

What is Haemovigilance?

The Serious Hazards of
Transfusion scheme

Aims

- Show the development of the SHOT haemovigilance system
- Changing nature of SHOT data
- How SHOT data have influenced transfusion practice
- Lessons we can learn
- Relationship between SHOT and MHRA

EMERGENCY BLOOD TRANSFUSION SERVICE
ROYAL SALOP INFIRMARY CENTRE
 Telephone: SHREWSBURY 206 SHREWSBURY

VOLUNTARY DONOR

Name Mr [REDACTED] Group 4
 Address Wellington
 Phone _____

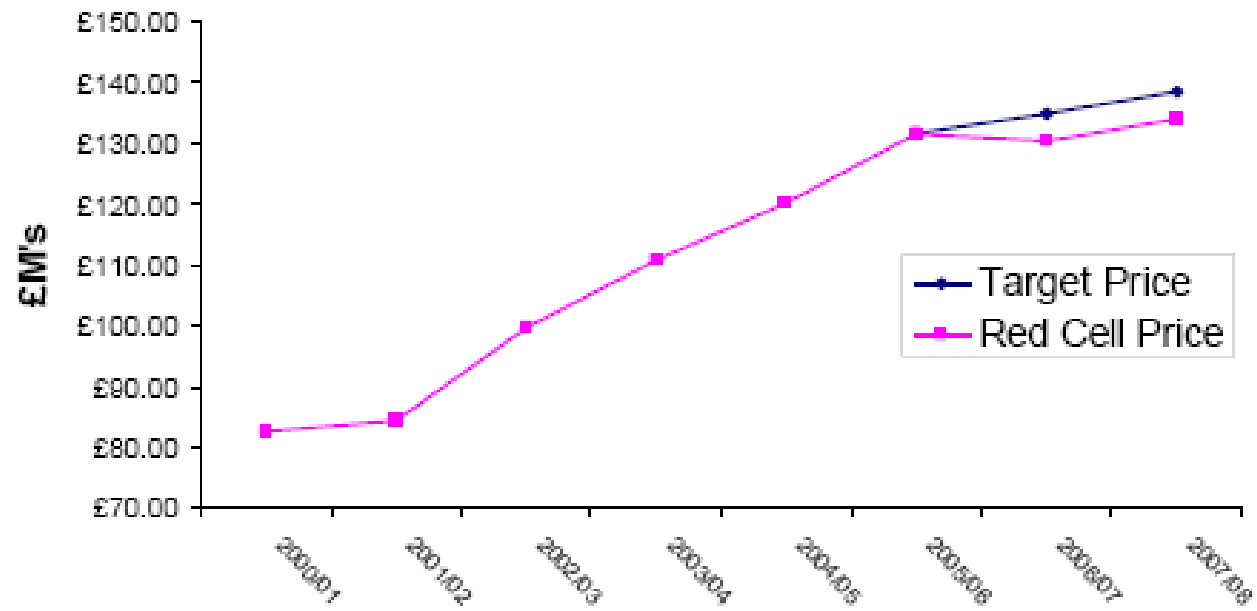
DATE	BLOOD DONATED	DATE	BLOOD DONATED
5. 7. 40	500 ccs	3. 4. 44	500 ccs
23. 6. 41	560 ccs		
18. 9. 41	500 ccs		
16. 11. 42	500 ccs		



What changed?

- 1970s: Awareness of hepatitis B and “non A non B hepatitis”
- 1983: Mystery illness in haemophiliacs later shown to be due to HIV
 - Increasing spending on blood safety
- 1980s First recognition of TRALI
- 1990s Understanding that “wrong blood” incidents are more common than infections or antibody problems

NHSBT Red Cell Price



What changed?

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 - Increasing spending on blood safety
- 1980s Increasing recognition of TRALI
- 1990s Understanding that “wrong blood” incidents are more common than infections
- And that’s without vCJD!

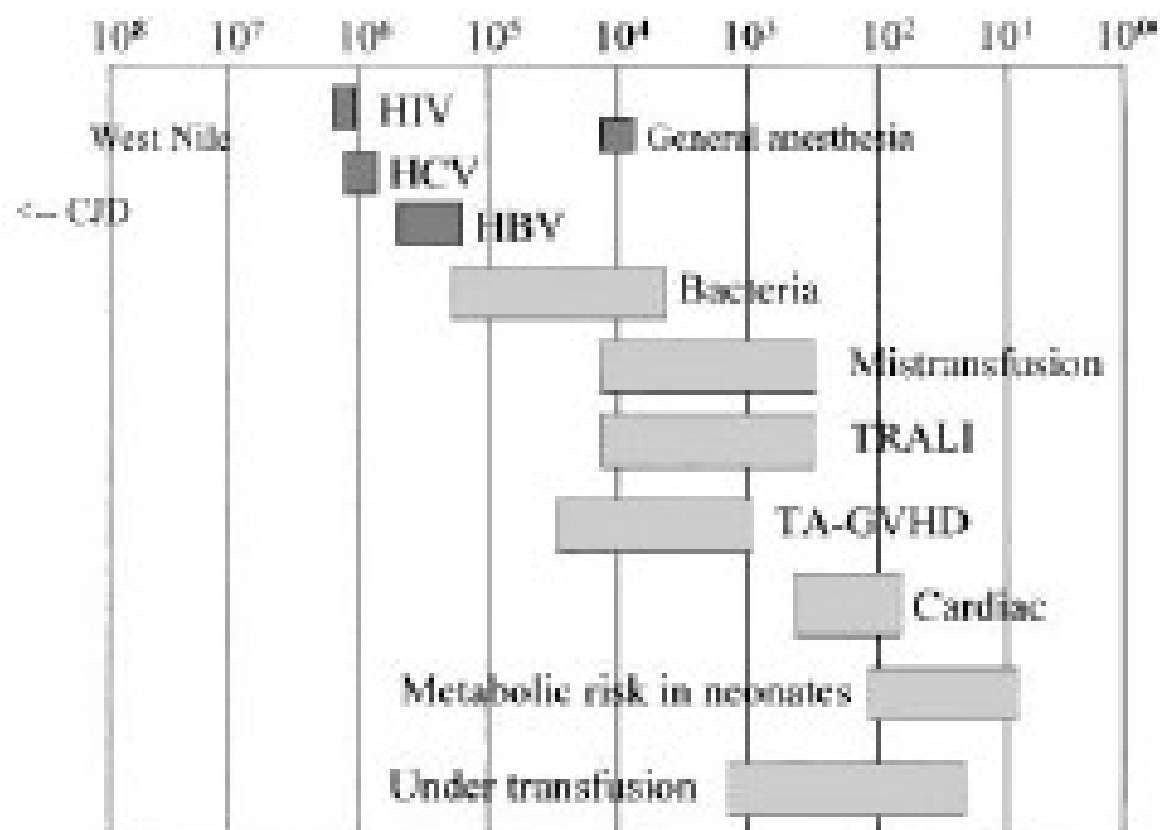


Fig. 2. Estimates of the current risk per unit of blood transfusion. The vertical bars represent log risk estimates (1-10, 1-100, etc.). The dashed edges to lighter shaded horizontal bars signify that the upper and lower estimates of risk are uncertain.

