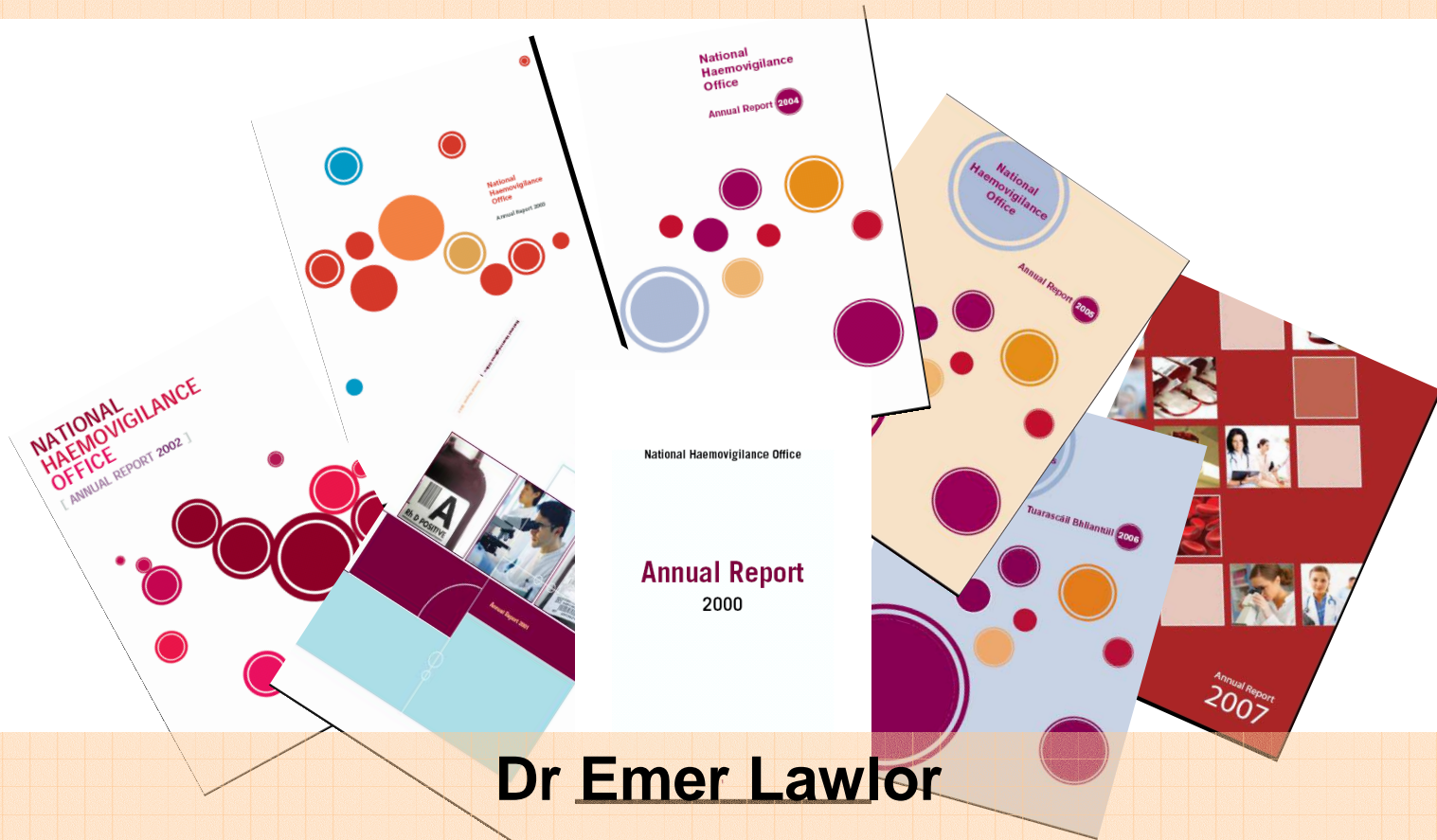


Deich Bliain ag Fas 1999-2009 or Ten Years A-Growing



Dr Emer Lawlor

Director National Haemovigilance Office IBTS

5th October 2009

Critical ingredients of Haemovigilance Scheme

- HVO in hospital –nursing or laboratory background- (but gaps in system up to 2007*)
- **Multidisciplinary** expertise in blood transfusion available in IBTS
- Up to end of 2005, anonymous reporting system based on professional responsibility
- Post EU Directives 2005/2006 **mandatory** reporting of SAE and SAR affecting quality and safety of blood product
- * *Strengers Report Feb 2007*

The Importance of being European...

