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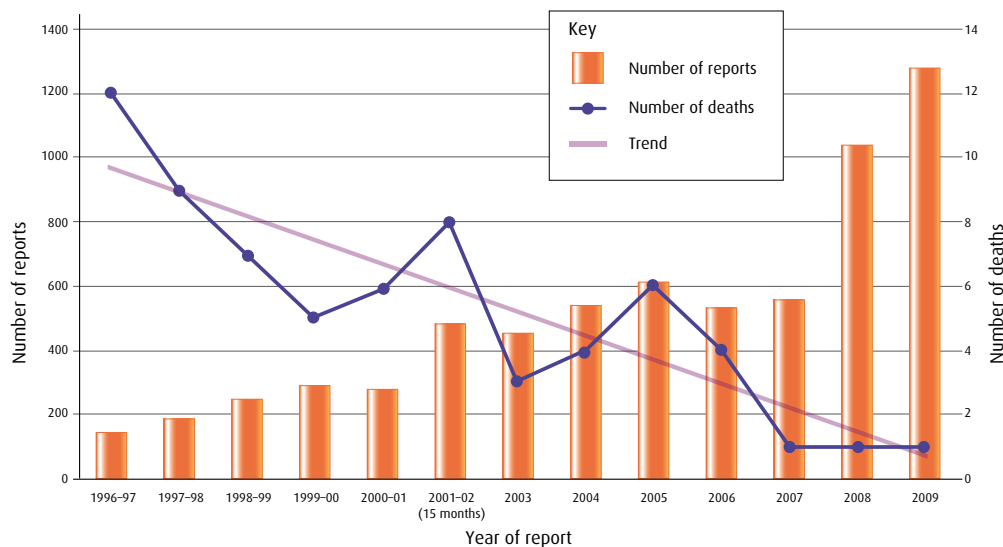
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Annual Report 2009 SUMMARY

Introduction

This 2009 report is the 13th annual report of data and evidence-based recommendations produced by SHOT. In the first year of SHOT reporting, 1996/97, there were 36 cases in which patients suffered major morbidity from transfusion (excluding 3 cases of potential D sensitisation in young women/girls), plus 12 deaths, resulting in a serious outcome for 48/141 or 34%, of cases reported. For this 2009 report 1279 cases were analysed: there are 73 cases of major morbidity (excluding anti-D related potential for major morbidity), plus one death definitely related to transfusion and 12 deaths in which the transfusion reaction may have contributed. The total number of patients with serious outcomes is 86/1279, i.e. a fall to 6.7%.

Trends in total reports and total deaths definitely attributable to transfusion between 1996 and 2009



This is the hallmark of an effective vigilance system, in that the participation in the scheme, and thus total reports, increases as users become engaged with the process while the number of serious incidents declines.

Participation in SHOT

SHOT has carried out detailed analyses of participation in haemovigilance reporting, publishing baseline data in the last (2008) report. These data show very important and positive trends in the patterns of reporting, with the number of organisations sending reports having increased substantially between 2006 and 2009. In 2006, 117 of 223 reporting organisations reported only errors and Near Miss events. In this report this number has reduced to 32 reporting organisations; however, the number of reporters sending reports of incidents in all three broad categories (errors, Near Miss and physiological reactions) has increased from 80 of 223 (36%) in 2006, to 206 of 255 (81%) in 2009. This reflects a big increase in awareness of blood safety issues and the direct benefits of participating in the scheme, and is a testament to the untiring work of members of the SHOT team in publicising SHOT and presenting SHOT data at numerous national and regional meetings, which has intensified since 2007.

Reporting to SHOT – new online system

SHOT reports are now collected directly from reporters into an online database, speeding up the process, increasing accuracy and completeness, and enhancing the potential for analysis of data. All types of reports, including all errors, reactions, Near Miss, anti-D and cell salvage related, and all MHRA reports are now collected by SHOT and the 'report to SHOT' box should always be ticked on the SABRE reporting page. Additionally, SHOT is keen to collect under- and over-transfusion cases, and all kinds of pulmonary complications of transfusion.