Dilemmas

- Were/are all transfusion safety initiatives evidence based?
- How do we promote transfusion safety without further increases in blood costs?

The Serious Hazards of Transfusion (SHOT) scheme

- Launched in 1996
- Voluntary anonymous system
 - “professionally mandatory”
- Funded by joint UK transfusion services

Aims of SHOT 1996

- Improve standards of hospital transfusion practice
- Inform policy within the transfusion services
- Aid production of clinical guidelines
- Educate users on transfusion hazards and their prevention

SHOT Mission Statement 2011

- Improve standards of hospital transfusion practice
- Inform policy within the transfusion services
- Aid production of clinical guidelines
- Educate users on transfusion hazards and their prevention
- Inform national policy on transfusion safety within the UK
- Inform Europe about transfusion safety in the UK

What did SHOT find in 1996?

- 15 ABO incompatible cases
 - 1 fatality
 - 2 with major morbidity
- 8 TTIs
 - 4 viral (Hep A, B, C, HIV)
 - 3 bacterial
 - 1 malaria
- 9 cases of TRALI
 - 2 fatal
- 4 Transfusion-associated GVHD
 - All 4 fatal

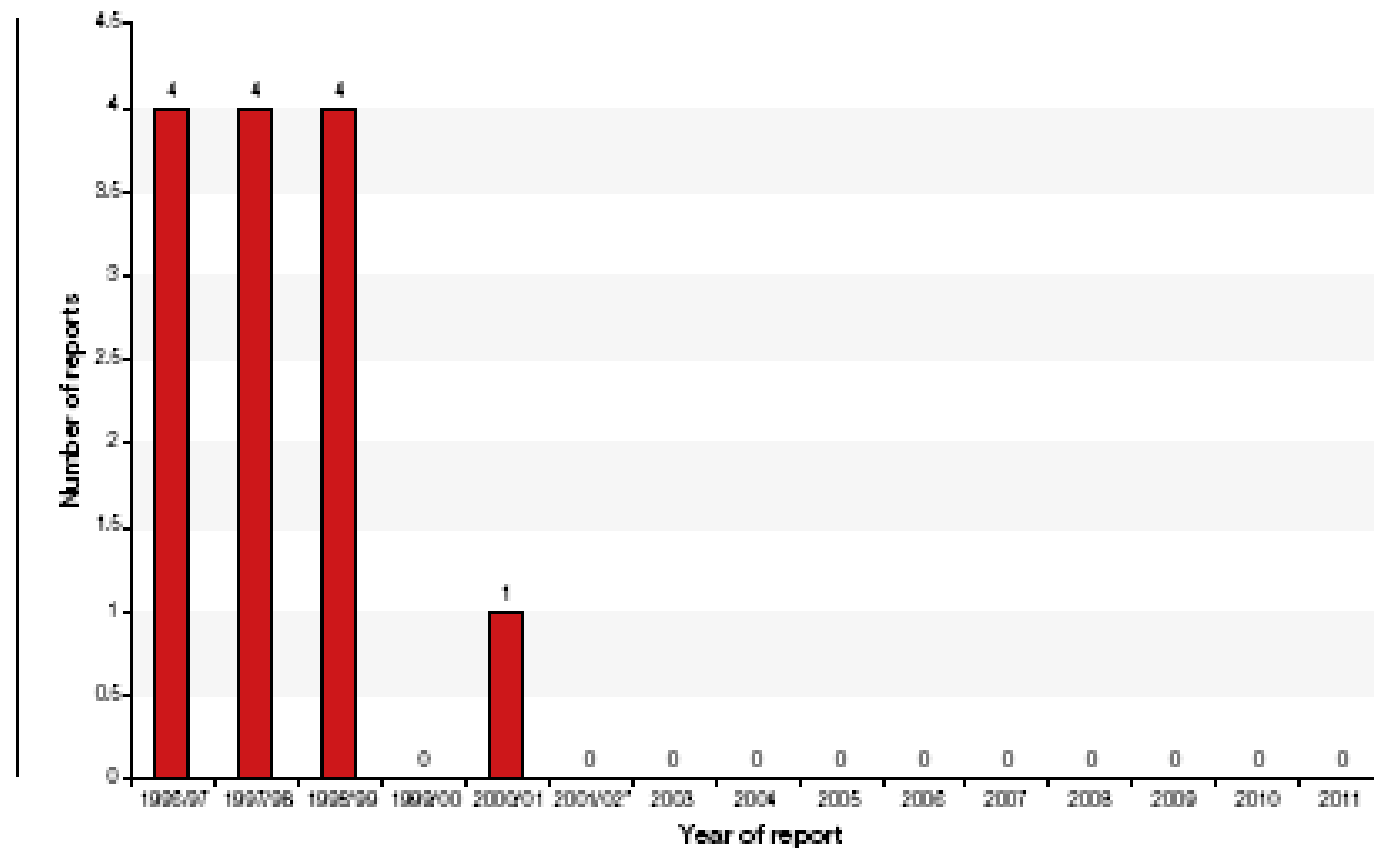
Transfusion-associated GVHD

- Very rare but almost always fatal
- Allo-engraftment of mature donor T lymphocytes
 - Shared HLA haplotypes between donor and recipient
 - Defective cell mediated immunity
- Risk groups include patients with Hodgkin's disease, those on purine analogues, recipients of IUT, HLA matched platelets, donations from 1st or 2nd degree relatives
- Prevention
 - Appropriate use of irradiated blood components

