

Annual NHO Report

National
Haemovigilance Office

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List of Abbreviations

| | |
|--------------|---|
| EBTS | Electronic Blood Track System |
| FNHTR | Febrile, Allergic and hypotensive reactions |
| HPRA | Health Products.Regulatory.Authority |
| HSE | Health Service Executive |
| HBB | Hospital Blood Bank |
| IUT | Intra Uterine Transfusion |
| LIS | Laboratory information systems |
| MNCMS | Maternal and Newborn Clinical Management System |
| NHO | National Haemovigilance Office |
| PPI | Positive patient identification |
| SAE | Serious Adverse Events |
| SAR | Serious Adverse Reactions |
| TACO | Transfusion Associated Circulatory Overload |
| TAD | Transfusion Associated Dyspnoea |
| TRALI | Transfusion related Acute Lung Injury |
| WBIT | Wrong Blood in Tube |

Introduction

Throughout 2021 the healthcare community continued to deal with challenges presented by the Covid-19 pandemic. The wider healthcare service worked hard to catch up on 'normal' healthcare which had been paused on several fronts during the early months of 2020. The Irish Blood Transfusion Service' (IBTS) saw increased demand for blood products in 2021. An increased demand and subsequent issue of greater numbers of blood products saw with it an overall increase in the number of reports submitted to the National Haemovigilance Office (NHO) in 2021.

The NHO noted an increase in the number of Serious Adverse Events (SAEs), Serious Adverse Reactions (SARs) and Near Miss reports in 2021. The increased number of reports received in 2021 corresponds with the numbers of reports seen in 2019, prior to the emergence of the Covid-19 pandemic. There was a decrease in the number of Wrong Blood in Tube (WBIT) reports received in 2021 which suggests that challenges posed by the Covid-19 pandemic may have led to the increase in the number of WBIT events seen in 2020.

On the 14th of May 2021, a further challenge presented itself to our healthcare system. The Health Service Executive (HSE) suffered a major ransom-ware cyber-attack which caused all HSE IT systems to be shut down. The cyber-attack prevented HSE staff from accessing electronic systems and records including laboratory information systems (LIS) and blood track. The disruptions contributed to transfusion errors and made haemovigilance reporting challenging for staff in the haemovigilance community.

Despite the many challenges during the year healthcare staff worked extremely hard to ensure the safe transfusion of quality products to our patients. Haemovigilance staff should be commended for continuing to report during very challenging times. Analysis of data submitted throughout 2021 enables us to identify areas of strength and weakness in both transfusion practices and haemovigilance reporting. Understanding system weakness and strength enables staff to develop mitigation strategies to prevent adverse events occurring should future challenges arise.

Participation in Haemovigilance

The NHO received 322 reports in 2021. SAEs and SARs comprise the majority (73%) of reports received (see Table 1). The number of SAE and SAR reports received in 2021 is comparable with the number of reports received in 2019. There was an increase in the number of WBIT reports submitted to the NHO in 2020. WBIT report numbers decreased in 2021 and are comparable with the number of reports received in 2019. Near Miss report numbers decreased for the third year in a row.

| Number of reports received by the NHO between 2019 and 2021 | | | |
|---|--------------|---------------|--------------|
| Report classification | 2019 (n=332) | 2020 (n= 313) | 2021 (n=322) |
| SAE | 100 | 83 | 102 |
| SAR | 135 | 118 | 133 |
| WBIT | 54 | 77 | 56 |
| Near Miss | 43 | 35 | 31 |

Table 1: Number and classification of reports received by the NHO between 2019 and 2021.

