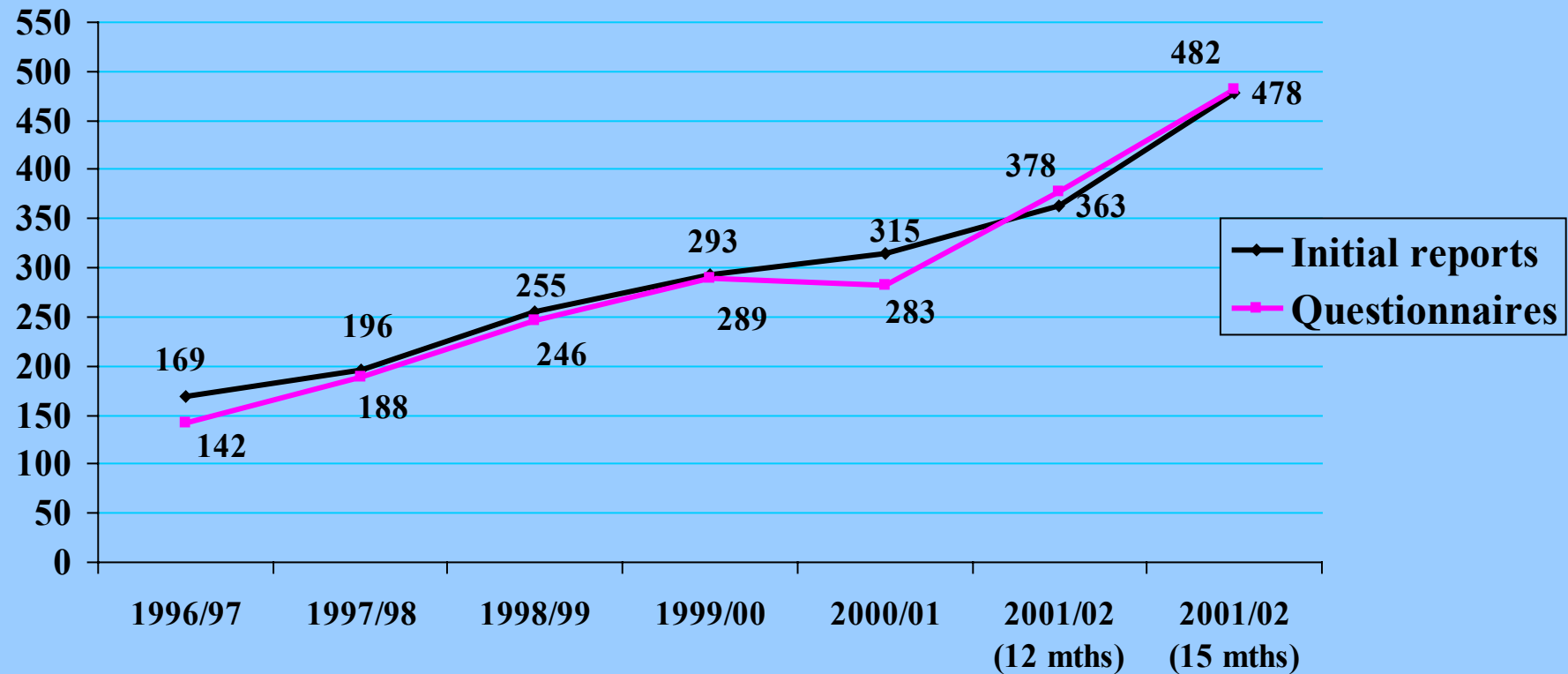


**OVERVIEW AND
RECOMMENDATIONS
FROM THE

6TH ANNUAL SHOT
REPORT
2001/2002**

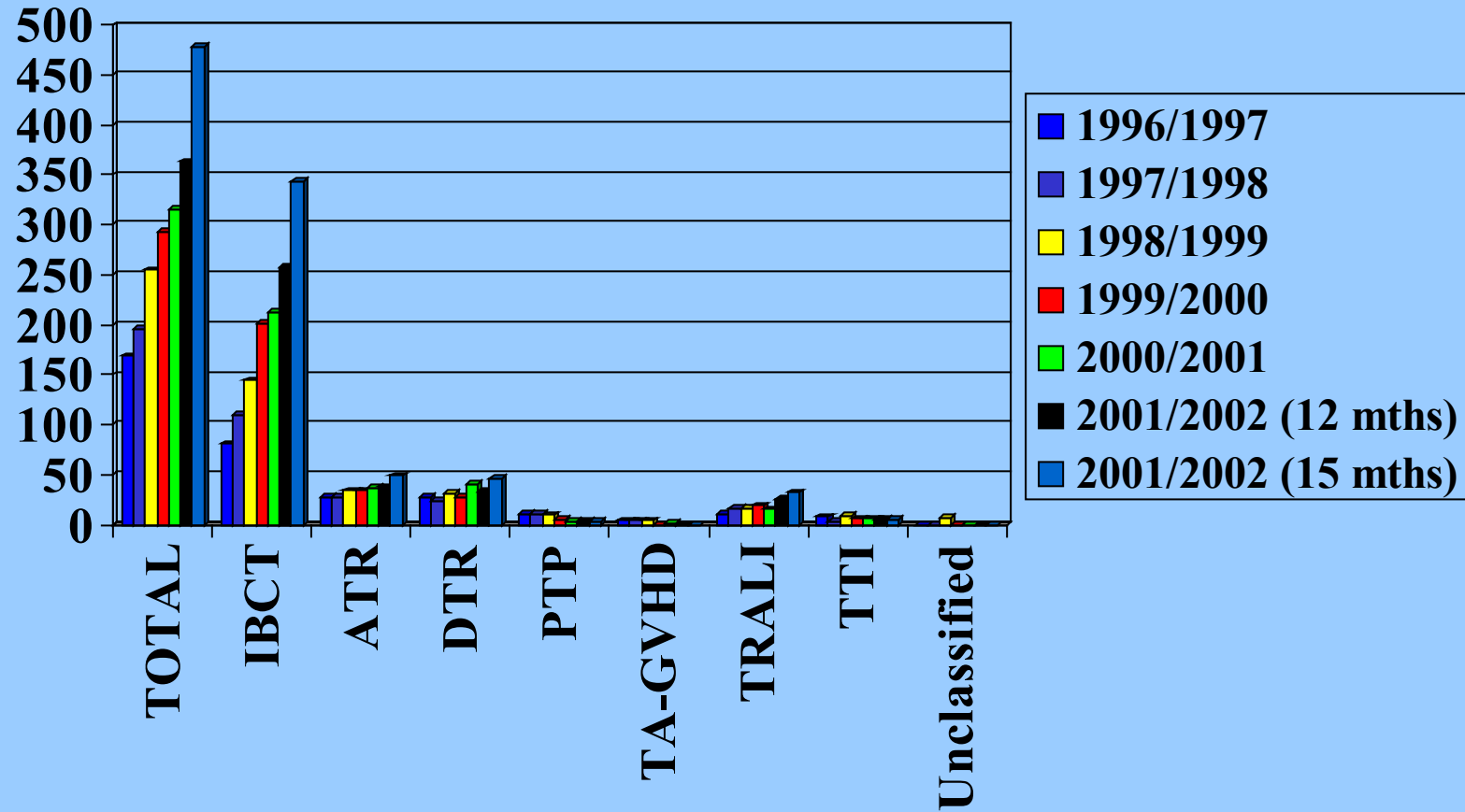
INCREASES IN REPORTING YEAR BY YEAR



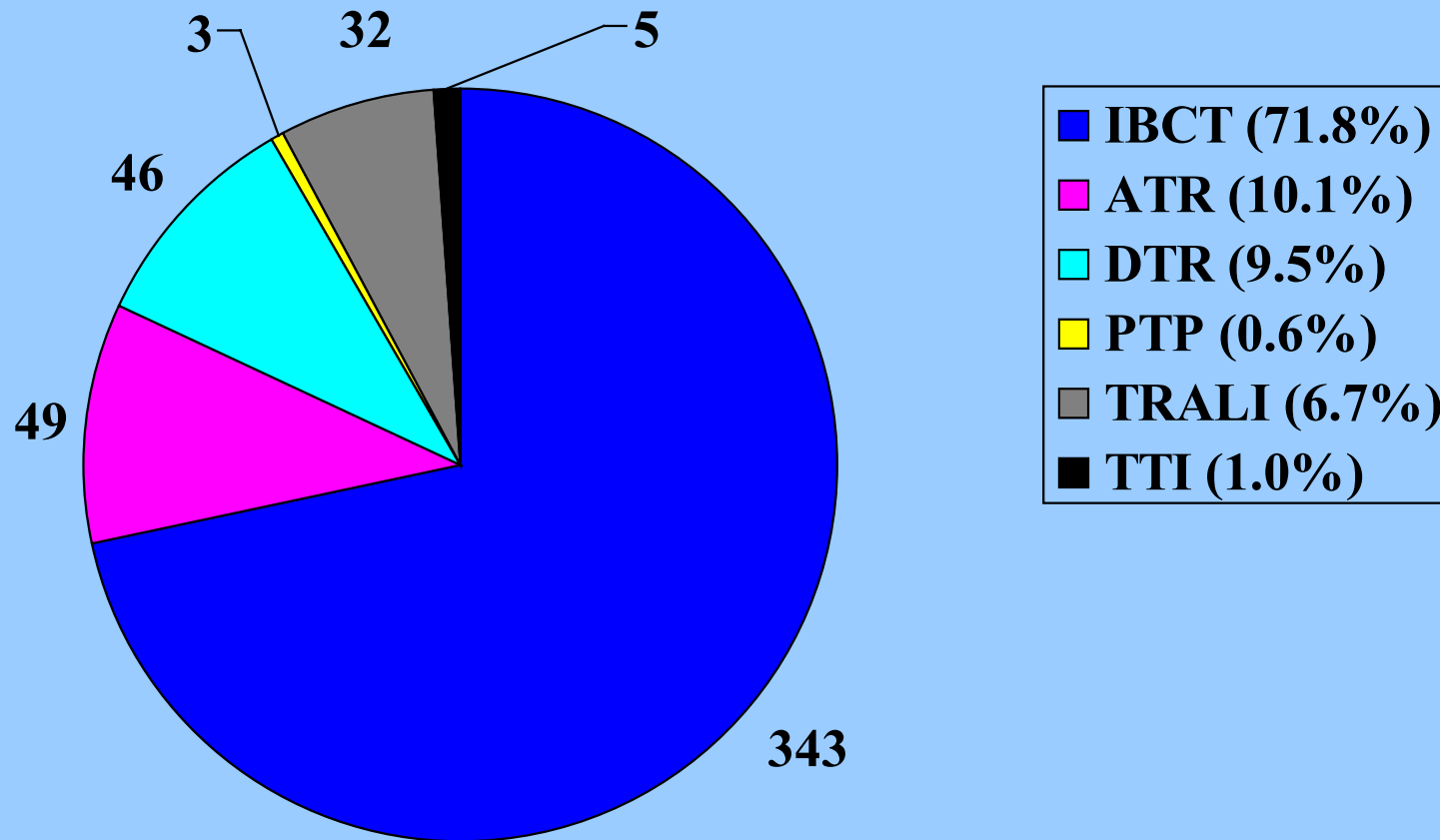
HOSPITAL PARTICIPATION 2001/2002

- ➔ **405** hospitals eligible to participate
- ➔ **378** participated in the scheme
- ➔ **187** submitted initial reports
- ➔ **191** indicated that they had seen no incidents
- ➔ **OVERALL PARTICIPATION = 93%**
(compared with 92% last year)

COMPARISON OF INITIAL REPORTS 1996 - 2002



OVERVIEW OF 478 CASES FOR WHICH INITIAL REPORTS WERE RECEIVED 2001/2002



TOTAL ISSUES OF BLOOD COMPONENTS FROM THE TRANSFUSION SERVICES OF THE UK IN FISCAL YEAR 2001/2002

| | |
|---------------------|------------------|
| Red cells | 2,683,463 |
| Platelets | 251,451 |
| Fresh frozen plasma | 385,236 |
| Cryoprecipitate | 88,253 |
| TOTAL | 3,408,402 |

TRANSFUSION RELATED MORTALITY/MORBIDITY IN 482 COMPLETED QUESTIONNAIRES 2001/2002

| | | Total | IBCT | ATR | DTR | PTP | TRALI | TTI |
|------------------------|-----------------------|------------|------------|-----------|-----------|----------|-----------|----------|
| DEATHS | Definitely attributed | 3 | 0 | 0 | 2 | 0 | 1 | 0 |
| | Probably attributed | 5 | 1 | 1 | 1 | 0 | 2 | 0 |
| | Possibly attributed | 8 | 3 | 1 | 0 | 0 | 4 | 0 |
| | TOTALS | 16 | 4 | 2 | 3 | 0 | 7 | 0 |
| | Unrelated | 33 | 18 | 5 | 6 | 0 | 4 | 0 |
| Major morbidity | | 35 | 9 | 0 | 2 | 1 | 18 | 5 |
| Minor or no morbidity | | 393 | 310 | 41 | 36 | 2 | 4 | 0 |
| TOTALS | | 482 | 346 | 48 | 47 | 3 | 33 | 5 |