T-A GVHD cases reported to SHOT

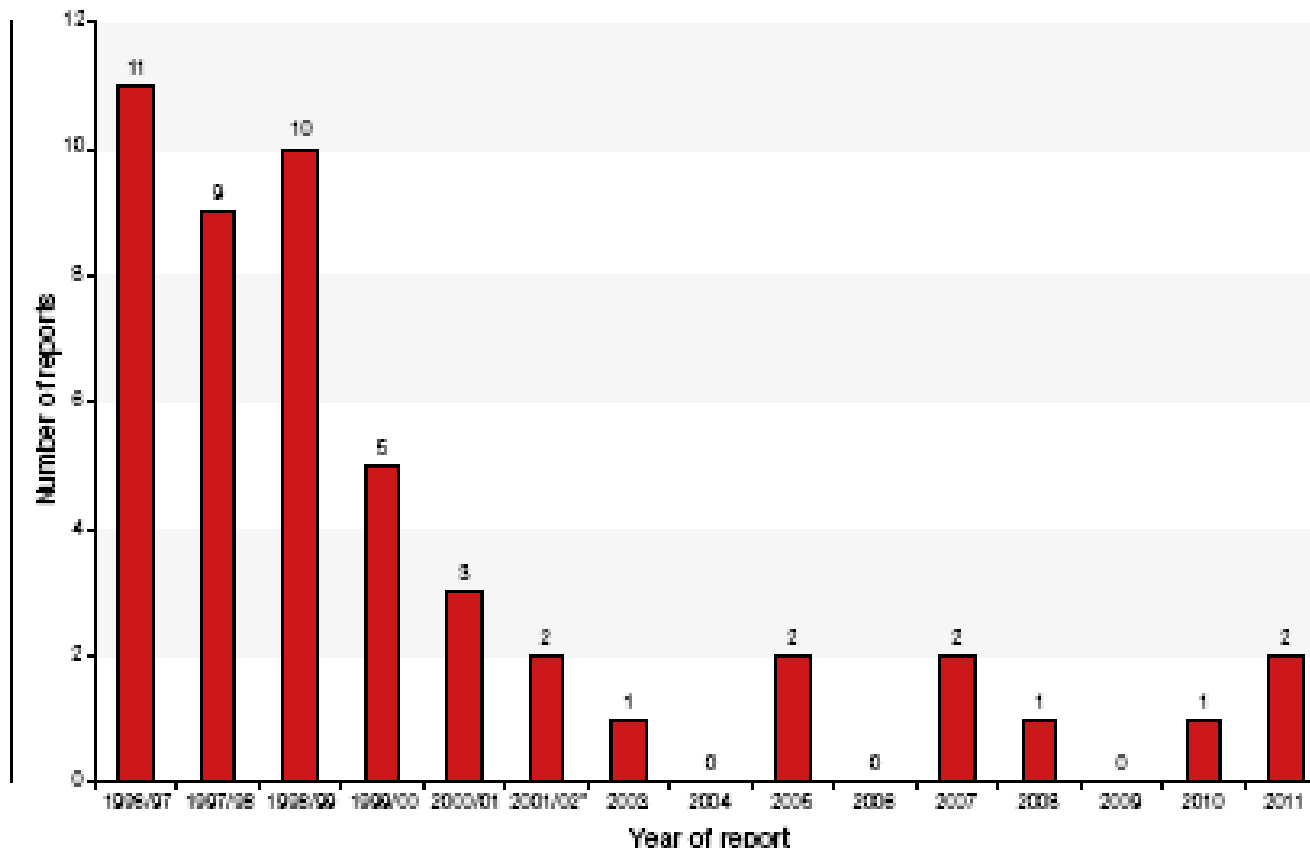
No new case of TA-GvHD was reported in 2011.

Figure 19.1
Number of cases of
TA-GvHD reported
to SHOT each year



Cases of Post-Transfusion Purpura

Figure 18.1
Number of cases
of PTP reported to
SHOT each year
(HPA antibody
positive)

