Adverse events

(Errors and Incidents)

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Transfusion Reactions in Patients
Dutch National Hemovigilance Office

With acknowledgements to

IHN /ISBT discussion partners

- SHOT: Clare Taylor
- NHO (Ireland): Marina Cronin, Emer Lawlor, Jackie Sweeney
- Norway: Oystein Flesland
- Canada: Pierre Robillard

TRIP colleagues Martin Schipperus and Pauline Zijlker-Jansen

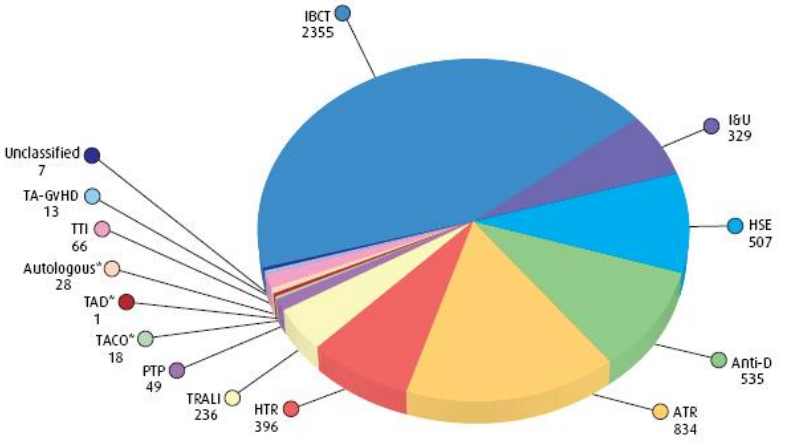
- Introduction
- Dimensions of adverse events
- Illustration: ABO incompatible transfusion
- Moving towards international surveillance definitions

- Part 2: Data (2008) from the EU serious adverse event reporting

Serious hazards of transfusion (SHOT)

1996-2008 60% of all reports were Incorrect Blood Component Transfused, Inappropriate & Unnecessary transfusions, Handling and Storage Errors

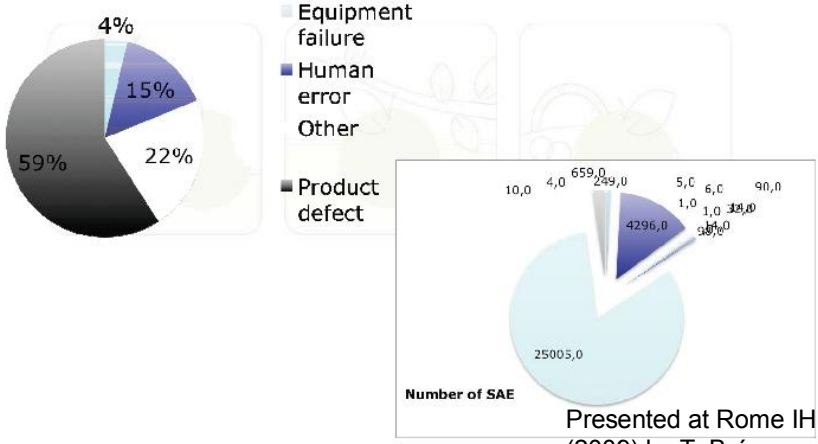
Figure 3
Cumulative numbers of cases reviewed 1996–2008 *n* = 5374



EU data (2007 reports)

Directorate-General for Health & Consumers

Serious Adverse Events

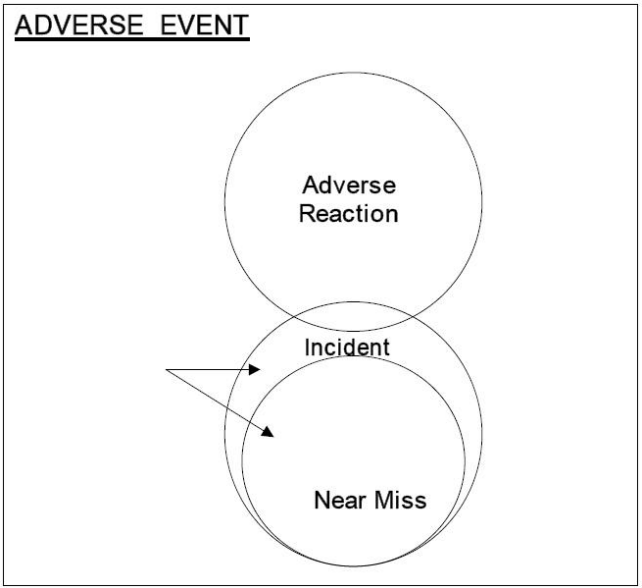


Presented at Rome IHN (2009) by T. Brégeon

comparing apples and pears?