**MAJOR MORBIDITY WAS DEFINED AS THE
PRESENCE OF ONE OR MORE OF THE
FOLLOWING:**

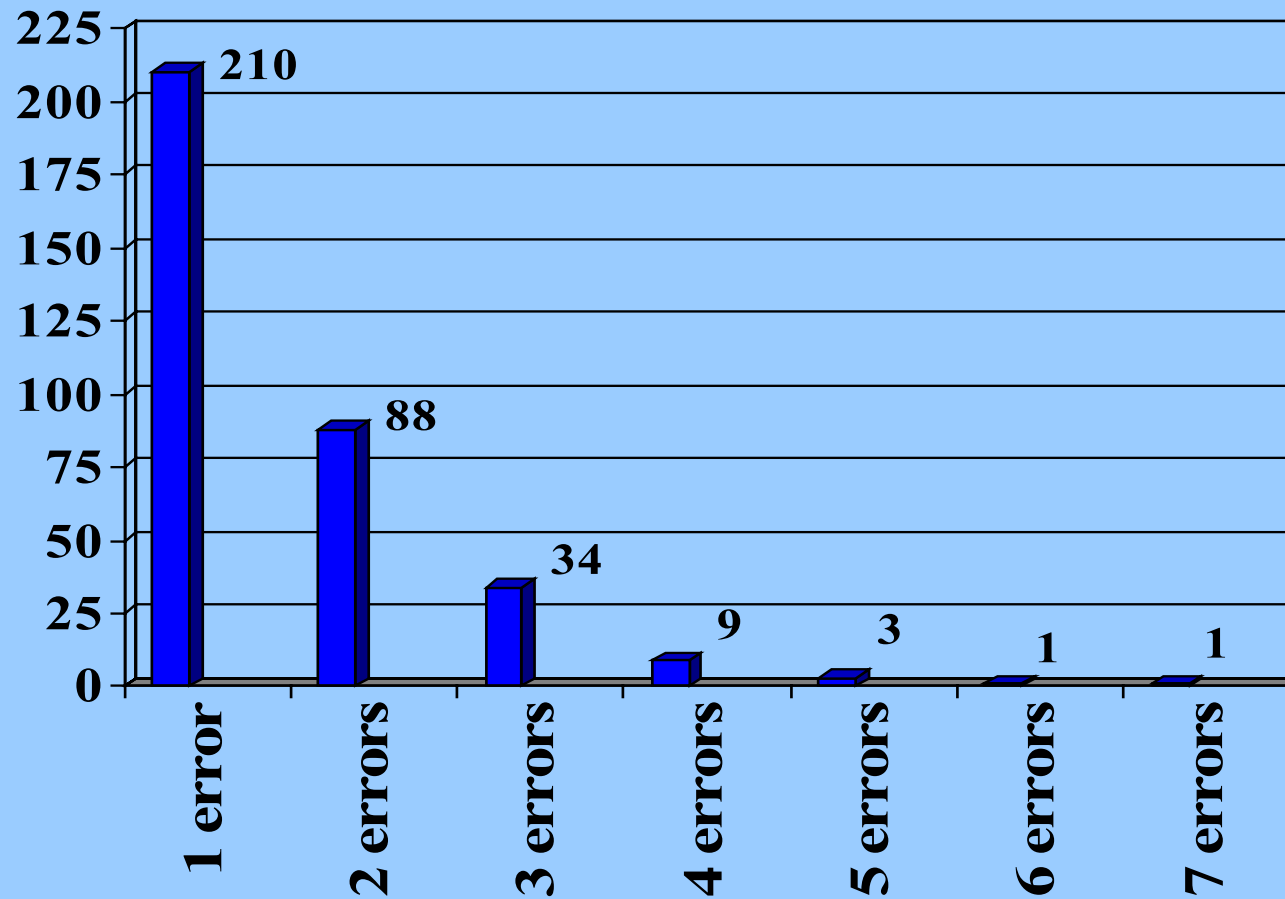
- Intensive care admission and / or ventilation
- Dialysis and / or renal dysfunction
- Major haemorrhage from transfusion-induced coagulopathy
- Intravascular haemolysis
- Potential RhD sensitisation in a female of child-bearing potential
- Persistent viral infection
- Acute symptomatic confirmed infection (viral, bacterial or protozoal)

