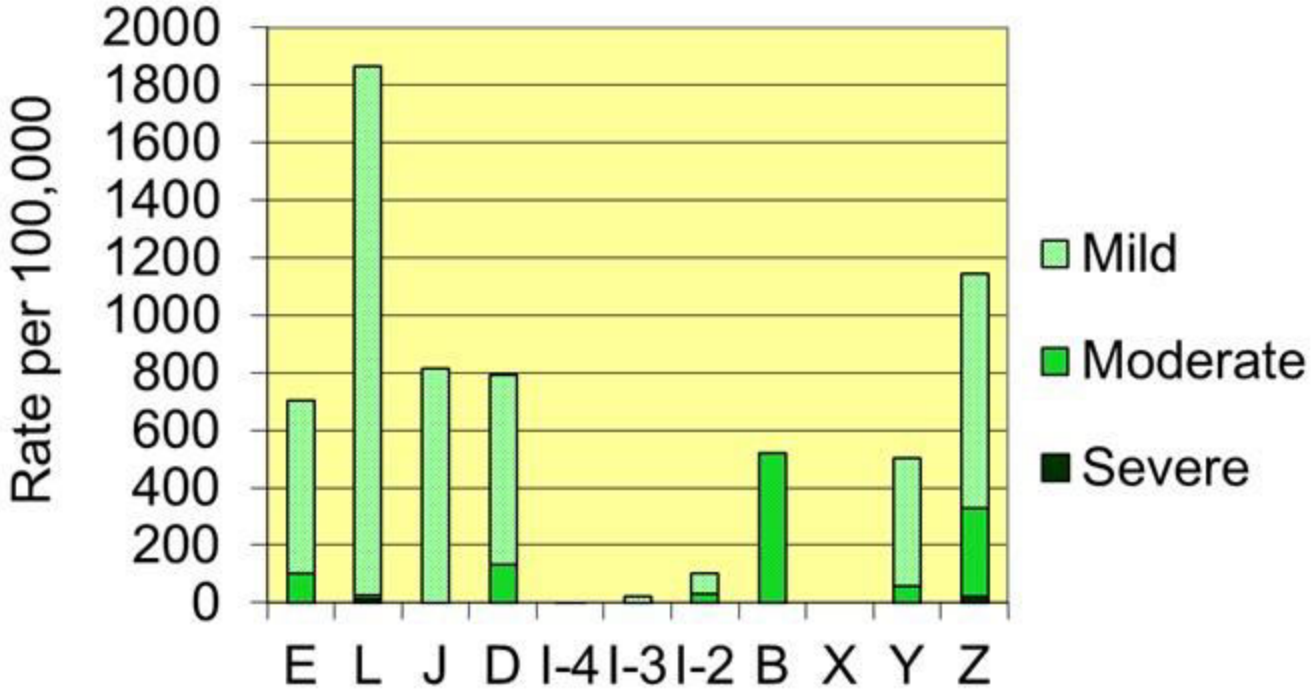
# Current status of ISBT/IHN definitions

- Donor complications, 2008 (on www); review in progress 2013
- Non-infectious transfusion reactions: 2011 (on www)
  - minor correction (TRALI) 2013
  - Revision of TACO definition in progress
  - Project on paediatric HV definitions launched 2013
- Transfusion-transmitted bacterial infections (draft; TTI working party)
- Errors and incidents in the transfusion chain (sentinel events only) adopted 2011. Further types may be added.

# Donor complications: vasovagal reactions (VVR)

National data from ISTARE (International surveillance database of adverse reactions and events; IHN)

## Rate and severity of VVR, 2010



# Vasovagal reactions

## Further classification?

- EU "serious": hospital admission, life-threatening, chronic morbidity (adopted by IHN/ISBT)
- Immediate vs delayed (IHN/ISBT: delayed = off site; US: onset after 15 mins)
- Mild vs moderate
  - IHN/ISBT: subjective symptoms vs objective; yes/no injury
  - US Biovigilance lists features
    - Loss of consciousness
    - Complications e.g. convulsions or loss of bladder control; time to of recovery
    - Outside medical care; injury

# Vasovagal reactions

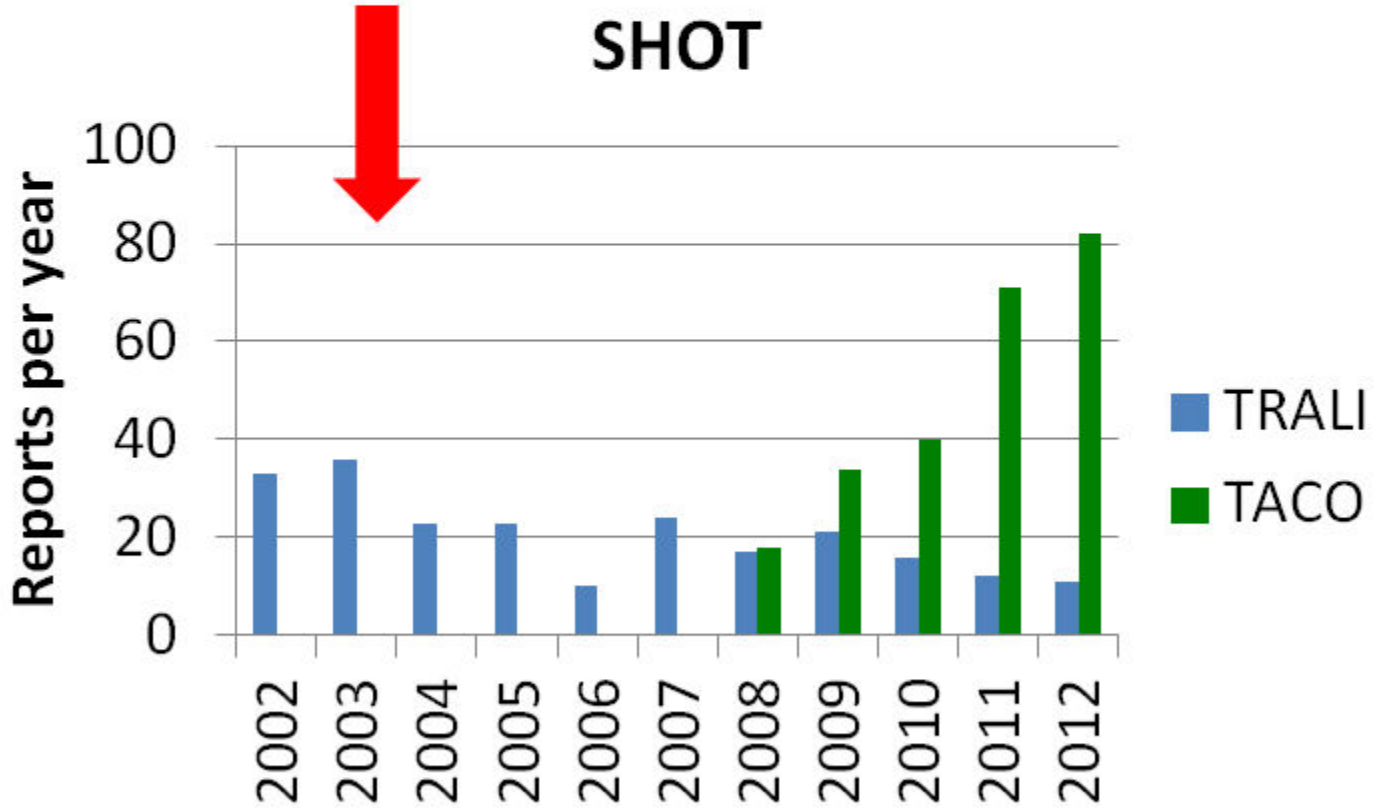
ISBT Cancun 2012:

Decision to revisit donor complication definitions to align with recent scientific advances, e.g.

- risk factors differ according to time of occurrence of vasovagal reactions (Bravo et al, 2011)
- Loss of consciousness associated with injury/risk of long-term harm
- Effective interventions available: which donors to target?

# TRALI/TACO

Does a system actually capture the reaction?




TACO captured from 2008

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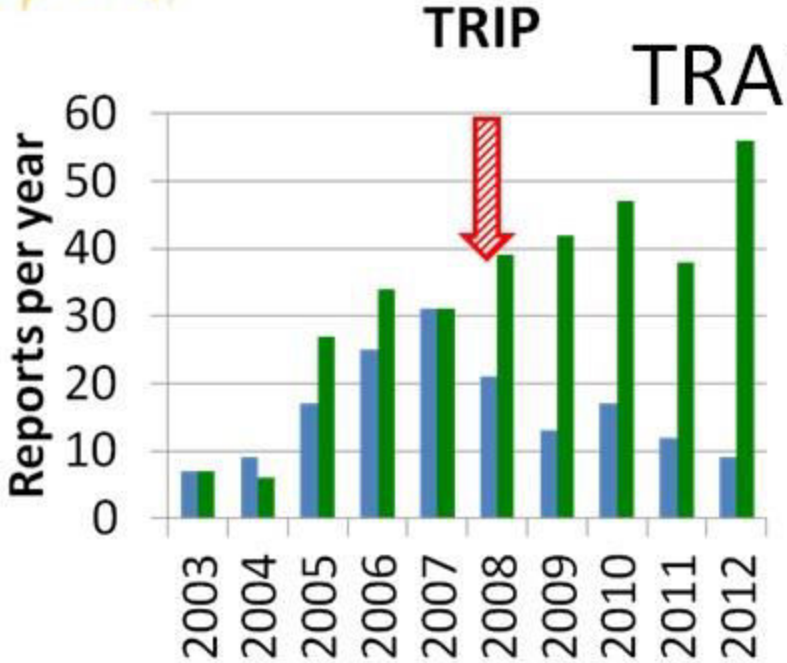
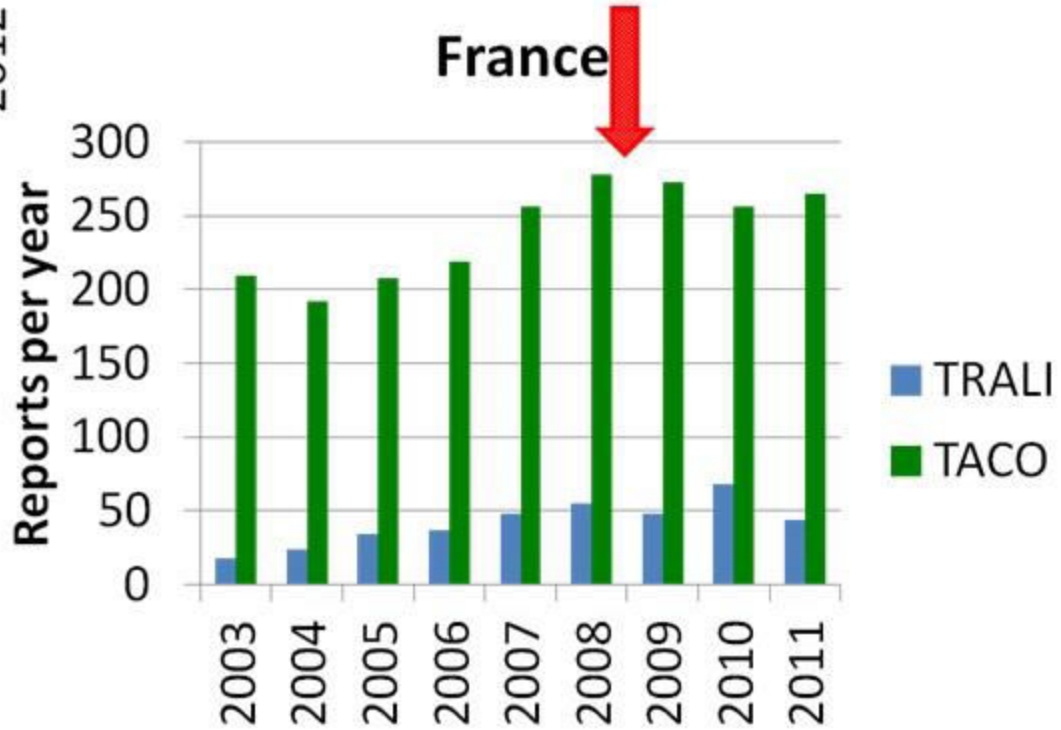
ISBT