Overarching categories (1)

ISBT definitions



Hotly debated in Cape Town, failed to reconcile with EU (Adverse Event) terminology

ISBT definitions

Adverse event is an undesirable and unintended occurrence before, during or after transfusion … It may be the result of an error or an incident and it may or not result in a reaction in a recipient.

Incident: patient is transfused with a blood component which did not meet all the requirements for a suitable transfusion for that patient, or that was intended for another patient. …

Near miss is an error or deviation from standard procedures or policies that is discovered before the start of the transfusion … could have led to a wrongful transfusion or adverse reaction

IBCT?

RBC unit intended for another patient

- unit on the drip stand, spiked with the IV line for administration
- tubing did not yet show any red or even pink colour
- Incorrect blood component transfused or near miss?
- Slippery slope argument
- Traceability?

Overarching categories (2)

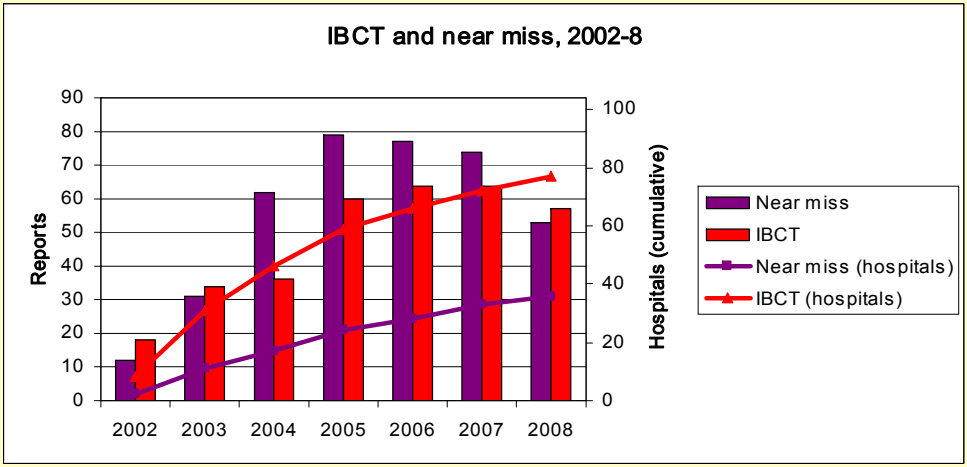
- Patient received unit which had been crossmatched for th
  label showed that p
  different unit numbe

Unit prescribed, selected and transfused on the basis of an incorrect Hb result (sample taken from drip arm)

Platelets prescribed (and selected and transfused) instead of plasma for patient with clotting factor deficiency

- Incorrect blood component transfused?
- Right blood to right patient?
- “Other incident”?

TRIP experience



Reporting to TRIP is the professional standard. Near miss reporting (“optional”) encouraged.

Dimensions of adverse events

How are they classified?

Types of IBCT event

(SHOT, 2008)

Classification by "top event"

What was wrong with the unit or transfusion?

A correct blood transfusion

- **Product** correctly collected, processed, tested, stored, labelled, distributed; no infectious agents (margin of risk)
- **Necessary**: appropriately prescribed (after investigations done on sample correctly taken from the right person)
- Correctly requested
- **Timely**: neither before the order to actually transfuse nor unnecessarily delayed

Professional standards

Legal requirements

Classification by “top event”

What was wrong with the unit or transfusion?

A correct blood transfusion …

- Component type and volume
- **Appropriate ABO and Rhesus D blood groups** (un-crossmatched O neg if emergency) using sample(s) from right person
- Assessment for irregular antibodies, additional (cross)matching as necessary
- Meets any **special requirements**
- Correctly **labelled**
- Issued and collected as per protocol