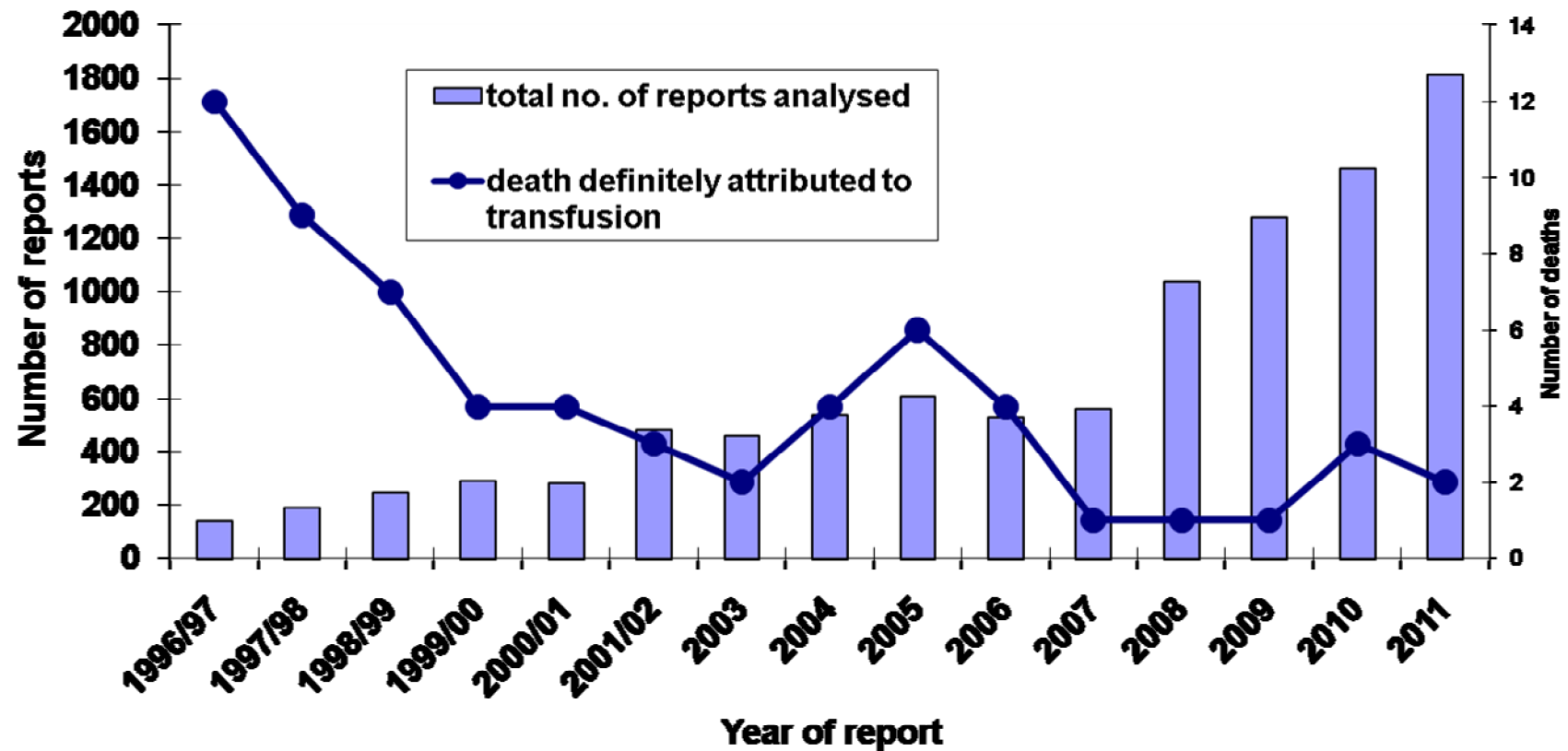


What happened?

What happened?

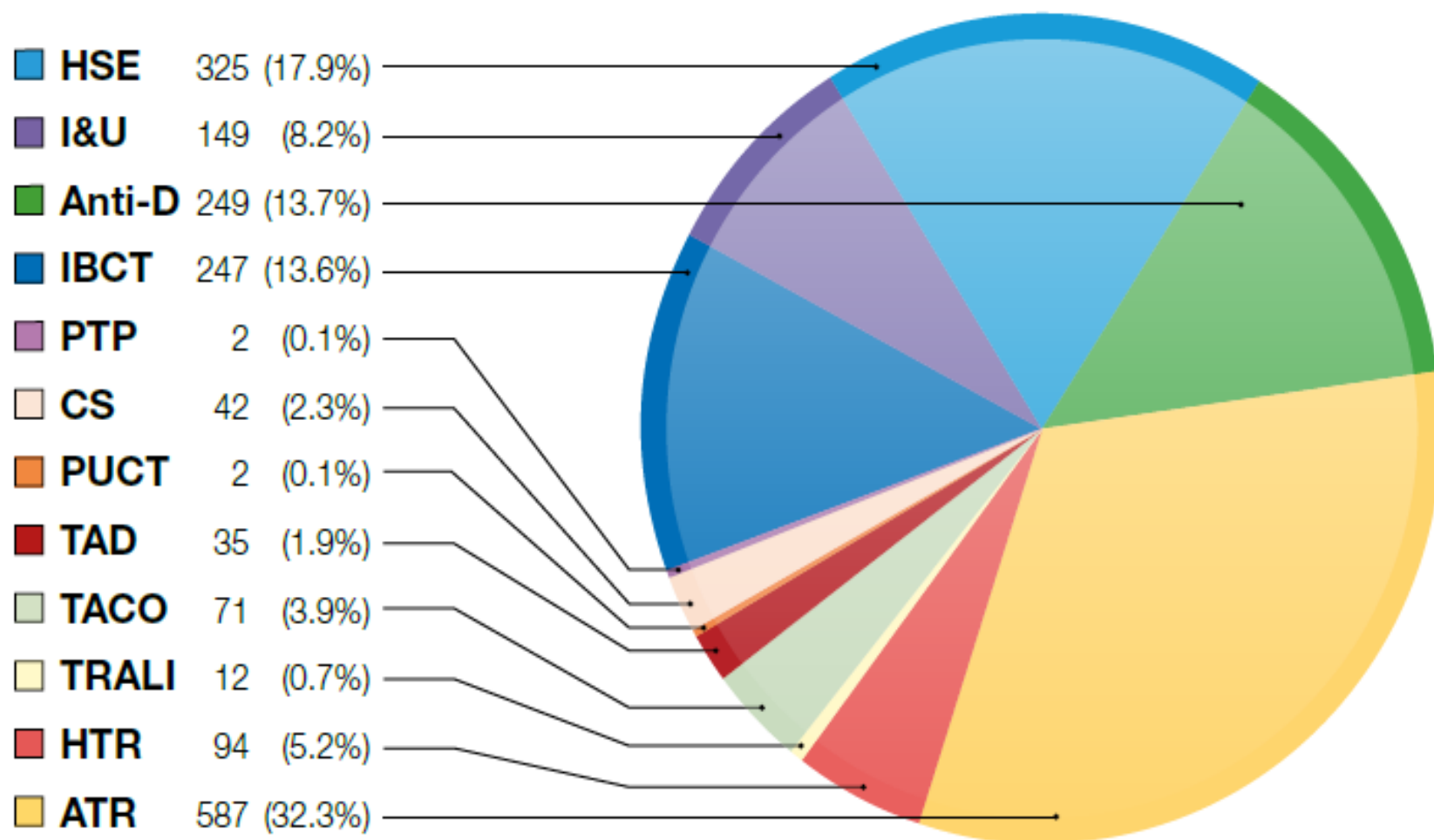
- 1999: due to concern about risks of v CJD transmission, leucodepletion phased in
 - Initially 99% of components $< 5 \times 10^6$ wbc per component
 - 1000 fold reduction
- 2005: European ruling
 - 90% $< 1 \times 10^6$ wbc per component
- As well as viable wbc, platelet microparticles reduced as well

