# Definitions and tools for haemovigilance

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- History
- Donor complications
- TRALI
- Incorrect blood component transfused
- Denominators
- An ongoing journey, multiple stakeholders

# 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

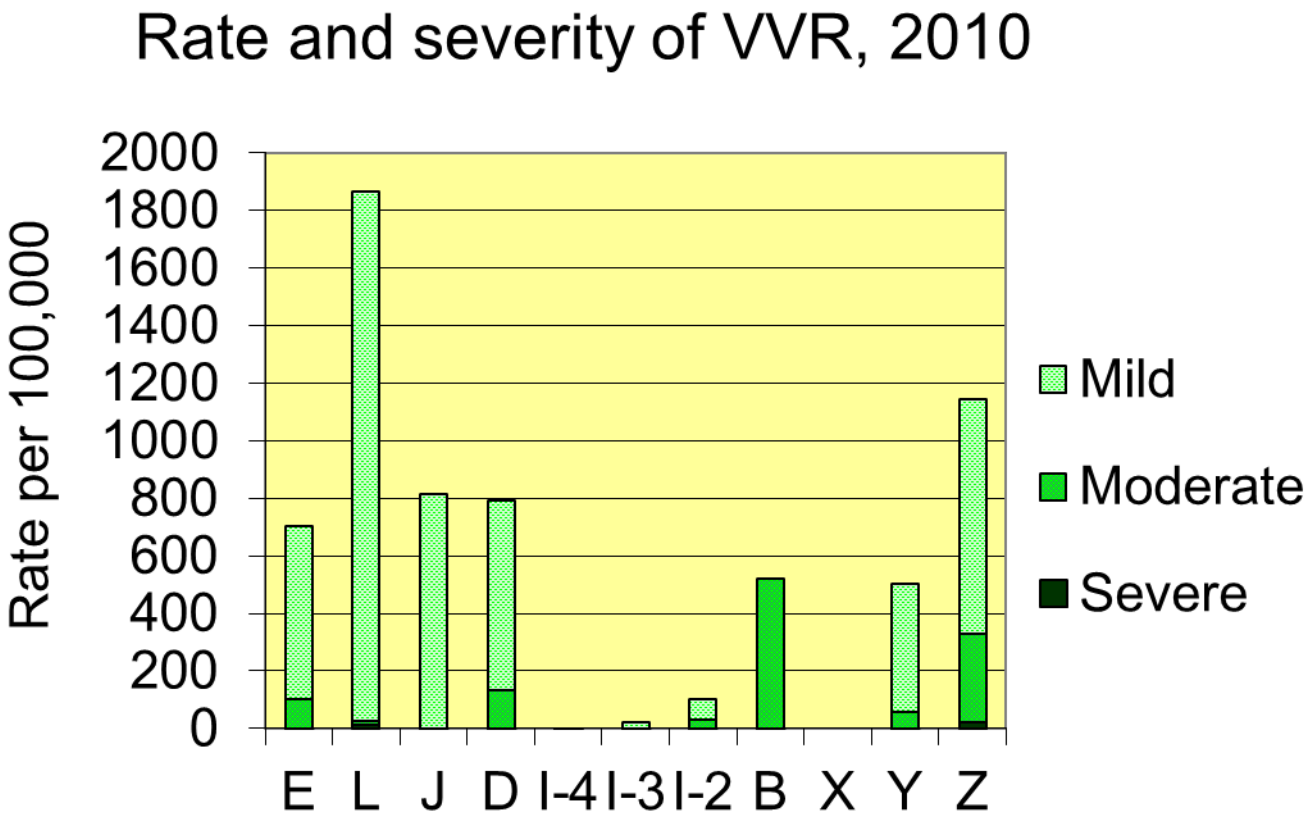
- European hemovigilance network, from 2004:
  - Draft definitions for adverse transfusion events ->heated debates, multiple rounds of corrections!
  - Draft definitions for donor complications
- ISBT haemovigilance working party, from 2005
- Activity on definitions merged between EHN (later IHN) and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

# Current status of ISBT/IHN definitions

- Donor complications: adopted 2008 (on www); review proposed and launched 2012
- Non-infectious transfusion reactions: adopted 2011 (on www); minor correction proposed 2012, under consideration
- Errors and incidents in the transfusion chain (sentinel events only) adopted 2011. Further types may be added.
- Transfusion-transmitted bacterial infections (draft; TTI working party)

# Donor complications: vasovagal reactions (VVR)

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



# Vasovagal reactions

Further classification?

