

Haemovigilance in Ireland 1999-2007

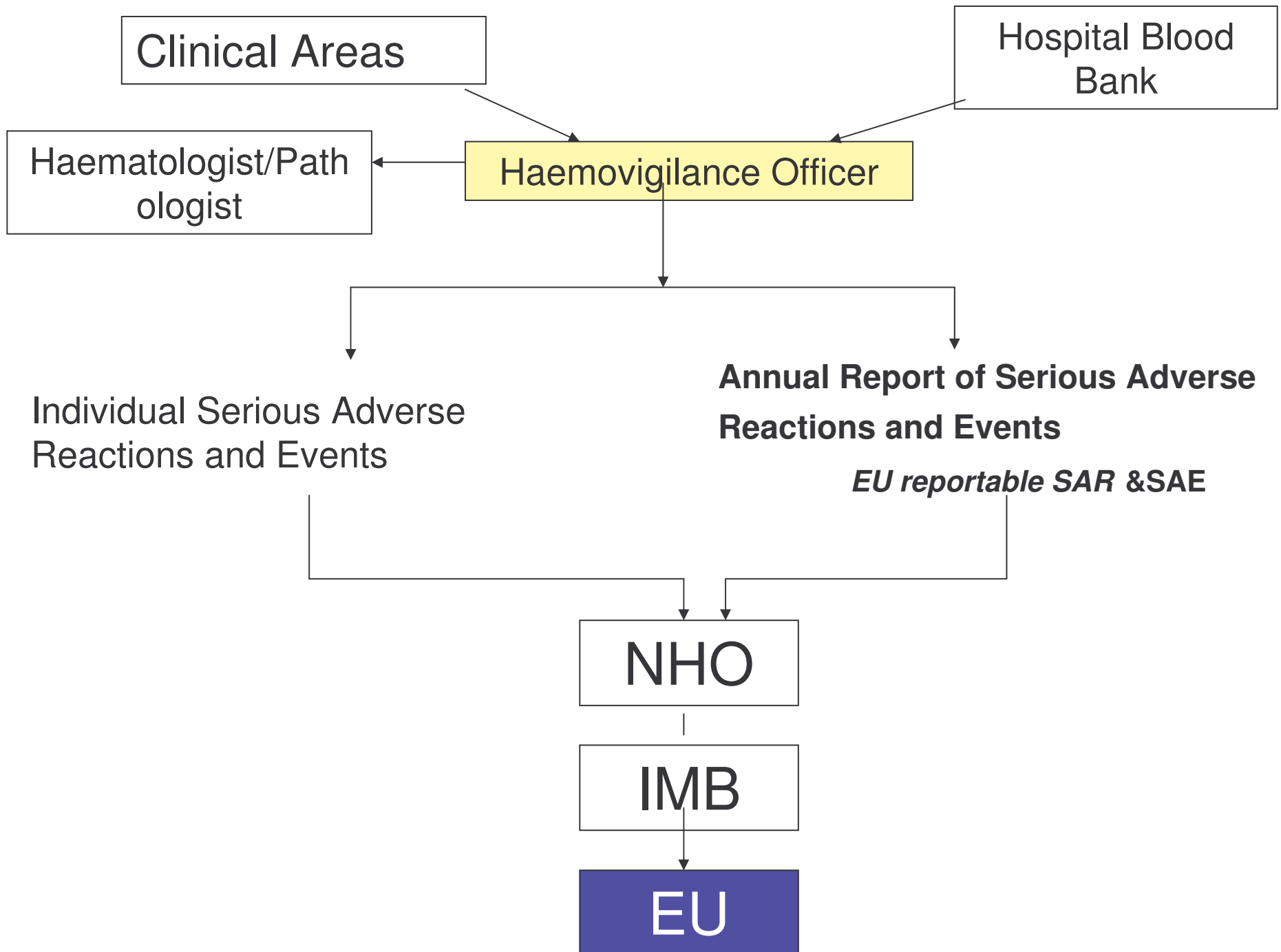
9th European Haemovigilance Seminar

27th February 2007

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National Haemovigilance Office