INCORRECT BLOOD COMPONENT TRANSFUSED

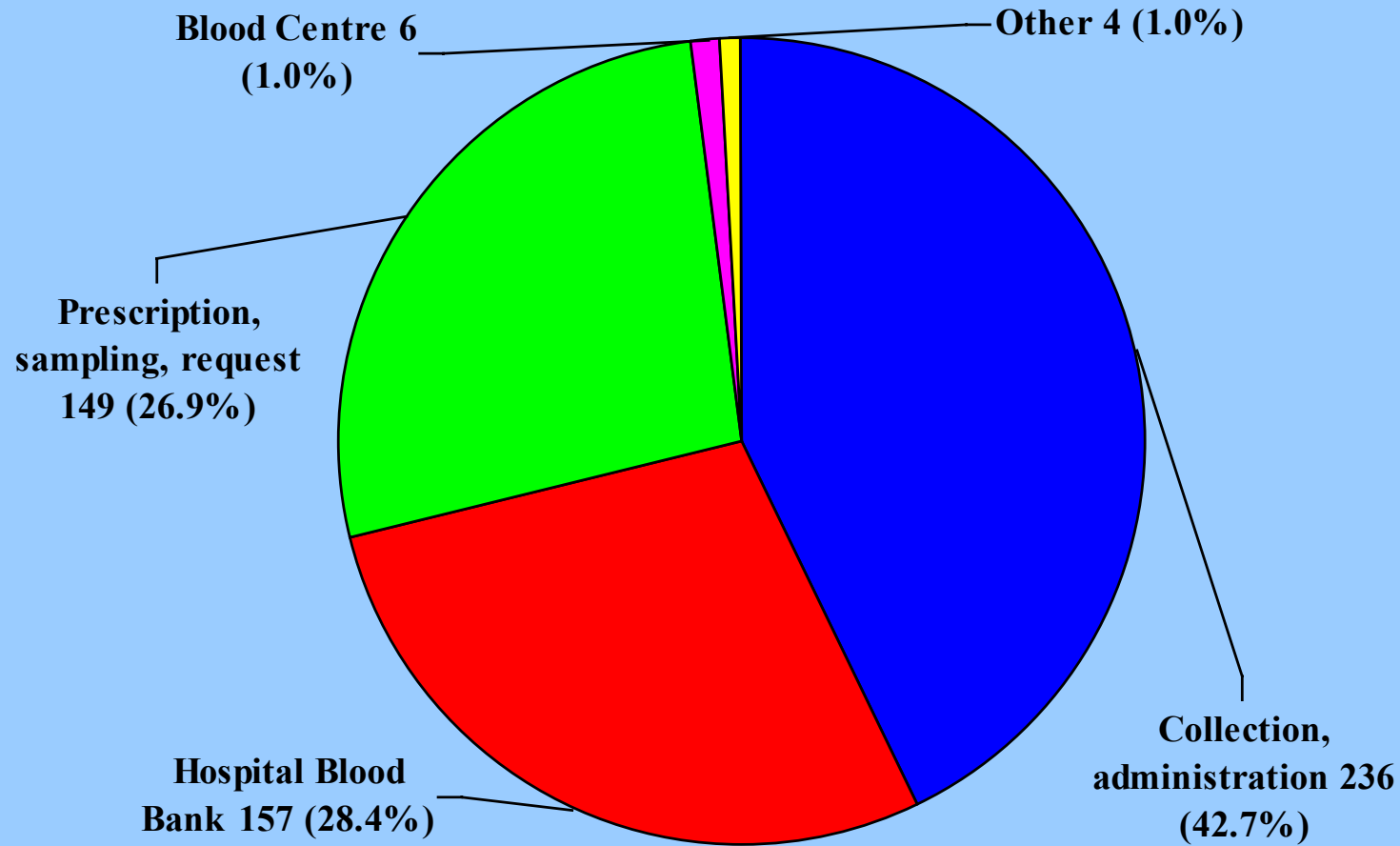
**ALL REPORTED EPISODES WHERE
A PATIENT WAS TRANSFUSED WITH
A BLOOD COMPONENT OR PLASMA
PRODUCT WHICH DID NOT MEET
THE APPROPRIATE REQUIREMENTS
OR WHICH WAS INTENDED FOR
ANOTHER PATIENT**

TOTAL NUMBER OF ERRORS PER CASE

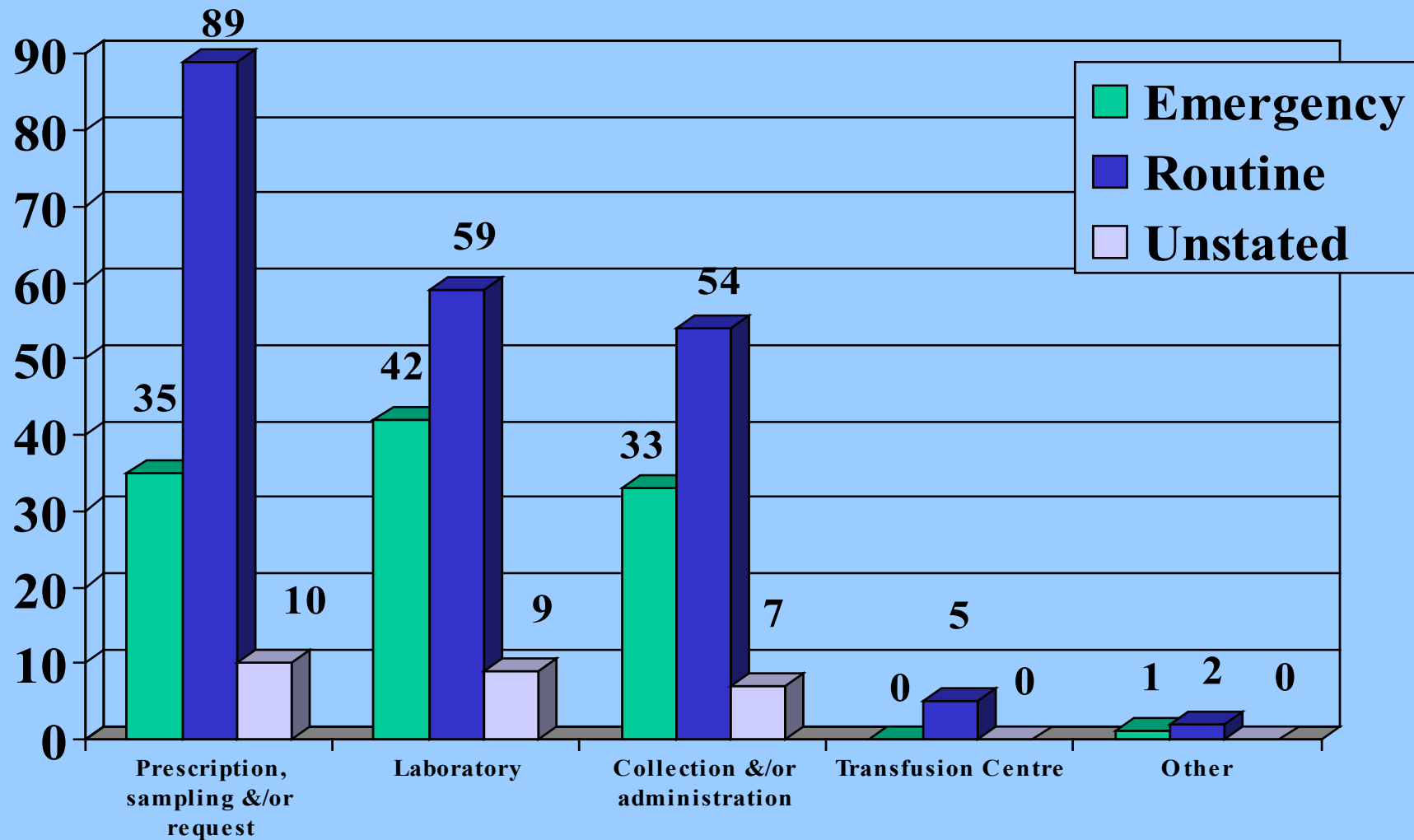
(total cases = 346; total errors = 552)



DISTRIBUTION OF ERRORS ACCORDING TO THE MAIN REPORTING CATEGORIES (n=552)



INCIDENCE OF ERRORS AT THE VARIOUS STAGES OF THE PROCESS OF EMERGENCY AND ELECTIVE TRANSFUSION



DISTRIBUTION OF PROCEDURAL FAILURES IN TERMS OF TOTAL ERRORS (1)