- EU “severe”: 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

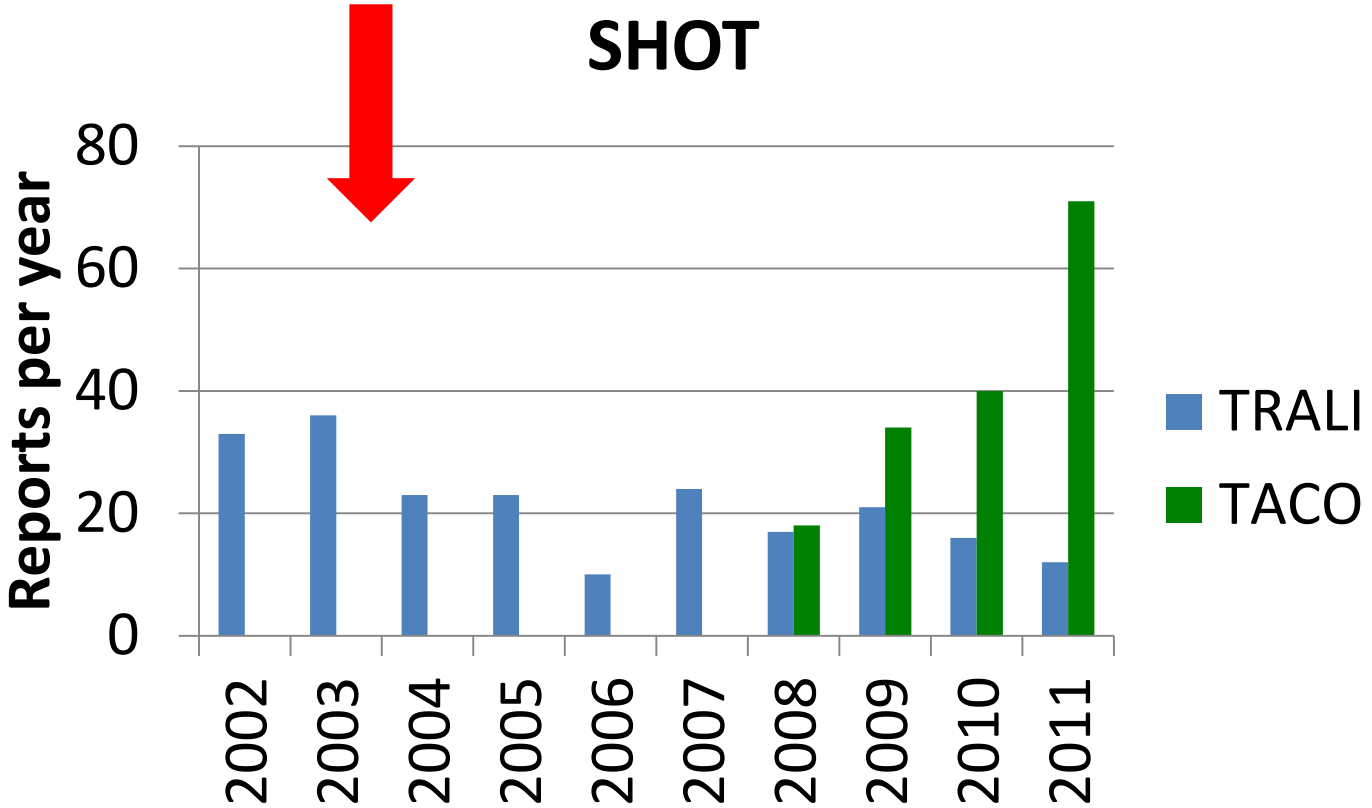
ISBT Cancun 2012:

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?

