2020 Annual SHOT Report – Supplementary information

Chapter 3: Headline Data: deaths, major morbidity, ABO-incompatible transfusions and errors reported in haemopoietic stem cell transplant (HSCT) patients

The following table shows the risk of major morbidity and mortality for the various reporting categories per 100,000 components issued in 2020.

Table 3.2: Risk of major morbidity and mortality per 100,000 components issued in 2020

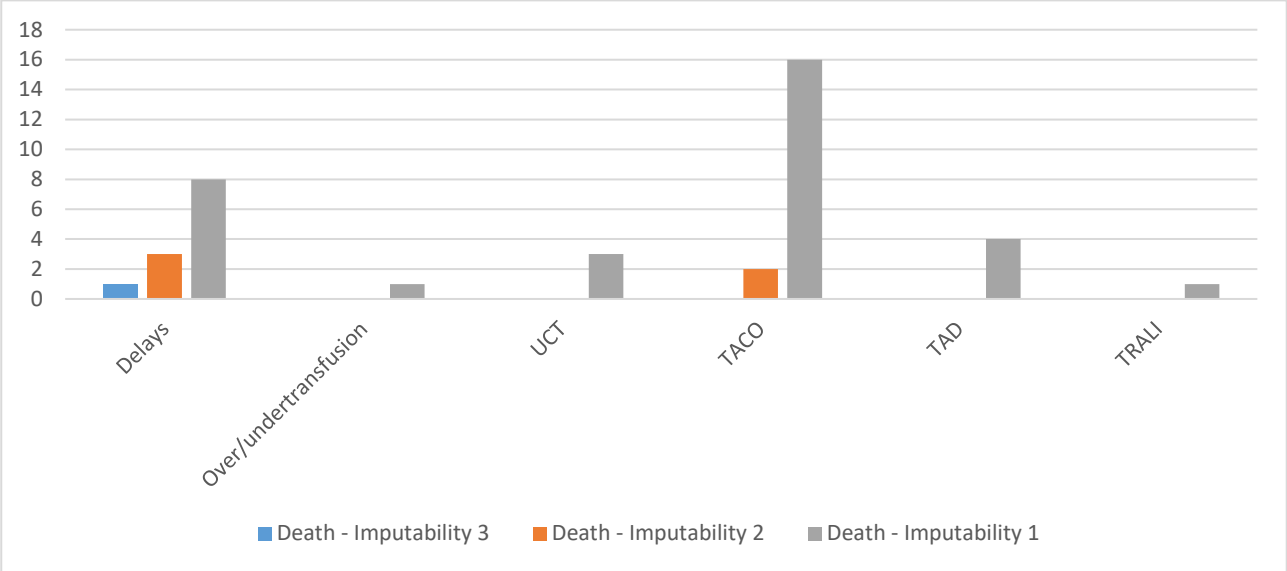
Total morbidity	**6.60**
Total mortality	**1.88**

	Mortality	**Major morbidity**
All errors	0.63	0.58
FAHR	0.00	3.86
HTR	0.00	0.58
TRALI	0.05	0.05
TACO	0.87	1.21
TAD	0.19	0.34
TAGvHD	0.00	0.00
PTP	0.00	0.00
CS	0.00	0.00
TTI	0.00	0.00
UCT	0.14	0.00
Paediatrics	0.14	0.92

Review of transfusion related deaths reported to SHOT

There were 39 deaths reported in 2020, this includes deaths definitely, probably and possibly (imputability 3, 2, and 1 respectively) related to the transfusion. This number is considerably higher than reported in previous years (see Figure 3.5 – cumulative data in Chapter 3 of the 2020 Annual SHOT Report) and has initiated a thematic analysis. Deaths reported in 2020 were noted mostly relating to TACO (n=18) and delays (n=12), and in which errors and omissions in patient care have, or may have, contributed to the patient's death (see Figure 3.12). Pathological reactions, such as, febrile, allergic, hypotensive and haemolytic reactions did not feature as contributory to deaths. Details of reviews into the various reporting categories can be found in the relevant chapters in the report.

Figure 3.12: Transfusion related deaths 2020 showing imputability



UCT=uncommon complications of transfusion; TACO=transfusion-associated circulatory overload; TAD=transfusion-associated dyspnoea; TRALI=transfusion-related acute lung injury

Structured incident investigations reports were performed, and shared with SHOT, for the single imputability 3 case and 4 of the 5 imputability 2 cases. Structured incident investigation was performed for only 18 of the 33 imputability 1 cases, with 7 of these being shared with SHOT.

