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ANNUAL REPORT 2007

SUMMARY

Introduction

It is 8 months since the last (2006) SHOT Annual Report was published. The Annual Report has been brought forward for two main reasons – firstly, to publish each year's data earlier in the year, and secondly, to be in line with the EU Blood Directive and the Blood Safety and Quality Regulations 2005, which require that annual adverse incident report summaries are sent by the Competent Authority to the EU Commission by 30th June of the following year.

SHOT is now entering its second decade of reporting, as one of the longest established haemovigilance systems in the world. Currently, haemovigilance systems are being initiated in Europe (in response to the EU Directive) and further afield, and SHOT continues to be used as a model in their development. SHOT has participated in the European Working Group on Haemovigilance, developing guidance for Competent Authorities reporting to the EU Commission, and has liaised closely with the European Haemovigilance Network (EHN).

SHOT continues to work with MHRA through the Blood Consultative Committee and its Adverse Events sub-group (chaired by Dr Clare Taylor). This group has a particular focus on reconciliation of annual data between SHOT and MHRA. SHOT continues to collect a wider scope of data than MHRA, extending into the professional and clinical arenas of transfusion practice. Details of what to report to SHOT and to MHRA are in the full Annual Report 2007.

Participation in SHOT

Although there has been an increase in reports both to SHOT and to MHRA this year, overall participation in reporting through SABRE to both organisations remains incomplete, with a rate of 25–30% of non-reporters among registered SABRE users. Non-participation in haemovigilance is a matter of great concern as for both professional and regulatory reasons it is imperative that all hospitals participate in the scheme.

Key findings in 2007

The issues surrounding education and training raised in the 2006 report are emphasised by the findings for 2007. There remains evidence that junior doctors are making critical decisions without adequate basic knowledge or experience. This is a professional matter, in which responsibility lies with the individuals themselves as well as with their employers.

Mortality is at an all-time low this year, but there is avoidable major morbidity. There were 12 cases of ABO-incompatible red cell transfusion this year, 9 arising from clinical error and 3 from laboratory error. The training and competency assessment required by the NPSA SPN 14 aims to reduce errors in phlebotomy, blood component collection and administration.

Overview of 2007 report

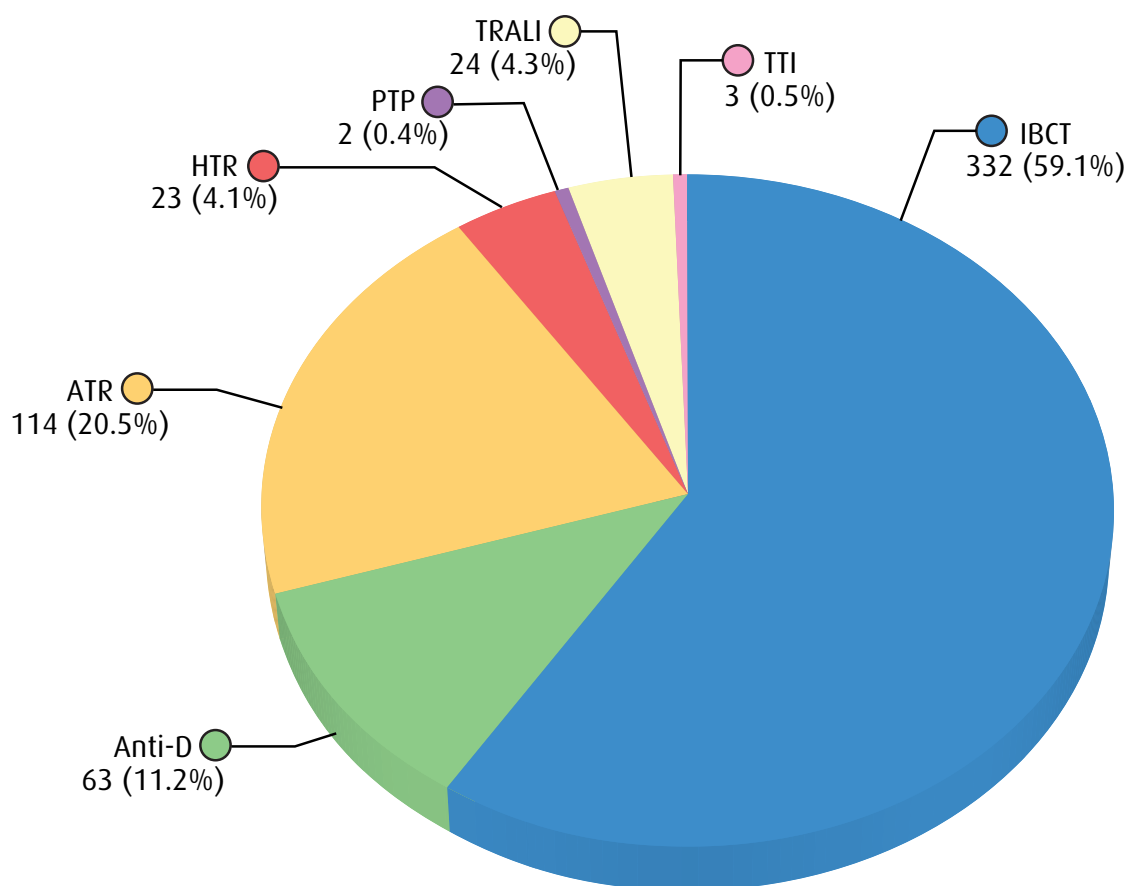
Data analysed for this report were collected between 1st January 2007 and 31st December 2007. This year, for the first time, cases of anti-D have been counted separately from IBCT. The total number of questionnaires reviewed (including anti-D) is 561, representing an increase of 5% from last year's total of 531.