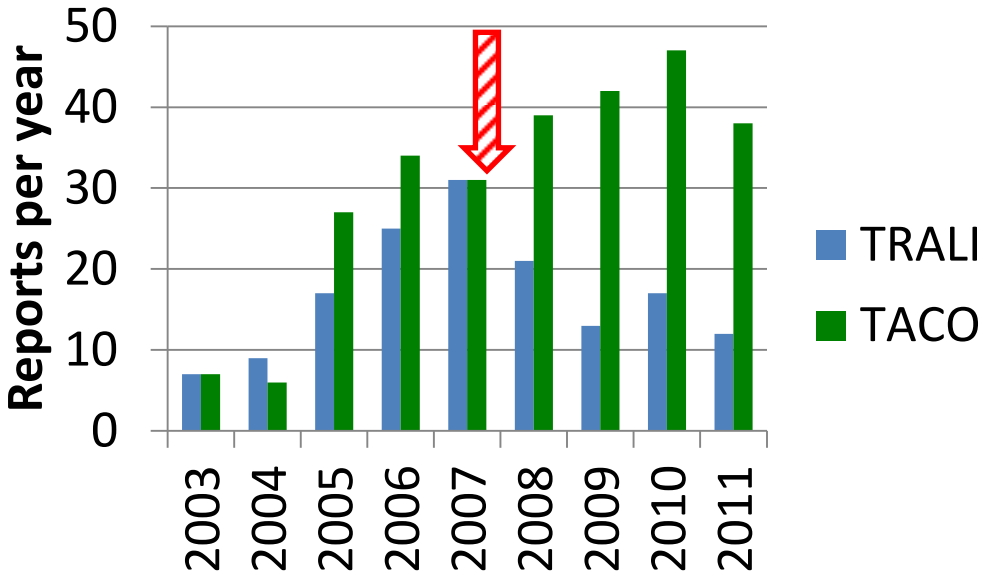
# TRALI/TACO

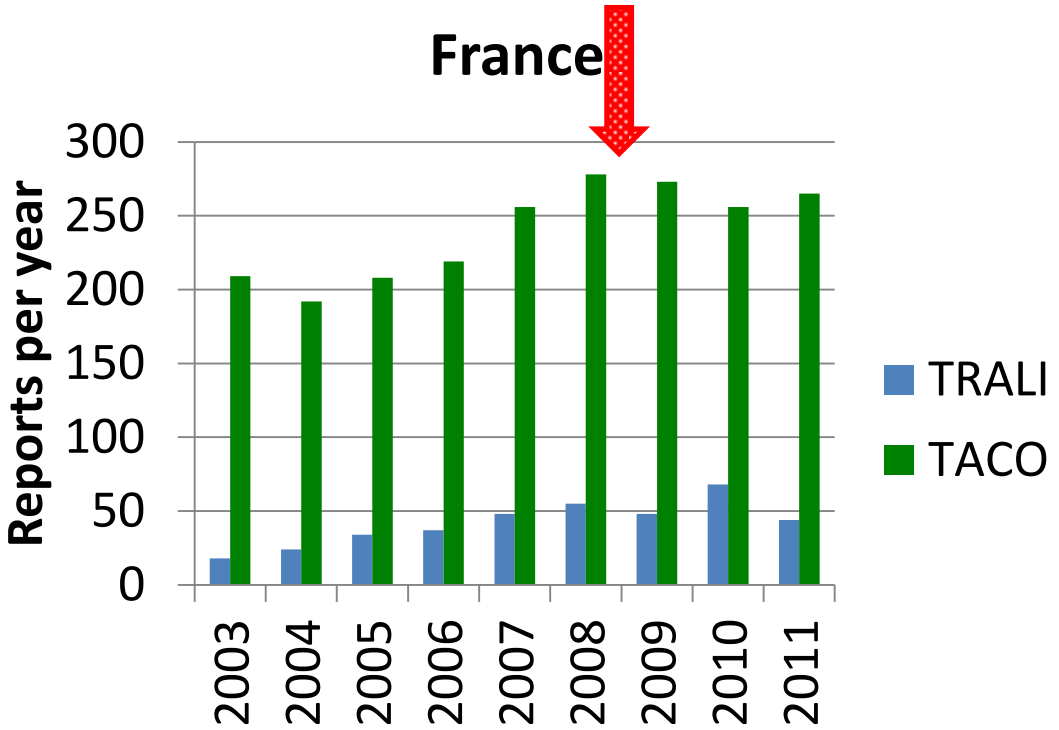
- Does a system actually capture the reaction?