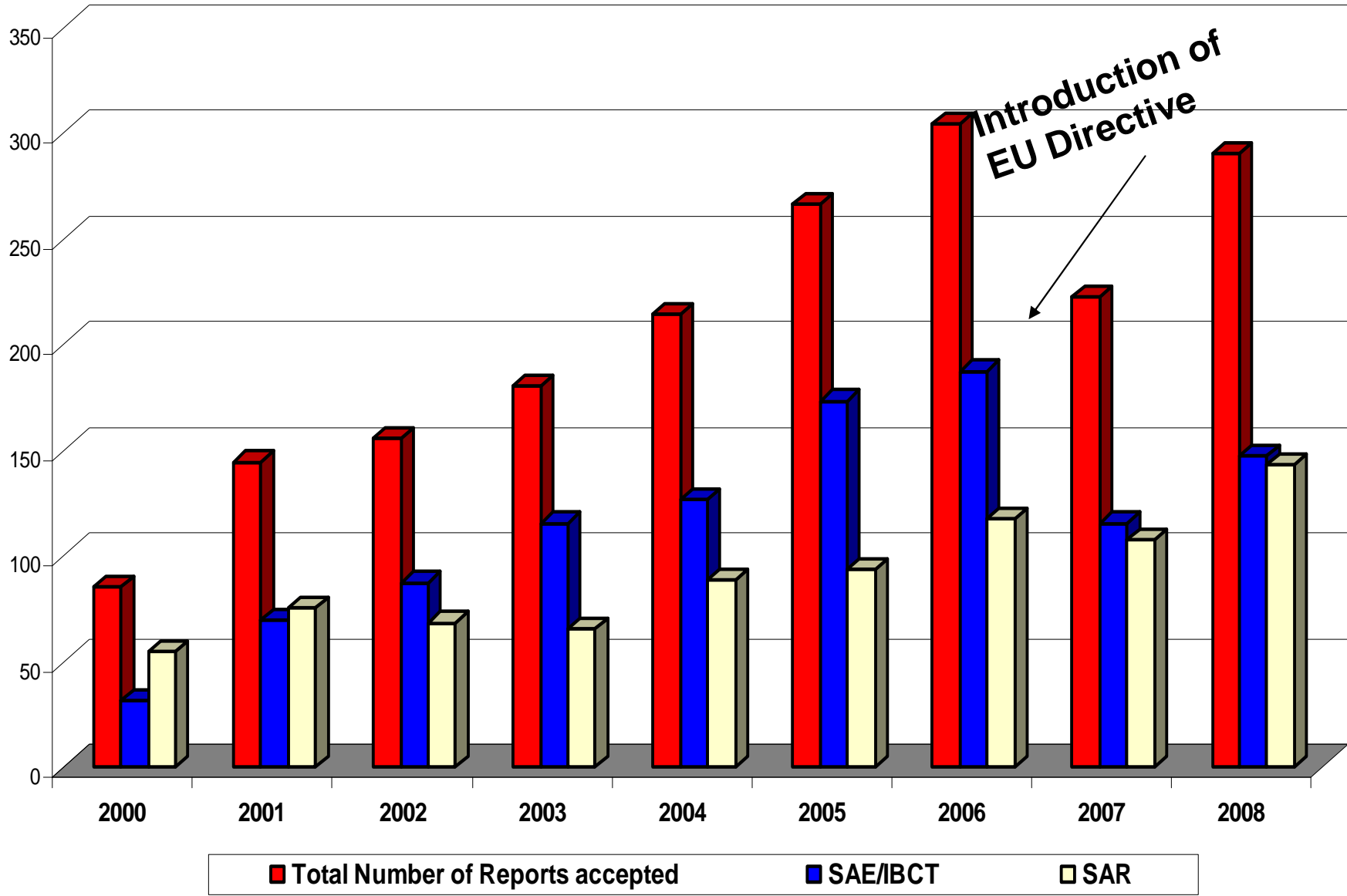


Have Directives 2002/98 /EU and 17/2006/EC made a difference to reporting patterns ?

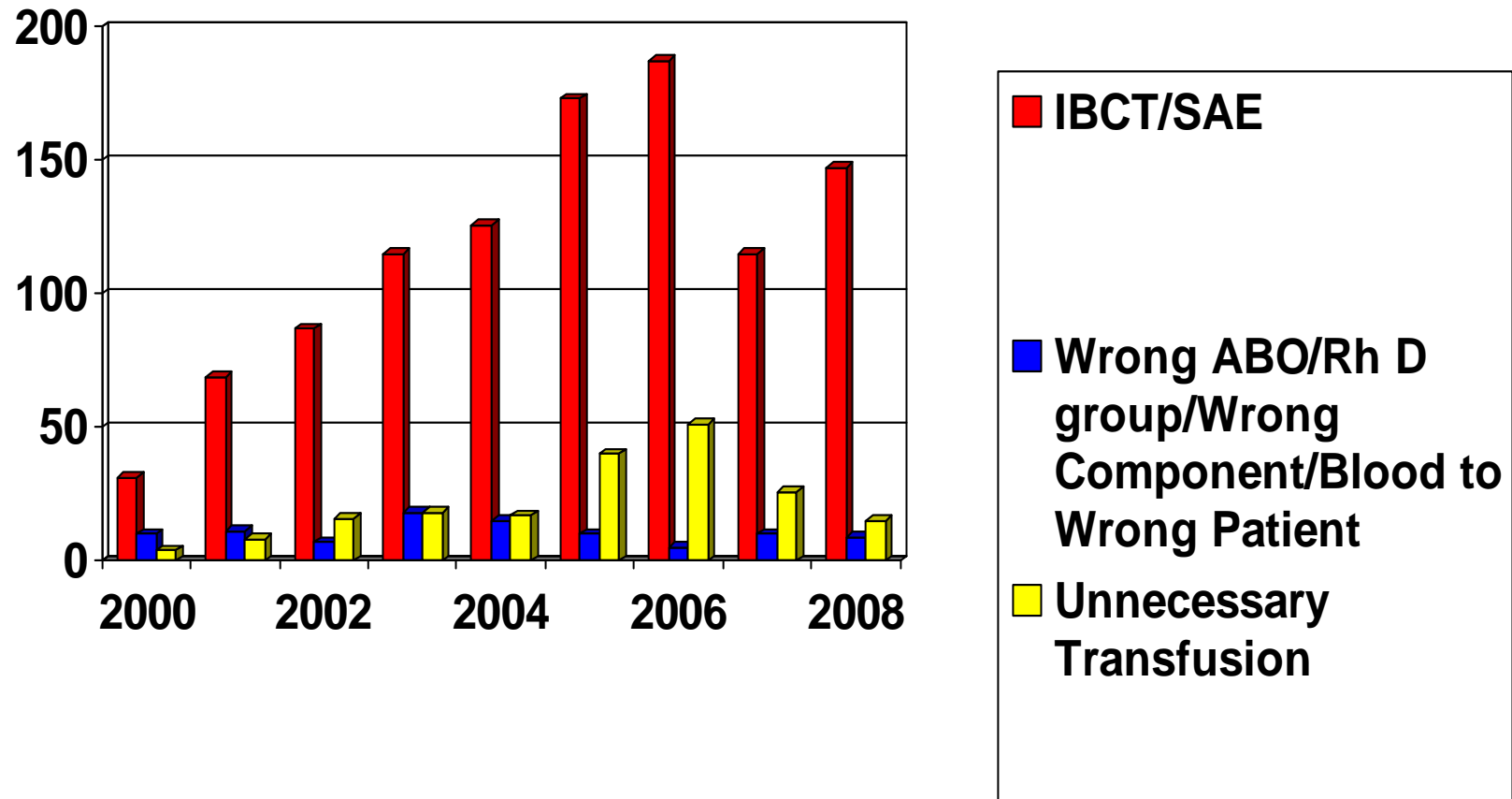


Safety of Product focused rather than patient focused.