Where transfusion-associated circulatory overload (TACO) was identified only 7 cases appear to have been subjected to structured incident investigation, 4 of these were shared with SHOT, despite this being a potentially avoidable complication. TACO remains difficult to diagnose, 2 cases were initially reported as transfusion-related acute lung injury (TRALI) but transferred following expert review, 1 case was identified as a result of traceability follow-up and another case was identified by the patient's family after reviewing the case notes. A TACO checklist was stated to have been used pre-transfusion in only 4/18 cases. COVID-19 was noted in 5 patients with TACO, 2 of these were recruited to the RECOVERY trial. Patients who suffer TACO often have co-morbidities, patient death in these cases may appear to be inevitable and RCA may be deemed unnecessary. However, a structured incident investigation may uncover areas for improvement to reduce the risk of TACO, which can be applied proactively in subsequent cases where pre-transfusion assessment and rapid escalation of transfusion reaction may save lives. This future potential application to TACO investigation was beautifully applied in one case and revealed deficiencies in documentation and clinical training in transfusion. structured incident investigation was more commonly applied in delays and under/overtransfusion, 11 of the 13 cases had reportedly been subject to structured incident investigation, with 6 of these being shared with SHOT.

Where structured incident investigation was performed, and shared (n=12), the quality of the investigation was generally good and included consideration of systems review and human factors. Root causes were multi-factorial, common themes included communication failures, knowledge and training deficiencies and inadequate staffing levels both in the clinical areas and in the laboratory. The effect of the COVID-19 pandemic was only mentioned in one case in relation to delays in investigation and discussion of the incident, despite 24/39 deaths occurring between March and

December 2020. Improvement actions were identified in 10 structured incident investigations, education and training was proposed as an intervention in 7 reports, audit/review of systems in 6 reports and changes to policies and guidelines in 5 reports. Other interventions included changes to information technology (n=2), improved documentation (n=2), simulation training (n=2), increased staffing (n=2), TACO checklist (n=1) and new equipment (n=1). Where actions were identified they often referred to review of systems, review of education and/or process mapping with no tangible improvement actions. Reviews and process mapping should be part of the structured incident investigation, not cited as an improvement action and this is indicative of an incomplete investigation process. It would be interesting to revisit structured incident investigations to see if the reviews have been completed and improvement actions implemented. Action plans did not always include responsibilities for implementation, time frames or sustainability of actions, and very few included any review of the effectiveness of the actions.

Structured incident investigation should be standard in all cases where transfusion may have contributed to death of a patient, as it provides an opportunity for learning and improvement. An effective structured incident investigation includes review of system design and human factors revealing all contributory factors and incidental finding that can then be addressed in the corrective and preventive actions (CAPA) (see SHOT Bite no.1(a): Incident Investigation). Corrective and preventive actions should address all findings, including those where resolution may be challenging. Interventions need to be SMART (specific, measurable, achievable, relevant and timebound) to be effective and truly reduce risk of recurrence. Vague actions, such as ‘educate ED nurses’ and ‘increase cell salvage training’ may be difficult to achieve without the specific details; ‘who’, ‘how’, ‘when’ and assurance that this has been completed. A review of the effectiveness of the interventions at a relevant time point following implementation will give assurance that adequate actions have been taken and that any improvements are sustainable. Improvement actions taken need to be embedded in the system to ensure that they are sustainable, for example, a one-off training session for a small group of staff employed at that time will not result in sustainable improvement, whereas including the learning into the regular transfusion training that all relevant staff must complete provides more resilience. Care must be taken to utilise the most effective intervention method, as described by intervention hierarchy (SHOT Bite No.1(b) Incident investigation follow up). It is accepted that some short-term remedial actions may be required in the immediate aftermath of an incident, these will inevitably be people focussed, including staff reminders, education and training, and changes to policies and procedures. However, system focussed, forcing interventions, such as using automation and IT, simplifying and standardising process, are much more likely to create sustained improvements and reduce risks of recurrence. The implementation of system focussed interventions should be accompanied by a change control process to ensure that no adverse impacts are introduced to the automation/IT, or to other related systems.