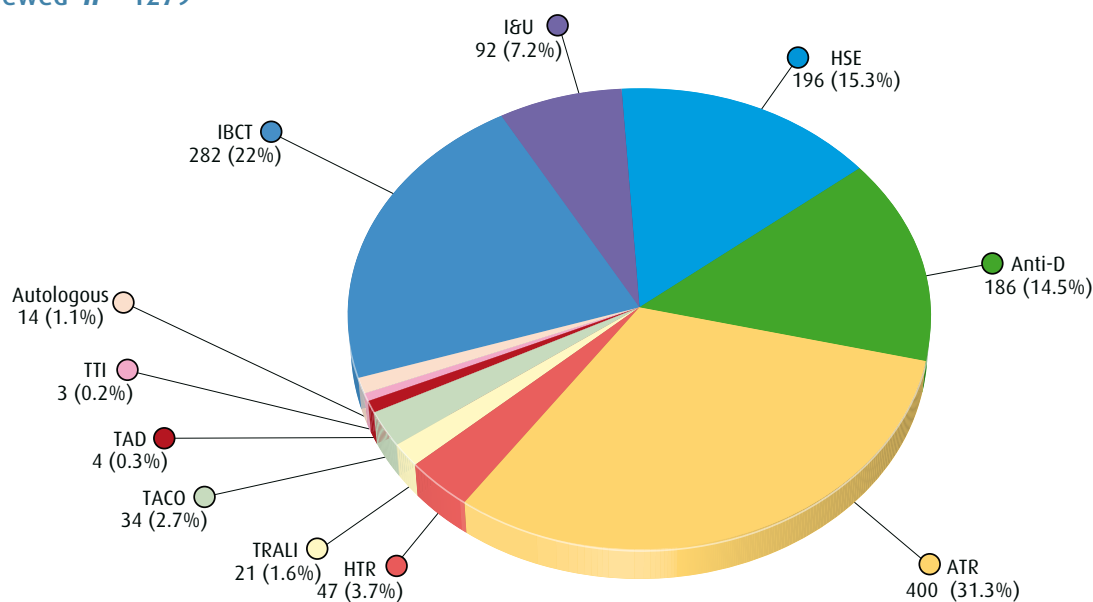
OVERVIEW OF 2009 REPORT

The total number of questionnaires reviewed this year is 1279. This represents an increase of 23% since 2008, when 1040 were reviewed. The figures are summarised in the table and figure below.

Summary of reports reviewed 2009

IBCT	I&U	HSE	ANTI-D	ATR	HTR	TRALI	TACO	TAD	PTP	TA-GvHD	TTI	AUTO-LOGOUS	Total
282	92	196	186	400	47	21	34	4	0	0	3	14	1279

Cases reviewed *n* = 1279



Yearly summary of issues by the 4 UK Blood Services 1999–2009

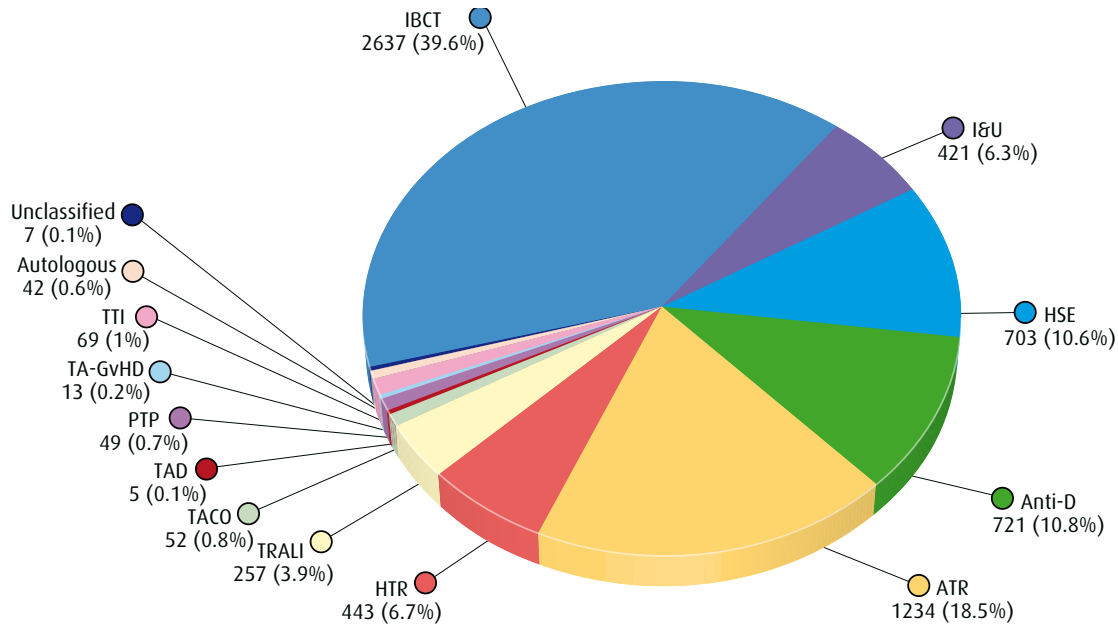
NB Additional 52,963 units of SD-FFP (Octaplas®) used in UK hospitals in 2008–2009