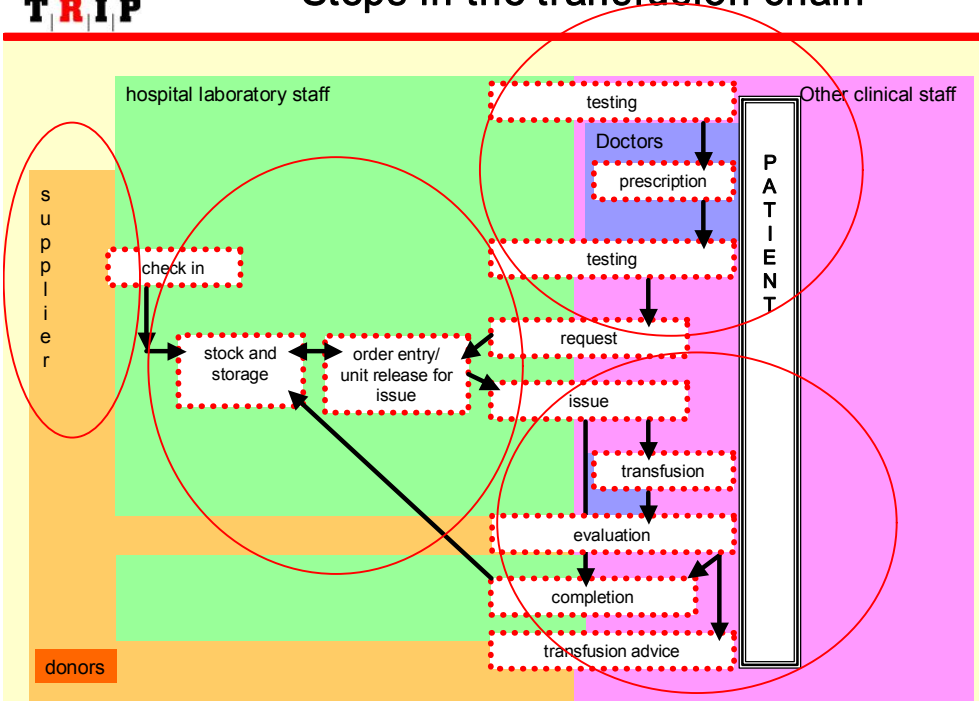
Classification by “top event”

What was wrong with the unit or transfusion?

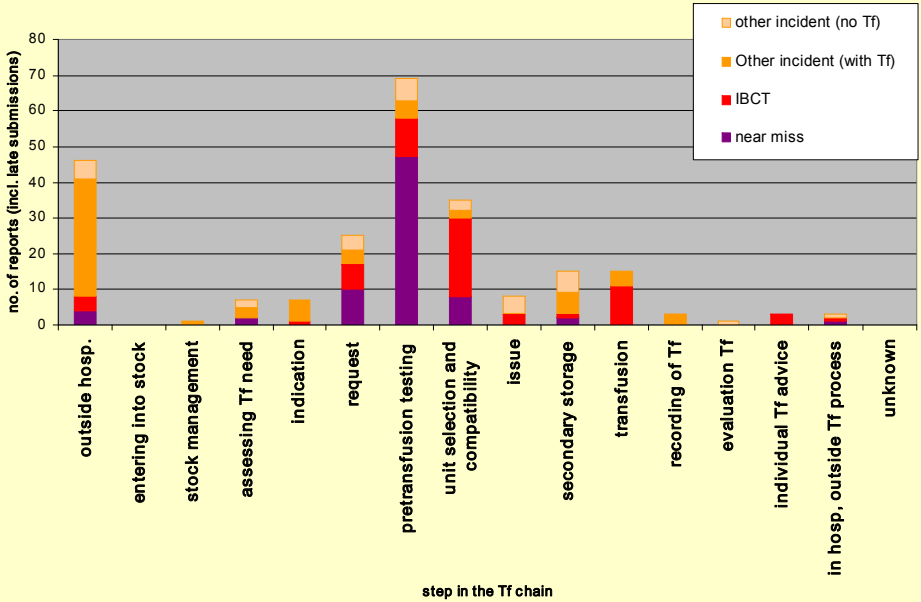
A correct blood transfusion …

- **Transport, storage and handling**
- Checked for **correct identity** of unit and patient
- **Administered** using correct materials after required clinical checks (temp. etc.)
- **Monitored**, any adverse reaction reported
- **Recorded** (record appropriately kept)
- **Evaluated**

Steps in the transfusion chain



Incident reports to TRIP, 2007



Where did the error arise?

- Blood service (supplier)
- Clinical area, prior to product selection
- Blood transfusion laboratory (hospital blood bank)
- Clinical area following issue

“Associated with quality or safety of blood products”

Step in the transfusion chain (EU)

- Screening
- Collection
- Testing
- Processing
- Storage
- Distribution
- Issue

Eg.Platelet unit distributed as "negative to date", later positive in the bacterial screen. Hospital informed by blood service; unit has been transfused without adverse reaction.

- –Collection?
- –Other suggestion: Testing, storage …?

Type of failure (root cause)

(What could have prevented the adverse event?)

EU

- Human
- Technical
- Product
- Materials
- Other

Eg. Donor "forgets" to report visit to malarious area

–Human error (the donor)?

–Poor questionnaire, poor screening technique (human error)?