Prescription, sampling & request

| | No. of errors |
|----------------------------------------------------------------|---------------|
| Sample taken from wrong patient | 6 |
| Details on request form incorrect | 14 |
| Details on sample incorrect | 13 |
| Prescription of inappropriate and/or incompatible component(s) | 19 |
| Inappropriate request | 83 |
| Other | 13 |
| Unknown | 1 |
| Total | 149 |

DISTRIBUTION OF PROCEDURAL FAILURES IN TERMS OF TOTAL ERRORS (2)

Hospital Blood Bank

| | No. of errors |
|--------------------------------------------|---------------|
| Transcription error | 3 |
| Failure to consult/heed historical record | 23 |
| Grouping error | 30 |
| Missed antibody(ies): Screen error | 5 |
| Missed antibody(ies): ID error | 2 |
| Missed incompatibility | 2 |
| Selection/issue of inappropriate component | 24 |
| Labelling error | 8 |
| Failure to irradiate | 9 |
| Crossmatch error | 2 |

DISTRIBUTION OF PROCEDURAL FAILURES IN TERMS OF TOTAL ERRORS (3)

Hospital Blood Bank

| | No. of errors |
|-----------------------------------------|---------------|
| Crossmatch wrong sample | 5 |
| Failure to follow protocol | 11 |
| Incorrect serological reasoning | 3 |
| Clerical error | 7 |
| Technical error | 7 |
| Failure to clear satellite refrigerator | 5 |
| Failure to detect error by Blood Centre | 1 |
| Other | 10 |
| Total | 157 |

DISTRIBUTION OF PROCEDURAL FAILURES IN TERMS OF TOTAL ERRORS (4)

Collection & Administration

| | No. of errors |
|-----------------------------------------------|---------------|
| Collection of wrong component | 39 |
| Failure to detect error earlier in the chain | 46 |
| Failure of bedside checking procedure | 103 |
| Wristband missing or incorrect | 4 |
| Inappropriate component selected by clinician | 6 |
| General administration error | 2 |
| Failure to follow protocol | 24 |
| Other | 12 |
| Total | 236 |

OUTCOMES OF IBCT EVENTS

- 2 deaths due to erroneous Hb results
 - 92F with g-i haemorrhage and CVA
FBC sample taken from drip arm 81g/L - 4 unit transfusion. Post-transfusion Hb 176g/L
 - 96F with g-i haemorrhage.
FBC sample tube under-filled - Hb 50g/L
3 unit transfusion given despite warning from lab
Post-transfusion Hb 200g/L

OUTCOMES OF IBCT EVENTS

- 2 deaths due to ABO incompatibility
 - 67F (Group O) terminally ill with bronchiectasis
not intended to receive blood
Given 1 unit Group A blood intended for another patient
 - 21M (Group B) with haematological malignancy
Given 4 units Group O FFP selected from freezer out-of-hours by nurse - no on-call transfusion service

OUTCOMES OF IBCT EVENTS

- 9 major morbidity
 - 5 ABO incompatible RBC transfusions (1 teenage F with major trauma died)
 - 1 actual & 2 potential RhD sensitisation in young F (1 discrepant D typing)
 - 1 incompatible platelet transfusion (Group O to Group B)

NEAR MISS PARTICIPATION

**146/405 (36%) HOSPITALS
REPORTED NEAR MISS**

**50% OF PARTICIPATING
HOSPITALS STATE THAT THEY
HAD EXPERIENCED NEAR MISS**

709 REPORTS SUBMITTED

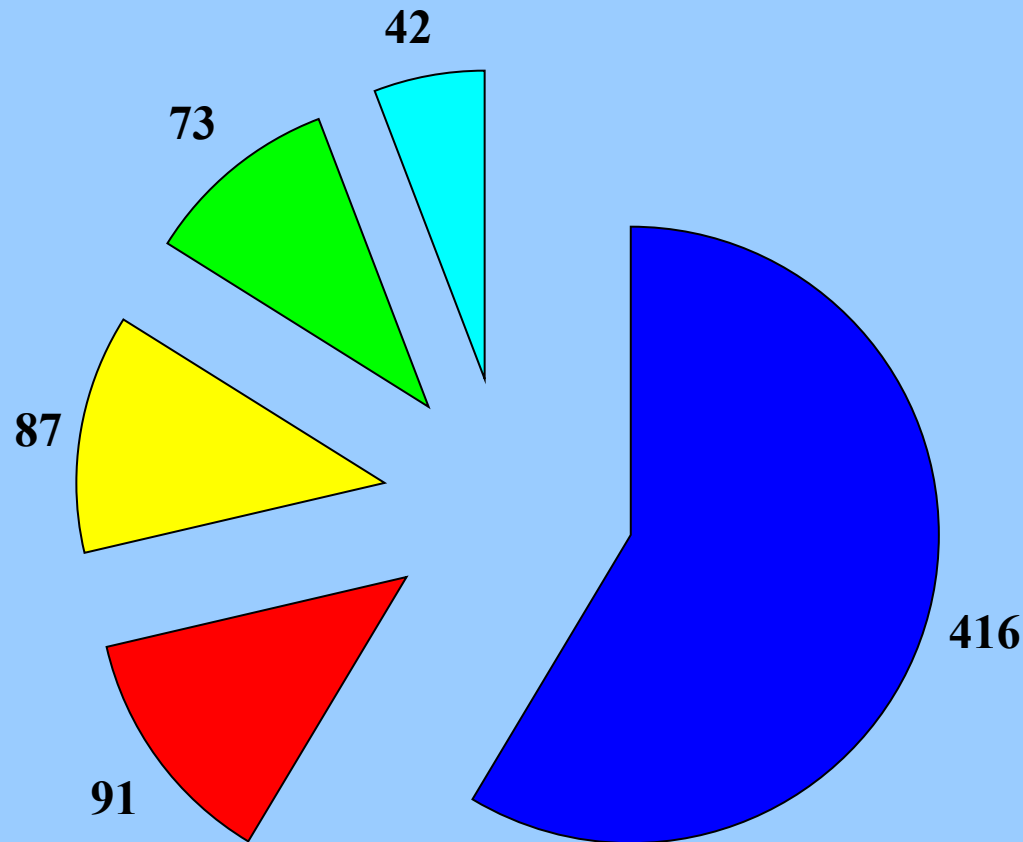
IMPORTANCE OF NEAR MISS REPORTING

- ➔ Valuable audit tool as often have the same root cause as actual transfusion events
- ➔ Can provide useful management information to identify deficiencies in systems