Breakdown of NHO incidents accepted 2000-2008 (n=1860)



Changing Profile of IBCT/SAE Reports 2000-2008



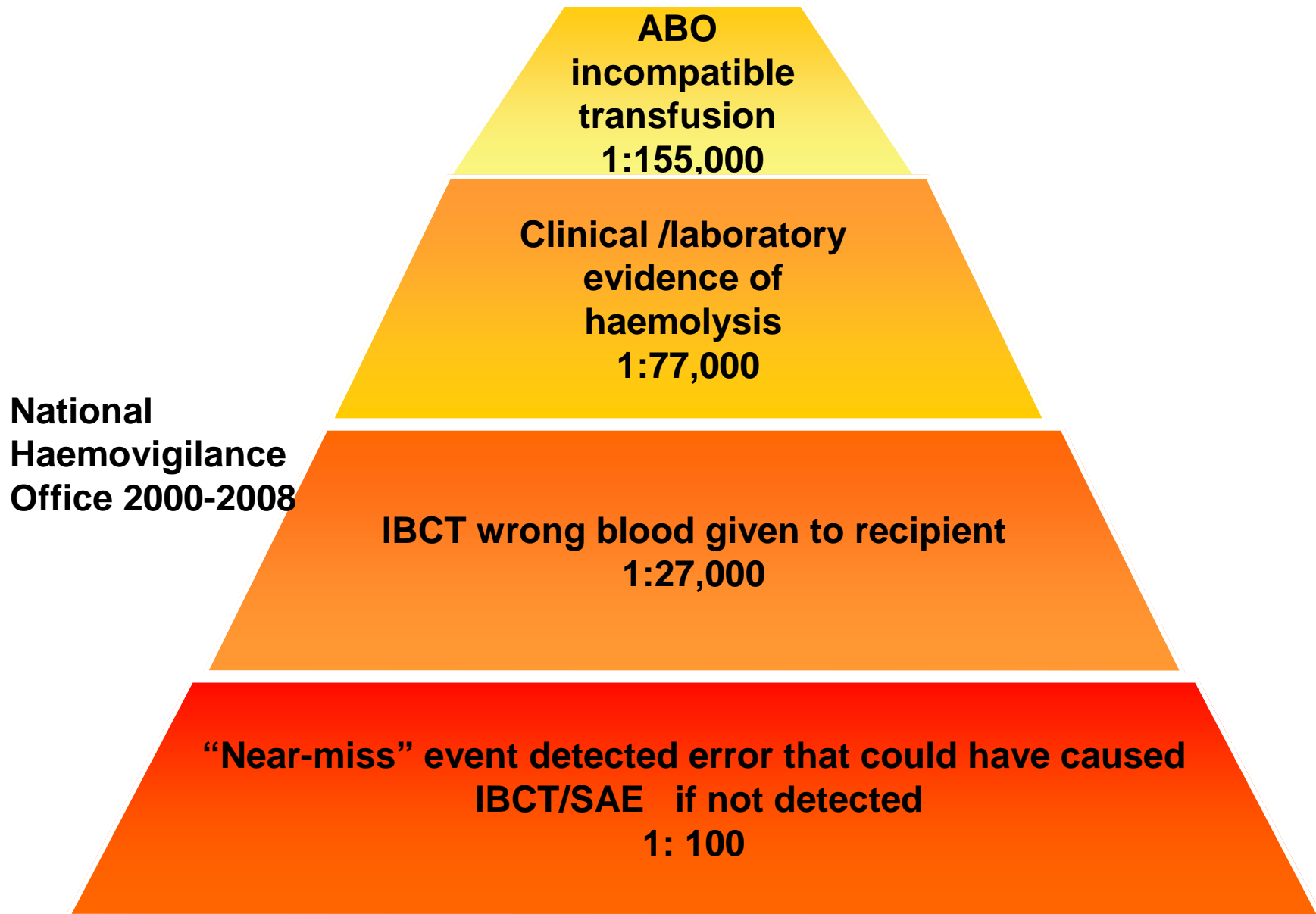
Analysis of Reactions Informing/Improving Practice

- Transfusion Associated Circulatory Overload (TACO)
- Transfusion Related Acute Lung Injury (TRALI)
- Haemolytic reactions – acute/delayed
- Suspected Transfusion Transmitted Infection