COVID-19 appears to have contributed in some degree to the increase in transfusion related deaths, being implicated as a co-morbidity in 5 TACO cases, but was not notable in cases of delayed transfusion, which are reviewed in detail in the ADU chapter. Despite the pandemic causing a significant strain on health service resources, challenges with patient care were not cited in the investigation reports, although it is accepted that SHOT do not have access to structured incident investigation reports for all incidents. Thorough investigation, including identification and implementation of improvement actions, is crucial in all potentially avoidable transfusion reactions and events and should be standard where there has been a death or major morbidity. All incidents

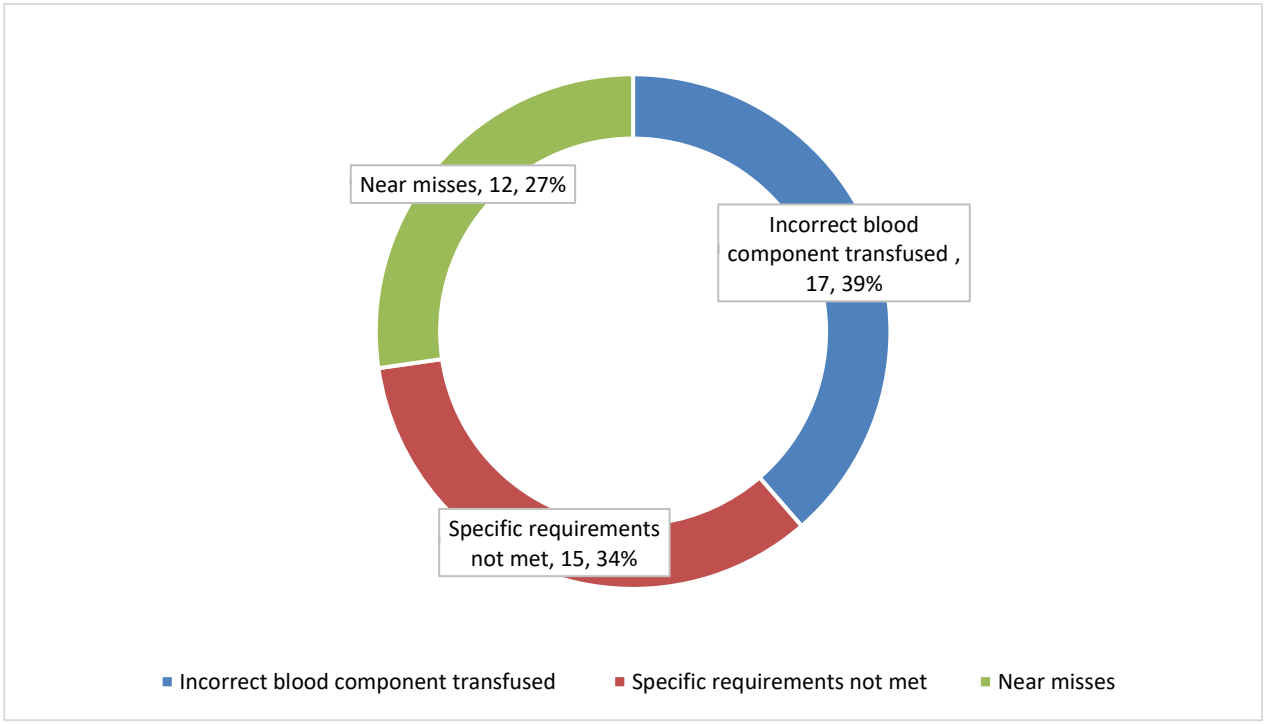
should be considered in terms of future potential, it is impossible to know how many lives have been saved because structured incident investigation and intervention principles have been applied to near miss events and cases where there is no clinical harm, but it has surely been time well spent.

Transfusion errors reported in haemopoietic stem cell transplant (HSCT) patients

This covers HSCT- related transfusion errors reported to SHOT in 2020. Solid organ transplants are not included in this analysis.

Transfusion errors continue to be reported in HSCT recipients. Most errors in this group of patients reported in 2020 involved incorrect blood component transfused (IBCT, n=17) and specific requirements not met (SRNM, n=15), a similar theme to that reported in the Annual SHOT Report 2019 which included an 8-year review. Near miss errors (n=12) were those detected prior to the transfusion and included 2 WBIT events.