# TRALI/TACO



# TRALI/TACO

## National Haemovigilance Office, Ireland

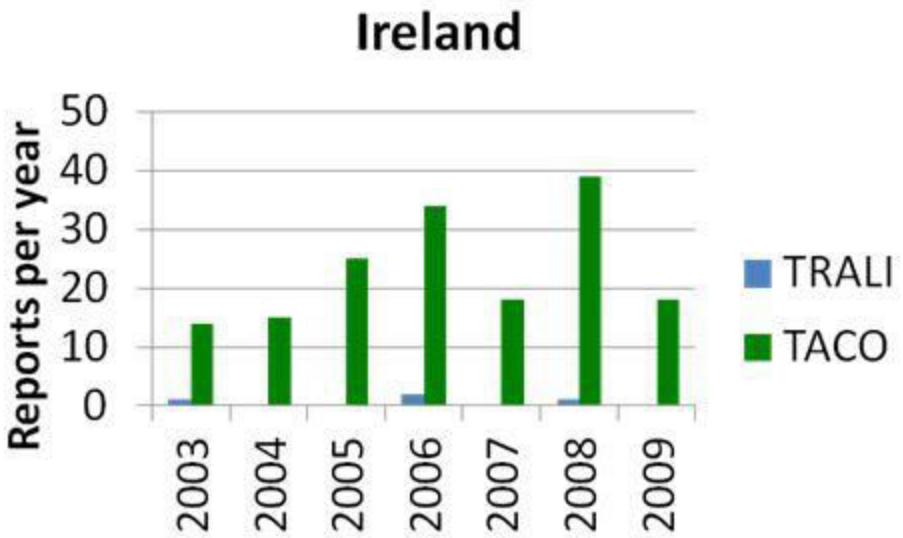
### 2008/2009 report

"during, or within some hours of transfusion and can include any or all of the following: dyspnoea, orthopnoea, cyanosis, tachycardia hypertension and pulmonary and/or pedal oedema. Chest auscultation reveals the presence of rales (**Popovsky, 2001).**

**ISBT definition "more restrictive": only 1 of the 39 NHO TACOs in 2008 would meet the ISBT definition**

"any four of the following occurring within 6h of completion of transfusion:

- Acute respiratory failure
- Tachycardia
- Increased blood pressure
- Acute or worsening pulmonary oedema on frontal chest radiograph
- Evidence of positive fluid balance"



# Case History 11 (TRALI)

from NHO report 2008/9

Admission for stabilisation of new DM; PMH of bowel disease, no cardiac or respiratory history. Developed haematemesis and melaena, shock, Hb 6.5 g/dL

"transfused with three RBCs prior to endoscopy which identified a large bleeding duodenal ulcer. Transferred to ICU, transfused a further two units RBCs. On the following day she was transfused two RBCs prior to transfer to theatre. She then received two units of SD plasma , 1L crystalloid and 500mls of plasma expander (total 2400 mls in about two hrs). She was stable intra-operatively with no obvious bleeding points. Half an hour after return to ICU the patient became acutely unwell. Her systolic blood pressure increased by 60 mm Hg and she had a tachycardia of 110/min, frothy sputum and blood stained secretions in her mouth. Her oxygen saturations disimproved (94% on 100% O2). She was re-ventilated and given frusemide 40mgs with no noticeable increase in diuresis. Chest X-ray showed bilateral perihilar alveolar consolidation consistent with pulmonary oedema, shock lung or aspiration. Her central venous pressure was 20 and remained between 15-20 over the next eight hours. At 08.00 hrs on day 3 she was in a positive balance of 2,396 ml. (Her weight was approx. 44 kg.) She received further doses of diuretic between day 3 and day 6. Chest X-ray on day 4 showed some improvement compared to day 2 but she continued to require ventilation until day 9."

TACO definition revision launched 2013

COMMENT The absence of HLA antibodies in the donors and clinical features suggested TACO. Against TACO was the failure to respond to diuretics and the long period before recovery. After discussion with the reporting physicians, the case was collected as possible TRALI.

# Incorrect blood component transfused

## Definition

The category Incorrect Blood Component Transfused (IBCT) includes all reported episodes where a patient was transfused with a blood component that was intended for another patient or which was of inappropriate specification and did not meet the particular requirements of the patient.

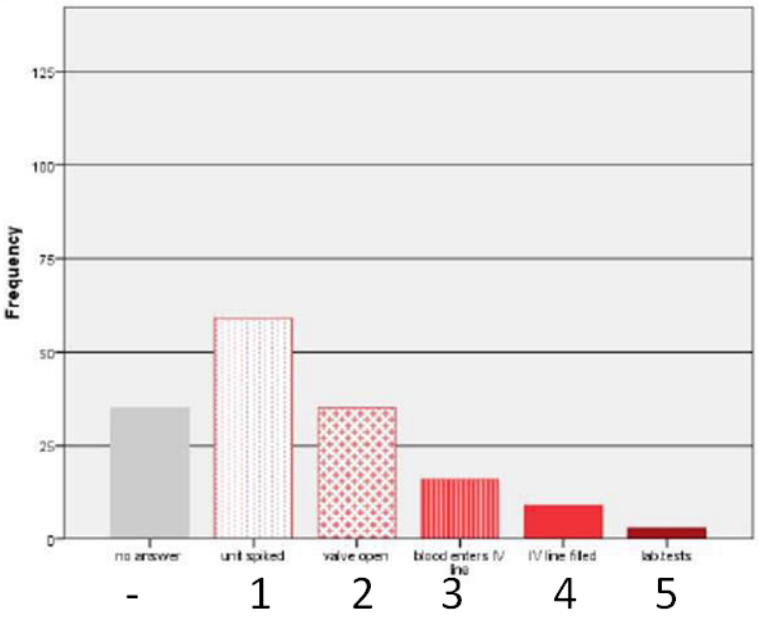
TRIP

Case

E. What in your opinion should be
which a transfusion is considere

1) Unit spiked (cannot be used

2) Unit spiked and valve opene

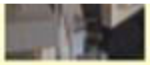



## ADDITIONAL MATERIAL

**1 The patient was transfused…**

Transfusion shall be deemed to have started when the final pretransfusion checks have taken place and the next step (according to local SOP or national guidelines) has been performed. In many countries this will be at the moment of spiking the unit.

filled with blood



5) Unit spiked, valve opened, IV line completely filled with blood and evidence of administration of donor blood (laboratory tests)