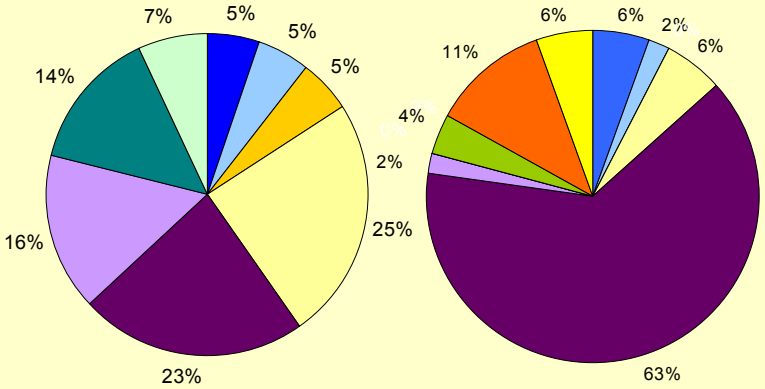
–Product problem (did not conform to specs)

–Failure to finance computerised questionnaire (management or system problem, other)?

Error analysis

- PRISMA, MERS-TM, other methods
- Practical breaking down into error types
- By whom was error made?
- Failed safety measures: each downstream error can also be analysed
- Root cause analysis (effect of circumstances)
  - Time of day / work pressure / availability of support staff and services
  - Staffing levels (e.g. on call versus core hours) / level of training
  - Computer ‘down’ or other IT problems

First error: type



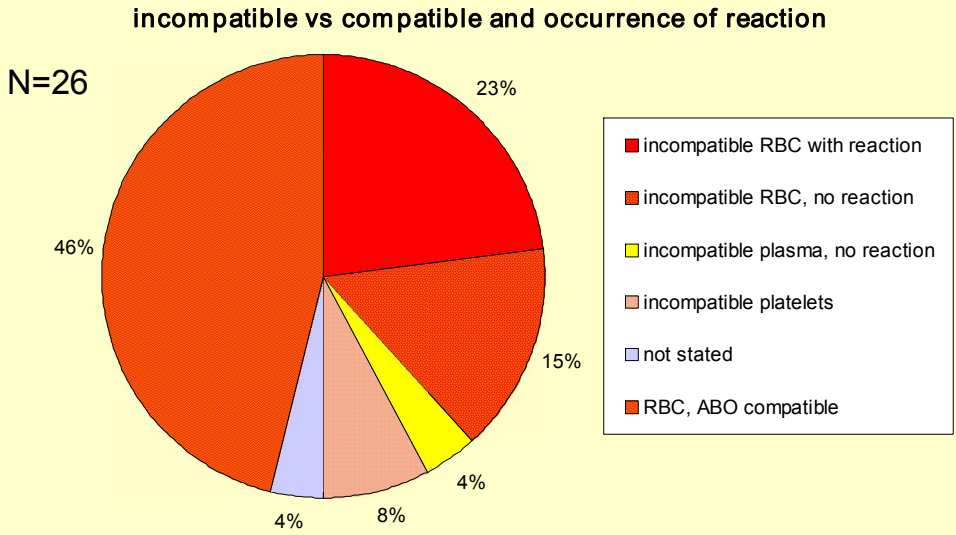
Risk

- High – medium – low?
- Broken down:
  - risk of anti-D formation
  - TA-GVHD
  - Risk of ABO incompatible transfusion
  - Etc.
- Was there (serious) harm to the patient?
  - Type of reaction, severity, imputability
  - NB were others put at risk?

–Unnecessary transfusion led to circulatory overload

–Wrong unit for patient, compatible, however allergic reaction which led to discovery of the error.

ABO incompatibility risk (2008)



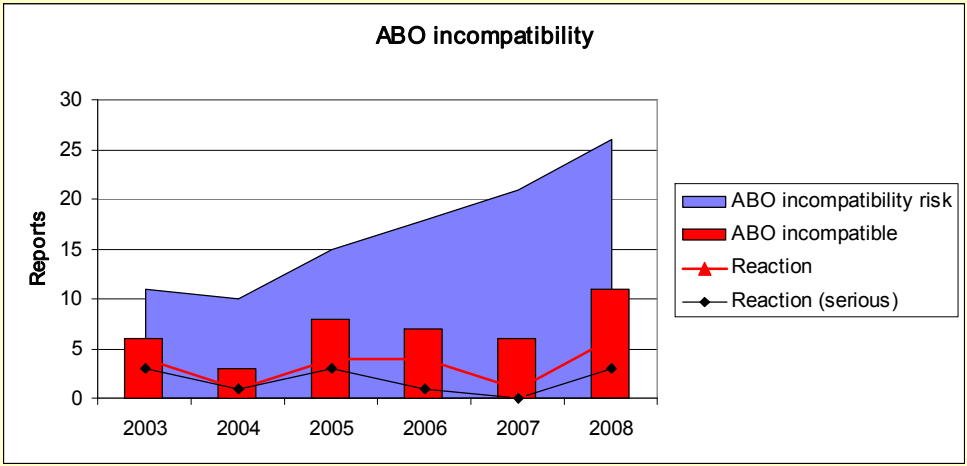
Multiple dimensions!