Blood component issues increased in 2021 from 2020 as the healthcare system returned to pre-pandemic activity levels (see table 2). It is quite likely that the reduction in components issued has had an impact on the reduced numbers of reports received for 2020.

| No. of components issued (2019-2021) | | | |
|--|---------|-----------|-------|
| | RCC | Platelets | Other |
| Total Number of components issued 2019 | 122,582 | 21,237 | 163 |
| Total Number of components issued 2020 | 113,766 | 21,049 | 92 |
| Total Number of components issued 2021 | 122,526 | 23,521 | 108 |

Table 2: Number of components issued by the IBTS (2019 – 2021).

There are 68 reporting establishments listed as capable of providing a blood transfusion in the Republic of Ireland. 32% of all sites listed have not submitted an SAE or an SAR in 2021. Sites that did not submit either an SAE or an SAR in 2021 were Category A hospitals, hospices or clinics where a low number of transfusions occur (<1000 units).

51% of SAE and SAR reports came from Hospitals which were in the blood usage category D (>6000 Units). Interestingly 25% of SAE and SAR reports came from hospitals categorised as blood usage category B (1000-3000 units). 12% of all SAE and SAR reports came from hospitals categorised as

blood Usage category C (3000-6000 units) and a further 12 % of reports came from hospitals categorised as blood usage category A (<1000 units) (see Table 3).

| Hospital Category | Total Number of reports received | Total DNP | Total SAE | Total SAE reportable to the competent authority | Total SAR | Total SAR reportable to the competent authority |
|--|----------------------------------|-----------|-----------|---|------------|---|
| Blood Usage Category A (<1000 units) | 29 | 4 | 12 | 4 | 13 | 7 |
| Blood Usage Category B (1000 – 3000 units) | 58 | 0 | 31 | 13 | 27 | 17 |
| Blood Usage Category C (3000 – 6000 units) | 29 | 3 | 12 | 6 | 14 | 8 |
| Blood Usage Category D (>6000 units) | 119 | 6 | 43 | 19 | 70 | 46 |
| Total no. of reports | 235 | 13 | 98 | 42 | 124 | 78 |

Table 3: Number and category of reports received by hospitals categorised by blood usage (2021).

Analysis of NHO reporting trends in SAE and SAR reporting indicates that the number of SAE and SAR reports received correlates with the number of reports issued. Despite the challenges to the healthcare system in both 2020 and 2021 there was not a significant rise in the number of SAE reports received. Reporting numbers for SAEs and SARs were similar to 2019 which suggests that haemovigilance reporting was not negatively impacted by the challenges that arose in 2020 and 2021.