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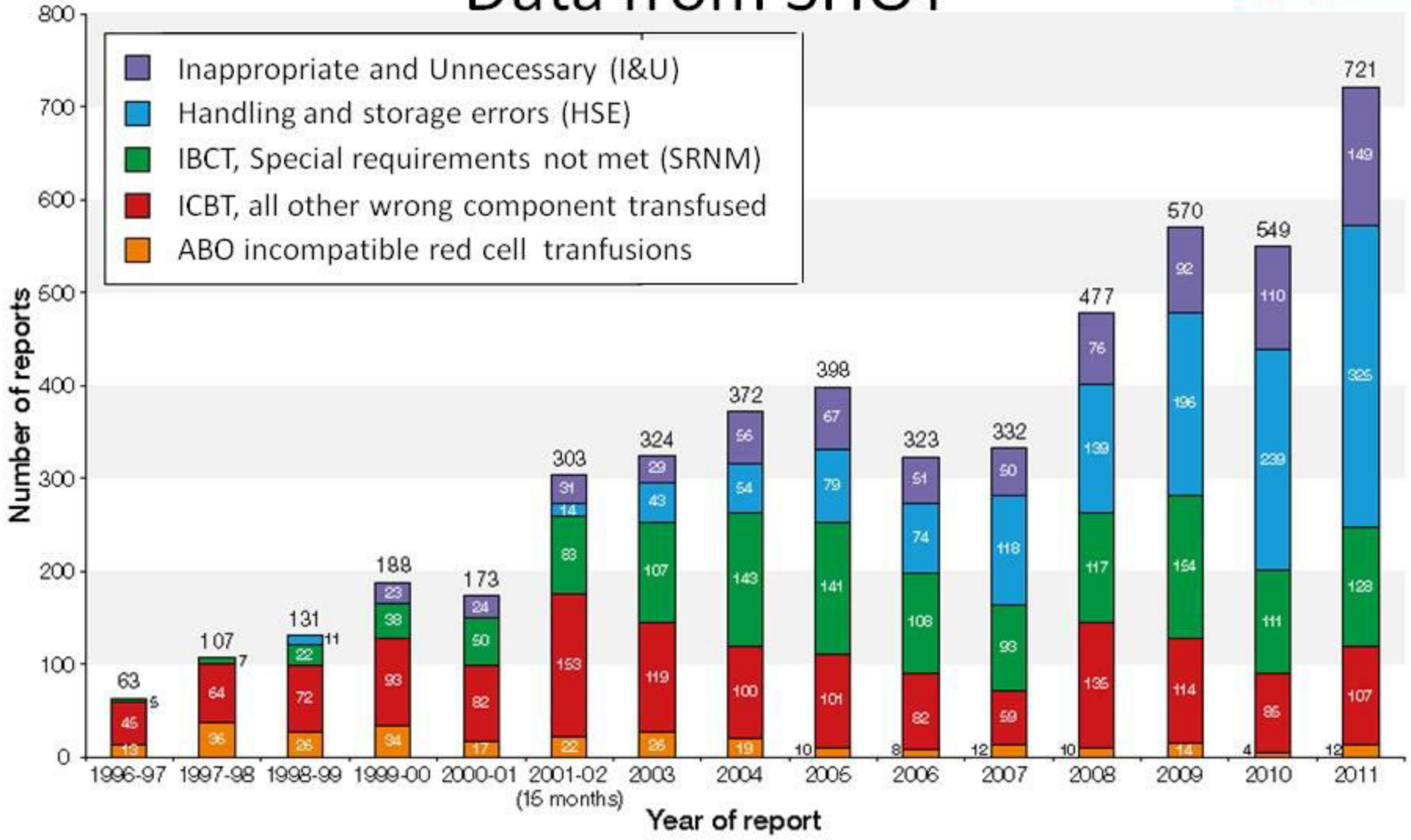
# Data from SHOT



# International comparison

| Country | Reports captured | per 1000 units | | | Status |
|---|---|---|---|---|---|
| | | Total reports | IBCT | ABO-incompatible RBC | |
| France 2011 | all | 2.5 | 0.07# | 0.001 | Mandatory |
| UK 2011 | serious | 1.0* | 0.08$ | 0.004 | Voluntary[1] |
| Ireland 2008-9 | serious | 1.22 | 0.72$ | 0.005 | Voluntary[1] |
| TRIP 2011 | all | 3.9 | 0.07 | 0.006 | Voluntary[1] |

#serious incidents with transfusion, grade 0 and grades 1-4

*including near miss

$not including handling & storage errors or inappropriate /unnecessary/delayed transfusions

[1]Originally voluntary, professionally mandated; later serious reactions/events subject to mandatory reporting

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ISBT

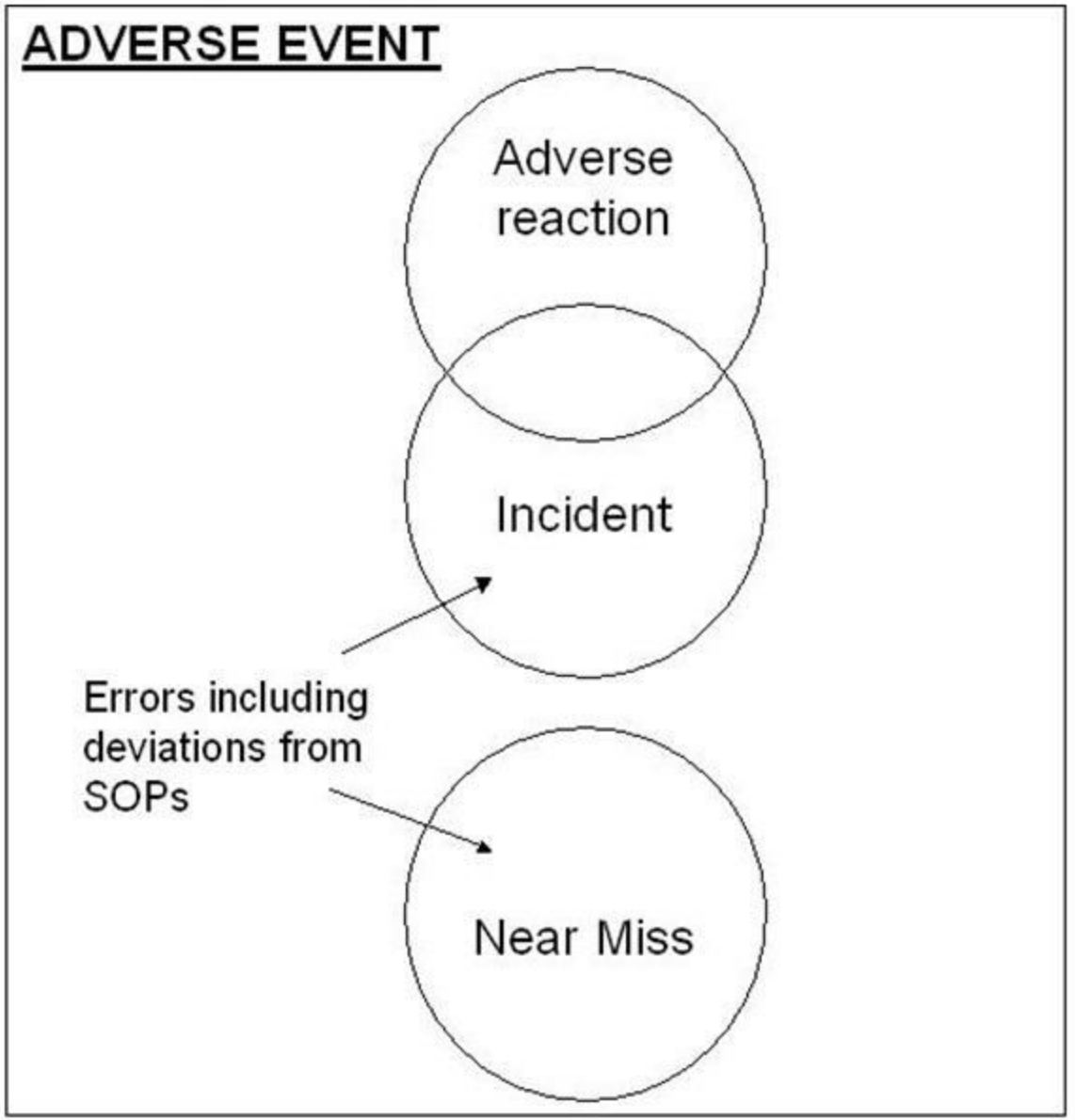
1. Sentinel events approach
   - New draft: distribution of inappropriate/unsafe blood component(s)
   - Adopted in 2011
     - Incorrect blood component transfused
     - ABO incompatible transfusion
     - Wrong blood in tube
2. Overarching concepts
   - Adverse event, adverse reaction, incident …

# Overarching concepts

Conflicting use of terms
ISBT
EU Directive,
Clinical studies,
Pharmacovigilance,

WHO definitions of key concepts from WHO patient safety curriculum guide

*Can we align with these and gain uniformity?*



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ISBT

## ISBT

An **adverse event** is an undesirable and unintended occurrence before, during or after transfusion of blood or blood component which may be related to the administration of the blood or component. It may be the result of an error or an incident and it **may or not result in a reaction** in a recipient

## Pharmacovigilance

An **adverse event** can therefore be any unfavourable and unintended sign (e.g. an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.

## EU Directive

**'serious adverse event'** shall mean any untoward occurrence associated with the collection, testing, processing, storage and distribution, of blood and blood components that **might lead to** death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity

## Council of Europe

**adverse event:** an unintended injury caused by medical management rather than by a disease process.

## WHO

**Harmful incident (adverse event)**: an **incident** that resulted in **harm** to a patient.

# Denominators: debate

- Adverse reactions / transfusion errors

Units issued (distributed) vs units transfused

50:500,000 = 1 per 10,000 = 0.01%

50:480,000 = 1 per 9,600 = 0.0104%

- Near miss – as for transfusion errors?

- Adverse events/errors/incidents in processing

"Due to the complex nature of calculating the number of units processed from single donations, the experts consulted by the European Commission on 26 March 2012 agreed that for the number of units processed should be given as the number of individual collections performed by blood establishments". (European Commisson Common Approach 2012)

# An ongoing journey

## Steps for agreeing and maintaining definitions

# New category or revision

- Scientific advance, perceived need / request for adjustment
- Consider in working group, follow steps of consultation, validation etc.
- Avoid frequent revisions!
- Ensure that past versions are still accessible

# Multiple stakeholders

- Members of IHN
- Members (mailing list) of ISBT haemovigilance working party
- Other organisations:

  WHO, Asia Pacific Blood Network, etc.

- Need to reach "all" who capture or analyse relevant data
- Method: notify relevant people / organisations; publicly accessible (web) publication of consultation document

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ISBT

# Validation

- Draft definitions tested by experts in classifying cases (real-life examples)
- Experts from both well-developed HV systems and young systems

# Steps to publication

- Adjustments indicated by validation exercise
- Final consultation
- Adoption, publication
  - website
- Inform stakeholders / organisations

# Ownership, accessibility, updating

- Definitions and experts within an international organisation (e.g. ISBT)
- Continuity of experts professionally involved in all areas of haemovigilance
- Accessibility of expert group for queries or proposals for new definitions
- Commitment to revisit: after 3 years? (set date)
- NB Ensure public accessibility

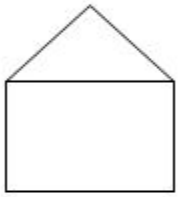
# Additional tools needed?

- Are there other reference sets?
  - Patient safety definitions (WHO)
  - Need to be aware of confusion through EU definition of "serious adverse event" (***may*** cause serious harm)
- E.g. recommended minimum investigations
- Flow chart(s) to assist classification?
  - According to predominant clinical feature
  - Is something an adverse event, reaction, near miss etc?
- Translation (help of WHO)

# An ongoing journey!

Participate in consultations and discussions:

J.wiersum@tripnet.nl



ISBT haemovigilance working party

- usually on Saturday before ISBT congress (European or International)

# Acknowledgements

Thank you to the organisers for inviting me!