- What was wrong
- Error or failure: where, who, why, how
- Further errors – where, who and why
- Discovery
- Potential risk
- Actual harm to individual – severity and type, outcome
- Possibility of wider impact
- Risk of repetition
- Preventive measure
- Evaluation of intervention

This gives millions of permutations!

In order to work together in improving transfusion safety we must agree on basic terminology for sharing information and learning from each other's work.

ABO incompatible transfusion



Note: in the first years of reporting to TRIP, information was less complete

Product-related?

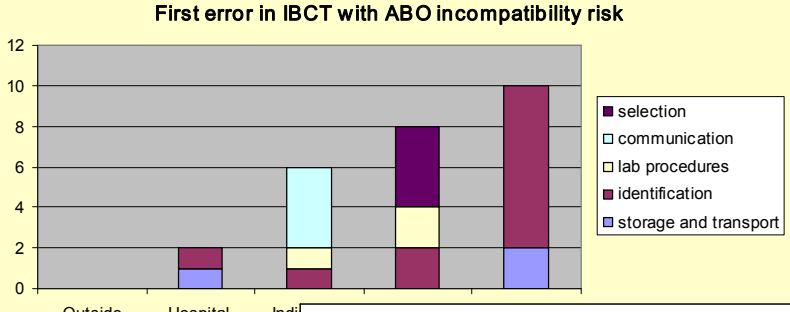
Directorate-General for Health & Consumers

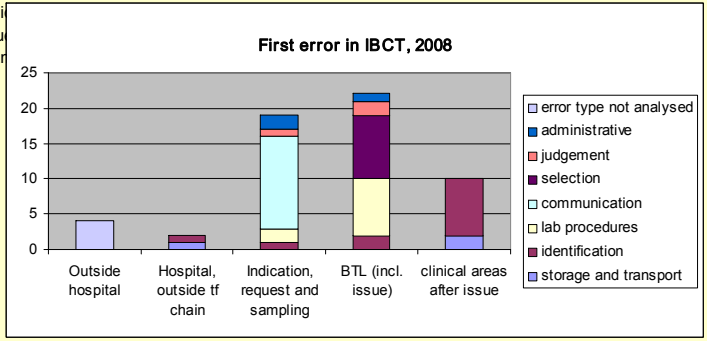
Year "2007"

Nbr of countries: 22		Total Nbr of SAR										SARs leading to death								
Category	Sub category	Not ass.	Level 0	Level 1	Level 2 A	Level 2 B	Level 3 A	Level 3 B	Tot. A	Tot. B	Total	Not ass.	Level 0	Level 1	Level 2 A	Level 2 B	Level 3 A	Level 3 B	Tot. A	Tot. B	Total
Immunological Haemolysis	Due to ABO incompatibility		10	4	4	0	38	0	56	0	56			0	1		0		1		
Immunological Haemolysis	Due to other allo-antibody	1	26	10	25	0	44	0	100	0	100		0	1	1		0		0		0
Non-immunological Haemolysis		1	26	0	2		1		27		27										
Transfusion-transmitted bacterial infection		14	96	10	10	7	0	7	100	14	153	1	10	0	1	1	1		10	1	14
Anaphylaxis/hypersensitivity		181	30	316	298		77		842		842	2	6	4	3				17		17
Transfusion related acute lung injury		15	199	45	75	1	45		379	4	383	11	25	6	6	0	4		52	0	52
Transfusion-transmitted viral infection	HBV		75	1	1				77		77		1	1	1				3		3
Transfusion-transmitted viral infection	HCV		83	1					84		84		1						1		1
Transfusion-transmitted viral infection	HIV 1/2	1	13				1	1	14	1	15	1							1		1

Total SAR A	Total SAR B	Deaths A	Deaths B
2,201	22	130	2

TRIP data on ABO incompatibility





Measures to prevent ABO incompatibility

Barcode technology

"Improving transfusion safety: implementation of a comprehensive computerized bar code-based tracking system for detecting and preventing errors"

Askeland et al. 2008, Transfusion 48: 1308-1317

(680-bed academic) hospital-wide use of improved wristbands and bar code scanners for identification of patients, blood samples and blood products

- Sample rejection rate improved (from 1.82% to 0.17%)
- Prevented identification errors at final transfusion step: 1 per month
- Misscans and skipped steps detected: 1%