TYPES OF NEAR MISS EVENTS

- **Sample errors**
- **Request errors**
- **Laboratory sample handling and/or testing errors**
- **Laboratory component selection, handling and storage errors**
- **Component issue, transportation, collection and administration errors**

NEAR MISS EVENTS 2001/2002 (n=709)



- Sample errors (59%)
- Laboratory component selection, handling & storage errors (13%)
- Laboratory sample handling &/or testing errors (12%)
- Component issue, transportation, collection & administration errors (10%)
- Request errors (6%)

TRANSFUSION-TRANSMITTED INFECTIONS

2001-2002

TRANSFUSION-TRANSMITTED INFECTIONS 2001/2002

- ➔ 34 post-transfusion infections reported
 - ➔ + 13 transfusion reactions
- ➔ No case of HBV, HCV, HIV or HTLV
- ➔ 5 confirmed TTIs
- ➔ All were bacterial contamination

TRANSFUSION-TRANSMITTED BACTERIAL INFECTIONS 2001-2002

- ➔ 1 x *Staphylococcus epidermidis* infection, 5 day old pooled platelets during treatment for myeloma
- ➔ 1 x *Staphylococcus epidermidis* infection, 5 day old pooled platelets
- ➔ 1 x *Morganella morganii* infection, 5 day old platelets during treatment for thrombocytopenia
- ➔ 1 x Group B *streptococcus* infection, 3 day old pooled platelets during treatment for myeloma
- ➔ 1 x *Staphylococcus epidermidis*, 5 day old pooled platelets during treatment for myelodysplasia

IMMUNE COMPLICATIONS OF TRANSFUSION

Acute transfusion reactions

Delayed transfusion reactions

Transfusion-related acute lung injury

Post-transfusion Purpura

Transfusion-Associated Graft-versus-host Disease

ACUTE TRANSFUSION REACTIONS

ALL REPORTED EPISODES WHICH OCCURRED AT ANY TIME UP TO 24 HOURS FOLLOWING A TRANSFUSION OF BLOOD OR COMPONENTS, EXCLUDING CASES OF ACUTE REACTIONS DUE TO INCORRECT COMPONENT BEING TRANSFUSED

ACUTE TRANSFUSION REACTIONS

- 48 reports
 - Red cells 17
 - Platelets + cryoprecipitate 1
 - Platelets 10 (4 apheresis, 6 pools)
 - Platelets + FFP 1
 - FFP 19 (1 SD, 1 cryopoor)
- 31/48 involved FFP +/- or platelets
- 27/34 allergic/anaphylactic reactions due to FFP +/- or platelets

ACUTE TRANSFUSION REACTIONS

Cumulative data show that ATR reactions to FFP are 4 times more frequent, and those to platelets 6 times more frequent than those to red cells, proportional to the number of units transfused.

ACUTE TRANSFUSION REACTIONS

- 2 deaths associated with ATRs
 - 69F with pre-existing AIHA recently transfused. Developed acute intravascular haemolysis post-tx
? Exacerbation of AIHA
 - 93M known anti-k recent AAA repair re-admitted with massive haemorrhage, tx in A&E with Group ORhDneg Kneg. Received 4 units before k neg blood available.

DELAYED TRANSFUSION REACTIONS

ALL REPORTED EPISODES WHICH OCCURRED MORE THAN 24 HOURS FOLLOWING A TRANSFUSION OF BLOOD OR BLOOD COMPONENTS. IN PRACTICE, THESE ARE ALMOST INVARIABLY DELAYED HAEMOLYTIC REACTIONS DUE TO THE DEVELOPMENT OF RED CELL ALLOANTIBODIES. SIMPLE SEROLOGICAL REACTIONS (ANTIBODY DEVELOPMENT WITHOUT A POSITIVE DAT OR EVIDENCE OF HAEMOLYSIS) ARE EXCLUDED

DELAYED TRANSFUSION REACTIONS

- 47 cases analysed
- 3 deaths
 - 2 definitely attributed to transfusion
 - 1 probably attributed to transfusion

DELAYED TRANSFUSION REACTIONS

- In 2/3 fatal cases the DHTR was not recognised.
 - In 1 patient this led to unnecessary laparotomy
- In 2 of the fatal cases there were critical delays obtaining compatible red cells
- Kidd +/-or c antibodies were implicated in 75% of cases and all of the deaths
- We have insufficient information to know whether these cases have been adequately investigated

TRANSFUSION-RELATED ACUTE LUNG INJURY

**ACUTE DYSPNOEA WITH HYPOXIA
AND BILATERAL PULMONARY
INFILTRATES OCCURRING
DURING OR IN THE 24 HOURS
AFTER TRANSFUSION, WITH NO
OTHER APPARENT CAUSE**

TRANSFUSION-RELATED ACUTE LUNG INJURY

- ➔ 15 in 2000/2001
- ➔ 26 new cases reported in 2001/2002
- ➔ 33 cases analysed in this year's report

DIAGNOSING TRALI

OF THE 33 CASES:

5 EMERGED AS PROBABLE

14 AS POSSIBLE

13 AS HIGHLY LIKELY

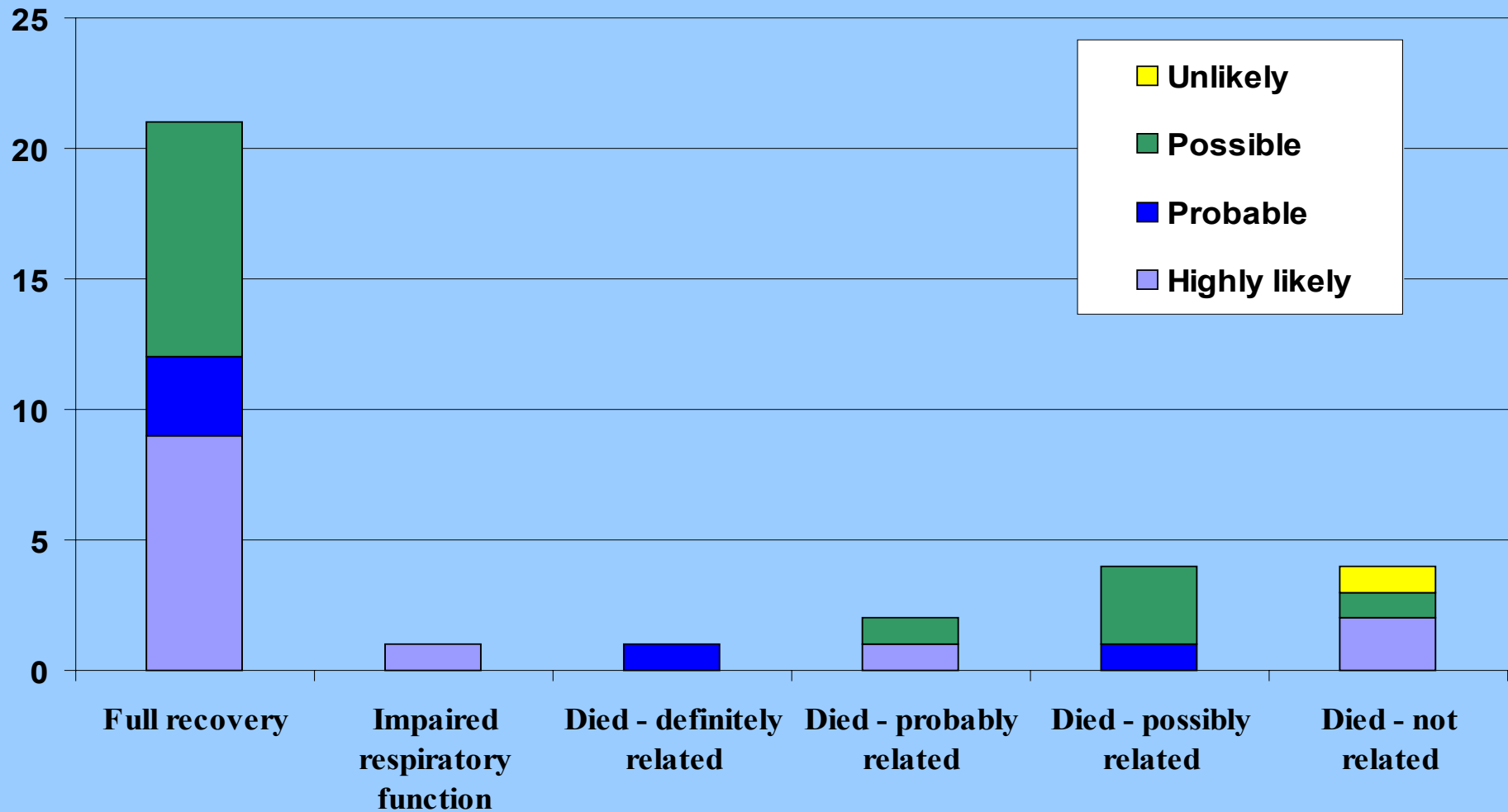
1 AS UNLIKELY

**THERE REMAINS, THEREFORE, A WIDE
DEGREE OF UNCERTAINTY ABOUT THE
DIAGNOSIS OF TRALI**

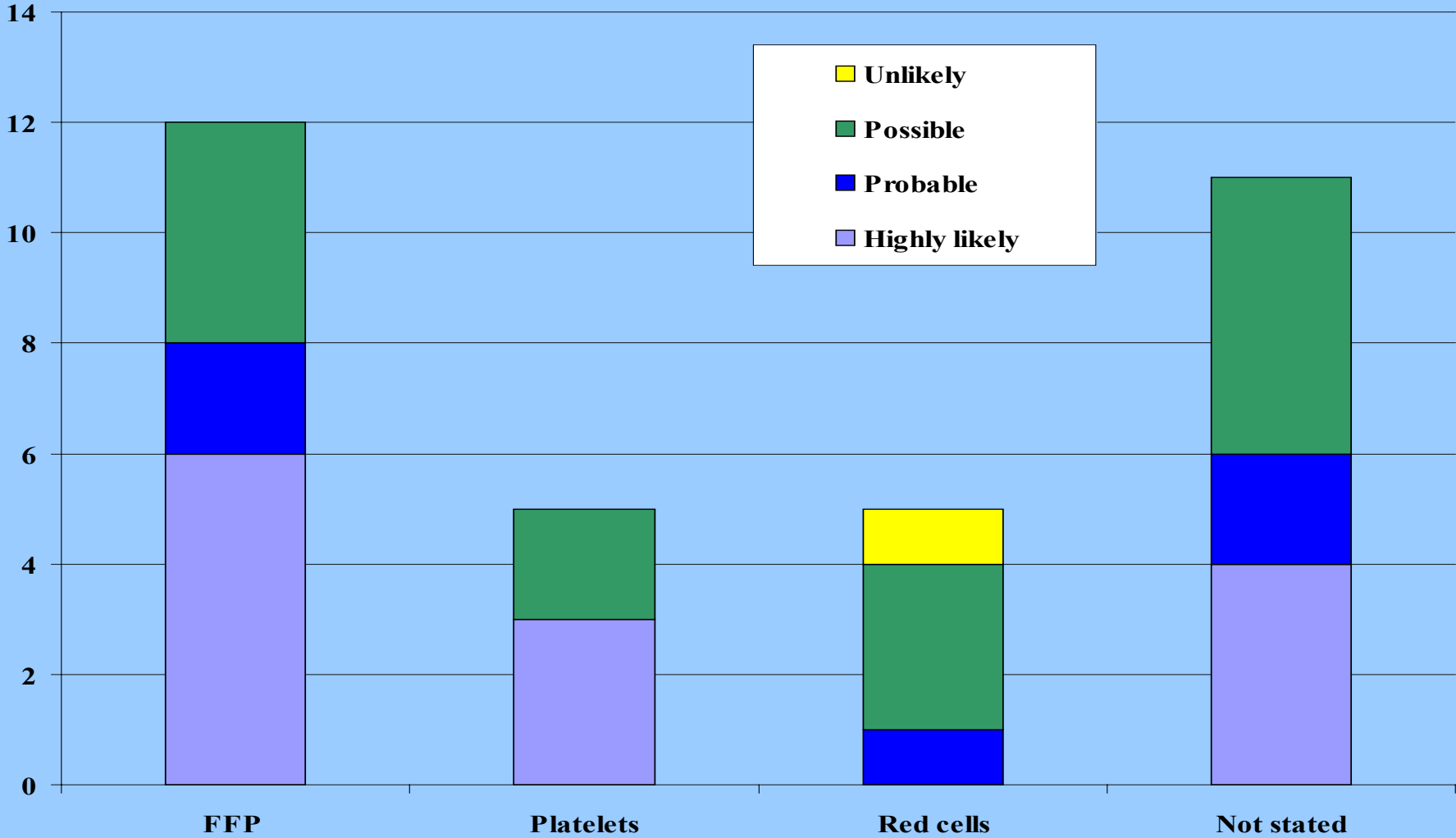
TRALI - OUTCOMES

- 7 deaths
 - 1 definitely attributable to transfusion
 - 2 probably attributable to transfusion
 - 4 possibly attributable to transfusion
- 18 patients suffered major morbidity
 - all but 1 made a full recovery

