IHN International Haemovigilance Network

TRIP Hemo-en biovigilantie

ISBT

Definitions and tools for haemovigilance

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- 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

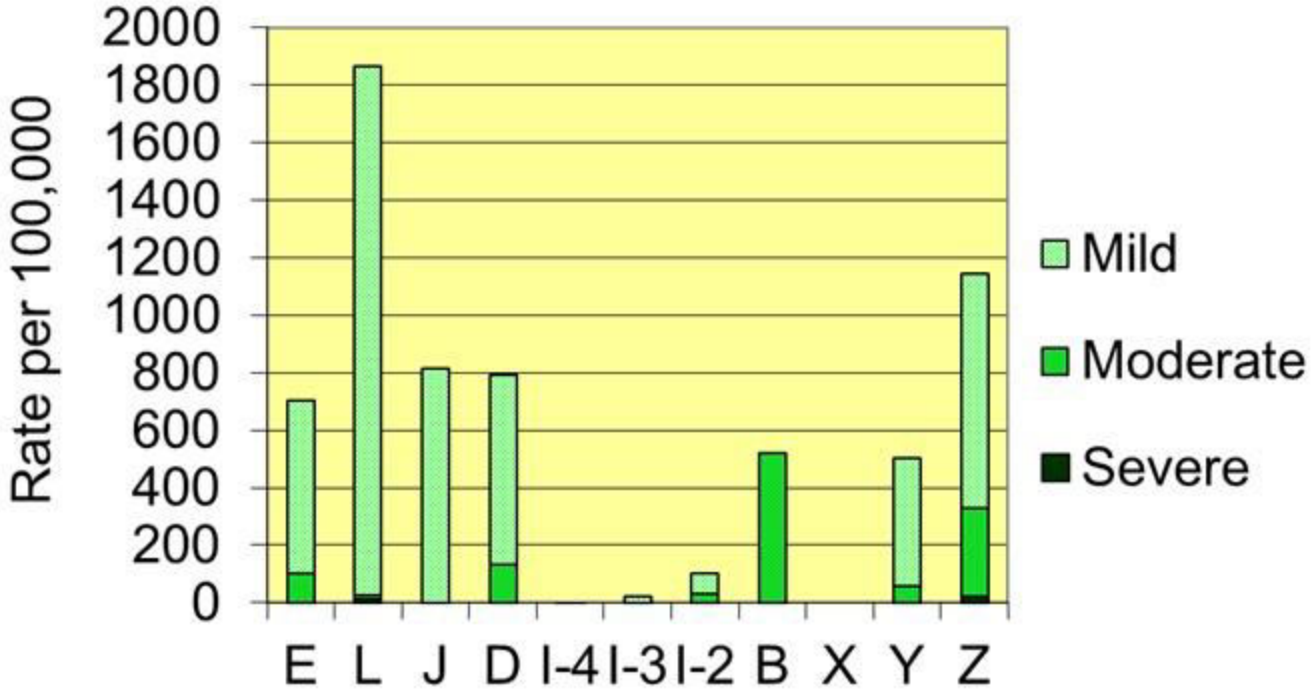
Current status of ISBT/IHN definitions