Thank you for your attention

# Traceability and the Use of Unique Identifiers

Pat Distler
pat.distler@iccbba.org

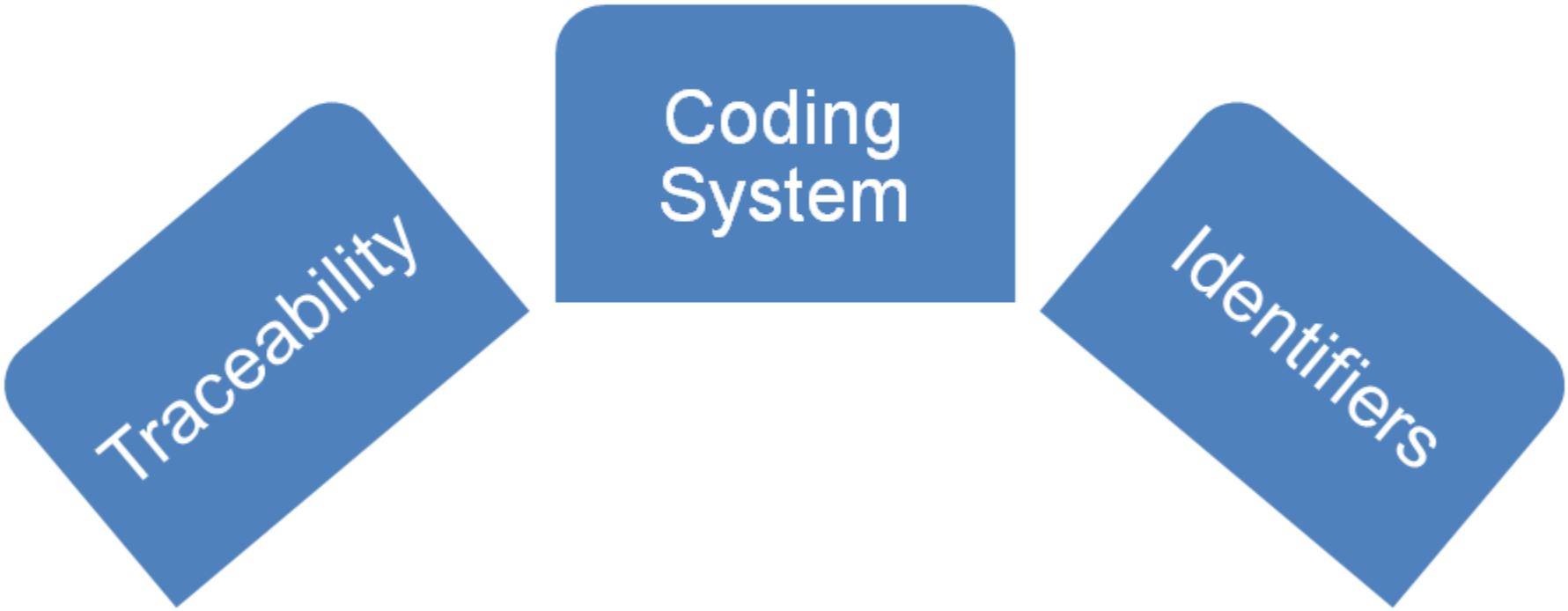
# TRACEABILITY FOR MEDICAL PRODUCTS OF HUMAN ORIGIN

DONOR  RECIPIENT

Capability of tracing a medical product of human origin (MPHO) from donor to recipient and vice versa

# Traceability

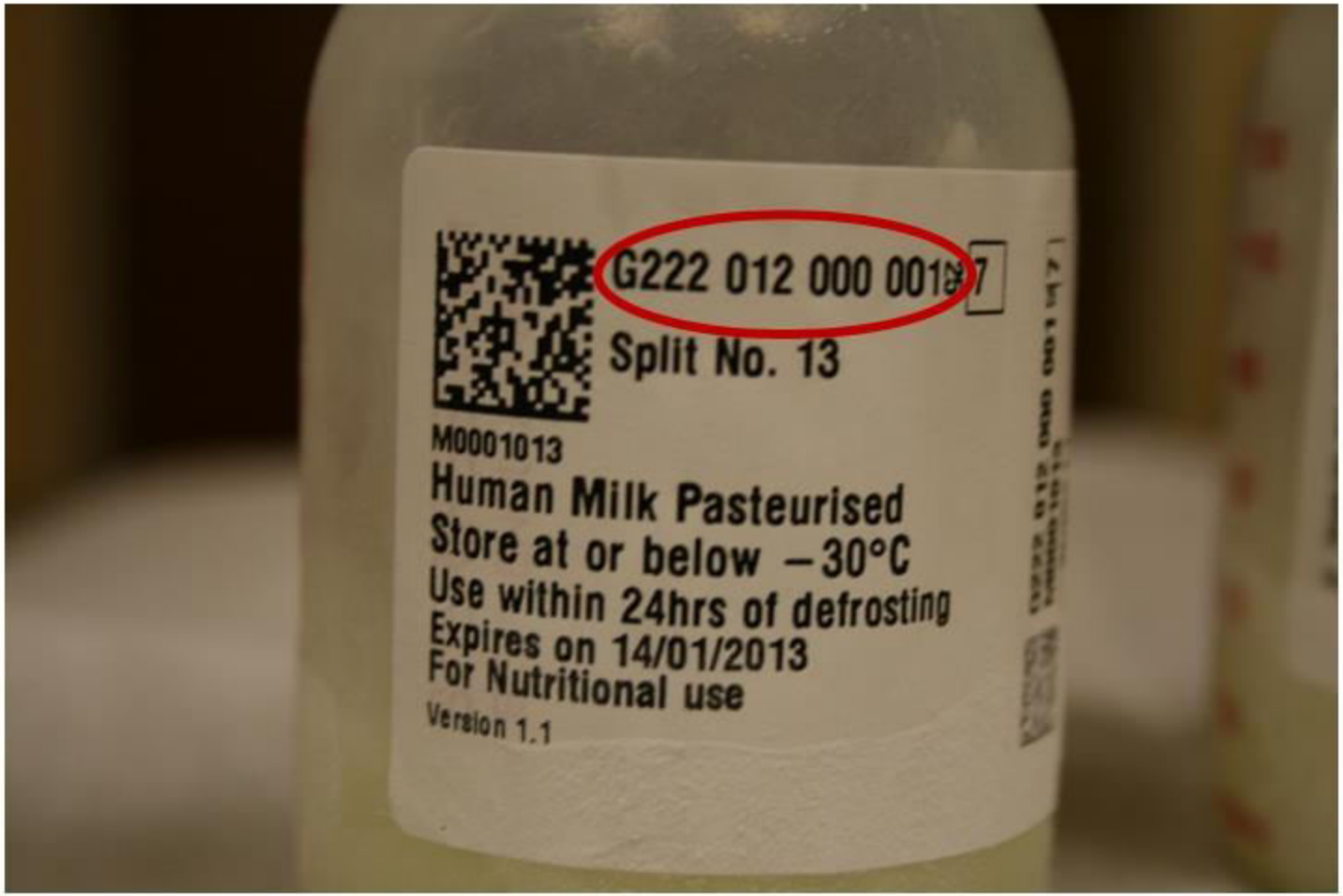
- Requires that each product be uniquely identified in order to provide a clear, unambiguous path
- Requires globally unique identifiers be assigned to each product


Coding System
Traceability
Identifiers

# Coding systems provide

- A mechanism to allow distinct items to be uniquely identified and consistently characterized to all participants within the system
- The means to allocate identifiers in a manner that avoids duplication
- The information infrastructure on which effective traceability can be built (if an automated system)

# Unique Identifier



# Coding systems support interoperability between computer systems

- Create codes and establish the meaning of the codes
- Provide the rules for how the codes are used
  - How the coding system is identified (e.g., first character is = or & with ISBT 128)
  - The length and format of all codes
  - What information may be encoded
  - What type of bar codes (symbology) may be used

# Establishing the meaning of the codes

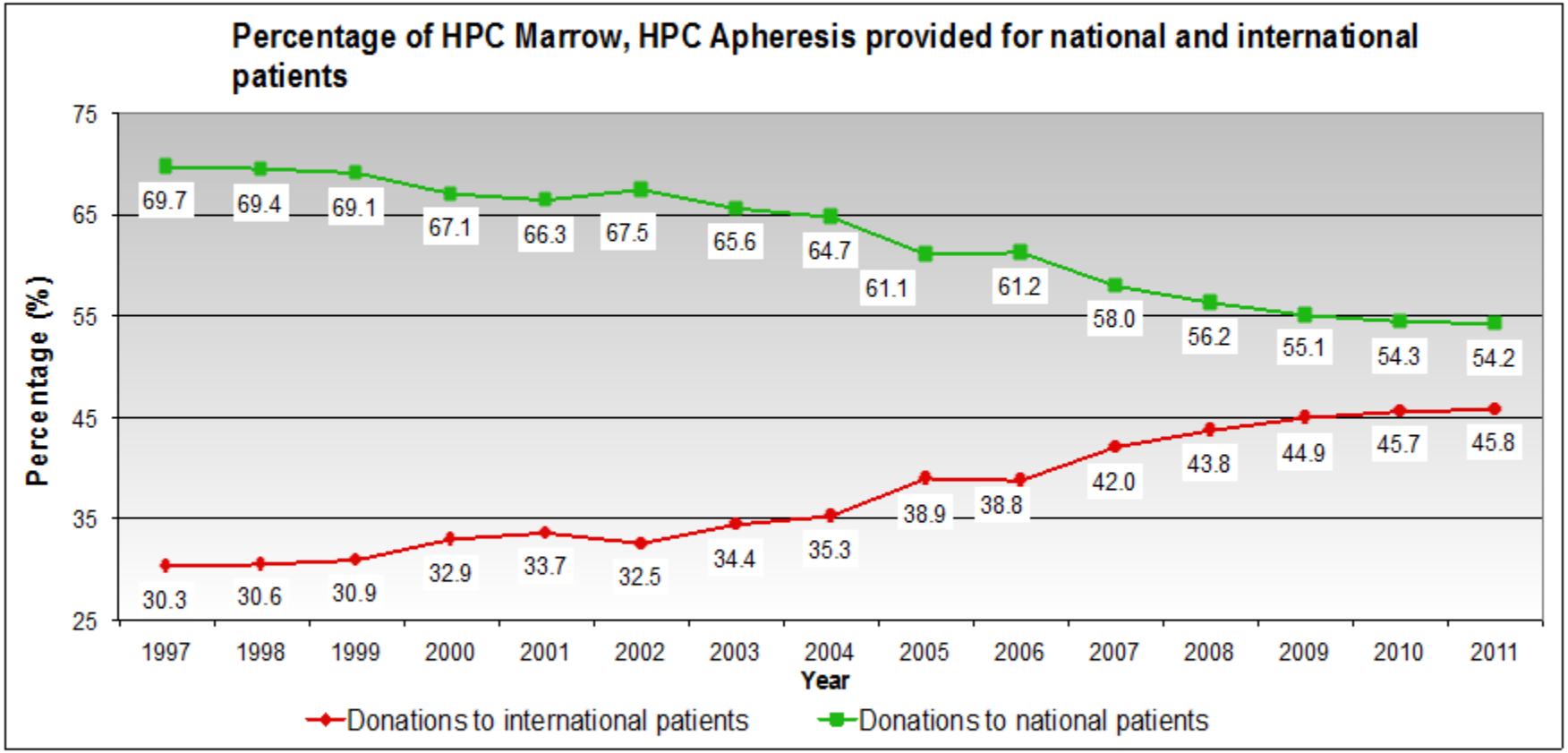
# WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation - 2008