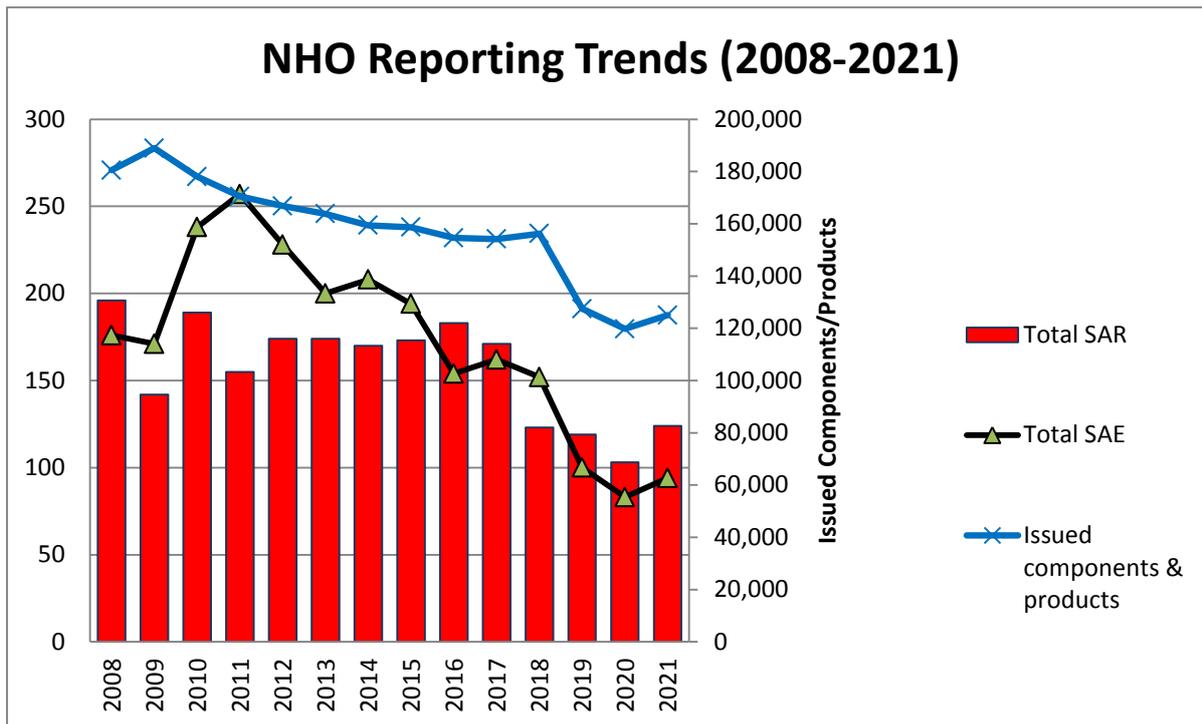


Figure 1: SAE and SAR reporting trends

The number of near miss reports has declined for the second year in a row. The decrease in number of near miss reports received in 2020 is also reflected in the number of units issued for the same year. Number of reports received from 2016 to 2019 did not correlate with number of reports issued for these years and may indicate that less SAEs occurred or that there was underreporting during this period.

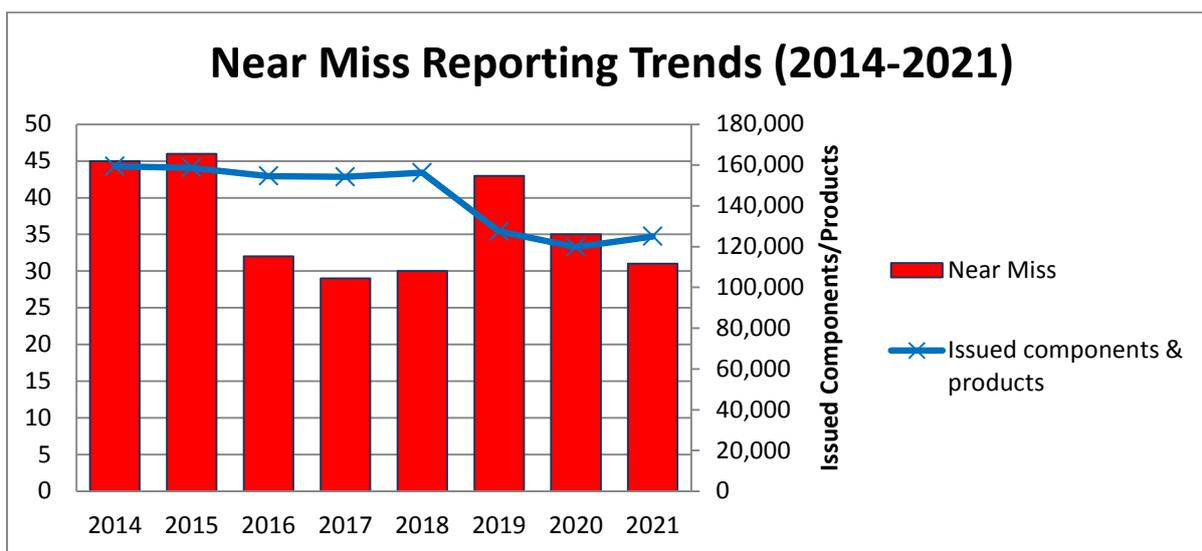


Figure 2: The number of near miss reports received by the NHO between 2014 and 2021