Summary of reports reviewed

IBCT	Anti-D	ATR	HTR	TRALI	PTP	TA-GVHD	TTI	Totals
332	63	114	23	24	2	0	3	561

Cases reviewed in 2007 n = 561

[Before 2006 the HTR category was referred to as delayed transfusion reactions]



Total issues of blood components from the Transfusion Services of the UK in the financial year 2006/2007

	Red blood cells	Platelets	FFP	Cryoprecipitate	Total
National Blood Service	1,864,271	217,401	260,159	100,738	2,442,569
Welsh Blood Service	96,317	8,321	13,141	2,699	120,478
Scottish National Blood Transfusion Service	218,025	23,343	24,166	8,915	274,449
Northern Ireland Blood Transfusion Service	57,025	6,409	8,978	4,320	76,732
TOTAL	2,235,638	255,474	306,444	116,672	2,914,228

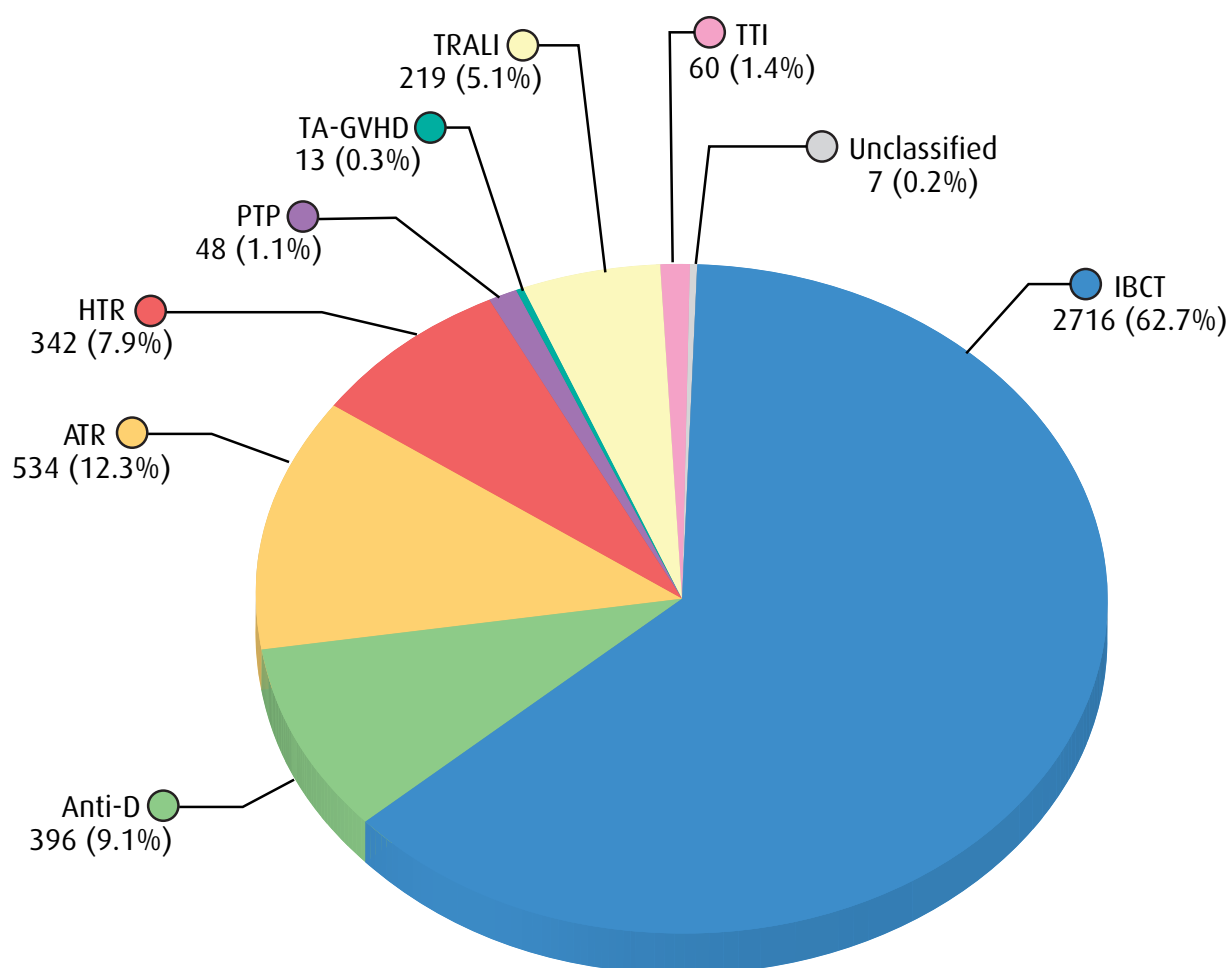
Yearly summary of issues by the four UK Blood Services 1999 - 2007