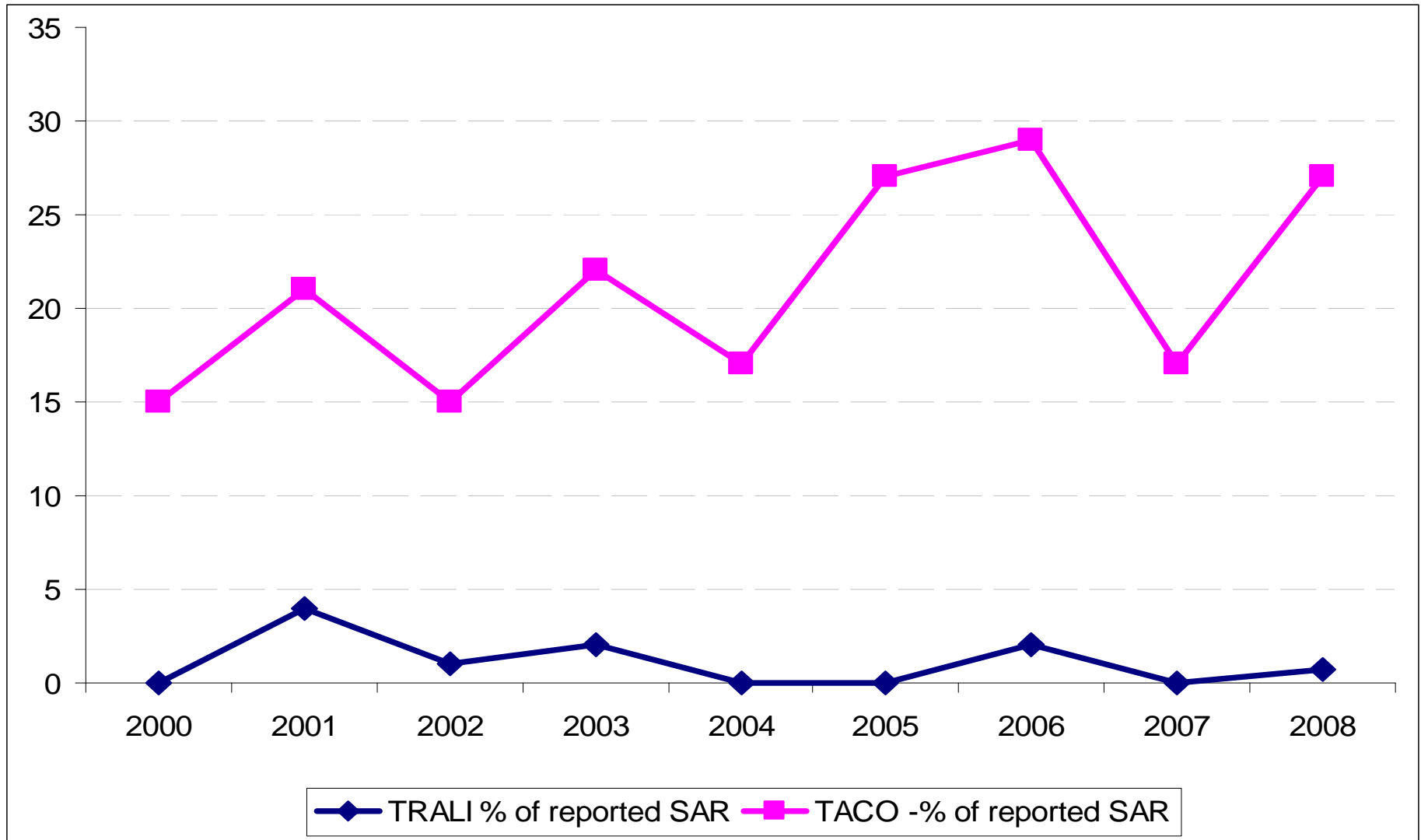
What are the risks of Transfusion in Ireland in last 10 years ?

- TACO - 5 deaths in 1.6 million units issued
1:324,000
- TRALI - 1 death
1 :1.6 million
- Risk of Haemolytic reaction?
- Risk of ABO incompatible transfusion?
- Transfusion Transmitted infection?

What is the risk of an incompatible Transfusion?



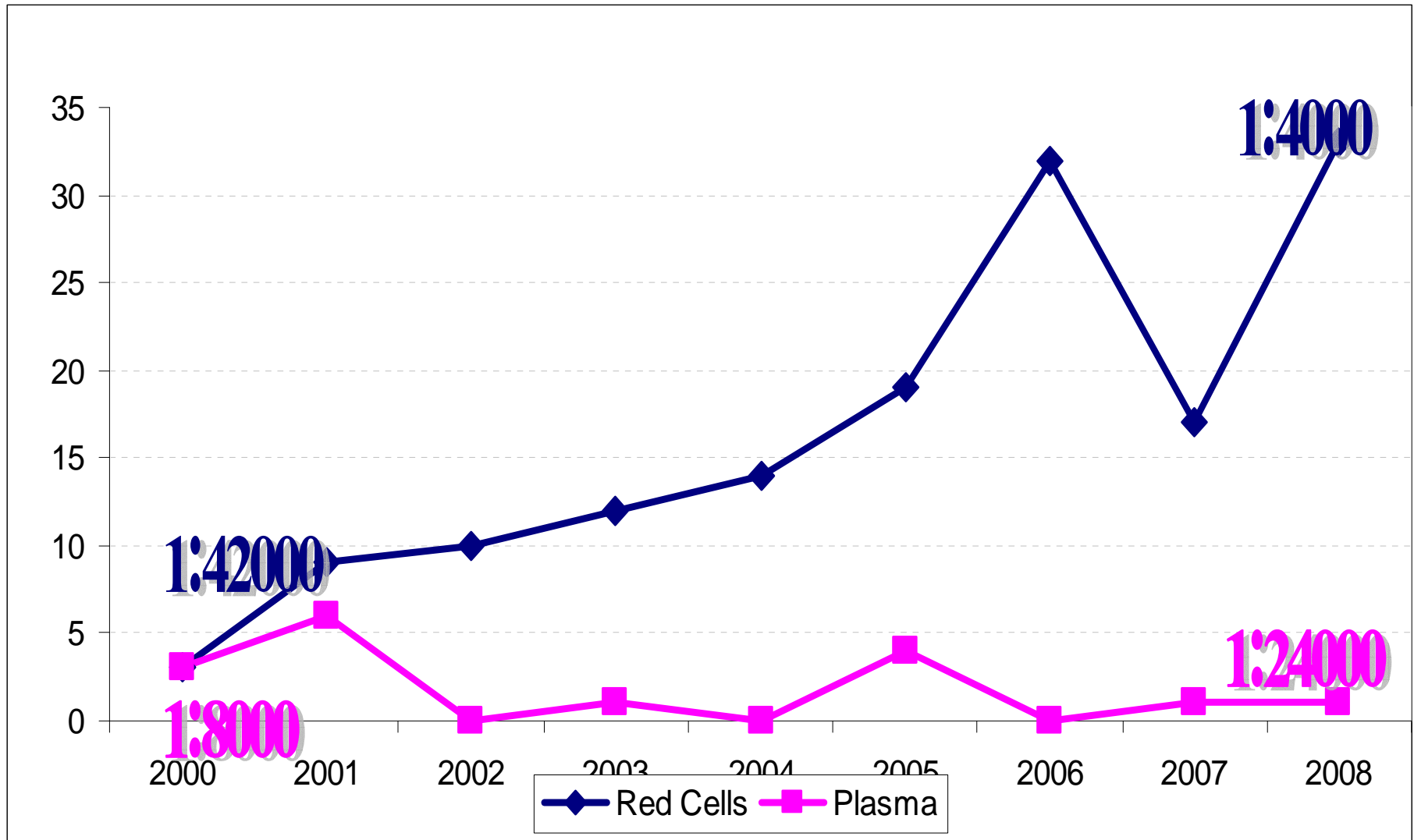
TACO & TRALI as a percentage of reported SAR 2000-08