2021 was the third year that the NHO captured WBIT events. The number of WBIT reports received in 2021 was comparable to the number of reports received in 2019. Interestingly the number of WBIT reports received by the NHO in 2020 increased despite the decrease in the number of units

issued by the IBTS. This data would suggest that the Covid 19 pandemic had an impact on the number of WBIT events that occurred in this year

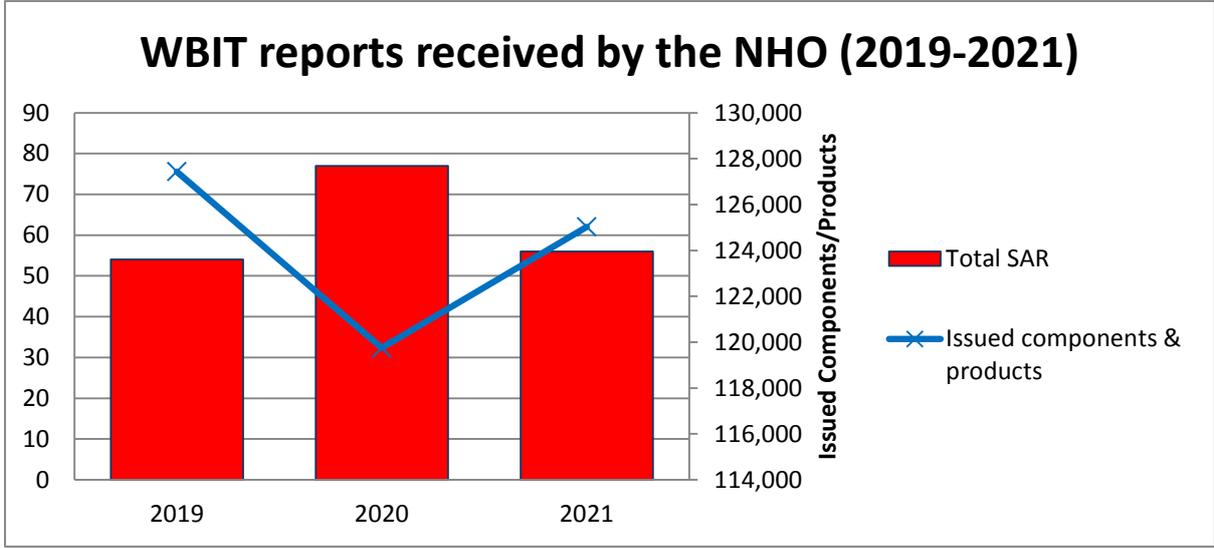


Figure 3: The number of Wrong Blood in Tube reports received by the NHO between 2019 and 2021

Serious Adverse Events (SAEs)

The NHO received 102 serious adverse event reports in 2021. 74 reports were accepted by the NHO and 32 reports were reported to the Health Products Regulatory Authority (HPRA). The breakdown in SAE reports can be seen in the figure below.