- 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

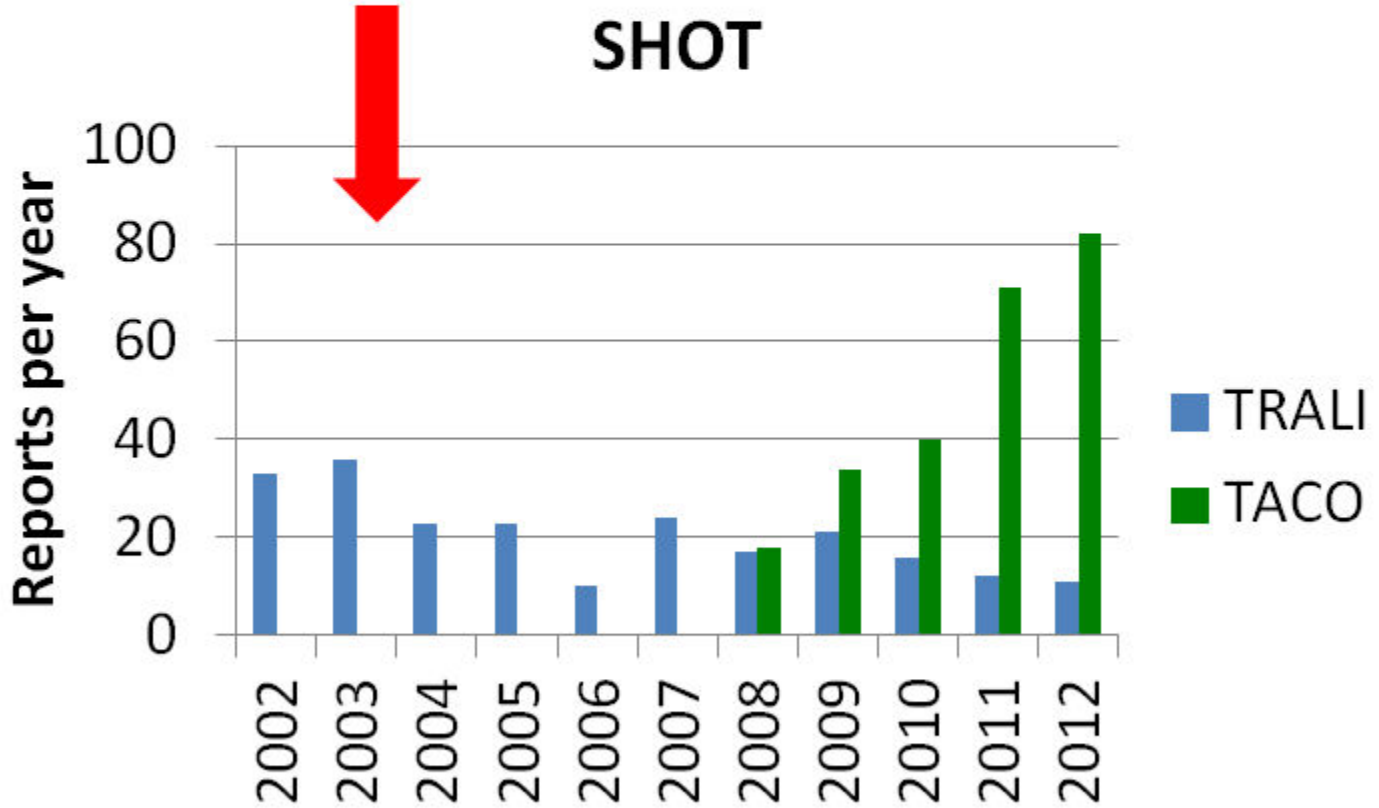
ISBT Cancun 2012:

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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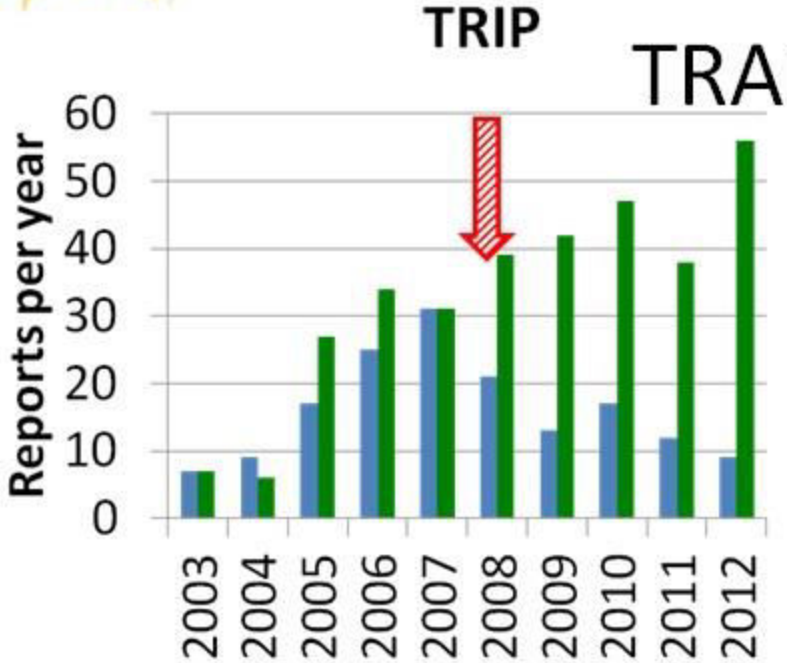
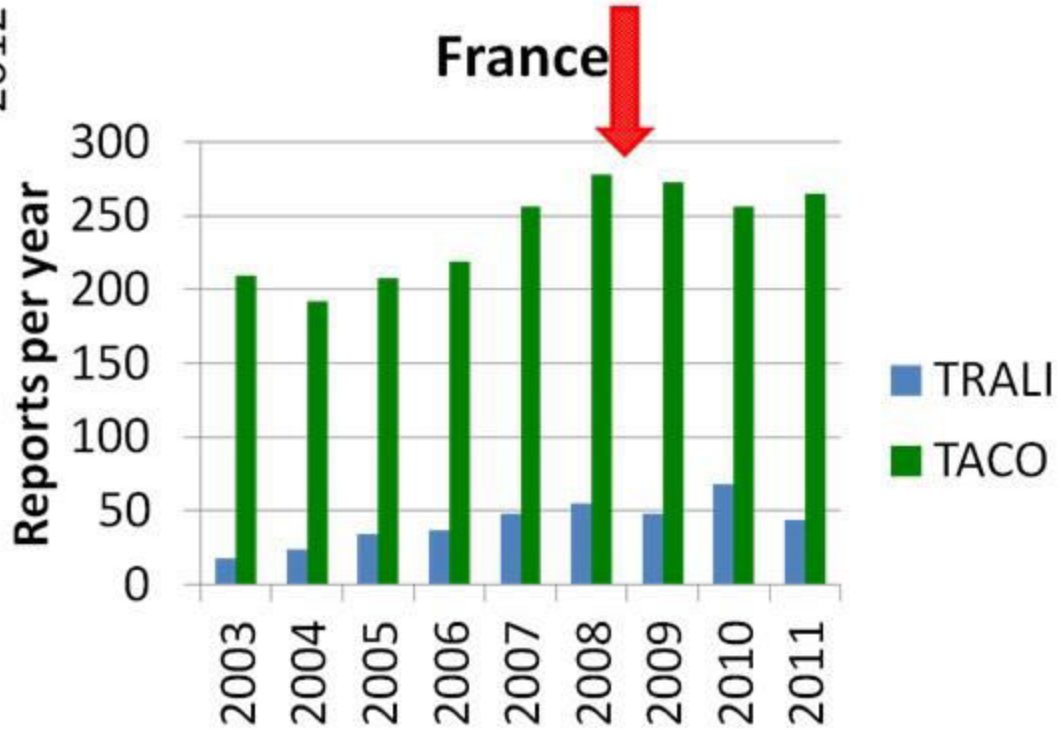
TRALI/TACO