OUTCOME OF CASES WITH LIKELIHOOD OF CASE BEING TRALI



COMPONENTS IMPLICATED IN TRALI INCLUDING LIKELIHOOD OF CASE BEING TRALI



POST-TRANSFUSION PURPURA

THROMBOCYTOPENIA ARISING 5-12 DAYS FOLLOWING TRANSFUSION OF RED CELLS ASSOCIATED WITH THE PRESENCE IN THE PATIENT OF ANTIBODIES DIRECTED AGAINST THE HPA (Human Platelet Antigen) SYSTEMS

CASES REPORTED

4 CASES REPORTED

(1 case excluded as platelet count was low before transfusion & no HPA antibodies were detected)

3 CASES ANALYSED

Case 1- clinical features consistent with PTP but negative serology

Cases 2 & 3 - classic features of PTP & in both cases the patient's serum was found to contain anti-HPA-1a

TRANSFUSION ASSOCIATED GRAFT VERSUS HOST DISEASE

NO NEW CASES WERE REPORTED
DURING 2001-2002

TA-GVHD REMAINS A FATAL
CONSEQUENCE OF TRANSFUSION

69 PATIENTS IN IBCT CATEGORY
WERE PUT AT RISK

SHOT EVENTS REPORTED IN PATIENTS LESS THAN 18 YEARS OF AGE CUMULATIVE DATA 1996-2002

A validated case reported to SHOT
involving a patient less than 18
years of age

CASES REPORTED

**A TOTAL OF 1630 ANALYSABLE REPORTS
RECEIVED SINCE OCTOBER 1996**

OF THESE

**141 (8.65%) INVOLVED PATIENTS LESS
THAN 18 YEARS OF AGE**

**EPIDEMIOLOGICAL STUDIES OF
TRANSFUSION RECIPIENTS SUGGEST
THAT THE FREQUENCY OF ADVERSE
EVENTS MAY BE DISPROPORTIONATELY
HIGH IN THIS AGE GROUP**

CATEGORIES OF ADVERSE EVENTS REPORTED AND THE RELATIVE PROPORTIONS SINCE OCTOBER 1996

| Nature of adverse events reported | Proportion of all reports | |
|------------------------------------------------------------|---------------------------|--------------------|
| | All ages | Less than 18 years |
| Incorrect blood component transfused (IBCT) | 63.9% | 80.1% |
| Acute transfusion reactions (ATR) | 12.2% | 10.6% |
| Delayed transfusion reactions (DTR) | 11.5% | 0.7% |
| Transfusion related acute lung injury (TRALI) | 6.6% | 6.4% |
| Transfusion associated graft versus host disease (TA-GVHD) | 0.8% | 1.4% |
| Post transfusion purpura (PTP) | 2.5% | 0.0% |
| Transfusion transmitted infection (TTI) | 2.2% | 0.7% |

OUTCOME

5 DEATHS DUE TO TRANSFUSION RELATED EVENTS AMONGST THE **141** CASES

3 DUE TO TRALI

2 DUE TO TA-GVHD

6 DEATHS FROM UNRELATED CAUSES

13 CHILDREN SUFFERED MORBIDITY OR HAVE A RISK OF FUTURE PROBLEMS DUE TO RhD SENSITISATION

EXAMPLES OF IBCT ERRORS

- ➔ **3** group A or B recipients were given group O FFP (laboratory error in **2** cases, anaesthetist error in **1** case).
- ➔ **3** patients received untreated FFP who should have received pathogen inactivated FFP; SDFFP (**1** case) & methylene blue FFP (**2** cases)
- ➔ **3** babies who had previous intrauterine transfusions were given non-irradiated blood.
- ➔ Excessively old blood was issued for exchange transfusion (**1** case) & not red cells of five days or less of age

**RECOMMENDATIONS
BASED ON
2001-2002 FINDINGS**

GENERAL RECOMMENDATIONS⁽¹⁾

- ➔ All institutions where blood transfusions are administered must participate in SHOT**
- ➔ An open learning & improvement culture must be developed in which SHOT reporting is a key element**
- ➔ Adequate resources must be made available for improvements in transfusion safety in hospitals**

GENERAL RECOMMENDATIONS⁽²⁾

- ➔ Hospital transfusion teams must be established & supported**
- ➔ SHOT recommendations must be on the clinical governance agenda**
- ➔ Appropriate use of blood components must be strenuously promoted**
- ➔ Training in blood administration should be implemented & competency testing developed to ensure an effective outcome**

GENERAL RECOMMENDATIONS⁽³⁾

- ➔ **Blood transfusion should only be prescribed by authorized clinicians**
- ➔ **Blood transfusion teaching must be included in all relevant academic curricula**
- ➔ **Hospital blood bank laboratory staffing must be sufficient for safe transfusion practice**

GENERAL RECOMMENDATIONS⁽⁴⁾

- ➔ Electronic aids to transfusion safety should be assessed & developed at national level**
- ➔ There is a need for a national body, with relevant expertise & resource, to advise government on priorities for improvement in transfusion safety**
- ➔ Clear policies for communication must be developed**

SPECIFIC RECOMMENDATIONS

- ➔ Patients receiving transfusion must be monitored
- ➔ All adverse reactions should be fully investigated & reviewed
- ➔ Information on previous transfusion history must be available to all who need it

SPECIFIC RECOMMENDATIONS

- ➔ FFP continues to be associated with significant risk of reactions including TRALI
- ➔ Reduction of the risk of TRALI demands a high priority

SPECIFIC RECOMMENDATIONS

- ➔ Particular care should be taken when providing blood for patients with a positive DAT, who are known to have an autoimmune haemolytic anaemia or have been recently transfused
- ➔ Withholding transfusion may be a greater risk than DTR

SPECIFIC RECOMMENDATIONS

➔ Transfusion-transmitted bacterial infection remains an avoidable cause of death & major morbidity & merits increased efforts to prevent bacterial contamination of blood components

SPECIFIC RECOMMENDATIONS

- ➔ Neonates and children are a vulnerable group with special transfusion requirements
- ➔ Laboratory, nursing & medical staff should all be aware of the special transfusion needs of neonates and infants. Education of these staff in paediatric transfusion practice is important
- ➔ The wearing & checking of identity bands is essential in the paediatric age group.

ACKNOWLEDGEMENTS

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