TACO 2000-2009

- Associated with 5 fatalities
- Majority involve red cell transfusions since NHO/ haemovigilance education campaigns on use of FFP/SD
- Majority involve elderly, small ,female patients
- Underlying disease
- Careful attention to fluid balance, prophylactic diuretics, slow rate of infusion

Incidence of TACO 2000-08



TACO

But overload can occur at any age if
volume of components excessive !

Overload in Bleeding Patients

- NHO 2000-2008: TACO 179 cases (approx 10%)
- 5 cases associated with resuscitation for severe bleeding in females under 30 years with no previous medical history
- Characterised by large volume transfusion of colloid /crystalloid followed by components

TRALI NHO 2000-2008

- 8 cases met criteria for TRALI (5) or possible TRALI (3)
- 4 cases involved RC, 1 FFP (2001), and 2 involved platelet concentrates (1 pooled and 1 apheresis) and 1 RC+SD plasma (possible TRALI 2008)
- The fatality was associated with apheresis platelets, from a female donor with a history of pregnancy
- A number of other reports (18) initially submitted as TRALI were reclassified on review as TACO (11), FNHTR (2) or unrelated to transfusion (5)

IBTS Measures to Reduce Risk of TRALI

- The NHO issued a leaflet on TRALI in 2002 warning of the risks and the need for appropriate transfusion.
- The IBTS introduced SD plasma in March 2002 as a vCJD risk reduction measure. SD plasma has not been convincingly implicated in TRALI
- Plasma from male donors only is used for suspension of pooled platelets and as FFP/cryoprecipitate since late 2002.
- From early 2004, the IBTS has deferred new and lapsed female platelet apheresis donors with a history of pregnancy
- Since early 2007, pooled platelets from NBC are in platelet additive solution (PAS) -risk reduction
- 2009/10 Evaluating PAS for apheresis donations also.

Suspected Transfusion Transmitted Infections (STTI) 2000-2008 45 cases

| | No.Reports | Excluded | Probable | Possible /Not Excluded |
|--------------------|------------|-----------|----------|------------------------|
| HCV | 11 | 11 | 0 | 0 |
| HBV | 11 | 9 | 0 | 2 * |
| HBV+HCV | 1 | 1 | 0 | 0 |
| HIV | 7 | 7 | 0 | 0 |
| Hepatitis A | 1 | 1 | 0 | 0 |
| Parasitic | 1 | 1 | 0 | 0 |
| Bacterial | 13 | 6 | 1 | 6 |

*Investigations could not be completed

Suspected Transfusion Transmitted Infections (STTI) n=45 cases

- **Number of TTI reports (probable,possible,not excluded)
9/1860 (0.49%) or 1:180,000**
- 2 viral infections, both HBV, one from transfusion in 1993 and 1 in 2001 could not be excluded as investigations could not be completed.
- Since 2002, IBTS introduced anti HB core testing and all HBV cases reported since then have been excluded.
- One of the 13 bacterial infections was considered probable (2001) and 6 possible (1 in 2006,1 in 2007,4 in 2008) *. There were no fatalities
- A number of reports were not collected as patient was found to have evidence of infection before the transfusion or donor investigations on archive before donation ruled out donor as source of infection (Rubella)
- When a patient is found to have recent evidence of HBV/HCV infection , assessment of possibility of nosocomial infection/other risks/reactivation (for HBV) should proceed in tandem with donor investigations.