Deaths definitely attributed to transfusion 1996/97 - 2011

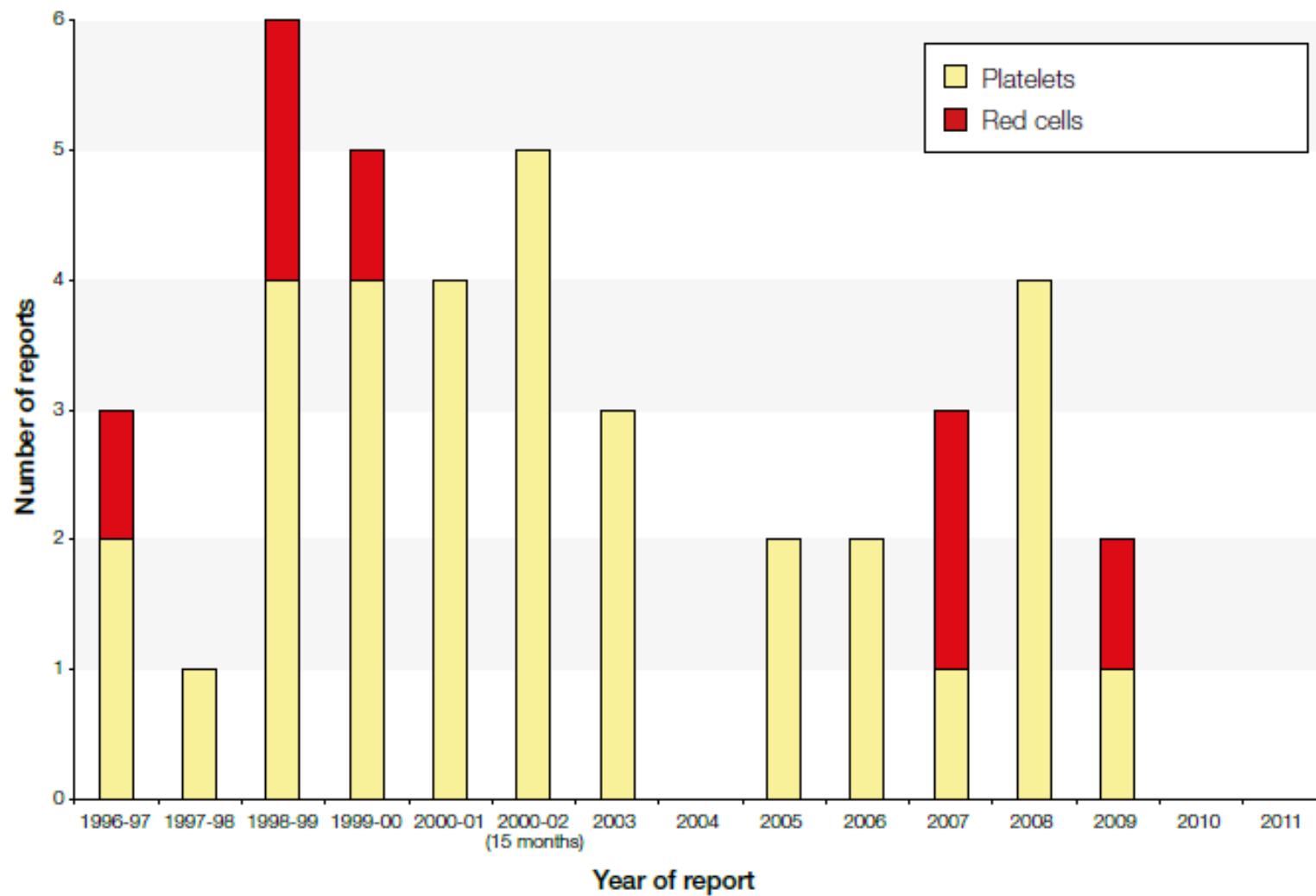


Cases reviewed in 2011 (excluding near miss and instances where the patient received a correct component despite errors having occurred – RBRP)

n=1815



Number of bacterial TTI incidents, by year of report and type of unit transfused (Scotland included from 10/1998)



Bacterial TTI from 2008

Report of transfusion-transmitted Group G streptococcus (2 recipients)

A unit of apheresis platelets was split to produce 2 platelet doses. Pack 1 was transfused to a teenager with acute lymphoblastic leukaemia (ALL) who reacted with allergy-like symptoms. Pack 2 was transfused to a female patient in her 50s with acute myeloid leukaemia (AML) who developed chills, nausea and a feeling of impending doom. The remains of both units were returned to the blood services for investigation, with a delay in the return of pack 1 due to the initial diagnosis of an allergic reaction.

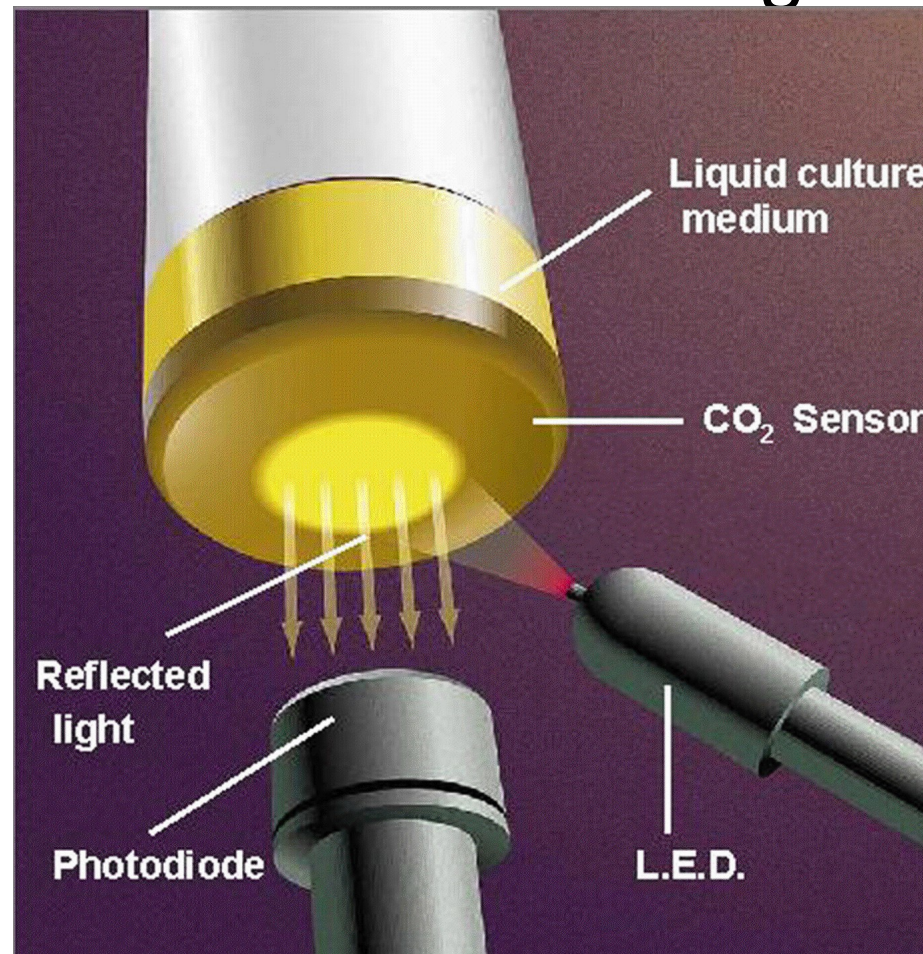
Blood cultures from both patients yielded Lancefield Group G streptococcus (GGS), as did cultures of both platelet units carried out at the blood services. GGS are known as both commensals and pathogens in animals and humans.²⁹ The apheresis donor denied any recent illness or change in bowel habit, but GGS was identified from their stool sample.