Year	Red blood cells	Platelets	FFP	Cryoprecipitate
1999/2000	2,737,572	249,622	365,547	94,114
2000/2001	2,706,307	250,259	374,760	95,456
2001/2002	2,679,925	251,451	385,236	88,253
2002/2003	2,678,098	251,741	377,381	92,768
2003/2004	2,607,410	264,539	372,855	95,417
2004/2005	2,428,934	258,528	313,019	102,719
2005/2006	2,316,152	259,654	320,852	106,139
2006/2007	2,235,638	255,474	306,444	116,672

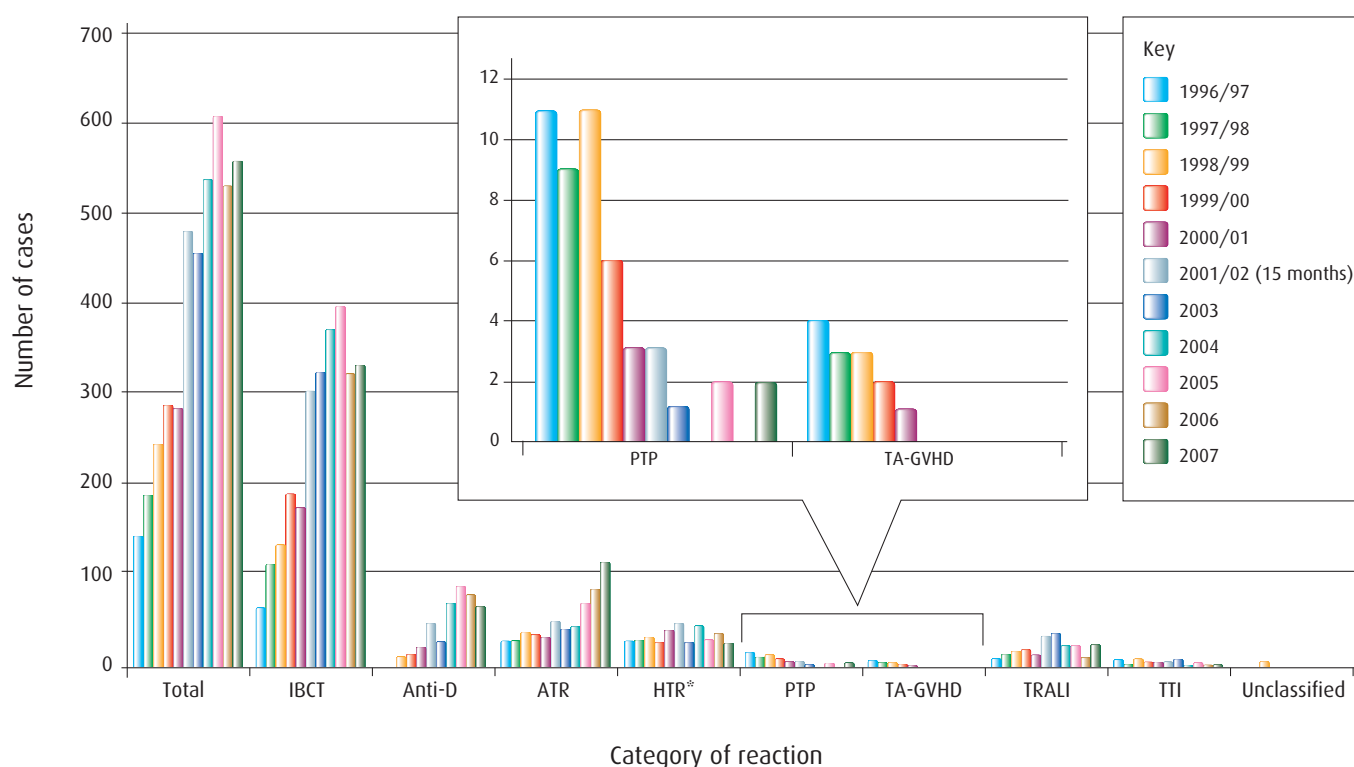
The total number of blood components issued from the transfusion services of the UK continues to decrease. The first table below shows data from 1999-2007, demonstrating a steady decrease in issues of red cells from UK Blood Services and resulting in a total decrease of 18% over 7 years. FFP issues have decreased by 16% over the same period. Platelet usage has increased by just 2%, whereas cryoprecipitate usage has increased by 24%.