Measures to prevent ABO incompatibility (2)

Bedside ABO compatibility check

"Failure of bedside ABO testing is still the most common cause of incorrect transfusion in the barcode era"

- Ahrens N. et al 2005 Transf Aph Science 33: 25-29
- Consecutive ABO-incompatible RBC transfusions in university hospital group, 1997 – 2004; mandatory pre-transfusion bedside ABO testing

8 patients received 13 ABO-incompatible RBC units; Errors of bedside ABO testing for 7 out of 8 patients

"Reliability of bedside ABO testing before transfusion

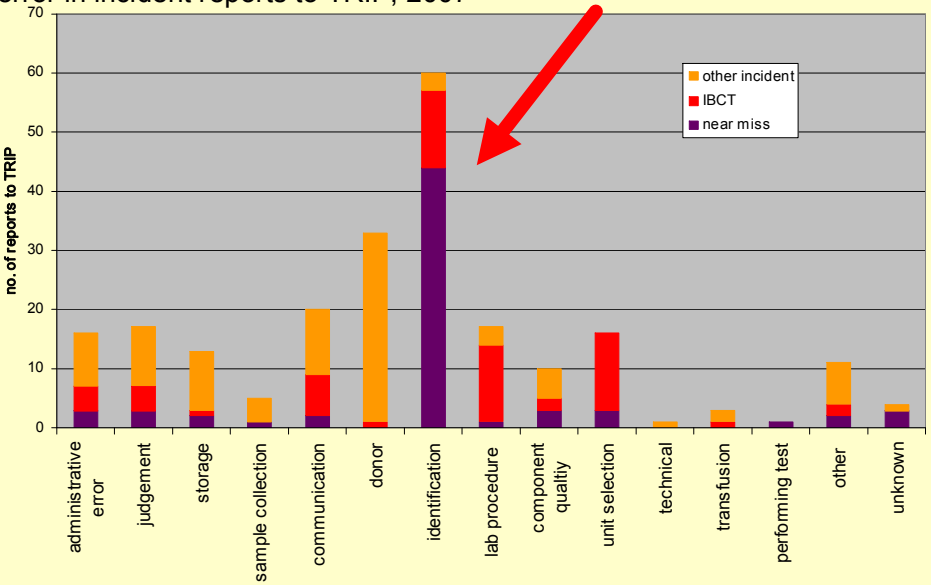
- Migeot V et al 2002 Transfusion 42: 1348-55
- Experiment comparing performance by nurses using two types of device

Up to 30% errors in performance, 16% incorrect transfusion decisions

Measures to prevent ABO incompatibility (3)

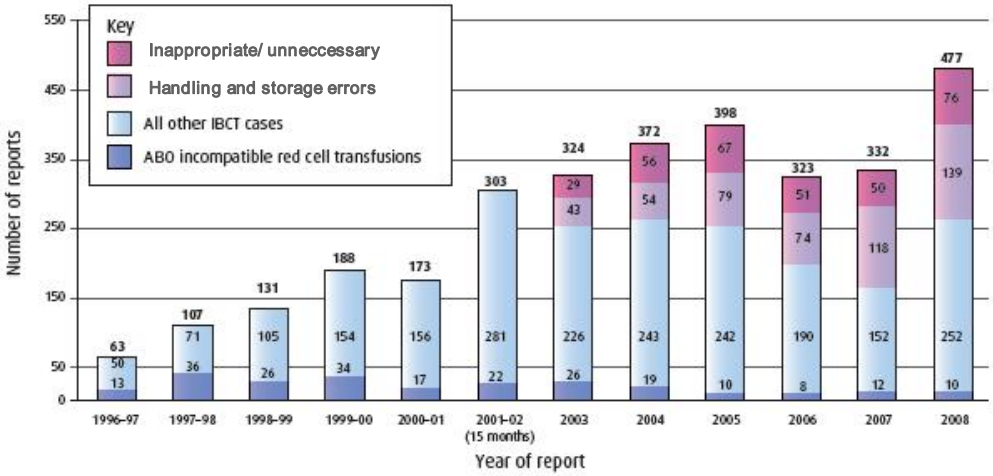
Double sample

First error in incident reports to TRIP, 2007



Monitoring trend

Figure 6
IBCT and ABO-incompatible red cell cases 1996–2008



SHOT 2008

Developing a definition

"ABO incompatible transfusion"

All cases where a unit (red blood cells, platelets or a plasma product) was transfused which was (unintentionally) ABO incompatible. Please include all such events

even if only a small quantity of blood was transfused

also if no adverse reaction occurred.

All cases are to be included, whether the first error occurred in the blood service, in the blood transfusion laboratory or in clinical areas."