Commentary for Guiding Principle 10:
Internationally agreed means of coding to identify tissues and cells used in transplantation are essential for full traceability.

# World Health Assembly of WHO (Resolution WHA63.22, 2010)

"Conscious of the extensive cross-boundary circulation of cells and tissues for transplantation...Urges Member States...to encourage the implementation of globally consistent coding systems for human cells, tissues and organs...to facilitate national and international traceability of materials of human origin for transplantation."

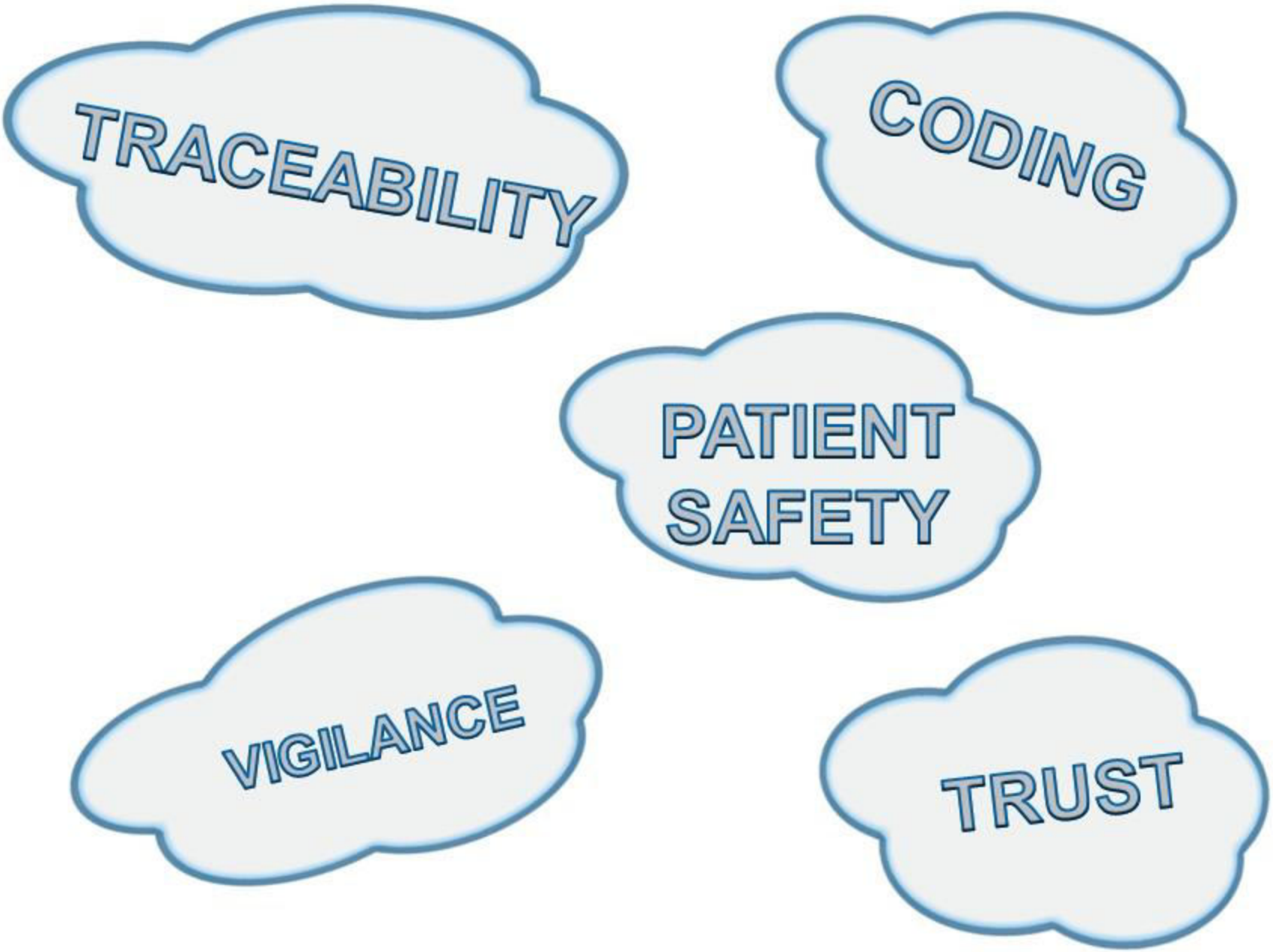
# Cell Therapy International Distribution

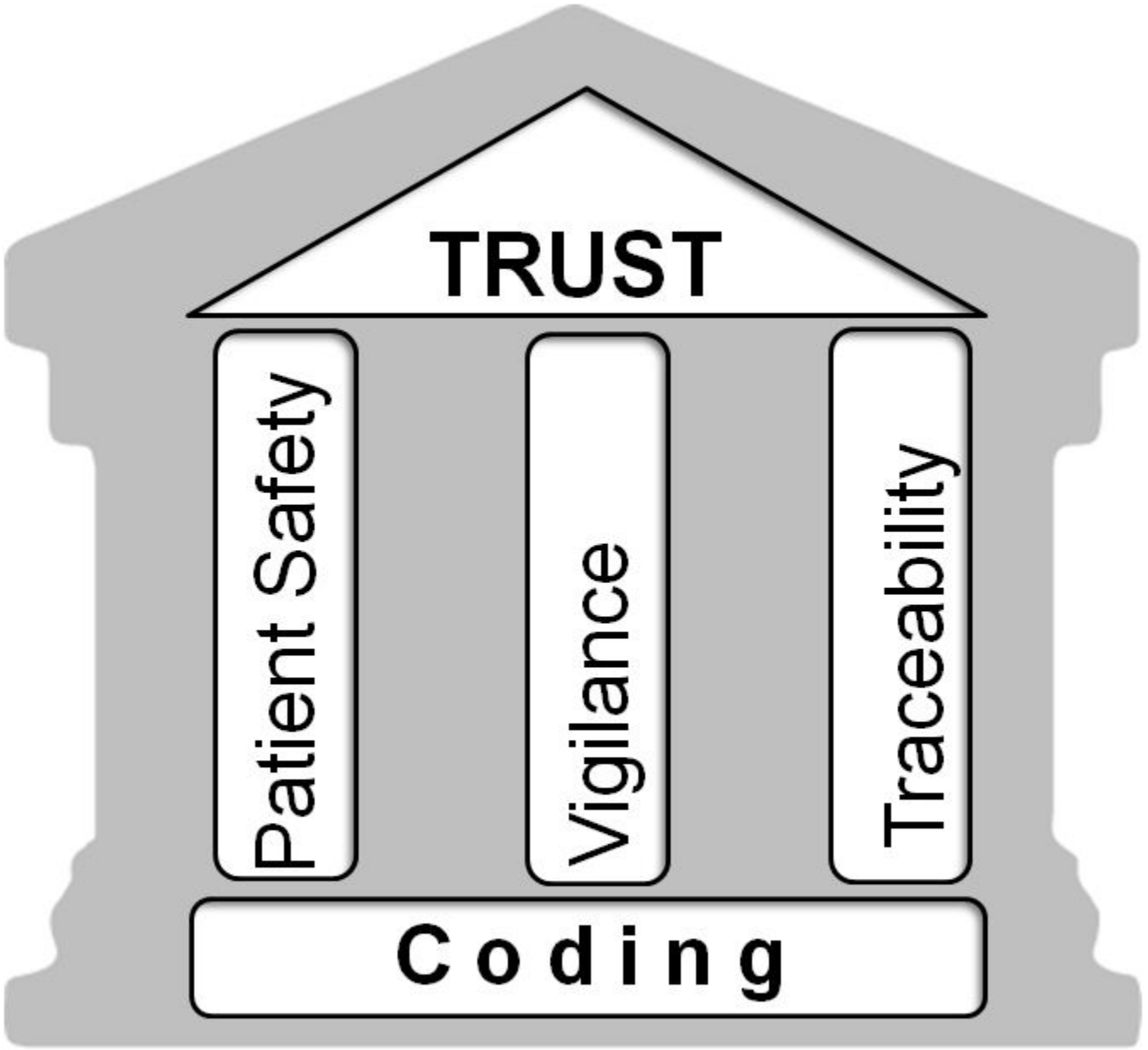



World Marrow Donor Association statistics

# WHO Organization-wide Initiative for Medical Products of Human Origin

- Three strategies for global governance
  - Global consensus on a series of principles inherent to the human origin of MPHO – in particular, prohibition on making the human body and its parts as such a source of financial gain
  - Global use of ISBT 128 for all MPHO to ensure unique identification, optimal traceability and interoperability between countries and across all MPHO for both routine and emergency use
  - Global collaboration on vigilance and surveillance of MPHO to support operation and oversight and to establish transparency for trust