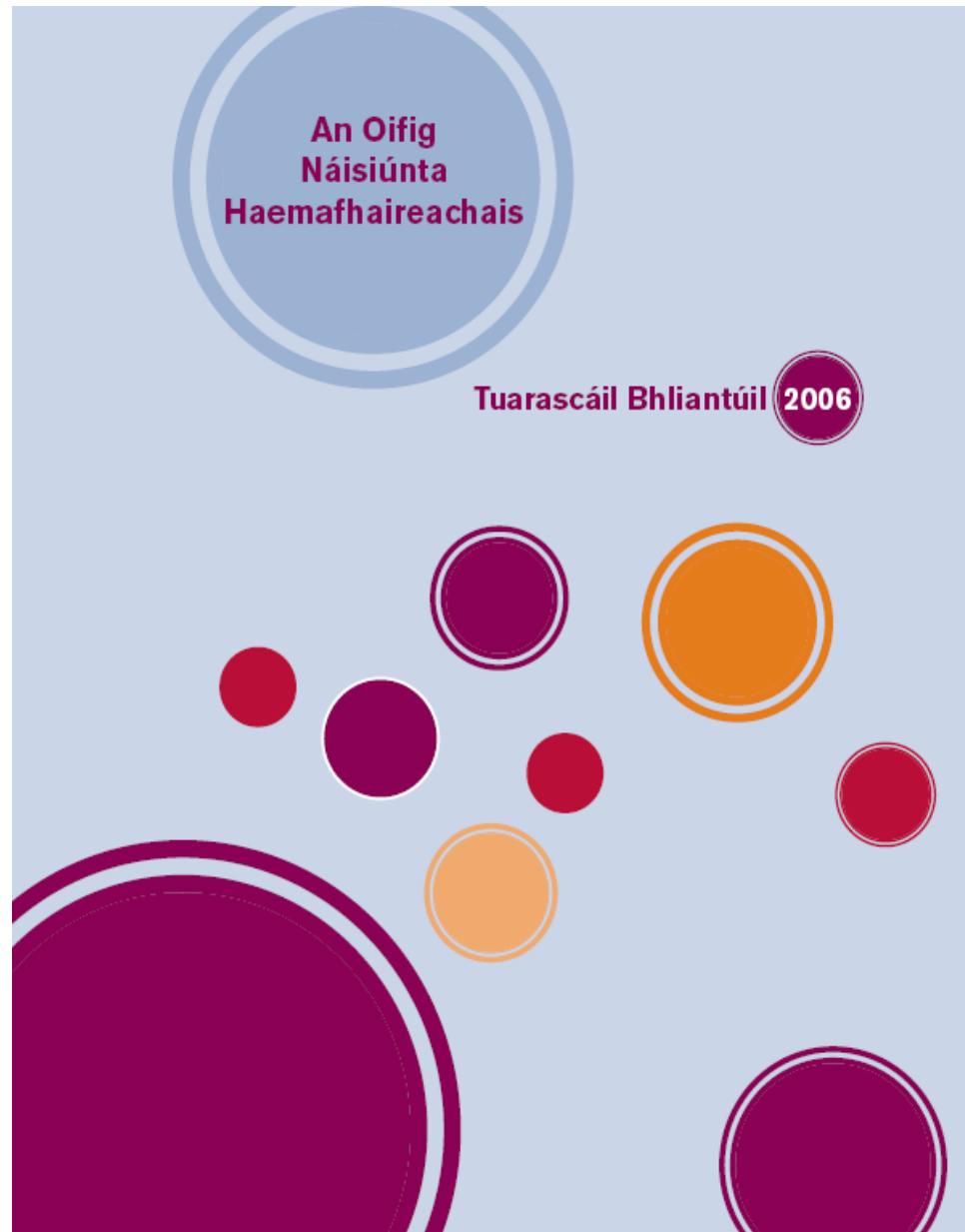
**Bacterial screening of platelets introduced in 2006*

Haemovigilance Initiatives

“Let me count the ways...”

How do I love thee? by [Elizabeth Barrett Browning](#) (1806-1861)

Annual Report
as Gaeilge
since 2005



9th EUROPEAN
HAEMOVIGILANCE
SEMINAR

FINAL ANNOUNCEMENT



DUBLIN CASTLE, DUBLIN, IRELAND



February 27th - 28th, 2007
www.ehndublin.eu

Near Miss Project 2003-2005

ORIGINAL PAPER

Vox Sanguinis (2007)

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DOI: 10.1111/j.1423-0410.2006.00866.x

Seven hundred and fifty-nine (759) chances to learn: a 3-year pilot project to analyse transfusion-related near-miss events in the Republic of Ireland

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¹National Haemovigilance Office, Irish Blood Transfusion Service, National Blood Centre, Irish Blood Transfusion Service, Dublin 8, Ireland

²Department of Pathology, College of Physicians & Surgeons, Columbia University New York, NY 10032, USA

Vox Sanguinis

Background The National Haemovigilance Office has collected and analysed reports on errors associated with transfusion since 2000. A 3-year pilot research project in near-miss event reporting commenced in November 2002.

Materials and Methods Near-miss reports from 10 hospital sites were analysed between May 2003 and May 2005. The Medical Event Reporting System for Transfusion Medicine was used to collect and analyse the data. Root cause analysis was used to identify causes of error.

Results A total of 759 near-miss events were reported. Near misses are occurring 18 times more frequently than adverse events causing harm. Sample collection was found to be the highest risk step in the work process and was the first site of error in 468 (62%) events. Of these, 13 (3%) involved samples taken from the wrong patient. Medical staff were frequently involved in error. The general wards and emergency department were identified as high-risk clinical areas, in addition, 78 (10%) events occurred within the transfusion laboratory. Three specific human and two system failures were shown to have been associated with the errors identified in this study.

Conclusions This study confirms that near-miss events occur far more frequently than adverse events causing harm. Collecting near-miss data is an effective means of highlighting human and system failures associated with transfusion that may otherwise go unnoticed. These data can be used to identify areas where resources need to be targeted in order to prevent future harm to patients, improving the overall safety of transfusion.

Key words: haemovigilance, MERS-TM, near-miss, transfusion safety.

Received: 26 September 2006,
revised: 27 November 2006,
accepted: 20 November 2006

Background/introduction

The National Haemovigilance Office (NHO) was established in 1999 to collect and analyse serious adverse events and reactions associated with transfusion in the Republic of Ireland. During the 5-year period from 2000 to 2004, approximately 675 000 blood components were issued from the

Irish Blood Transfusion Service (IBTS) and a total of 778 reports of adverse events/reactions were received by the NHO [1]. Of these, 428 (55%) were adverse events, 13 involving ABO-incompatible red cell transfusions. This correlates to a risk of receiving an ABO-incompatible red cell transfusion at 1 : 49 169 units issued, suggesting that significant risks of error continue to be associated with transfusion which outweigh other more publicized risks such as viral infection. Similar findings have been reported through other haemovigilance systems [2].

Much work has been done to analyse adverse events in transfusion. Adverse event reporting systems, however, are reactive and by the time lessons have been learned,

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Standards /Competencies

Minimum Requirements for Blood Bank Compliance with Article 14 (Traceability) and Article 15 (Notification of Serious Adverse Reactions and Events) of EU Directive 2002/98/EC



This document has been compiled by the IMB/INAB Expert Group on Blood and Blood Components and should be used in conjunction with the ISO15189 Standard.

- **NHO Competency and Professional Profile documents.**
 - These documents outline suggestions on a professional profile for HVOs and competencies for haemovigilance and traceability
- Developing a professional profile for Haemovigilance Officers
- Competence for hospital based Haemovigilance Officers

Education

- NHO in partnership with the School of Nursing, Dublin City University, currently deliver 3 degree level modules and 2 post graduate modules. **135** students have completed these modules (2005 to date).
- NHO has facilitated training for the implementation of the SNBTS /LearnProNHS E-Learning programme and is a member of the editorial group (2007).