- ISBT/IHN Subgroup invites you to participate

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Learning points

1. Vigilance and safety culture
2. Not everything is reported
3. Multiple dimensions!

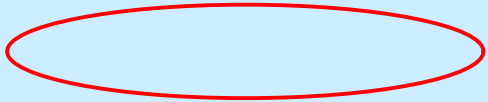
4. Focus on “your” part of the transfusion chain
   - Analyse in order to target safety improvement measures
5. Sharing, comparing and monitoring trends
   - agreed definitions for sentinel events
   - main concepts defined, e.g. severity
   - In harmony with other groups (e.g. WHO patient safety)

Part 2

Serious Adverse Events and mandatory reporting in the EU

Draft results of the 2009 reporting exercise (events in 2008)
by kind permission of M. Thomas Brégeon

EU blood directive 2002/98/EC and
daughter directive 2005/61/EC



Reported activity (2008)

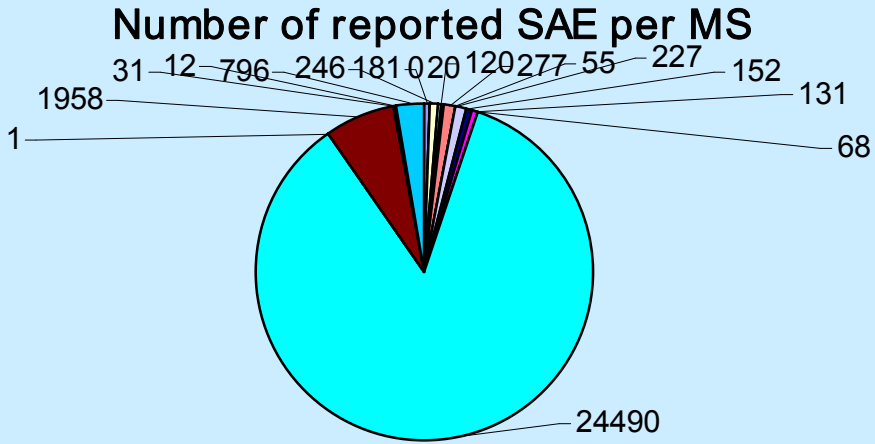
- Data from 19 Member States
- Units issued (or distributed)
  - 15.7 million RBC concentrates
  - 2.1 million platelet units
  - 4 million plasma
- Units transfused: 9 MS
- Recipients transfused: 6 MS

DATA on SARE (2008)

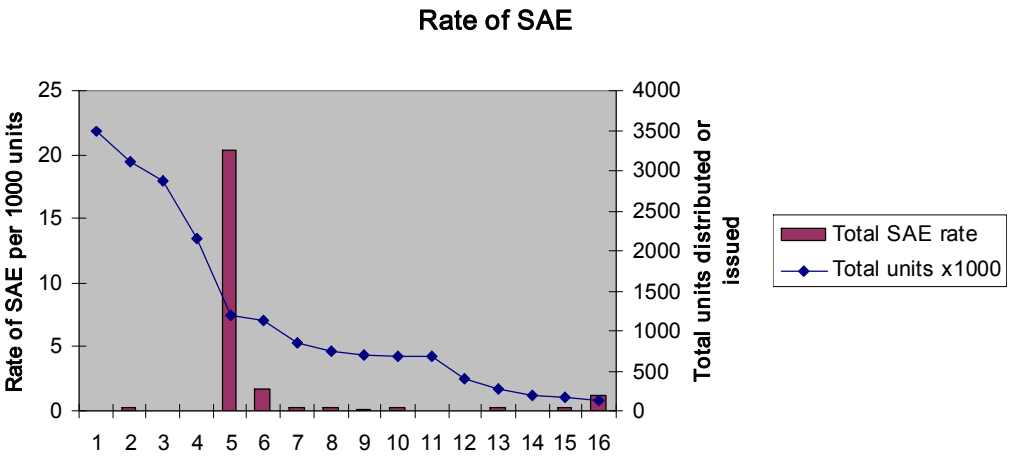
- SAR: 24 MS
- SAE: 21 MS (of which 5: nil to report)

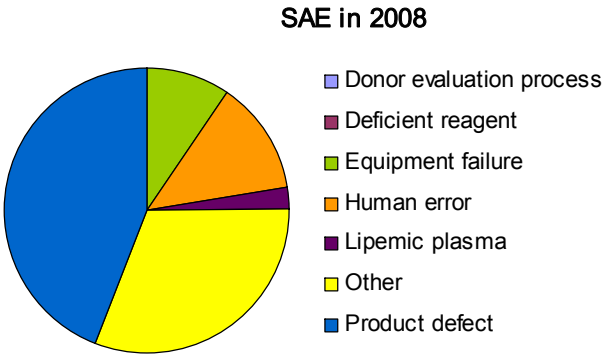
- Improvement from last year's reporting exercise