- Set up in 1999 in response to recommendations of Finlay Tribunal 1997
- To collect serious adverse reactions and events
- IBTS service reporting to Irish Medicines Board
- Features of both SHOT and French systems
- Professional responsibility/anonymised
- Haemovigilance Officers (HVO) in Hospitals



Disadvantages for HVO

- Lack of any needs analysis prior to the setting up the posts led to lack of resources, support and isolation
- *“I was homeless working out of the boot of my car”.*
- *“I was at the end of a phone.....but really I could have died here and no one would know”*
- However: using their skills of audit and persuasion they persuaded hospital management that there was a need for their role and the resources to carry it out.

Extracts from Interviews with HVO from MSc Nursing
Thesis Royal College of Nursing 2006 Geraldine Peelo

Remit of NHO

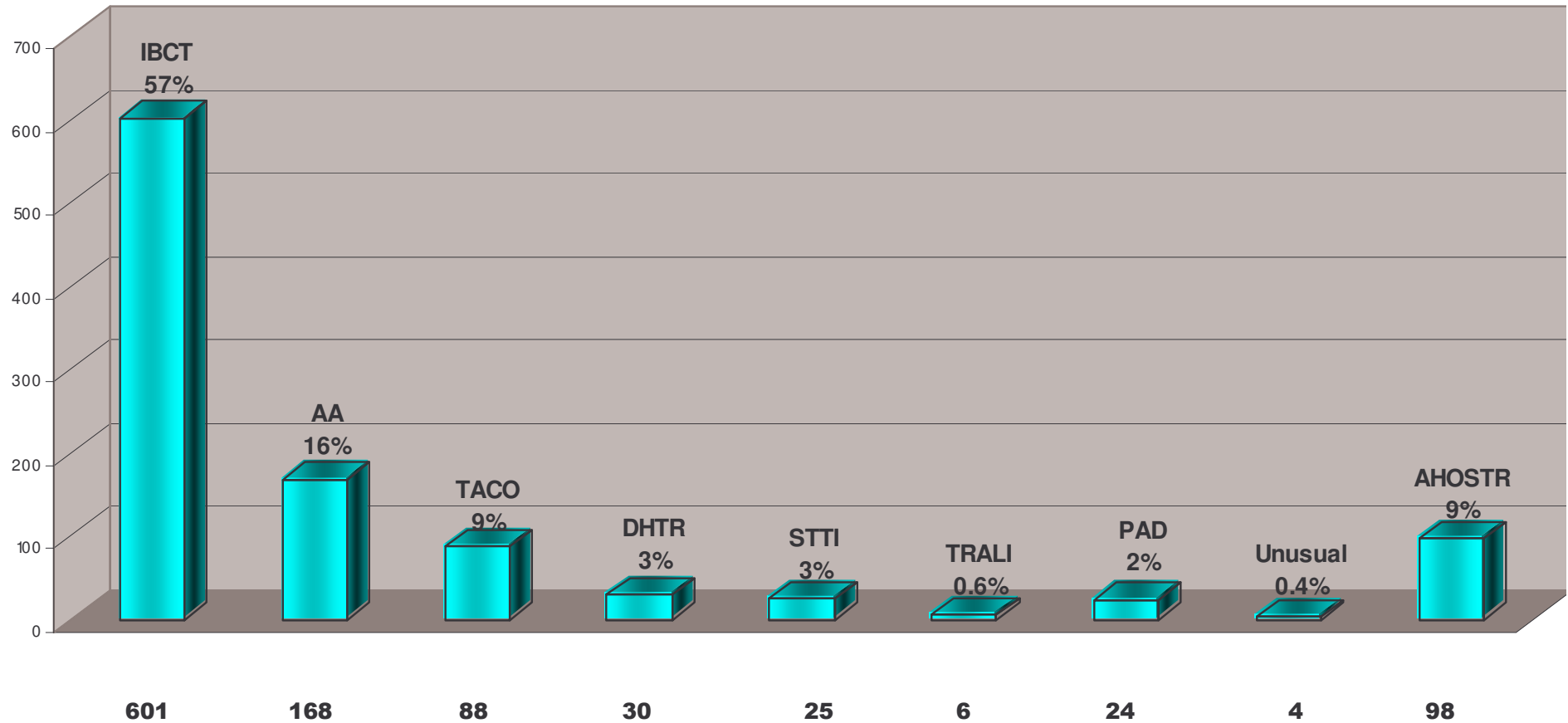
- Receive, collate and follow up reports from hospitals and general practitioners of adverse reactions to blood components and provide feedback information to reporters, as appropriate.
- Advise on the follow-up action necessary, particularly with regard to suspected hazards.
- Report adverse reaction to the IMB according to an agreed procedure.
- Support the training of hospital-based transfusion surveillance officers under the haemovigilance programme.
- Provide medical and scientific analysis of adverse reaction reports.
- Advise on improvements on the safety of transfusion practice based on the data made available by hospitals.
- Advise on clinical guidelines and hospital practice in relation to the use of blood components.
- Advise on the recording of transfusion data by hospital staff.
- Support as appropriate the training of medical, nursing and technical staff in haemovigilance.
- Support the audit function of hospitals in relation to transfusions.
- Report to the National Blood Users Group on a periodic basis.