All 5 isolates (from both patients, both packs and the donor) were sent to a national reference laboratory for typing, and were found to be of the same strain. The likely but unproven chain of transmission was from donor gut to venepuncture site via the donor's fingers, and from there to the donated component. As with the previous case, it cannot be guaranteed that this chain of transmission would be prevented by donor arm cleansing (see commentary).

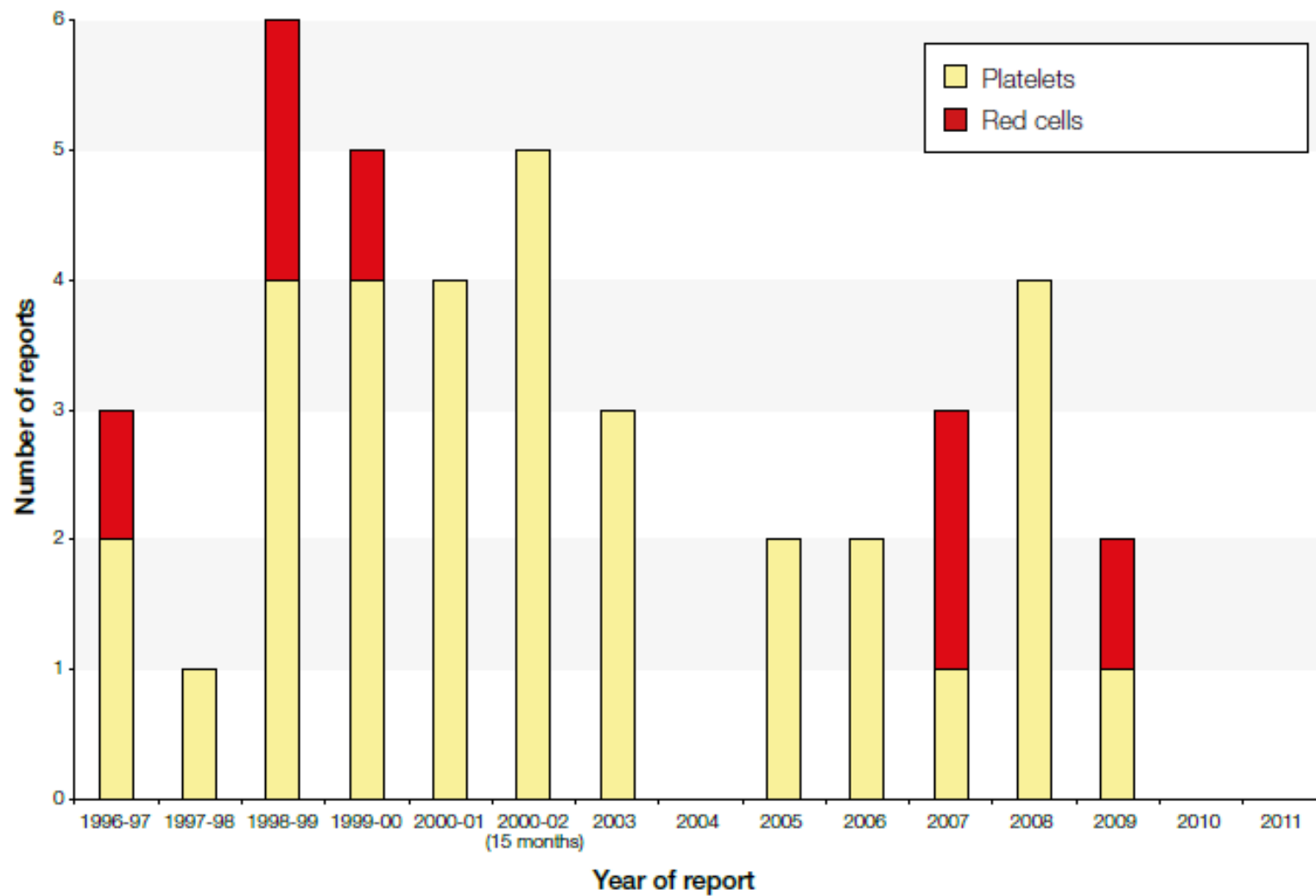
Strategy to reduce bacterial TTI

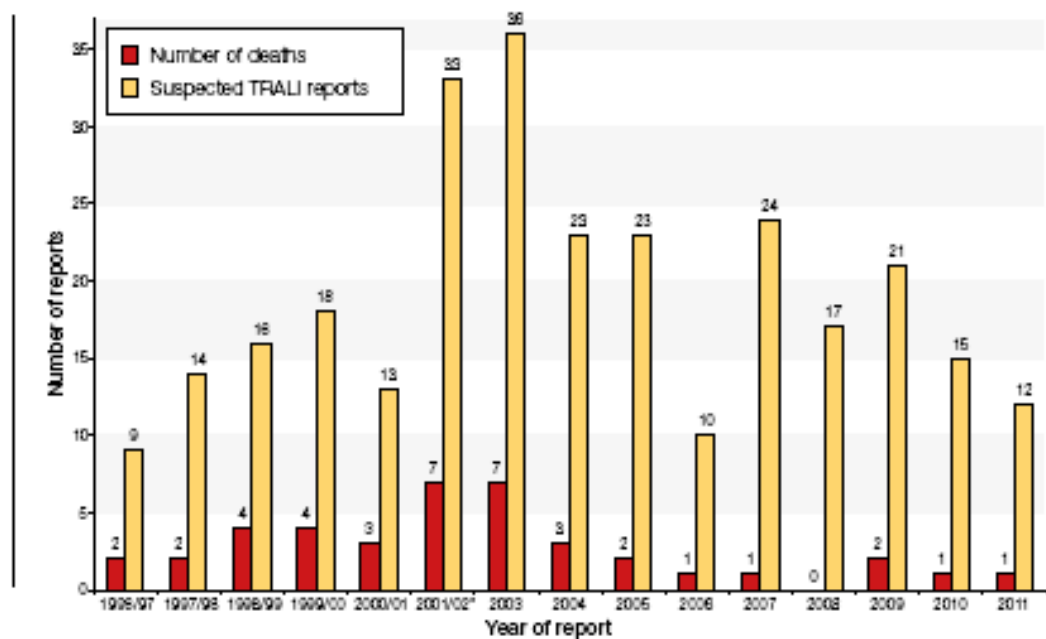
- Donor screening
- Post donation information
- Arm cleaning
- Diversion pouches
- Bacterial screening
- Withdrawing associated components when adverse reactions reported