Year	Red Blood Cells	Platelets	FFP	Cryoprecipitate	Totals
1999–2000	2,737,572	249,622	365,547	94,114	3,446,855
2000–2001	2,706,307	250,259	374,760	95,456	3,426,782
2001–2002	2,679,925	251,451	385,236	88,253	3,404,865
2002–2003	2,678,098	251,741	377,381	92,768	3,399,988
2003–2004	2,607,410	264,539	372,855	95,417	3,340,221
2004–2005	2,428,934	258,528	313,019	102,719	3,103,200
2005–2006	2,316,152	259,654	320,852	106,139	3,002,797
2006–2007	2,235,638	255,474	306,444	116,672	2,914,228
2007–2008	2,174,256	258,419	295,085	117,699	2,845,459
2008–2009	2,209,153	266,312	306,740	121,555	2,903,760

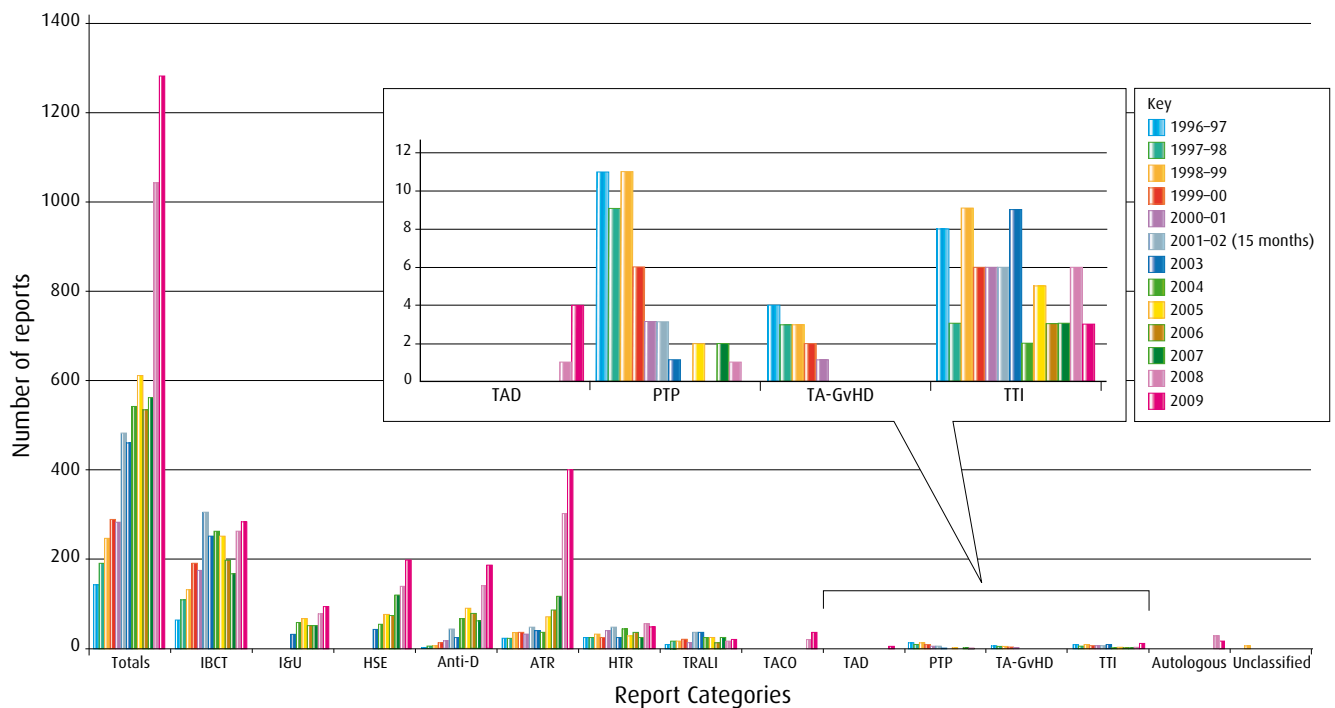
Total issues of blood components from the Transfusion Services of the UK in the financial year 2008–2009