Serious Adverse Events and Reactions Captured by the NHO

Serious Adverse Events :

- Incorrect Blood Component transfused (SHOT,1996)
- **Severe Adverse Reactions:**
 - Acute Haemolytic or Other Severe Acute Transfusion Reactions
 - Severe Anaphylactoid/Anaphylactic reactions
 - ***Transfusion Related Acute Lung Injury***
 - ***Transfusion Associated Circulatory Overload***
 - Delayed Haemolytic reactions
 - Post Transfusion Purpura
 - Suspected Transfusion Transmitted Infections
 - Graft Versus Host Disease
 - Predeposit Autologous Donation reactions
 - Other

Six Year Overview of SAR and SAE (n= 1044)



IBCT- Incorrect Blood Component Transfused

AA- Severe Acute Anaphylatoid/ Anaphylactic Reaction

TACO- transfusion Associated Circulatory Overload

DHTR- Delayed Haemolytic Transfusion Reaction

STTI- Transfusion Transmitted Infection

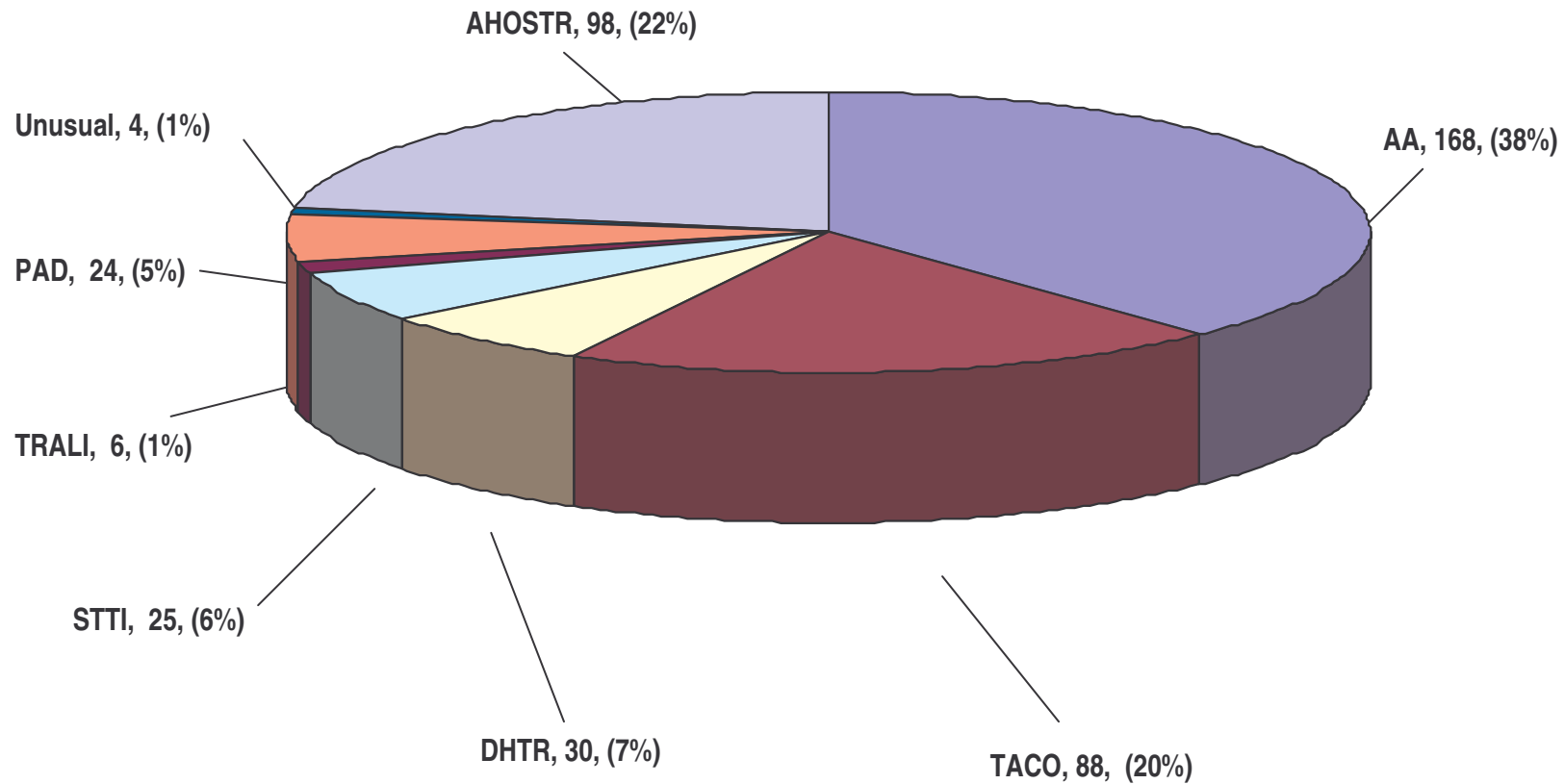
TRALI- Transfusion Related Acute Lung Injury

PAD- Pre- Deposit Autologous Donation

AHOSTR- Acute Haemolytic or Other Severe Acute Transfusion Reaction

Denominator: approx 1,000,000 blood components issued

Serious Adverse Reactions (n= 443)



AA- Severe Acute Anaphylactoid/ Anaphylactic Reaction

TACO- Transfusion Associated Circulatory Overload

DHTR- Delayed Haemolytic Transfusion Reaction

STTI- Suspected Transfusion Transmitted Infection

TRALI- Transfusion Related Acute Lung Injury

PAD- Pre Deposit Autologous Donation