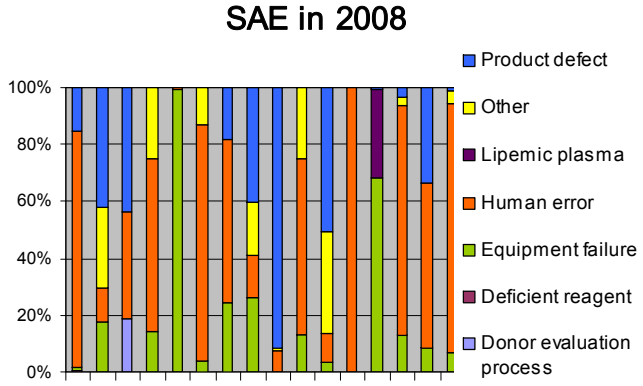
Reported SAE

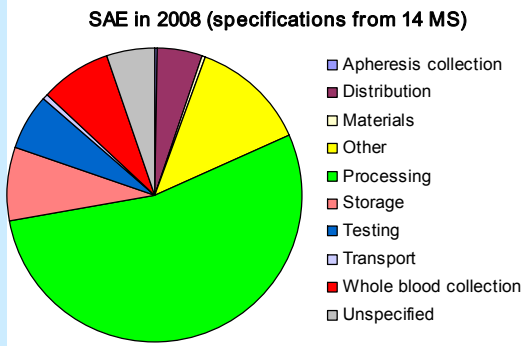


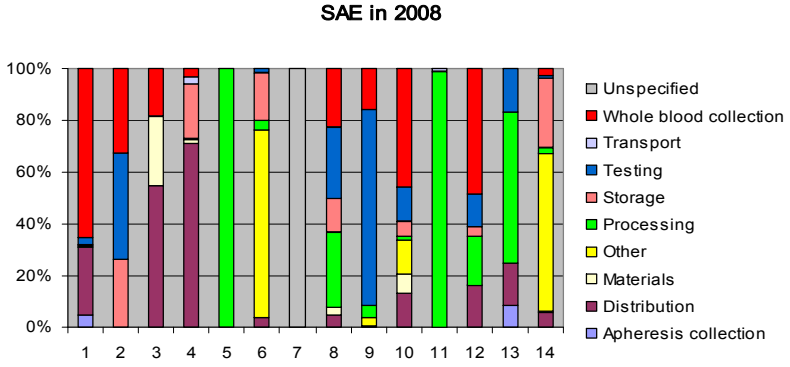
Reported SAE




SAE in 2008
Donor evaluation process
Deficient reagent
Equipment failure
Human error
Lipemic plasma
Other
Product defect


SAE in 2008
100%
80%
60%
40%
20%
0%
Product defect
Other
Lipemic plasma
Human error
Equipment failure
Deficient reagent
Donor evaluation process


SAE in 2008 (specifications from 14 MS)
Apheresis collection
Distribution
Materials
Other
Processing
Storage
Testing
Transport
Whole blood collection
Unspecified


SAE in 2008
100%
80%
60%
40%
20%
0%
1
2
3
4
5
6
7
8
9
10
11
12
13
14
Unspecified
Whole blood collection
Transport
Testing
Storage
Processing
Other
Materials
Distribution
Apheresis collection

Need for further clarification

- Which SAE should be reported
- Assessment based on practice
- Various domains and actors (some outside the formal boundaries of hemo-vigilance)

We must not think in silos!

Serious Adverse Events
The Commission perspective

1. Serious Adverse Events are defined by the Blood Directive…
2. … but experience shows that the concept still requires legal refinement
    1. Delineation between deviations, adverse events and serious adverse events?
    2. Where the SAE happens in the transfusion chain is not neutral: inside or outside the scope of the Blood Directive?
3. At this stage, the Commission and the Member States could not answer these questions: the annual reports to the Commission are of limited quality and value.

Serious Adverse Events
The Commission perspective

1. The “legal” perspective of Serious Adverse Events complements the learning points mentioned earlier: A proper management of SAE requires a holistic approach going beyond legal and professional boundaries.
2. ISBT/IHN sub-group on Adverse Events would directly support the ongoing stepwise process for achieving a “Common approach for definition of reportable serious adverse events and reactions as laid down in the Blood Directive”.
3. Third version of the Common Approach planned for end 2010: input from the ISBT/IHN will be highly welcome.

Thank you