TRACEABILITY
CODING
PATIENT SAFETY
VIGILANCE
TRUST


TRUST
Patient Safety
Vigilance
Traceability
Coding

# ISBT 128 Coding System

- Global coding system designed to support traceability
  - Allows assignment of globally unique identifiers
  - Provides standardized terminology, coding, and labeling format
  - Created by the Working Party on Information Technology of the ISBT in 1990's

# 75 Countries with Facilities Registered to Use ISBT 128

# Blood - China


# Stem Cell - Denmark

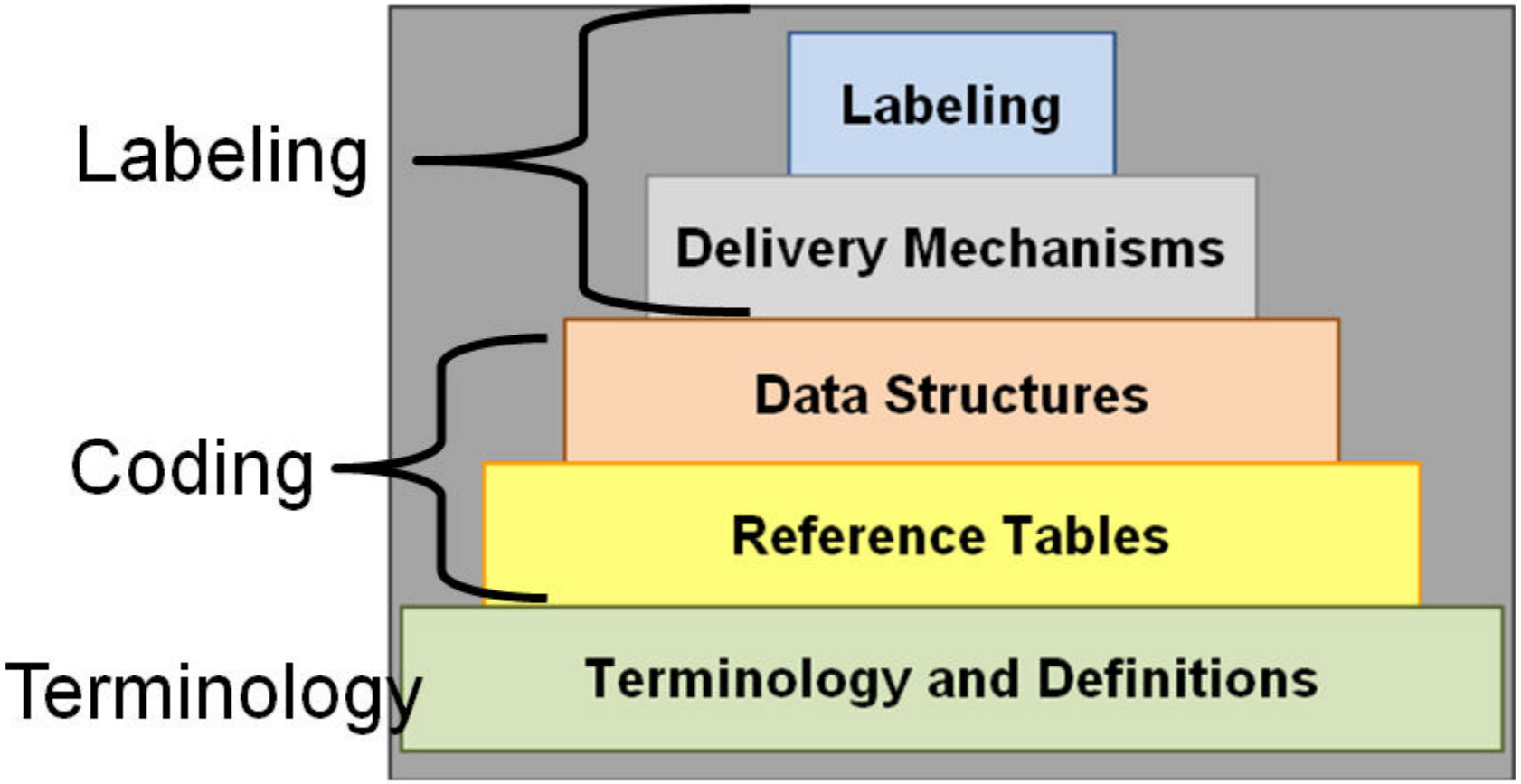

# Milk Bank- Scotland

# Tissue - Poland


# Ocular - Canada

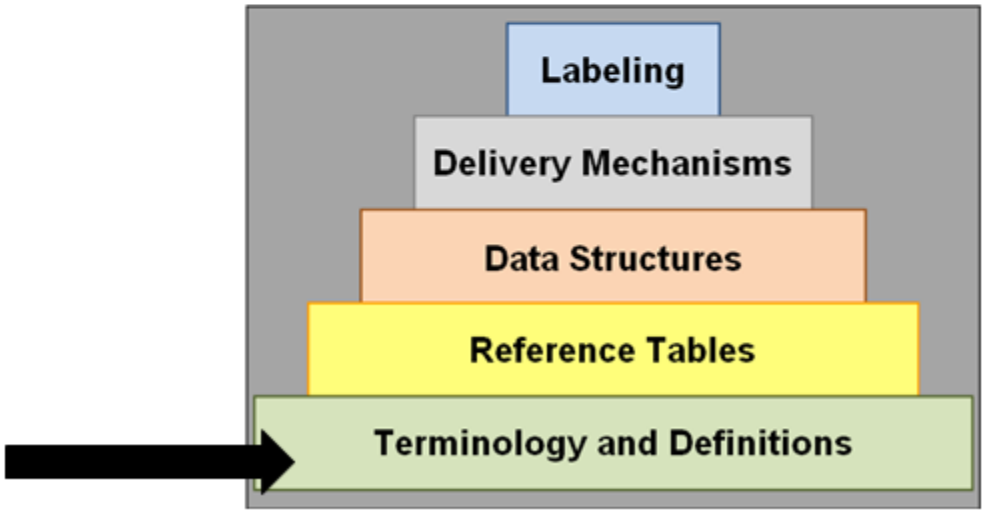
# Support from scientific and professional societies

# ISBT 128 Coding System Pyramid



# ISBT 128 – Standardized Product Codes

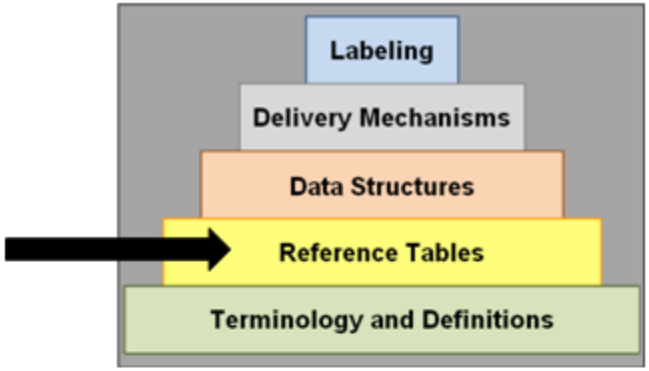
- Terminology is the first step in standardization
- Defined by expert groups (Technical Advisory Groups or TAGs)
- Terminology is available for all to use



# ISBT 128 Terminology

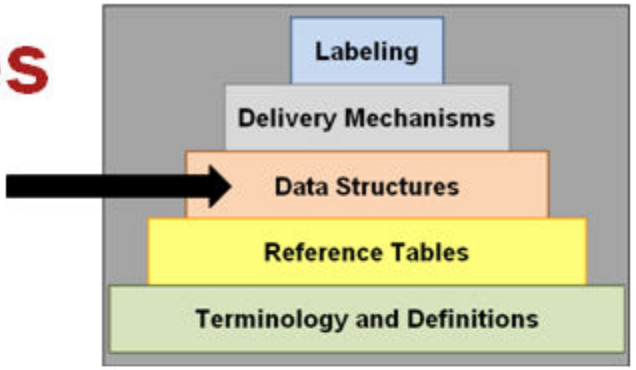

- Products are described in terms of Classes, Modifiers, and Attributes
  - "Classes" are broad categories of products (e.g., Red Blood Cells)
  - "Modifiers" provide the next level of detail (e.g., Apheresis)
  - "Attributes" are details about the product (e.g., Irradiated)
- Example: **Washed POOLED PLATELETS |No anticoagulant/20-24C|Open System|Buffy coat platelet preparation|2 units**

# Descriptions entered into a reference table and codes assigned




| CODE | PRODUCT DESCRIPTION |
|---|---|
| E7221 | PLATELETS\|CPD/500mL/20-24C\|Bacterial test |
| E7222 | Apheresis FRESH FROZEN PLASMA\|NaCitrate/XX/ <-25C |
| E7223 | Apheresis FRESH FROZEN PLASMA\|ACD-A/XX/ <-25C\|For mnf:noninjectable |
| E7224 | Washed POOLED PLATELETS\|None/XX/ 20-24C\|Open\|Buffy coat plts prep\|2 units |

# Codes into Data Structures



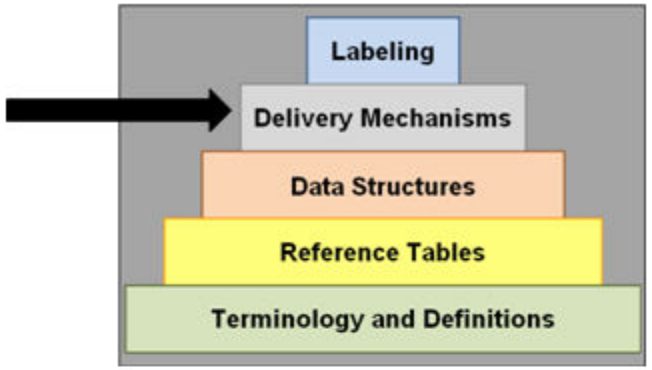

=<S1234X00

Data Identifier

Data Content

- Data Identifier
  - Indicates an ISBT 128 data structure
  - Indicates the type of data (e.g., product code)
  - Allows data to go into the right field
- Data Content
  - Provides control by defining the type and number of characters (“rules”)