AHOSTR- Acute Haemolytic or Other Severe Transfusion Reaction

There were no reports of Graft Versus Host Disease or Post Transfusion Purpura

Severe Anaphylactoid/Anaphylactic Reactions (AA)

- SAR accounted for 43% (443) of all reports received with AA reactions being the largest reaction category (n=168 or 38% of all reactions).
- Between 2000 and 2002, 21 AA reports involved plasma (19 FFP and 2 solvent detergent (SD) plasma).
- The number of reactions associated with plasma has fallen since the introduction of SD plasma in 2002 with only 3 AA cases associated with plasma reported between 2003-2005.
- Ninety-six (96) (57%) of AA reactions were related to platelets, the majority associated with pooled platelet concentrates.

Acute Haemolytic or Other Severe Transfusion Reactions(AHOSTR)

- Ninety-eight (98) reactions were reported in this category.
- The majority of reactions in this category represented Febrile Non Haemolytic Reactions (FNHTR) associated with red cell (RC) transfusions.
- Only 4 cases were due to immune haemolysis.
- 2 of the 4 reports of haemolysis involved a patient with Paroxysmal Haemoglobinuria (PNH) where haemolysis was due to incompatible plasma in ABO incompatible HLA matched platelets.
- None of these reactions were associated with ABO incompatibility
- However 8 of the 14 cases of ABO incompatibility reported in IBCT were associated with reactions.