Transfusion Service	Red Blood Cells	Platelets	FFP	Cryoprecipitate	Totals
National Blood Service	1,849,370	226,644	260,265	104,954	2,441,233
Welsh Blood Service	94,806	8,834	12,777	2,475	118,892
Scottish National Blood Transfusion Service	211,813	23,969	27,077	13,370	276,229
Northern Ireland Blood Transfusion Service	53,164	6,865	6,621	756	67,406
TOTAL	2,209,153	266,312	306,740	121,555	2,903,760

Cumulative numbers of cases reviewed 1996–2009 *n* = 6653



Comparison of report types 1996–2009



Cumulative mortality/morbidity data 1996–2009

	Total	IBCT	I&U	HSE	ANTI-D [†]	ATR	HTR	TRALI	TACO	TAD	PTP	TA-GvHD	TTI	AUTOL-OGOUS
Death in which transfusion reaction was causal or contributory	138	27	4	0	0	19	11	42	5	0	2	13	15	0
Major morbidity probably or definitely attributed to transfusion reaction (imputability 2/3)	495	116	3	0	25	58	48	165	18	1	13	0	48	0
Minor or no morbidity as a result of transfusion reaction	5998	3439	161	335	361	1154	383	50	29	4	34	0	6	42
Outcome unknown	15	11	0	0	0	3	1	0	0	0	0	0	0	0
TOTAL*	6646	3593	168	335	386	1234	443	257	52	5	49	13	69	42

* Total excludes 7 cases from 1998–1999 that were not classified

† Cases with potential for major morbidity included in the Anti-D data are excluded from this table

SUMMARY OF 2009 REPORT

Transfusion-related mortality and major morbidity

There was 1 death reported in 2009 which was considered to be directly due to the transfusion: this is a proven case of transfusion-transmitted *Pseudomonas koreensis* infection in an elderly man undergoing palliative care for carcinoma.

There were a further 12 deaths in which the transfusion contributed to a varying extent to the death of a patient who was already very unwell. These consisted of 3 IBCT events resulting in ABO-incompatible transfusion, 2 inappropriate and unnecessary transfusion (over-transfusion), 1 ATR, 2 TRALI and 4 TACO.

The total number of cases of major morbidity for 2009 is 73, plus 127 cases of potential major morbidity from late administration or omission of anti-D. The details are listed and discussed in the relevant chapters of the full SHOT Annual Report 2009.

Incorrect blood component transfused (IBCT)

A total of 282 cases are included in this category, representing a further increase in reports of 7.6% since 2008. A total of 14 ABO-incompatible red cell transfusions were given, 10 resulting from bedside administration errors, 2 from wrong blood in tube phlebotomy errors and 2 due to laboratory errors.

There were no deaths caused directly by transfusion, but 3 patients died following reactions that were considered to have contributed to their deaths: all 3 related to ABO-incompatible transfusion. There were also 3 cases of major morbidity from ABO incompatibility. In 2 of these the patients were also D incompatible. There were 5 further D-incompatible transfusions (1 administration error, 1 phlebotomy error and 3 laboratory errors).