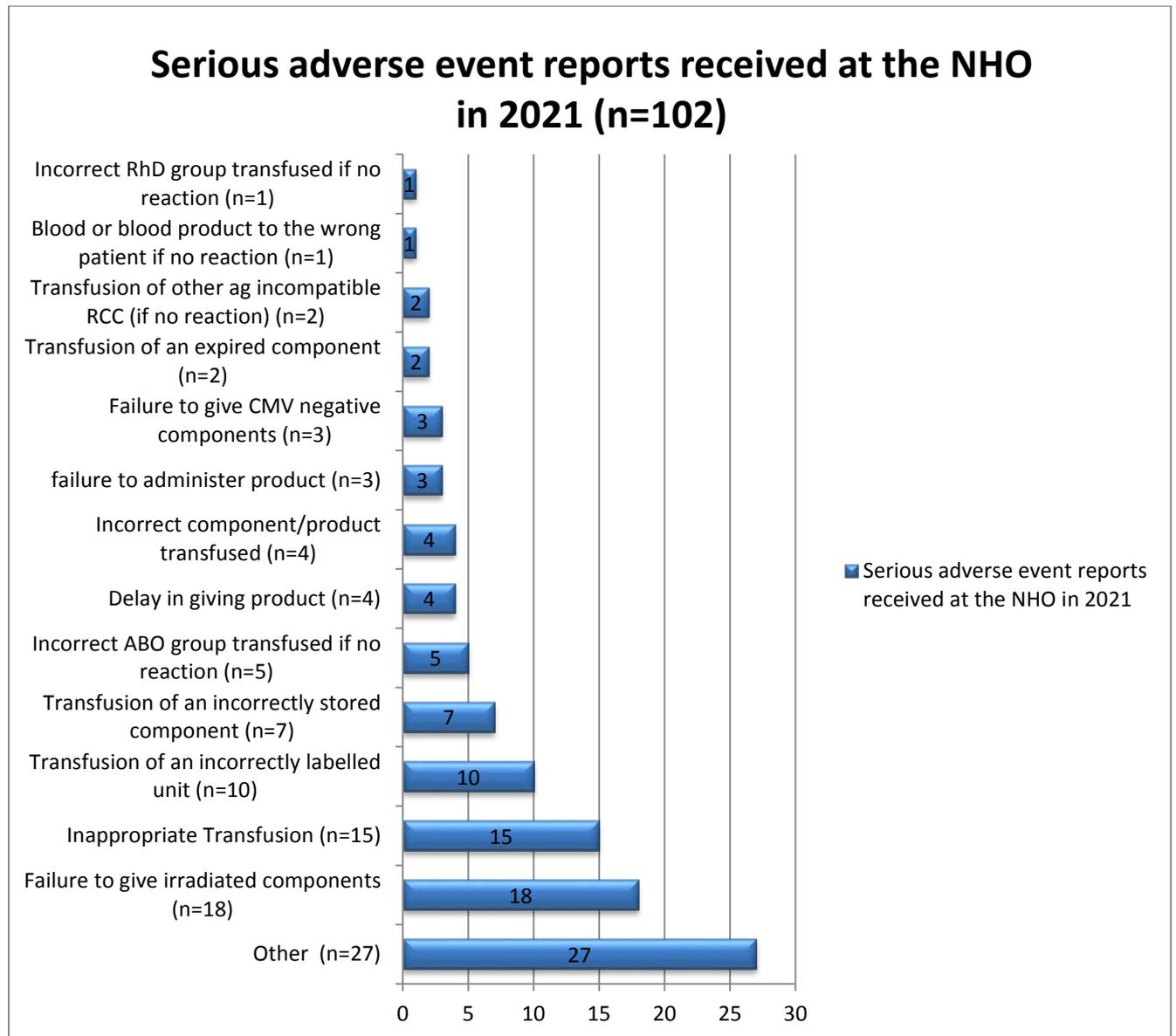


Figure 4: Categories of serious adverse events reported to the NHO in 2021

Other (n=23)

The NHO received 23 reports designated other from respondents in 2021. All reports were accepted and 10 were reported to the HPRA.

Errors occurred at different stages of the transfusion process. There were 9 reports designated other from transfusion stage designated other; 6 reports from the lab processing- blood transfusion stage; 6 reports from the administration stage, 2 reports from stage designated lab processing- other.

Error types varied. The majority of reports (n=9) were classified as other and included pump faults, over transfusion, exposure to an additional donor, and failure to prescribe transfusion rate. Three reports cited incorrect transfusion times as the error that occurred. There were two reports each of incorrect giving sets being used, incorrect result from technical error and communication errors. There was one report each of incorrect component issued, incorrect details on sample and incorrect details recoded during initial admission.