Cumulative numbers of cases reviewed 1996-2007 (n = 4334)

[Before 2006 the HTR category was referred to as delayed transfusion reactions]



Comparison of report types 1996-2007
[Before 2006 the HTR category was referred to as delayed transfusion reactions]



Cumulative mortality / morbidity data 1996-2007

	Total	IBCT	Anti-D	ATR	HTR *	PTP	TA-GVHD	TRALI	TTI
Death in which transfusion reaction was causal or contributory	115	24	0	14	10	2	13	40	12
Major morbidity probably or definitely attributed to transfusion reaction (imputability 2/3)	376	107	24	22	34	13	0	133	43
Minor or no morbidity as a result of transfusion reaction	3821	2907	39	495	296	33	0	46	5
Outcome unknown	15	11	0	3	1	0	0	0	0
TOTAL **	4327	3049	63	534	341	48	13	219	60

* The HTR category was referred to as delayed transfusion reaction (DTR) until 2006 and did not include acute reactions.

** Excludes 7 cases from 1998/99 that were not classified.

Summary of 2007 report

Transfusion Related Mortality

There was 1 death reported during 2007 probably attributable to transfusion. This occurred as a result of a case judged to be probable TRALI.

There were 3 cases in which the patient died and the transfusion reaction was considered to be contributory. One of these occurred as a result of an acute transfusion reaction and involved an 8-month-old female infant who suffered an anaphylactic/anaphylactoid reaction following the transfusion of FFP. A further 2 cases in which a transfusion reaction was considered to be contributory are reported in the HTR chapter in the main report.

Therefore, the 2007 report, with 1 probable transfusion-related death, has the lowest reported mortality rate from blood transfusion since SHOT reporting began in 1996.

Incorrect blood component transfused

There were 332 events analysed in 2007 (excluding anti-D related cases). This is comparable to last year's figure of 323 IBCT cases.

The total number of blood components issued from the blood transfusion services of the UK for the financial year of 2006/7 decreased to 2,873,488. However, a comparison of the reporting rate allowing for the decrease in component usage shows that reporting has increased to 11.4 cases per 100,000 components transfused in 2007 compared with 10.6 in 2006. The detailed subdivision of the cases is shown in the main report. The table below allows a direct comparison with categories from 2006.

Type of event	Number 2006	Number 2007
'Wrong blood' events where a patient received a blood component intended for a different patient or of an incorrect group	54	46
Other pre-transfusion testing errors (excluding erroneous Hb)	28	20
Blood of the incorrect group given to recipients of ABO or D mismatched PBSC, bone marrow or solid organ transplant	8	5
Transfusion of blood of inappropriate specification or that did not meet the patient's special requirements	108	93
Inappropriate or unnecessary transfusions	51	50
'Unsafe' transfusion where there were handling or storage errors	74	118
Total	323	332

In 96 of the 332 IBCT cases (29%) the error originated in the laboratory. Thirty-three percent of the wrong blood errors in 2007 originated in the laboratory.