TRALI/TACO

National Haemovigilance Office, Ireland

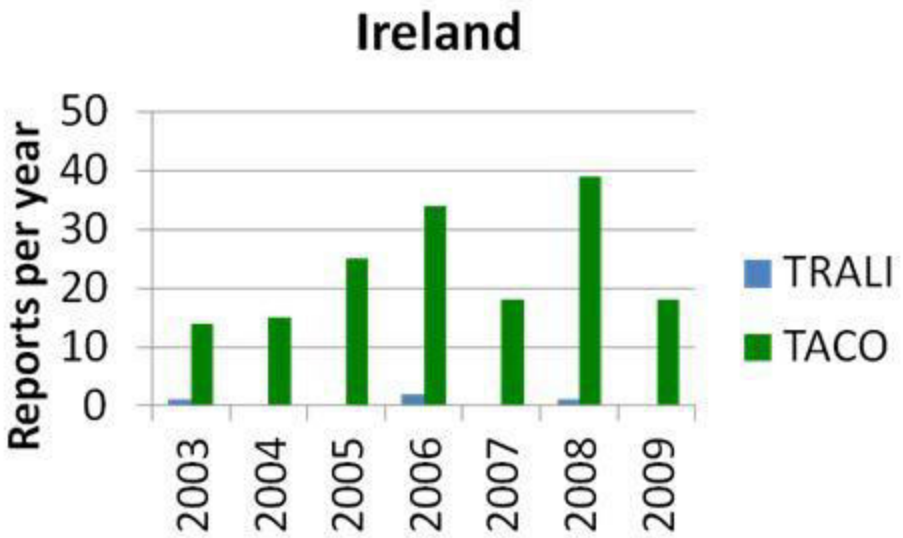
2008/2009 report

"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.

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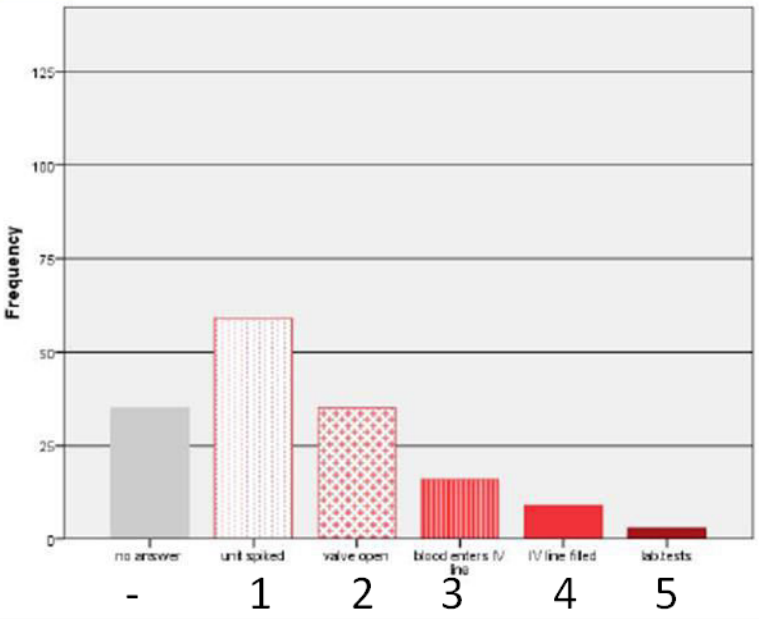
Case