# Data Structures into Bar Codes



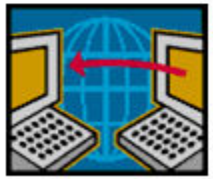

=<T1295003


Linear bar code

=<T1295003

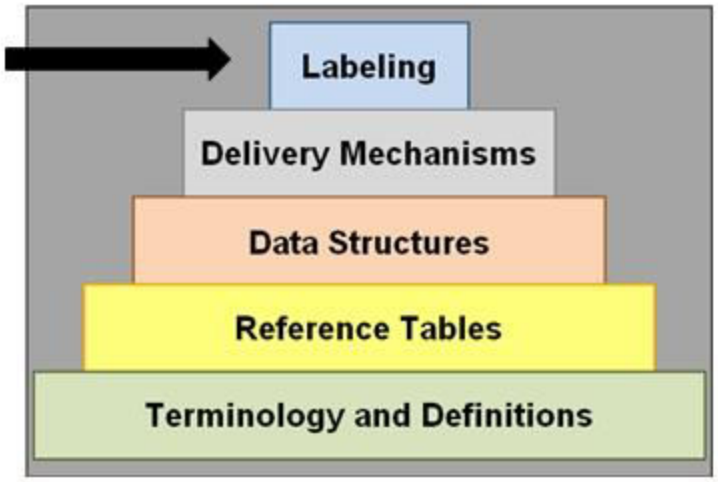
2-D Symbol

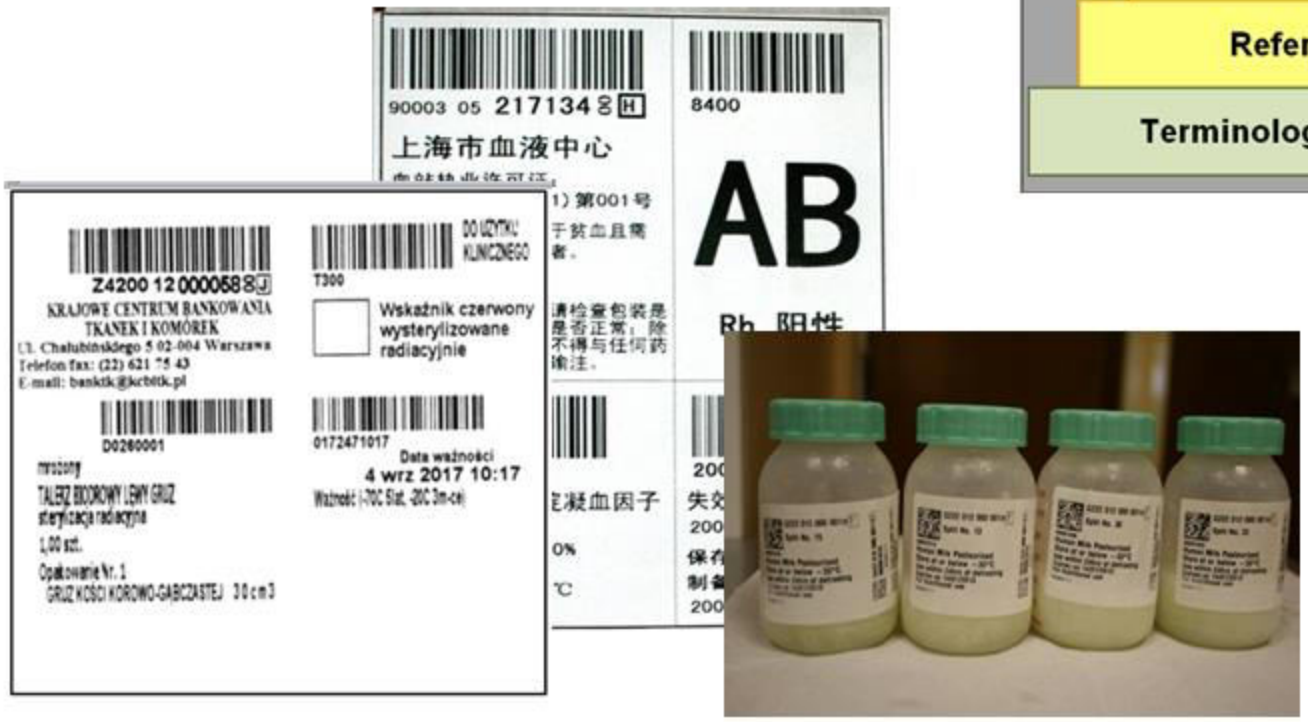
RFID

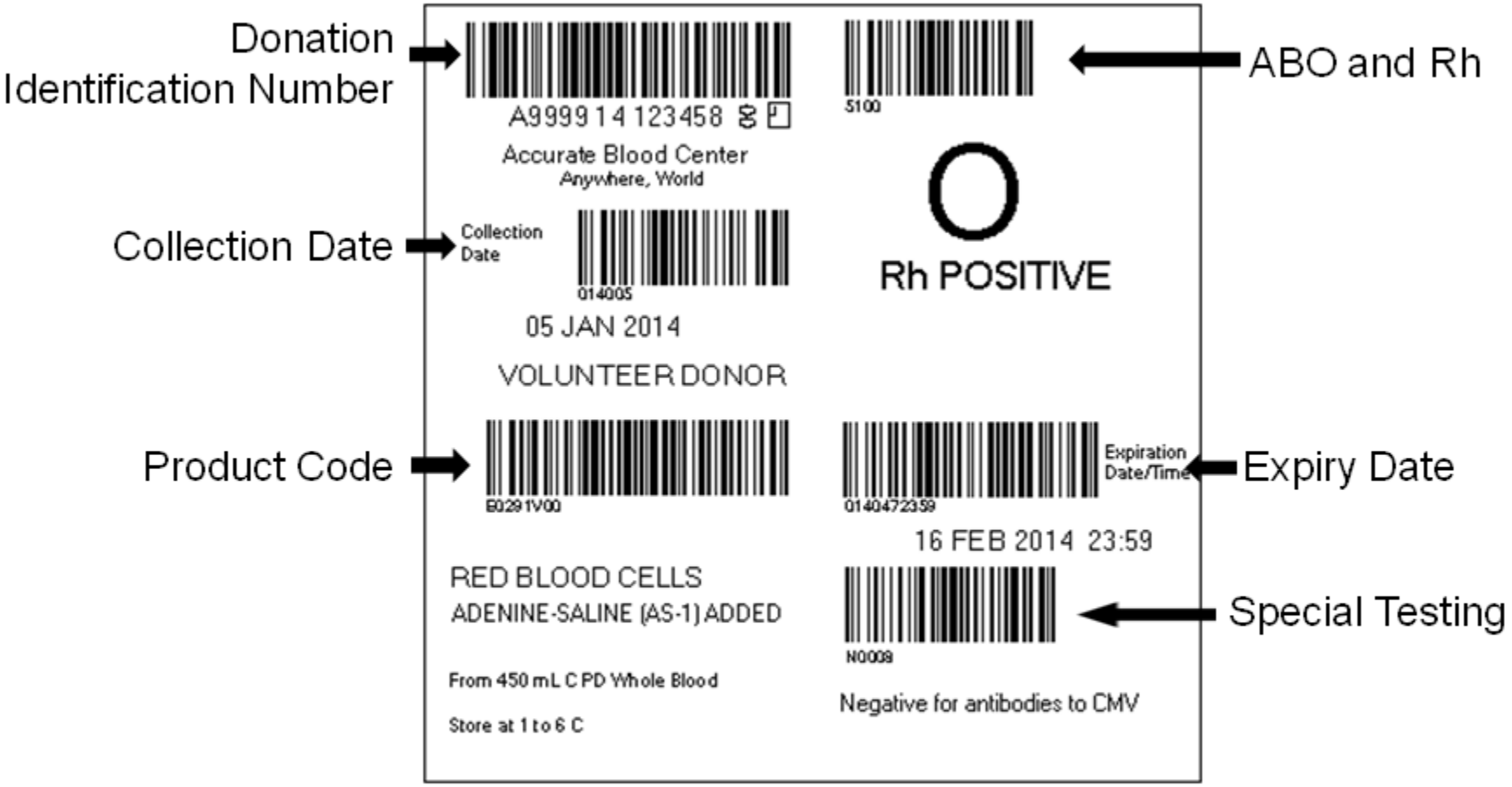


Computer to Computer Communication

# Bar Codes onto Labels or Other Documents





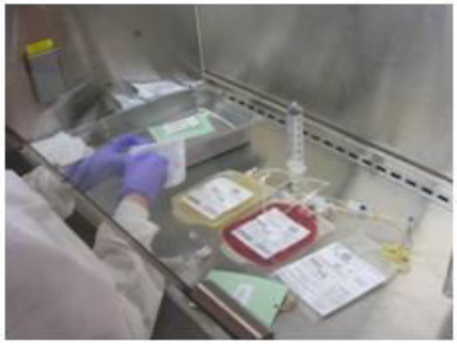

ISBT 128
More than Identification


S0020 08 015114 = 3 H
O RhD pos
Donator
R50321 –
Name
Tapp. datum
0080460738
15 FEB 2008 07:38
Avslutad 12:36
Riktad
S0154200
0080481314
Använd senast
HSC, aferes
17 FEB 2008 13:14
Öppet system
delenhet 1
Recipient
19 861222 –
Volym 108ml
Lösning ACD – A
Lagringstemp 2 – 6C
iA
Name
Donator
Recipient
Tapp datu 15 FEB 2008
S0020 08 015114 = 3
S0154200
HSC, aferes
Öppet system: delenhe