Colourimetric sensor detects CO_2 given off as a result of bacterial growth



Number of bacterial TTI incidents, by year of report and type of unit transfused (Scotland included from 10/1998)





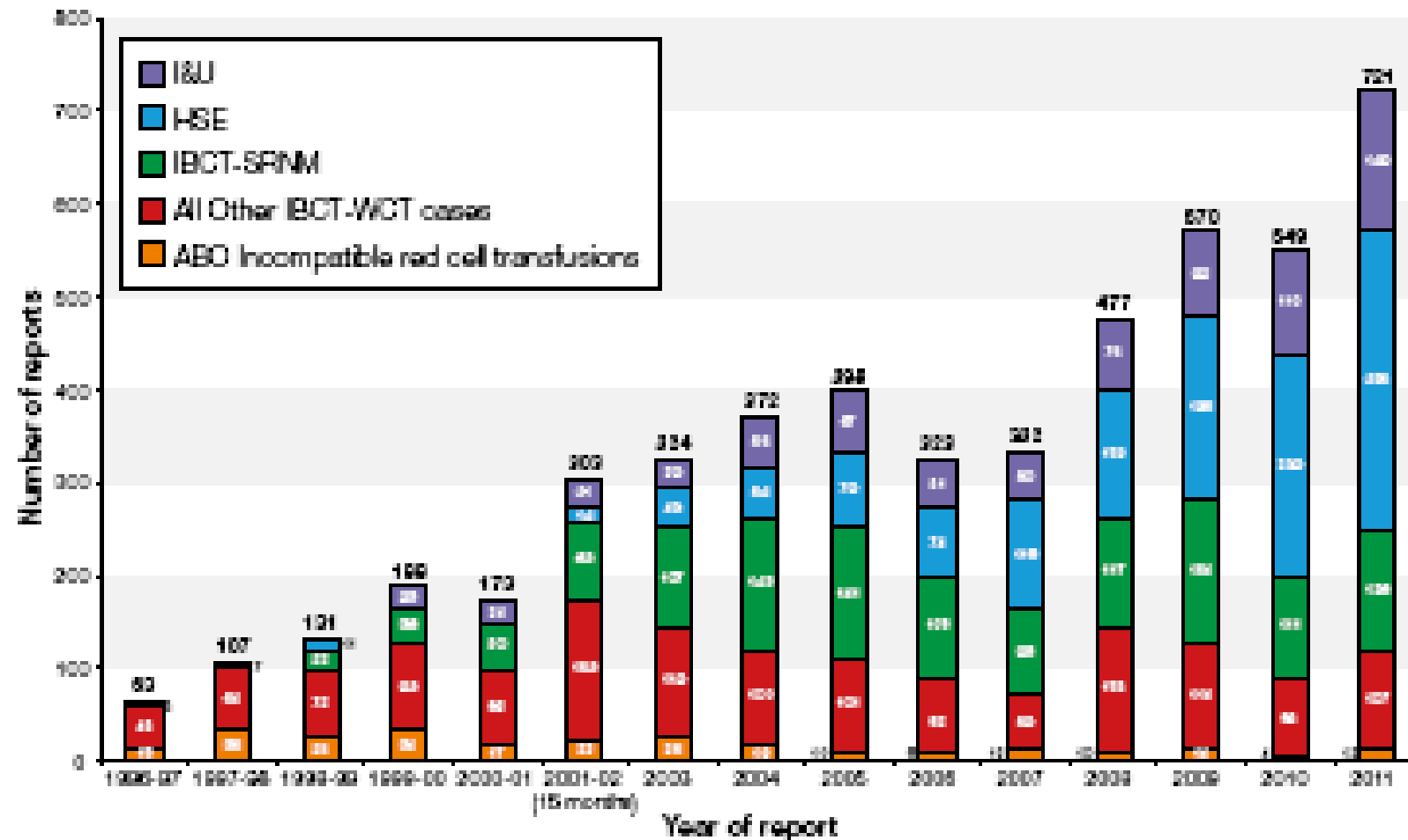
TRALI case Imputability (SHOT criteria)	Number of cases
Highly likely	0
Probable	1
Possible	2
Unlikely	9
TOTAL	12

What happened?

What happened?

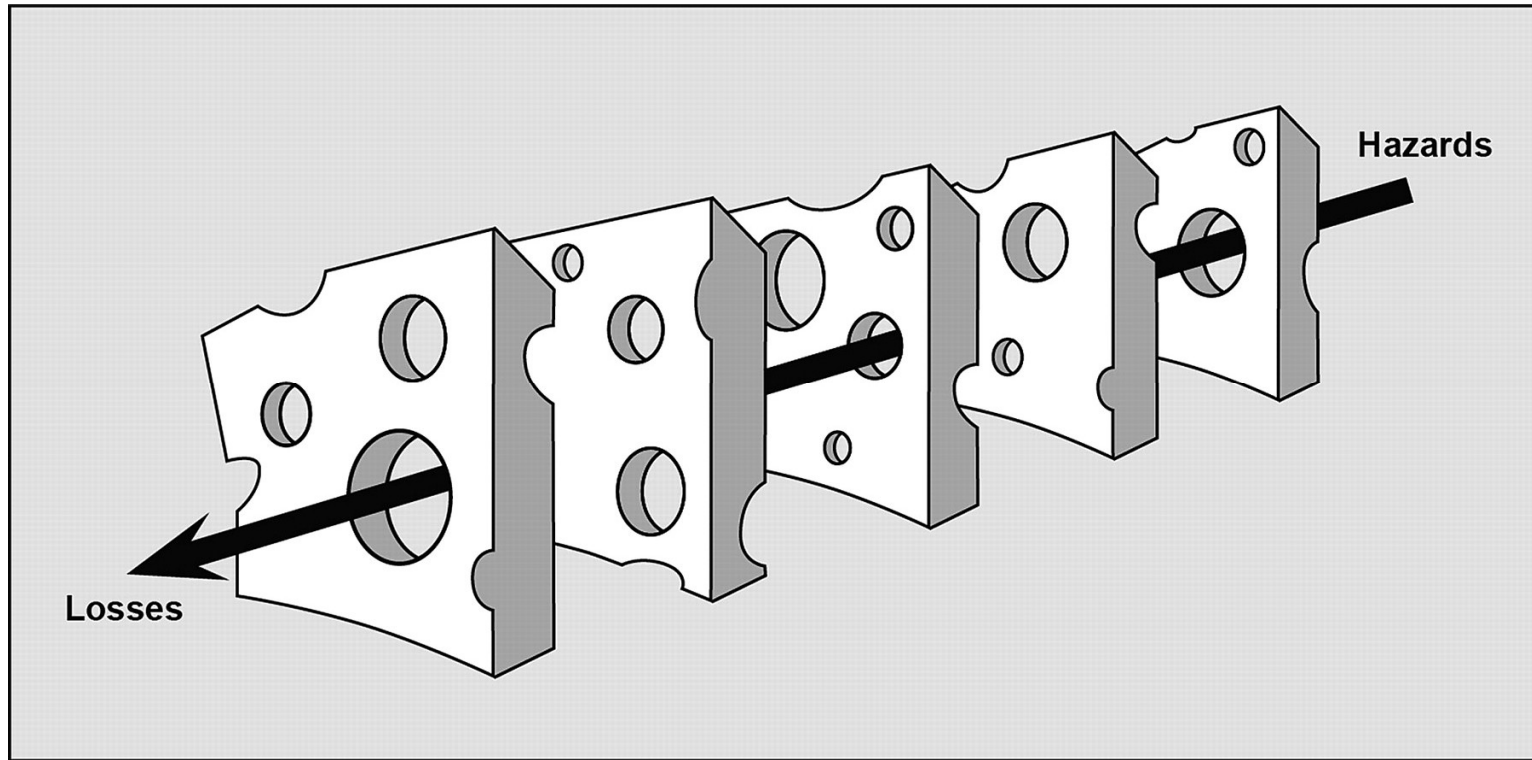
- The effects of leucodepletion initially offset by increased recognition
- Move to all male plasma
- All female platelet donors now screened for HLA and HNA antibodies