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

1) Unit spiked (cannot be used

2) Unit spiked and valve opene

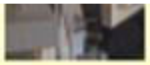


ADDITIONAL MATERIAL

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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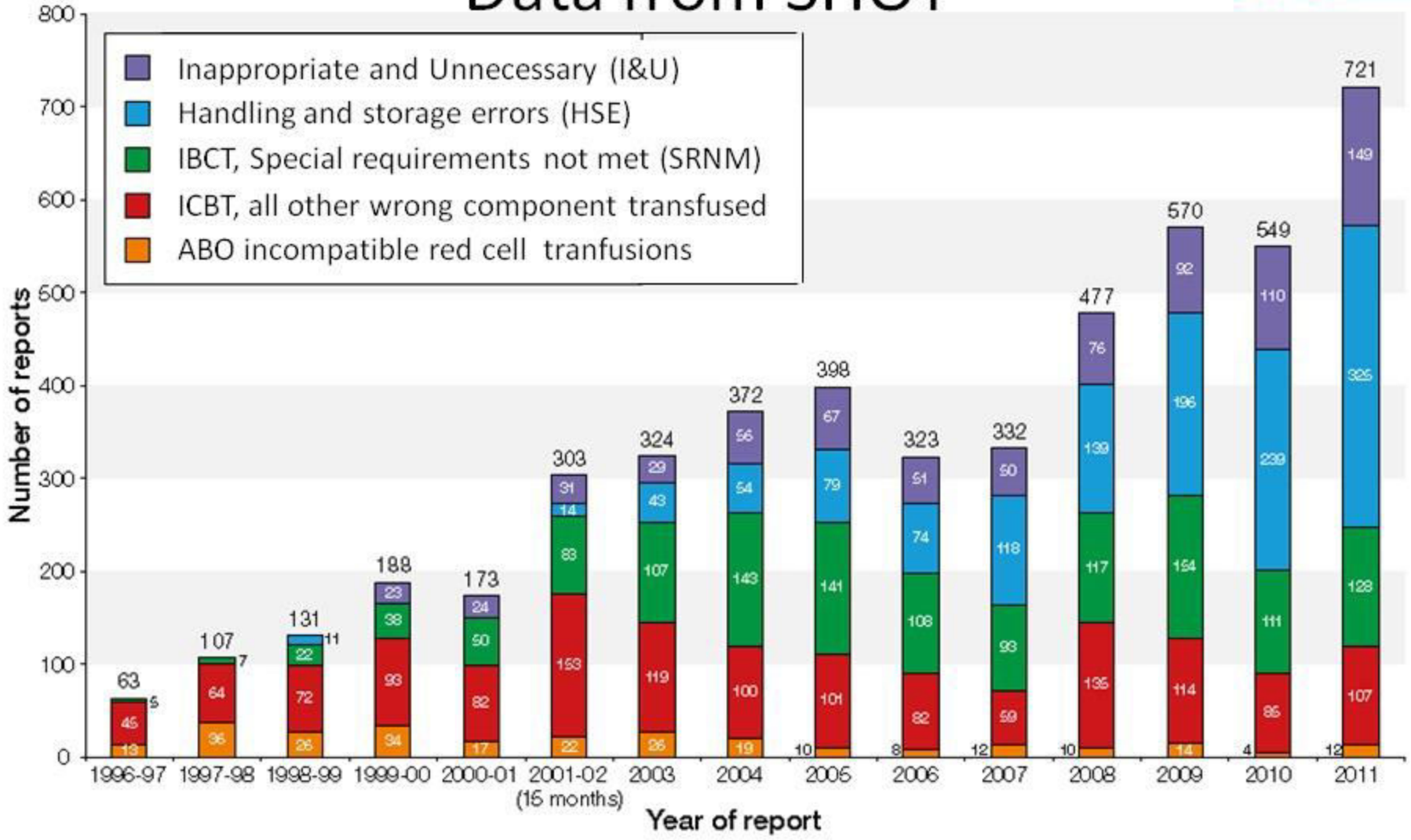
Data from SHOT