Figure 3.13: Transfusion errors in HSCT patients reported to SHOT in 2020 n=44



A deep dive into these errors can be found here.

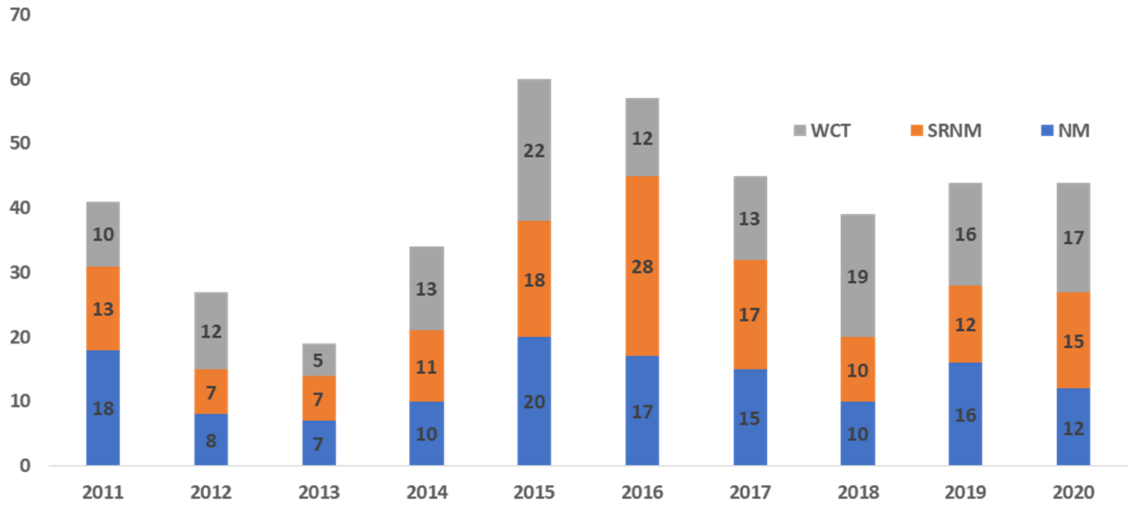
The most common errors were failure to provide irradiated components (n=14) and administration of components of the incorrect ABO and/or D type (n=21). These errors occurred due to failures within the communication process for specific requirements, or failures to add or heed the information recorded in the laboratory information system (LIMS). Common themes were also seen in the near miss events. Electronic issue of red cells via the LIMS is commonly used by laboratories but is not acceptable practice when the patient has received an ABO incompatible HSCT. Within the SRNM errors, 27% related to inappropriate use of electronic issue. No deaths in transplant patients were

attributable to errors, one case was noted where the patient's transplant was delayed due to failure to provide irradiated components in the period prior to the transplant.

Case 3.1: A patient whose blood group was B D-positive received an ABO-incompatible stem cell transplant. The transplant protocol was not sent to the laboratory and consequently the LIMS was not updated with information relating to the ABO/D type for component transfusion. The laboratory released an A D-positive platelet component for the patient, fortunately the clinical team compared this to the transplant protocol, noted that the first choice for platelets should have been B D-negative, and returned them to the laboratory. The laboratory was then notified of the transplant protocol which also stated requirement for O D-negative red cells. It was noted at this point that the patient record on the LIMS still allowed B D-positive red cell release via electronic issue.

The figure below summarises all the HSCT related transfusion errors reported to SHOT 2011-2020 (n= 410).

Figure 3.14: Cumulative data of incidents reported to SHOT relating to HSCT patients 2011-2020 (n=410)



NM=Near misses, SRNM= Specific requirements not met, WCT= Wrong component transfused (SRNM and WCT are categorised under IBCT=Incorrect blood components transfused)

Key messages: Robust communication processes must be in place between the transplant centre, all laboratories providing transfusion support, the referring centre, and any other shared care organisations. Communication must include specific requirements and recommendations for safe ABO/D component support along with the date of the transplant. Laboratories must have reliable processes for adding the specific requirement information to the patient record in the LIMS in a timely manner. Information relating to specific requirements must be easily accessible in the LIMS, flag and alert functionality must be used to its full potential to support safe provision of components. Laboratories must ensure that patients who have received an ABO-incompatible HSCT are excluded from electronic issue. These measures will help ensure safer transfusions in these patients.