Suspected Transfusion Transmitted Infections (STTI)

- Twenty-five (25) STTI were reported making up 3% of SAR/SAE reported.
- There were 22 suspected viral infections (HIV=6,HCV=6,HBV=9,HCV+HBV=1)
- There were 2 suspected bacterial infections :
 - One case of *serratia marcescens* associated with red cells
 - One case of *coagulase negative staphylococcus* with platelets
- There was 1 suspected case of parasitic infection (*Toxoplasma gondii*).
- Only one STTI case, the bacterial infection of platelets with *coagulase negative staphylococcus* was confirmed. The patient made a full recovery.
- Transfusion was considered unlikely or excluded as a cause in 22 of the remaining cases. In two further cases (both HBV) the infections could not be excluded as the investigations could not be completed.

Transfusion Associated Circulatory Overload (TACO) 2000-2005

- There were 88 cases of TACO reported between 2000-2005.
- Majority (76%) associated with red cells and older patients (69%)
- There were 14 cases associated with use of FFP/SD plasma.
- Three of the four cases where TACO may have contributed to mortality were associated with transfusion of plasma FFP/SD plasma.
- The NHO issued leaflets in 2000 and 2002 on appropriate use of FFP and SD plasma.

TRALI 2000-2005

- There were 6 cases collected as TRALI.
- Two cases involved RC, one involved FFP(2001), and three involved platelet concentrates (2 pooled and 1 apheresis).
- The case of TRALI (2003) associated with apheresis platelets, which were from a female donor with a history of pregnancy, led to the death of the patient
- TRALI was confirmed/ considered highly probable in 4 cases and possible in one case. The final case was considered unlikely.
- A number of other reports (11) initially submitted as TRALI were reclassified on review as TACO (7), AHOSTR (2) and unrelated to transfusion (2)