# Unique Identifiers in ISBT 128

- Donation Identification Number (DIN) creates uniqueness for each donation

- Product Code creates uniqueness for each product made from a donation

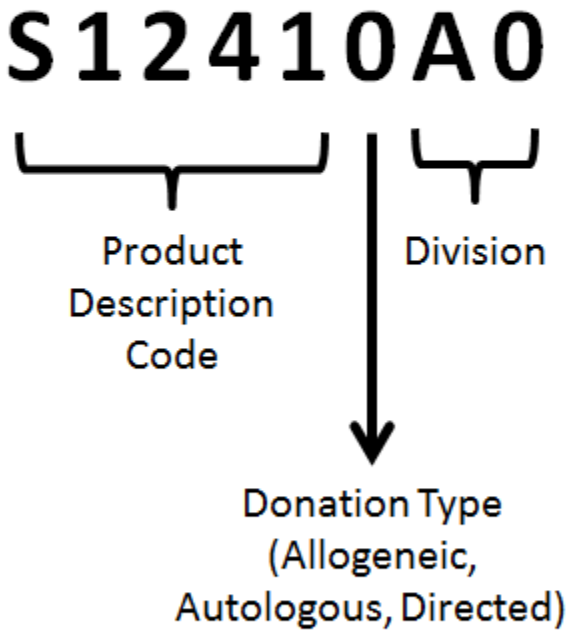


# Donation Identification Number

A9999 12 123456


- Facility Identification Number: Assigned by ISBT 128 to ensure each number is globally unique
  - 5-Character alphanumeric code
  - ICCBBA maintains a database of all FINs available to registered users
  - "Look-up" program available to all on the ICCBBA website
- Year Code: Ensures uniqueness for 100 years
- Sequence Number: Facility ensures uniqueness of the sequence number

# ISBT 128 Product Code – Blood and Cells



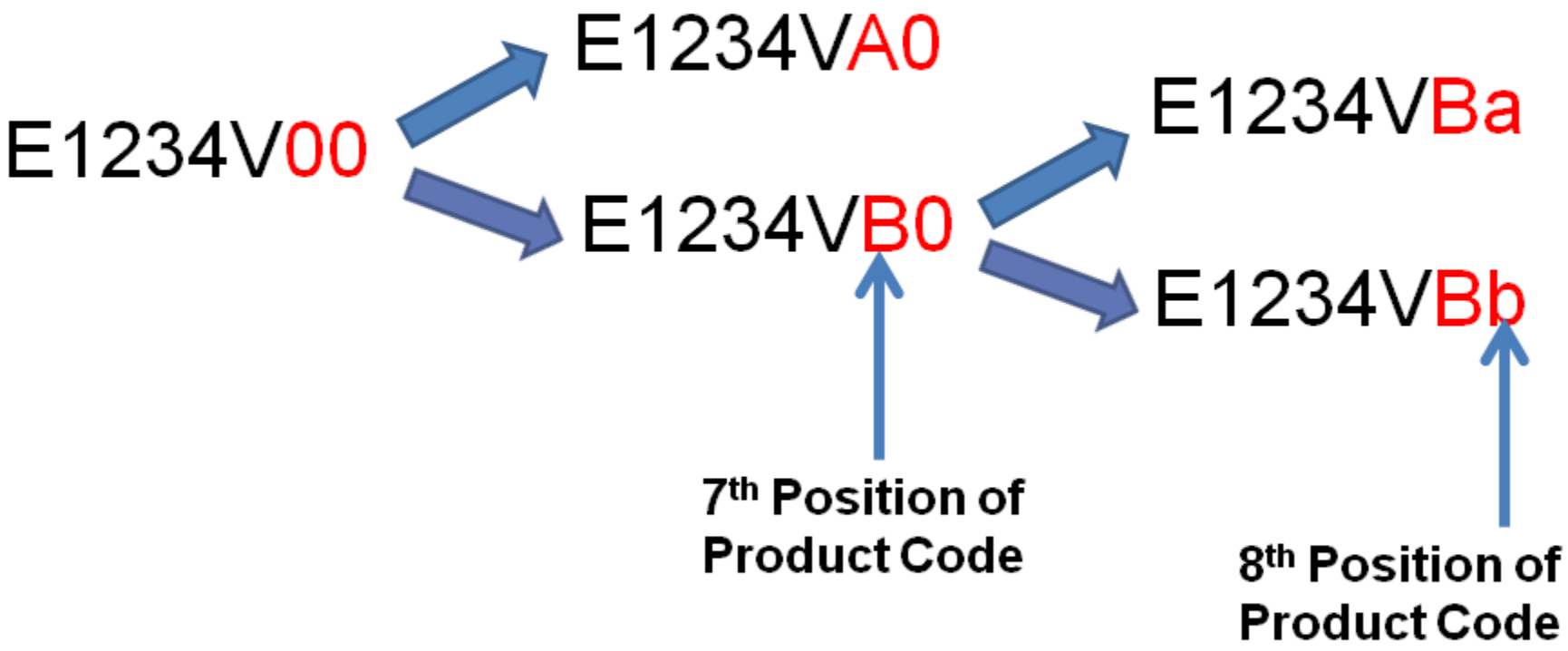
# Product Descriptions assigned computer codes

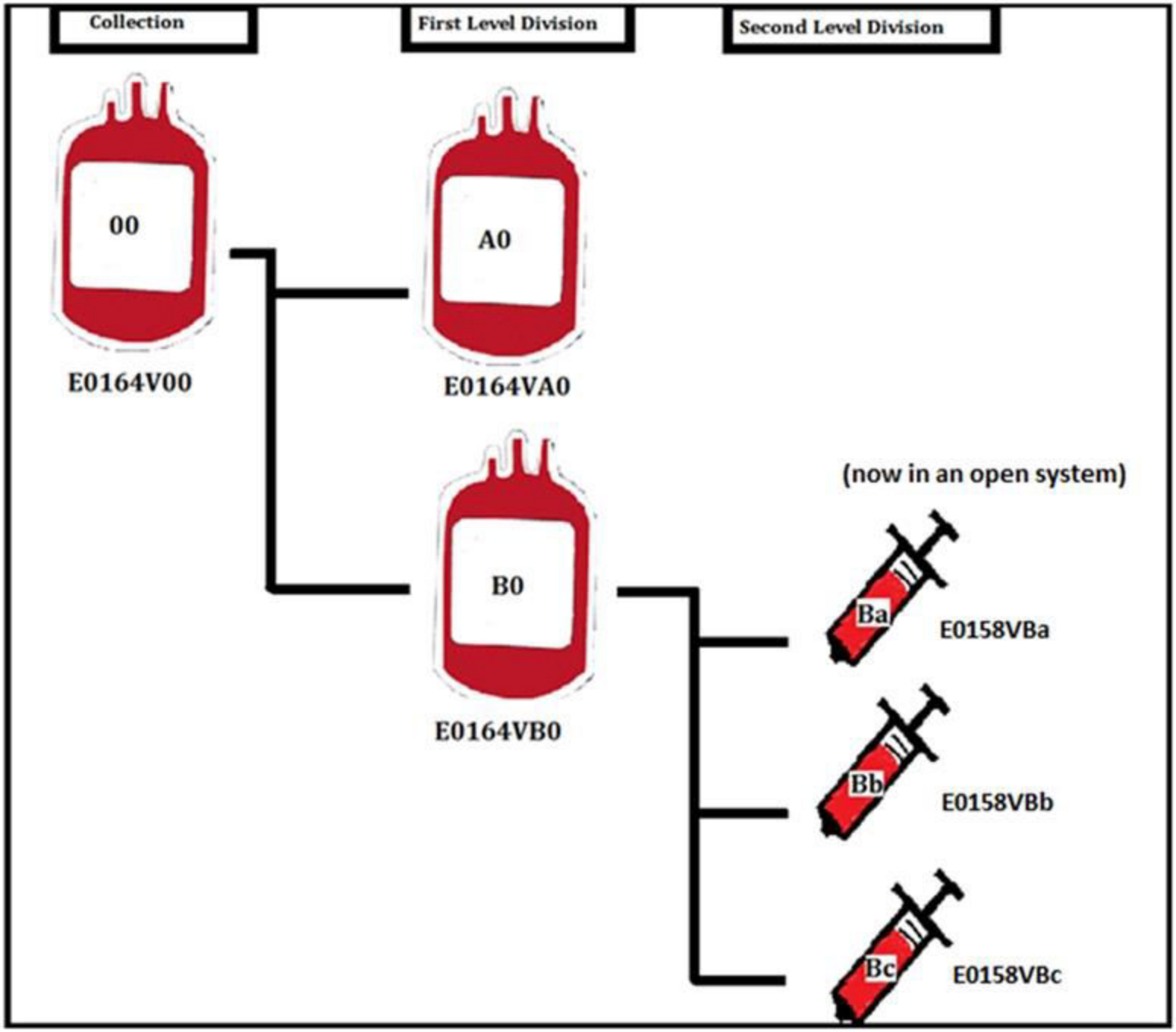
| Product Description Code | PRODUCT DESCRIPTION |
|---|---|
| S1851 | HPC, CORD BLOOD\|None/XX/refg\|Thawed Washed |
| S1852 | MNC, APHERESIS\|None/XX/refg\|Thawed Washed\|Non-mobilized |
| S1853 | HPC, MARROW\|None/XX/refg\|Thawed Washed |

# Donation Type Codes

| Character | Type of Donation |
|---|---|
| 0 (zero) | Not specified (null value) |
| V | Volunteer homologous (allogeneic) donor (default) |
| A | Autologous collection, eligible for crossover |
| 1 (one) | For autologous use only |
| X | For autologous use only, biohazard |
| D | Volunteer directed collection, eligible for crossover |

# Divisions – Blood and Cells




Collection
First Level Division
Second Level Division
00
E0164V00
A0
E0164VA0
B0
E0164VB0
(now in an open system)
Ba
E0158VBa
Bb
E0158VBb
Bc
E0158VBc

# Traceability & Coding Systems

- Global
- Across all Medical Products of Human Origin (MPHO)
- Create uniqueness for a minimum of 30 years

# The World Health Organization Global Forum on Blood Safety (2013)

Adoption of ISBT 128 has been identified by WHO as an important element in a global strategy for governance of MPHO

# ISBT 128

- Well-established system that is unique in being designed specifically to provide traceability between donor and recipient for medical products of human origin
- Provides a global approach to identifiers, terminology, coding, and labeling for medical products of human origin

ISBT 128
More than Identification