Reports caused by human error



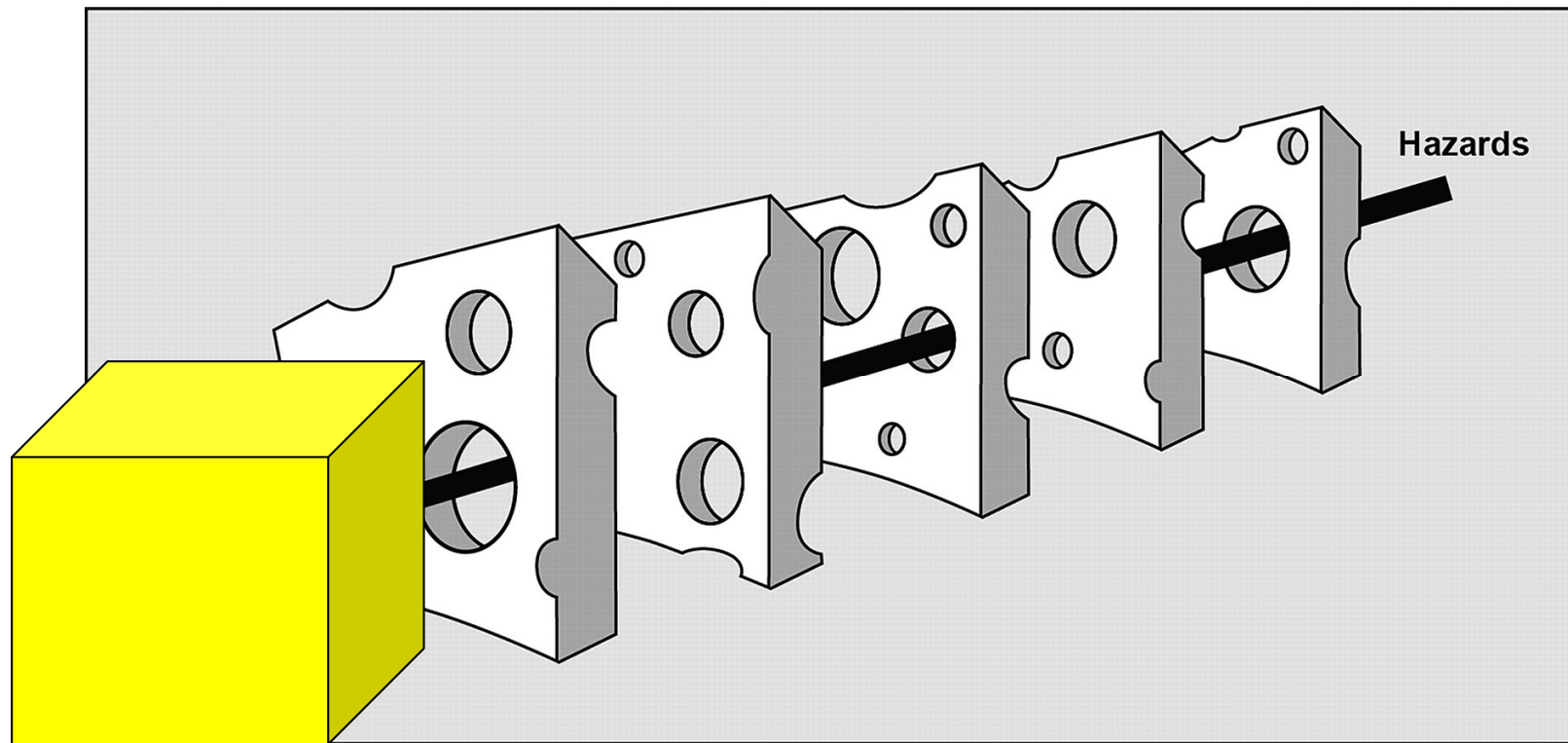
2011 SHOT report

- Blood was delivered to the ward for patient X but was not handed over to a nurse
- Patient Y on this ward had required resuscitation following sudden haematemesis
- Emergency (flying squad) blood ordered for Y
- Blood for X was put on Y's bed
- As X's blood was O neg, it was assumed to be flying squad intended for Y (although labelled as being for X)
- Fortunately, as Y was B pos and X's was O neg, no ill effects (silent mistransfusion)



What went wrong?

- Collection of unit and delivery to ward
- Bedside check



Yet another haemovigilance scheme!

Medicines and Healthcare
Regulatory Authority, MHRA

MHRA

- The “competent authority”
- Ensures hospital and blood transfusion centres comply with European BSQR regulations, 2005
- Mandatory reporting of serious incidents and events
- SHOT and MHRA data differ
- Efforts to harmonise the 2 systems