Research

- DCU RN4CA5 EU grant - Health Care Resources Planning in Nursing –**skills** as well as numbers – reporting of Adverse reactions/events to blood included.

Expertise/ Advice

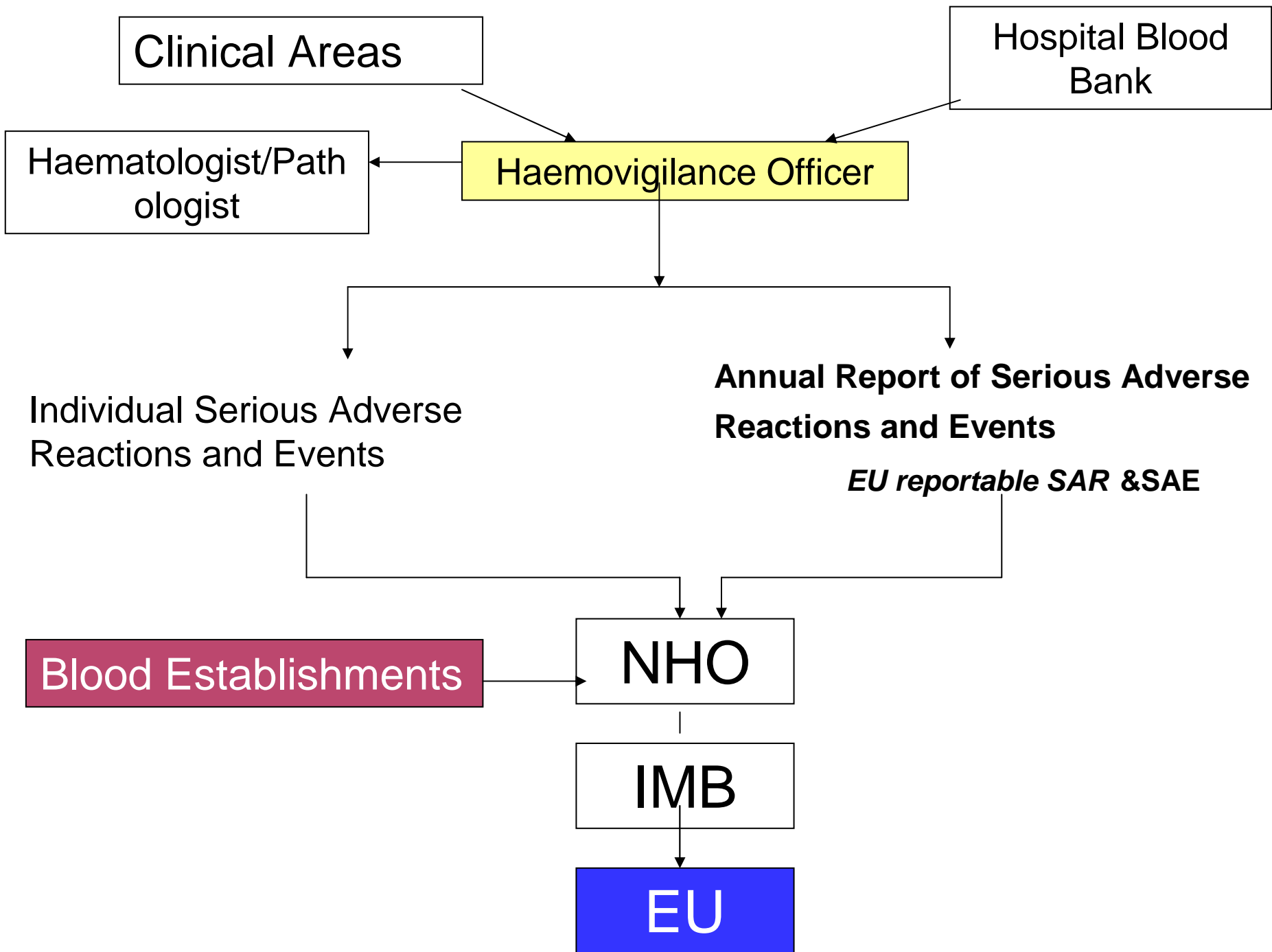
EU Working Party (with IMB)

- Definitions of Serious Adverse Events and Reactions EU 2007- 2009

Submissions to Reports

- Commission on Patient Safety and Quality Assurance **NHO Submission on promotion of safe transfusion practice/adverse event reporting (2008)**
- The Health Information and Quality Authority. Recommendations for the Implementation of Unique Patient Health Identifiers in Ireland (2009).

The NHO was able to provide detailed information on areas of transfusion which would benefit from the introduction of a unique patient health identifier



Wish list for the next 10 years

External

- Enhance role of NHO in relation to patient safety and develop formal links with stakeholders- Professional Bodies, Colleges, HSE etc
- Competency for medical students, practitioners