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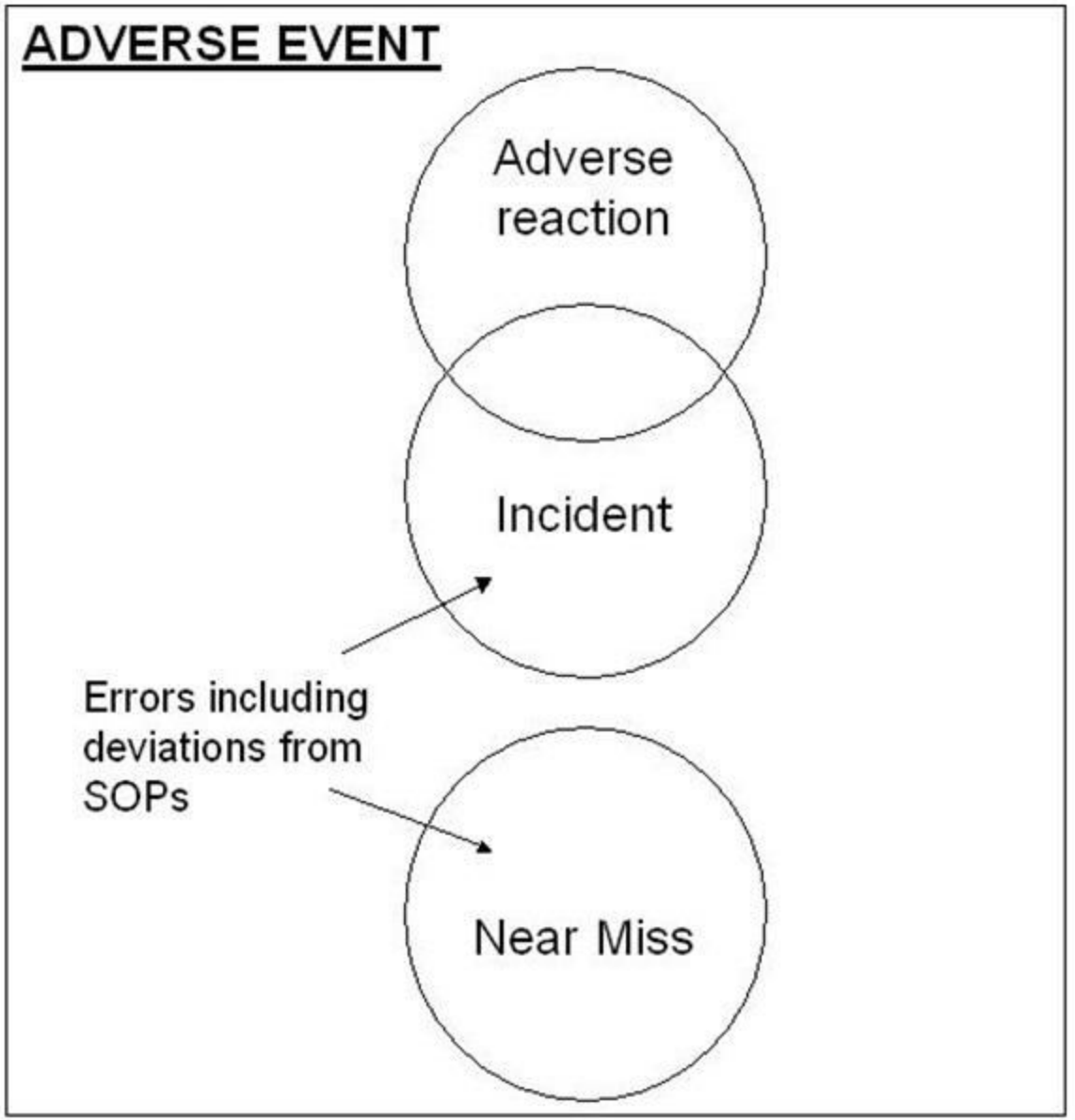
1. Sentinel events approach
   - New draft: distribution of inappropriate/unsafe blood component(s)
   - Adopted in 2011
     - Incorrect blood component transfused
     - ABO incompatible transfusion
     - Wrong blood in tube
2. Overarching concepts
   - Adverse event, adverse reaction, incident …

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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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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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

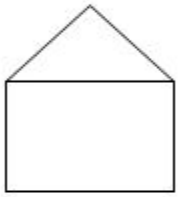
Additional tools needed?

- 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