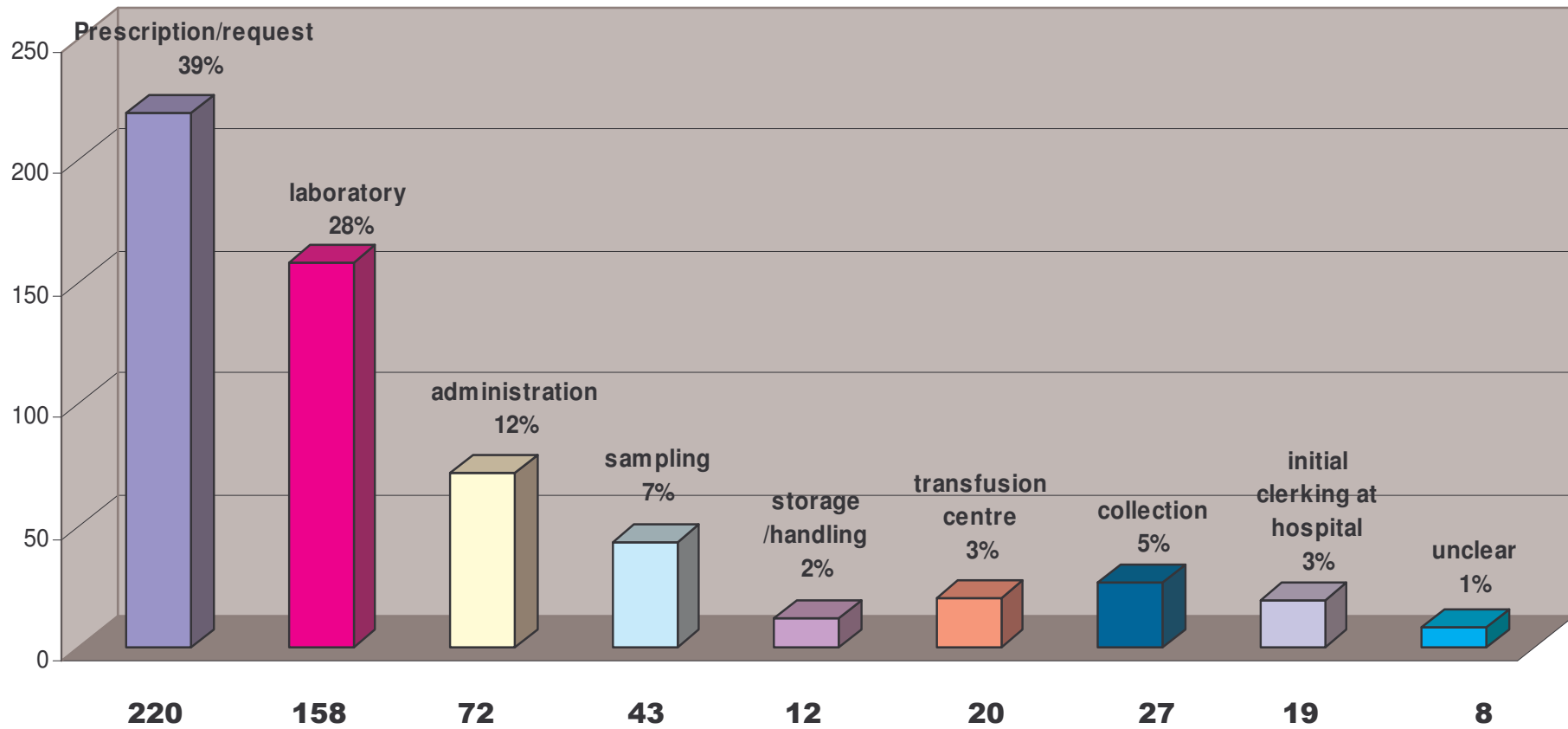
IBTS Measures to Reduce Risk of TRALI

- 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.

Serious Adverse Events 2000-2005

- 601 (57%) reports were SAE or Incorrect Blood Component Transfused (IBCT) ⁵
- 181 (37%) of SAE (since 2001) considered High Risk or Level 1 IBCT.
- 22 SAE involved transfusion of red cells of the wrong ABO group.
- 14 of these involved transfusion of ABO incompatible red cells. There were no fatalities related to these transfusions.
- The risk of receiving red cells of a wrong ABO group was calculated as 1:37,000 and that of receiving ABO incompatible blood was 1:55,600.

Site of First Error 2000-2005



n= 579



Picture: www.bbc.co.uk, 12th January 2007

The Irish Times, 12th January 2007

NHO Educational Remit

- *Support the training of **hospital-based haemovigilance officers** under the haemovigilance programme*
- *Support as appropriate the training of **medical, nursing and technical** staff in haemovigilance*
- *Advise on the recording of transfusion data by hospital staff*

Supports:

- Workshops
- Annual Conferences
- Poster Competitions
- Induction/training programmes NBC
- National HVO Audits (2004)
- Hospital visits (2006)
- **Near Miss Project (2003-2005)**
- **DCU Haemovigilance Modules (2005-)**
- **SNBTS E-Learning (2007)**

Seven Hundred and Fifty Nine
Chances (759) Chances to
Learn:

National Haemovigilance Office
Near Miss Research Project

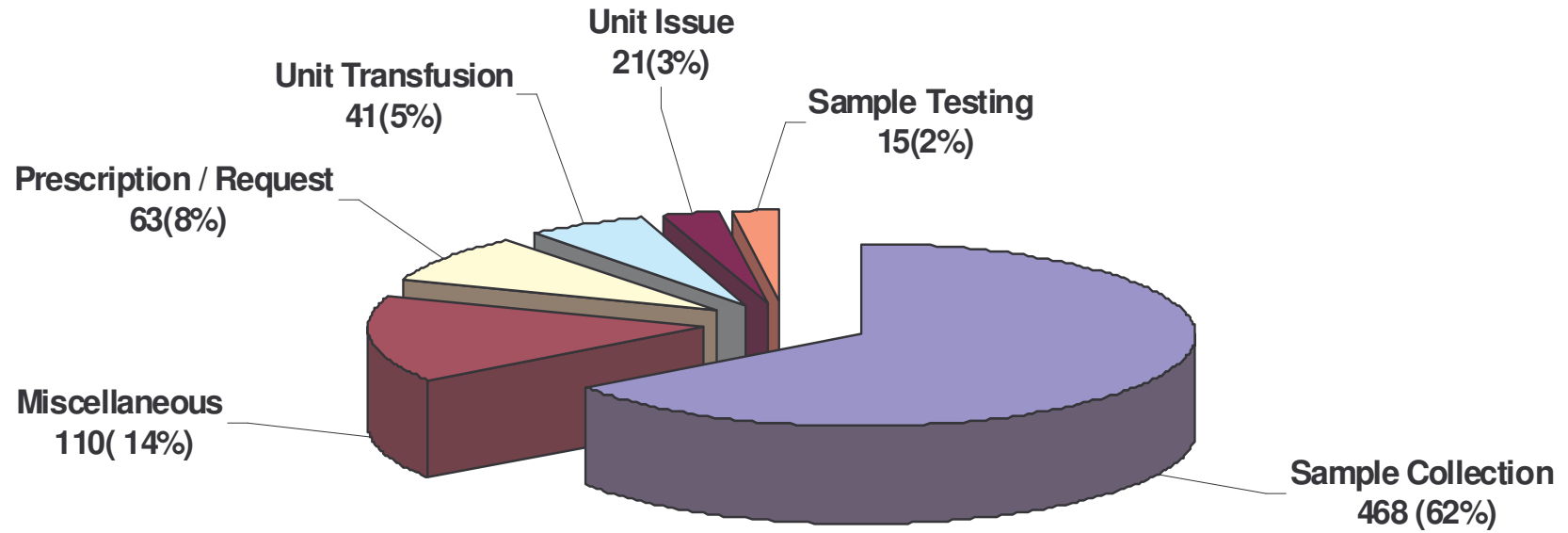
D Lundy, S Laspina, H Kaplan ,B Rabin

Fastman,E Lawlor

Vox Sanguinis 2007 Online

Near Miss Project

1st Site of Error



n=718

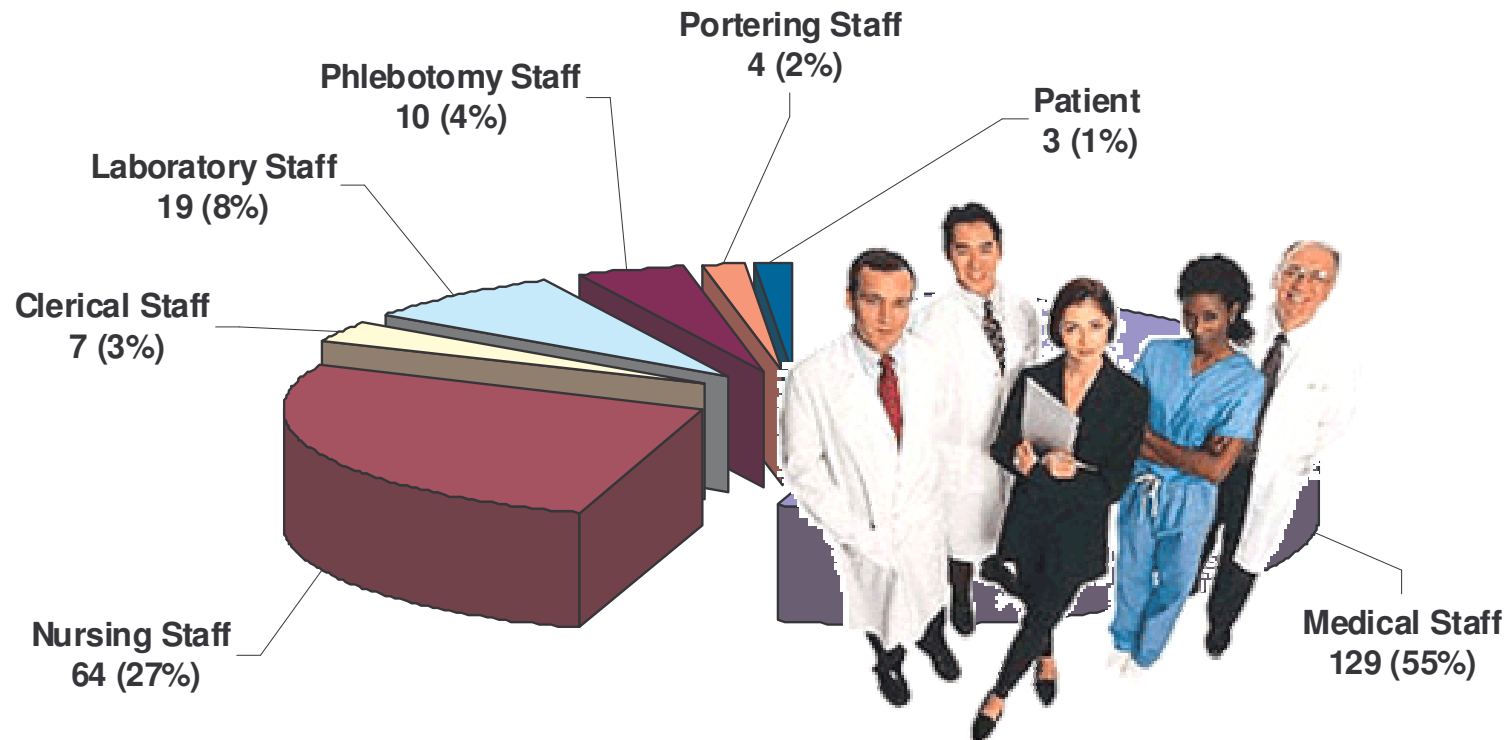
Near Miss Project

Breakdown of Sample Collection Errors

- Out of the 468 events where the 1st site of error was Sample Collection;
- 296 (39%) involved incorrectly labelled samples
- 13 of these events involved the sample being taken from the wrong patient
- 13 involved the sample being taken from the correct patient but being labelled with another patients details
- (Total of 26 Wrong Blood in Tube (WBIT) events)

Near Miss Project

Who was Involved In Error



Near Miss Project

Personnel involved in WBIT

- Doctors involved in 19 out of 26 WBIT incidents either because wrong patient bled or patient sample into wrongly labelled tube
- Root cause failure to identify patient and remote labelling away from bedside
- Is the process or the person?

NHO Report 2005: Unnecessary Transfusions

- Forty (23%) of IBCT reports in 2005 were unnecessary transfusions
- Eight due to sample problems (5)/haematology laboratory errors(3)
- Five due to using the wrong Hb result
- Twenty-seven(27) were due to errors in clinical decision making
 - 18 associated with FFP/SD plasma