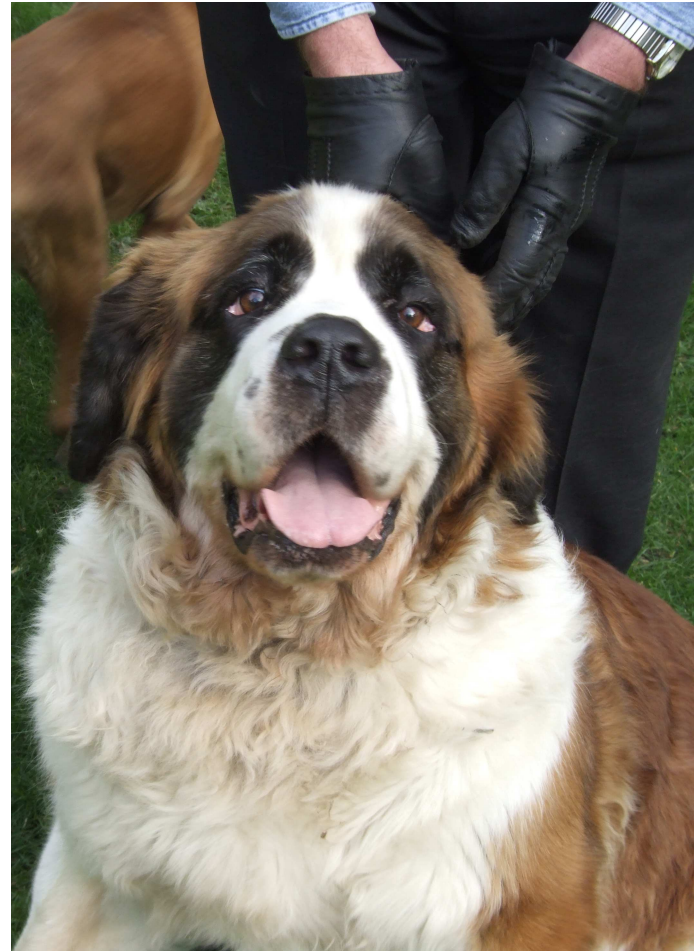
Commission on Patient Safety and Quality Assurance Report 2008

- **Recommendation 8.3 Adverse event reporting sub-group**
‘To recommend specific measures by which learning from adverse events should be disseminated throughout the system, including the facilitation of rapid alerts as necessary.’
‘This sub-group should include representation from the HSE, independent hospitals, HIQA, professional regulatory bodies, CIS, patients, IMB, MHC and *Irish Blood Transfusion Service (IBTS)*.’

Internal

- Update Handbook (153 clinical queries in 2008- 61% Is this reportable to NHO?)
- Online reporting to ensure capture of mandatory and non mandatory reports
- Increase educational role
- Increased analysis/ development audit tools

‘Mighty things from small beginnings grow...’*



John Dryden* *Annus Mirabilis* quote
sourced by Cathy Scuffil .

NHO Team Members

1999-2009

Past HVOs

- Donna Harkin
- Phil Keane-Egan
- Derval Lundy
- Ann O'Connor
- Siobhan O'Connor
- Mairead Sheahan

Temporary Director (2005)

- Stefan Laspina

Past Administrative Staff

- Paula Bolger
- Marie Carolan
- Angie Corr
- Elaine Corrigan
- Maria Flanagan
- Gillian Horgan
- Marion O'Raw

Present

- Roisin Brady
- Marina Cronin
- Kathleen Heery
- Emer Lawlor
- Cathy Scuffil
- Jackie Sweeney
- Marcia Kirwan (seconded to DCU)

Source of Inquiries

- In 2008 153 clinical inquiries were collected by the NHO
- 148 from hospital based HVOs
- 2 from Blood Establishments
- 1 from the Competent Authority
- 1 from a member of the public
- 1 from medical supply company

Classification of Enquiries

- 61 % = Is it reportable to the NHO?
- 32% = Practice related
- 7% = Miscellaneous

INCIDENCE OF TRALI PER Component

- UK, 1996 - 2002
 - **Red cells** 23/12 million = 1: 520,000
 - **FFP /cryo** 31/1.8million = 1: 58,000
 - **Platelets** 16/1.2million = 1: 75,000
- Ireland 2000-2008
- Red cells - 5 in 1.2 million =1:240,000
- FFP/Cryo (no cases since SD plasma)
1 : 60,000
- Platelets 2 in 192,000= 1: 96,000

Breakdown of NHO incidents accepted 2000-2008 (n=1860)

| Year | IBCT /SAE | AA | TACO | DHTR | STTI | TRALI | PAD | Unusual/ Unclassified | AHOSTR | *TAD | *Hypotensive Reaction | TOTAL |
|--------------|------------------|------------|-------------|-------------|-------------|--------------|------------|------------------------------|---------------|-------------|------------------------------|--------------|
| 2000 | 31 | 22 | 8 | 2 | 7 | - | - | 1 | 14 | | | 85 |
| 2001 | 69 | 35 | 16 | 1 | 2 | 3 | 3 | 3 | 12 | | | 144 |
| 2002 | 87 | 31 | 10 | 9 | 3 | 2 | 5 | - | 8 | | | 155 |
| 2003 | 115 | 23 | 14 | 9 | 4 | 1 | 6 | - | 8 | | | 180 |
| 2004 | 126 | 35 | 15 | 4 | 3 | - | 7 | - | 24 | | | 214 |
| 2005 | 173 | 22 | 25 | 5 | 6 | - | 3 | - | 32 | | | 266 |
| 2006 | 187 | 29 | 34 | 4 | 8 | 2 | 0 | 0 | 40 | | | 304 |
| 2007 | 115 | 40 | 18 | 6 | 4 | 0 | 0 | 5 | 34 | | | 222 |
| 2008 | 147 | 41 | 39 | 4 | 8 | 1 | 0 | 6 | 40 | 2 | 2 | 290 |
| TOTAL | 1050 | 278 | 179 | 44 | 45 | 9 | 24 | 15 | 212 | 2 | 2 | 1860 |

‘Mighty things from small beginnings grow...’*



John Dryden* *Annus Mirabilis* quote sourced by Cathy Scuffil .

Acute Allergic and Anaphylactic Reaction per type of platelet component issued 2008 (N=28)

| Type of platelet issued | Number issued in 2008 | Incident of reaction per unit issued |
|---|-----------------------|--------------------------------------|
| Platelets Pooled Leucocyte Depleted in plasma | 1,009 | 1 per 336 units issued |
| Apheresis Platelets | 13,754 | 1 per 917 units issued |
| Platelets pooled in Plasma Additive Solution | 9,848 | 1 per 984 units issued |

- *Fiche bliain ag fás.* Twenty years growing.
- *Fiche bliain faoi bhláth.* Twenty years in bloom.
- *Fiche bliain ag cromadh.* Twenty years declining.
- *Fiche bliain gur cuma ann nó as.* Twenty years when it doesn't matter whether you're there or not.