TACO captured from 2008

# TRALI/TACO


TRIP
Reports per year
50
40
30
20
10
0
2003
2004
2005
2006
2007
2008
2009
2010
2011
TRALI
TACO


France
Reports per year
300
250
200
150
100
50
0
2003
2004
2005
2006
2007
2008
2009
2010
2011
TRALI
TACO

# TRALI/TACO

## National Haemovigilance Office, Ireland

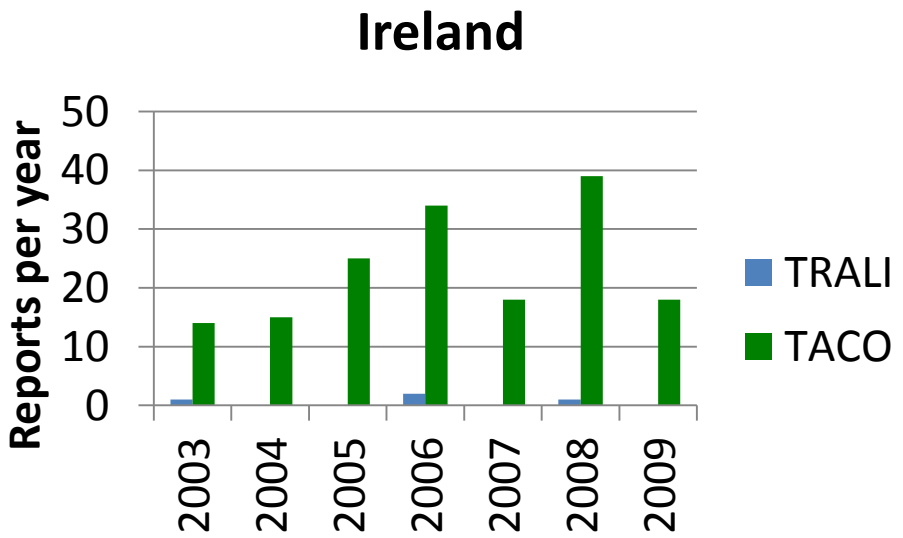
### 2008/2009 report

"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"



# SAR Case History 11 (TRALI)

from NHO report 2008/9

Admission for stabilisation of new DM; PMH of bowel disease, NO cardiac or respiratory history

Haematemesis and melaena, shock, Hb 6.5 g/dL

"transfused with three RBCs prior to a 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 hours). 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 60mmHg 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 increased 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 millilitres. (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."

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.