A total of 149 (53%) of IBCT cases resulted primarily from a laboratory error and 133 (47%) from clinical and ward-based errors. In 2008 these figures were both 50%. Special requirements not met (SRNM) accounted for 154 reports, of which 87 were clinical errors and omissions and 67 originated in the laboratory. The biggest subgroup comprised the 91 patients who should have received irradiated blood but who did not.

Properly carried out patient identification, and a complete bedside check, could have prevented the 40 blood administration errors, the 4 wrong blood in tube (WBIT) errors and at least 8 of the laboratory cases of wrong blood (total 52 cases). This excludes SRNM cases that may also have been preventable at the bedside.



Inappropriate and unnecessary transfusion (I&U)

In 2009 a total of 92 cases were reported in the I&U category, an increase of 21% since last year. Two patients in this group died following over-transfusion, and this may have contributed to their deaths. In total 15 cases were paediatric, double the number for 2008, and these in particular related to the rate and volume of components given to small children. The 2 cases of severe morbidity were in paediatric patients; one required venesection after over-transfusion, and the other involved a baby with long-term sequelae following delayed and inadequate treatment of severe neonatal anaemia. SHOT is keen to collect and analyse data on under- and over-transfusion (see also TACO below).

As in previous years, the majority of cases relate to lack of knowledge and errors of judgement (often due to inexperience) in clinical staff. Education and senior support of staff dealing with transfusion-related problems remains a major objective for the Royal Colleges.

Handling and storage errors (HSE)

There were 196 cases in this category this year, an increase of 41% since 2008. There was no mortality and no major morbidity arising from these incidents. Once again the largest group was of cold chain errors, 84 cases, the majority (62 cases) relating to inappropriate storage of components. This year the second largest group concerned excessive time to transfuse, 69 cases, whereas in 2008 the next most frequent error was transfusion of expired components. Overall 43 (22%) of cases related to laboratory errors, while the majority (153, 78%) arose outside the laboratory and were the responsibility of clinical, portering and transport staff.

All staff involved in the transfusion process must understand the basic storage requirements of blood components. The cases in the SHOT report are those where the component was transfused, thereby posing a risk to a patient, but an additional concern is the many components wasted due to insufficient care being taken of cold chain requirements.

Anti-D related events

A total of 186 anti-D related events were reported to SHOT in 2009, an increase of 36% compared with 2008. There was no known fetal mortality from omission of anti-D, but there was 1 neonate who suffered HDN which had been missed due to an assumption that the anti-D detected was prophylactic, when it was in fact immune. There were 127 cases of potential major morbidity where anti-D had been omitted or given more than 72 hours after the event. Clinical causes accounted for 80% of the errors, compared with 66% in 2008.

There must be full traceability for anti-D administered to patients. If it has been given late or omitted for a woman of childbearing potential, the recipient should be followed up actively to check for formation of immune anti-D.

Acute transfusion reaction (ATR)

There were 400 reports in this category in 2009, an increase of 33% on last year's 300 cases. No deaths occurred as a direct result of ATR, but there was 1 case in which a patient died and the transfusion reaction possibly contributed to the death. There were 27 cases of major morbidity, the majority (17) being anaphylactic reactions. Once again the minor reactions were the most frequent, with 193 febrile and 84 uncomplicated minor allergic reactions.

It is essential that moderate or severe reactions are properly investigated, and the possibility of bacterial contamination considered and acted on appropriately. Reactions which later prove not to be bacterial must be reported in the ATR category.

Haemolytic transfusion reaction (HTR)

There were 47 reports in this section, 8 AHTR and 39 DHTR, a slight reduction from 2008 when there were 55 cases. There were no deaths caused, nor contributed to, by these reactions. There were 3 cases of major morbidity from AHTR and 5 cases from DHTR; 2 required ITU admission, and 6 suffered deteriorating renal function including 1 who required dialysis.

Reactions are frequently reported in patients with sickle cell disease, who are vulnerable to haemolytic reactions because they have a high rate of sensitisation, are prone to episodes of hyperhaemolysis, have clinical symptoms which can mask HTRs, and often move between different treatment centres. A national register of patients with antibodies would be very helpful in managing such patients.