There are no transfusion-related deaths (definite or contributing to mortality) arising from IBCT in 2007. Twelve ABO-incompatible red blood cell transfusions were given during 2007, 9 as a result of clinical errors including 1 phlebotomy error and 3 as a result of laboratory errors.

Anti-D events

There were 63 anti-D events reported this year compared with 77 in 2006. There was potential sensitisation of a woman of childbearing age to the D antigen in 24 cases, satisfying the SHOT definition of major morbidity. There were a further 35 cases in which anti-D was inappropriately administered resulting in unnecessary exposure to a human blood product.

Transfusion-Related Acute Lung Injury

Thirty-six cases of suspected TRALI were received in this reporting year, of which 12 were withdrawn on further analysis. Of the 24 cases analysed, 8 were considered to be highly likely to be TRALI and a further 4 to be probable TRALI. The remaining 12 cases were possible or unlikely. There was 1 case of mortality directly related to a probable case of TRALI. There were no deaths in which a TRALI reaction contributed to death but there were 15 cases of major morbidity.

The increased number of TRALI cases investigated this year is partly due to some having been carried over from 2006 because they occurred late in the reporting year and final reports of investigations were not received until 2007. However, the mortality rate, equal to that in 2006, is again the lowest since reporting began in 1996 and is likely to be related to the change to preferential use of male plasma.

Acute transfusion reaction

There were 115 cases of acute transfusion reaction reported during 2007. This represents another increase in the number of reports, this time of 35%, since the previous year. There was also a 25% increase between 2005 and 2006. This is likely to be due to the effect of the Blood Safety and Quality Regulations, which came into force in 2005, bringing a requirement to report all serious transfusion reactions to the Competent Authority. Since the definition of 'serious' remains rather grey, there has generally been an increased tendency to report reactions. There were 27 anaphylactic or anaphylactoid reactions, 12 severe allergic reactions, 2 hypotensive reactions, 21 febrile reactions with other symptoms/signs, 37 minor allergic reactions and 16 isolated febrile reactions.

There were no cases of definite transfusion-related mortality but 1 case in which the transfusion reaction contributed to the death of the patient. There were 5 cases of major morbidity.

Cases of transfusion-associated circulatory overload (TACO) have not been included in the ATR chapter. Those that have occurred this year are included in the IBCT chapter as they are related to inappropriate transfusion, and they have also been discussed in a separate TACO chapter in the main report.

Haemolytic transfusion reaction

There were 23 cases of haemolytic transfusion reaction reported this year, which is a decrease compared with 2006. Three of these were acute haemolytic transfusion reactions, of which 1 was a clear case of major morbidity relating to intravascular haemolysis following an ABO-incompatible platelet transfusion. There were 20 delayed haemolytic transfusion reactions and in 2 of these the reaction was felt to have contributed to the death of the patient. There were 4 additional cases of major morbidity in this group.

Post-transfusion purpura

In 2007 there were 2 cases of post-transfusion purpura, neither of which suffered mortality or major morbidity. Both these 2 confirmed cases occurred in females, 1 associated with HPA-1a antibodies and the other with HPA-1b antibodies. These figures continue the sustained decrease in the number of cases of PTP, which has been observed since the introduction of universal leucodepletion in 1999.

TA-GVHD

There were no cases of transfusion-associated graft-versus-host-disease in 2007.

Autologous blood transfusion

There were 3 cases associated with autologous blood transfusion, of which 2 are included in the ATR chapter and 1 in the IBCT chapter. These are also discussed together in a separate chapter in the main report.

Transfusion Transmitted Infections

During 2007, 25 reports of suspected transfusion-transmitted infection were made from blood centres throughout the UK. Three proven cases are detailed in this 2007 SHOT report. Twenty-one cases were concluded as not transfusion-transmitted infection and 1 case is still pending completion of the investigations. The 3 cases all relate to transfusion-transmitted bacterial infection. Notably, 2 of these related to red cell packs and just 1 to platelets. There have been no further reports of transmission of vCJD by blood transfusion.

MAIN RECOMMENDATIONS

SHOT general recommendations this year focus once again on the education of junior doctors, and the need for qualified, trained and competent staff to be responsible for transfusion safety, both in the laboratory and in the clinical arena.