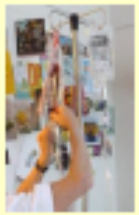
# Incorrect blood component transfused

**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.

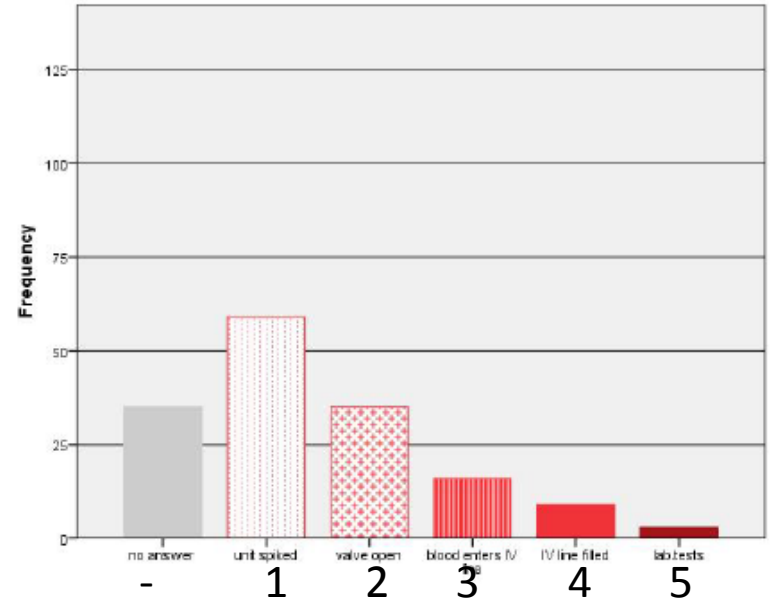
# Case 5

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



1) Unit spiked (cannot be used f

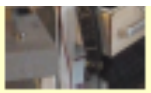
2) Unit spiked and valve opened




## ADDITIONAL MATERIAL

**1 The patient was transfused…**

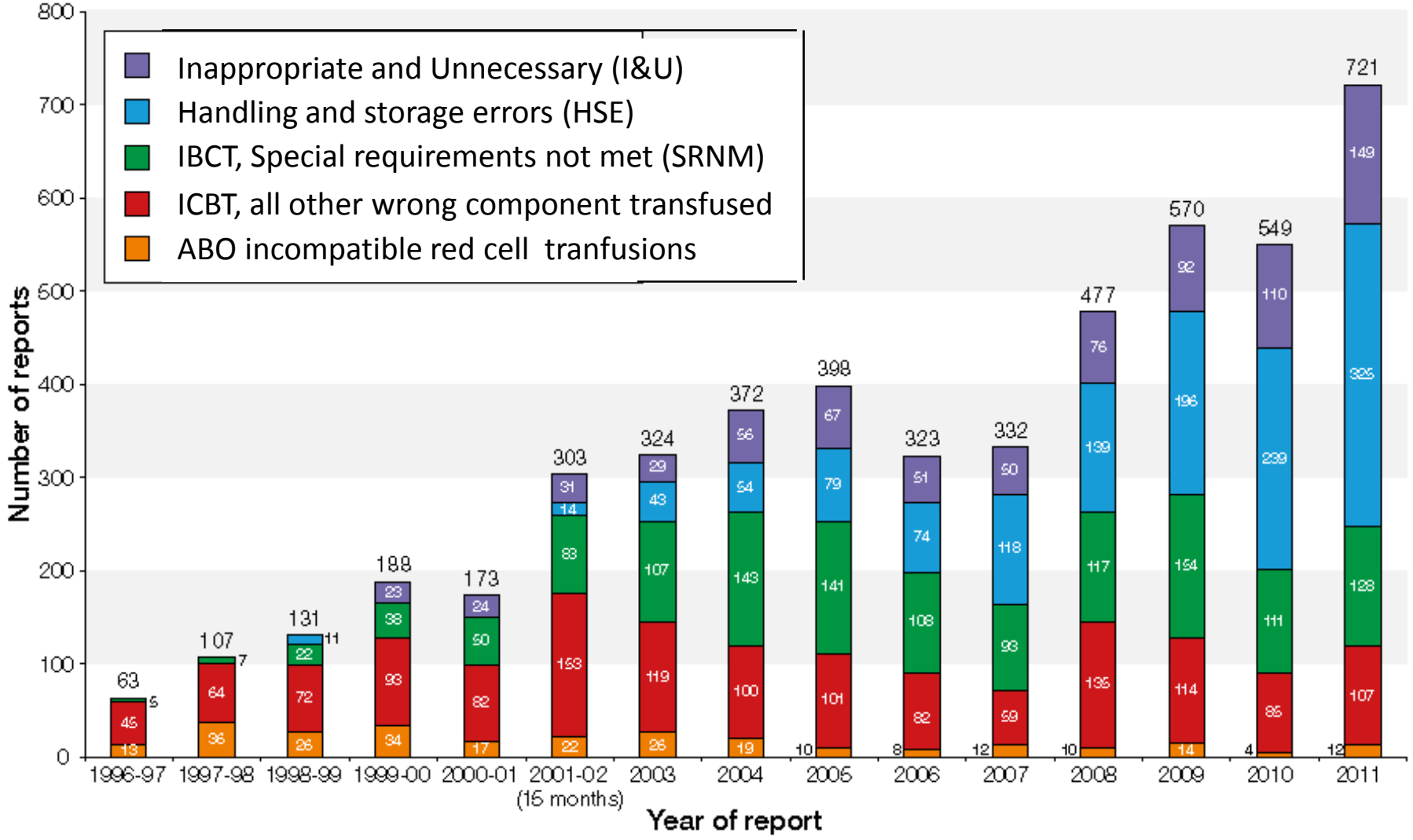
Transfusion shall be deemed to have started when the final pretransfusion checks have taken place and the next step (according to local SOP or national guidelines) has been performed. In many countries this will be at the moment of spiking the unit.



filled with blood

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

# 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

# Denominators: proposals for discussion

- 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

# 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 (no fee!!!)

# 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) => WHO patient safety definitions are preferable.
- 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:

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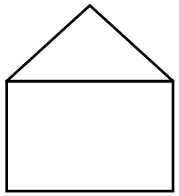

ISBT haemovigilance working party

10:30 – 17:00 on Saturday June 1st 2013
(day preceding start of ISBT congress)

# Acknowledgements

Thank you to the organisers for inviting me!

TRIP contact people

Thank you for your attention