Transfusion-related acute lung injury (TRALI)

There were 21 cases included this year: the graph in the full report showing TRALI cases by year of transfusion, rather than year of report, shows a continuing downward trend in numbers. There were no deaths definitely due to TRALI, but 1 patient death was probably related, and 1 possibly related to TRALI. Eighteen patients were treated in ITU; 13 were admitted because of the episode, constituting major morbidity, and 5 were already on ITU before the event and are also included as major morbidity. Ten patients required mechanical ventilation. Antibodies concordant with HLA antigens in recipients were found in 8 donors, all female: the components implicated were FFP (2 cases), platelet pools (3 cases) red cells in OA (3 cases, one of whom also received cryoprecipitate).

This reinforces the absolute requirement for provision of 100% male plasma for FFP and for suspension of platelet pools across all the UK blood services.

Transfusion-associated circulatory overload (TACO)

In 2009, 34 cases of TACO were reported, approximately twice as many as last year. There were no deaths definitely related to TACO, but 2 deaths probably related and 2 possibly related. There were 9 cases of major morbidity in which the patient was transferred to ITU. Three further patients were already in ITU at the time of the event so major morbidity was difficult to assess (but are included as major morbidity in the table on page 4). TACO therefore accounts for the highest number of cases of mortality and major morbidity in this annual report.

TACO is a relatively common complication of transfusion especially in the elderly and those with additional risk factors. Clinicians should be aware of the possibility of TACO, and its risk factors, and know how to minimise the chance of its occurrence bearing in mind also the appropriateness of the decision to transfuse (see I&U above).

Transfusion-associated dyspnoea (TAD)

Four cases of TAD were reported in 2009, with no mortality or major morbidity. One patient required CPAP as a result of the reaction.

TAD is a heterogeneous entity and cases are likely to have varying physiological mechanisms. Reporting of all pulmonary complications of transfusion is essential if further understanding of these is to be achieved.

Post-transfusion purpura (PTP)

There were no cases of PTP reported in 2009.

Transfusion-associated graft-versus-host disease (TA-GvHD)

No cases of TA-GvHD have been reported in 2009, nor any since 2000–2001. However, 2 cases occurred following transfusion of leucodepleted components (in 1998–99 and 2000–01). The absence of new cases must not be allowed to justify a relaxation of local practice in relation to provision of irradiated components. Irradiated components are administered to over 300,000 susceptible patients each year, and it is a highly effective method of preventing this universally fatal complication.

Transfusion-transmitted infection (TTI)

There were 3 reports this year, from 2 incidents. In the first incident, an expired apheresis platelet pack was contaminated with *Streptococcus pneumoniae*: associated units had been transfused to an adult with AML and 3 neonatal packs to a baby. Both patients suffered reactions, including a fever of 39.8°C in the adult patient and 40.5°C in the baby, but the reactions had not been identified as transfusion related. The second incident concerned an elderly patient with a malignancy who received red cells contaminated with *Pseudomonas koreensis*. He developed a pyrexia of 39.6°C and died the following day of transfusion-transmitted sepsis.

Patients developing moderate or severe pyrexia following blood component transfusion must be suspected of having bacterial sepsis, and be investigated and treated appropriately.

Autologous transfusion

There were 14 cases reported in this section in 2009, 6 relating to intraoperative cell salvage and 8 to postoperative cell salvage. Five adverse reactions were reported to postoperative, unwashed autologous transfusion, including pyrexia, rigor and bradycardia. There were 3 cases of hypotensive reaction related to reinfusion of intraoperatively cell-salvaged blood.

SHOT is continuing to collect all cases related to autologous transfusion, including those collected in collaboration with the UK Cell Salvage Action Group.



Paediatric cases

Altogether 110 cases (9% of all SHOT reports in 2009) related to patients under 18 years of age, including 34 cases in infants under 1 year old. As before, the majority of paediatric reports were error related (IBCT, handling and storage, inappropriate and unnecessary transfusion), comprising 58% (64) of reports in children, compared to the 42% of adult reports which are error related.