- Transfusion Medicine must be part of the core curriculum for doctors in training. This could be delivered as a two-stage process: a basic level of working knowledge should be mandatory for FY1 and FY2 doctors, and a higher level for specialist trainees in all clinical hospital disciplines. Progression to the next stage of a hospital career would require this to be signed off as completed.

Action: NBTC, General Medical Council (GMC), Postgraduate Medical Education and Training Board (PMETB), Royal Colleges, Deaneries

- Professional, accredited staff must take responsibility for transfusion safety in the laboratory and in clinical practice. Trusts must ensure that the skill mix of staff is appropriate, so that specialised transfusion personnel are available at all times. Transfusion practitioners and biomedical scientists (BMSs) should be encouraged to obtain qualifications in transfusion medicine and this should be facilitated by employers.

Action: NBTC, National Transfusion Laboratory Collaborative (NTLC), British Blood Transfusion Society (BBTS), Institute of Biomedical Scientists (IBMS), Hospital Trust Chief Executive Officers (CEOs)

- Obstetricians and midwives must be familiar with the national guidance for routine antenatal anti-D prophylaxis and the rationale behind it. National guidance regarding all anti-D prophylaxis should be standardised. There is a need for clear and unambiguous advice to ensure that all hospitals are able to develop local guidelines that reflect national consensus.

Action: NBTC, NHS Blood and Transplant (NHSBT) Appropriate Use of Blood Group, BCSH, Royal Colleges of Midwives, Obstetricians and Gynaecologists, General Practitioners (GPs), HTCs and HTTs

- Participation in haemovigilance must be improved as it is mandatory in the UK and the rest of Europe. Figures from both SHOT and MHRA show that a substantial number of hospitals, including some high users, are not sending reports. This is in breach of European and UK legislation. Trusts with difficulties in meeting this requirement should seek assistance from the UK haemovigilance bodies, the DH, or the Blood Transfusion Services (BTS).

Action: DH, MHRA, SHOT, Hospital Trust CEOs, Hospital Transfusion Committees (HTCs), Hospital transfusion Teams (HTTs), BTS

Summary remarks

In this SHOT Annual Report many cases demonstrate a remarkable lack of understanding of the reasoning behind the decision making process in transfusion. Underpinning knowledge and familiarity with transfusion protocols has also been found to be absent. A large number of cases are process failures but there are also cases showing a worrying disregard for protocol and an offhand attitude to bedside checking. There are still patients receiving blood without a prescription and patients with no identification receiving components. Blood is being prescribed following a decision based on incorrect results or poor or absent clinical reasoning. Transfusion Medicine education must be formally incorporated into the core curriculum of the medical and nursing Royal Colleges, and should be mandated for qualification or career progression. If qualified, educated and competent staff take full responsibility for ensuring patient safety, the type of cases described in this 2007 SHOT Annual Report and its predecessors could be consigned to history.

New developments

Developments in the SHOT team

Since the last report in November 2007, SHOT has embarked on a team-building process starting with a new Operations Manager, Mr David Mold, who will join SHOT during summer 2008. One of his initial tasks will be an options appraisal process of potential IT systems to support SHOT's data input, storage and analysis, encompassing past, current and future SHOT data. Two further new appointments, a clinical incidents specialist and a laboratory incidents specialist, are planned.

Near Miss Events

Near Miss data have not been collected during 2007. A pilot of pre-laboratory Near Miss errors relating to phlebotomy and sample labelling took place in April 2008. There was a good participation rate and the data are currently being analysed. The second part of the pilot, looking at laboratory-related Near Miss events, will take place in the Autumn 2008. A chapter in this Annual Report outlines the classification of Near Miss events into the pre-transfusion testing phase, the testing phase and the collection and blood administration phase of the transfusion process. The potential barriers in place to prevent error are also discussed.

National Transfusion Laboratory Collaborative

The SHOT-initiated National Transfusion Laboratory Collaborative has produced evidence-based recommendations around laboratory automation and staffing numbers, skill mix and qualifications. It is imperative that appropriate resource is made available to correct the current deficiencies, which are increasing risk for patients.

Cell Salvage

A collaboration between SHOT and the UK Cell Salvage Action Group resulted in the commencement in June 2008 of a pilot collecting adverse events data relating to cell salvage.

Further updates on these initiatives will be available on the website (www.shotuk.org) and in the Newsletter.

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SERIOUS HAZARDS OF TRANSFUSION

SHOT

SUMMARY