 - 8 pooled platelets
 - 1 red cells

JOAN MIRÓ



Possible solutions

- Increased exposure at medical school undergraduate level
- Audit
- SNBTS e-learning project

Conclusions

- The Haemovigilance system in Ireland has had a positive impact on blood centres and hospital transfusion practice in Ireland.
- The data collected provides a useful base-line to assess the adequacy of mandatory reporting introduced as a result of EU Blood Directive 2002/98/EC.
- The findings confirm that non-infectious risks of transfusion are much higher than the risks of transfusion transmitted infection.
- The recommendations in the Annual Reports provide a benchmarking tool for Hospital Transfusion Committees when reviewing practice in their own hospitals.

Challenges

- To ensure discharge mandatory functions derived from EU Directives
- To enhance support for education including education of doctors
- Support hospital audit practices



The Guardian Haemovigilance Dog

NHO Team

Past..... and Present

Paula Bolger
Angie Corr
Elaine Corrigan
Maria Flanagan
Donna Harkin
Gillian Horgan
Phil Keane-Egan
Stefan Laspina
Siobhan O'Connor
Caroline O'Neill
Mairead Sheahan

Roisin Brady
Marie Carolan
Marina Cronin
Marcia Kirwan
Derval Lundy
Ann O'Connor
Cathy Scuffil
Jackie Sweeney

AND the staff of the Irish Blood Transfusion Service