Incidents termed 'paediatric-related', rather than occurring in children by chance, include a large number of errors relating to dose and rate of transfusion for small children, and the correct use of 'flying squad' red cells. Special requirements are frequently missed (25 cases), in particular indications for irradiation and MB-FFP for children under 16 years old.

Near Miss events

Near Miss data were not analysed in 2009.

The new online SHOT database is now collecting brief details of all Near Miss events (including all SAEs reported via SABRE) and these will be analysed in the next report.

KEY MESSAGE AND RECOMMENDATIONS

Laboratory and clinical IT systems

2009 has seen the advent of a new subcategory of human error, specifically related to the use of IT systems both clinically and in the laboratory. Undoubtedly the occurrence of certain errors can be reduced by appropriate implementation of IT-based checking systems, but new possibilities of error may also be introduced. Over-reliance on IT and believing that it circumvents human error can result in a decrease in understanding of and engagement with the transfusion process among the staff involved. Adequate knowledge and skills are no less essential in the presence of a vein-to-vein electronic tracking system, and education and training must be comprehensive and appropriate to the staff groups involved at each stage.

Recommendation

Hospital transfusion laboratories need to liaise closely with manufacturers to develop and implement standard, detailed specifications for electronic systems in the laboratory, at the bedside and at the clinical-laboratory interface. An education package including minimum knowledge and skills, the appropriate use of these systems, and appreciation of their limitations should be a part of this joint project.

Action: CMOs' blood transfusion committees in England, Wales, Scotland and Northern Ireland working with stakeholders, blood transfusion services, clinical and laboratory transfusion specialists, manufacturers

Pulmonary complications of transfusion

The existing pulmonary categories are TRALI, TACO, allergic and anaphylactic reactions causing bronchospasm, and transfusion-associated dyspnoea (TAD). There are always additional cases reported to SHOT which are very hard to categorise within the definitions used by SHOT, based on ISBT definitions. Some cannot be included because they occur after the 6-hour cut-off post transfusion. The new online SHOT database collects all pulmonary complications of transfusion. This will be refined in the future to allow reporting of cases that do not currently fit existing definitions. For haemovigilance systems to identify new patterns of complications, or new causes of reactions, atypical data should be included.

Recommendation

All pulmonary complications of transfusion should be recorded and reported to haemovigilance systems even if they do not fully fit existing criteria. Research should be initiated to evaluate the current inclusion and exclusion criteria, especially for TRALI and TACO. A register of possibly implicated donors should be kept by the blood services.

Action: SHOT and its reporters, UK blood services and their R&D directorates

Patient identification

The patient identification errors occur due to staff not following established protocols, resulting in no true check of the patient taking place, and these errors are occurring despite the introduction of training and competency-assessments for all staff involved in the process. While professional responsibility must be taken by all personnel involved at each stage in the process (SHOT recommendations 2007) it cannot be escaped that the final 'bedside' patient ID check is the last chance to detect certain errors that can occur earlier in the chain, as well as being a critical point for new errors. Patients have been empowered, and encouraged, to ask doctors and nurses whether they have washed their hands before they make physical contact with the patient – this approach should now be used to ensure positive patient identification.

Recommendation

A patient education campaign should empower recipients of blood transfusion, and all patients undergoing tests, procedures and surgery, or receiving drugs and therapies, to ask the staff, before they carry out the intervention: *'Do you know who I am?'*

Action: NBTC, DH, Trust/hospital CEOs

Clinical handover

The European Working Time Directive has been implemented by law across the UK but few practical arrangements have been put in place by Trusts to deal with the inevitable problems for patient care that this poses. Proactive new systems are required, and need to be implemented by high-level management within Trusts/hospitals to ensure effective handover between shifts and teams, and continuity of patient care.

A new initiative by the Royal Colleges, spearheaded by the Royal College of Physicians, has developed a set of cross-disciplinary national standards and templates with e-learning modules in order to facilitate local implementation of a patient handover system. This tool allows a rolling electronic or paper update of current care, planned treatment and problems of patients, which is then used as the basis for a formal handover session at times of changing shift or on-call team.

Recommendation

Trusts must implement the use of a documented handover tool, such as the one recently developed by the Royal Colleges, as part of a formal patient handover system.

Action: DH, Trust CEOs

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