Human failure was cited as the causative factor in 21 reports and system failure cited on 5 reports. The human failure errors were identified as below:

- Failure to adhere to policy and procedure- 14 reports
- Failure in communication and co-ordination – 4 reports
- Carrying out task incorrectly – 3 reports
- Slip – 2 reports
- Other- 2 reports
- Monitoring – 1 report
- Patient related – 1 report

System failures included failures in design (n=1); materials (n=1); policies and procedures (n=1), culture (n=1); management priorities (n=1).

Failure to give an irradiated component (n=18)

The NHO received 18 reports of failure to give an irradiated component. Seventeen reports were accepted and seven of the seventeen reports were reported to the HPRA.

The majority of these errors occurred at the prescription stage of the process (n= 8), errors also occurred at lab processing (n=3), other (n=3), sampling (n=1), and initial clerking (n=1). One respondent left this section blank.

Prescription request errors were identified on 13 reports. The remainder of the reports (n=4) identified processing errors as the causative factor. 5 of the reports that found prescription errors as the causative factor came from one site. The cyber-attack was identified as a causative factor in 2 reports where processing errors occurred.

Three reports involved paediatric patients. Two reports involved infants (a one month old and 1 day old baby who had previously received an Intra Uterine Transfusion (IUT)). The remaining report involved a child between 5 and 11 years of age.

Human failure was cited as a causative factor in 16 reports and system failure cited on 3 reports. The human failure errors were identified as below:

- Failure to adhere to policy and procedure- 14 reports
- Knowledge - 6 reports
- Other - 2 reports.
- Failure in communication and co-ordination - 1 report.

System failures reported included policies and procedures (2 reports) and other (2 reports). Both reports that classed the system error as other involved errors that occurred as a result of the HSE cyber-attack.

Qualitative analysis of the details provided by the respondents suggests that failures in communication between clinical staff and lab staff were contributory factors in more than one event.

Staff members involved in these incidents includes doctors (n=11), nurses (n=5) and lab staff (n=4). The locations where the events occurred include wards (n=5), ICU (n=2), and Accident and Emergency (n=1).

Case 1a – Prescription Error and failure to give an irradiated component

A one month old paediatric patient with suspected Severe Combined Immunodeficiency Disorder was administered a non-irradiated paedipack. The patient had been admitted with congenital neutropenia and low Hb. The patient had been transferred from a maternity hospital critically unwell. The hospital Consultant Haematologist was not initially involved in the patient's care even though the patient had been under the care of a haematologist in the maternity hospital. The lab was unaware of the patient's requirements as no details of special requirements were recorded on the request form. The error was discovered when the patient needed an additional unit and the lab realised that special requirements were needed for that patient. Unfortunately this patient died, but death was not a result of transfusion. A flag was placed in the blood transfusion lab for irradiated products. Haemovigilance staff was aware of the need to drive education amongst medical staff regarding special requirements. Human error and knowledge were selected as causative factors for this case.

Case 1b – Processing error and cyber attack

A 71 year old female patient with Hodgkin's lymphoma was prescribed red cells for anaemia. The patient received 2 units of non-irradiated red cells. The laboratory information system was not working at the time of processing because of the HSE cyber-attack. The patient's special requirements were documented on the request form but not noticed by the medical scientist. The medical scientist was under pressure all as work processes had to be checked manually as a result of the HSE cyber-attack. The manual checking slowed down work processes and this system failure combined with the medical scientist's concern of not making a clerical error meant that the Medical scientist missed the special requirement. During retrospective issue of product on the LIS following retrieval of the system the error was noticed. The patient was not affected by the event. The Consultant Haematologist was informed of the error immediately. The Medical Scientists involved were informed of the error and the correct procedure to follow when processing crossmatch results. Appropriate lab procedures were reissued to medical scientists for review and revision of process. This error was attributed to human error. The system failure that led to the error was not documented on the report.

Inappropriate Transfusions (n=15)

The NHO received 15 reports of inappropriate transfusions. All reports were accepted and none of these reports were reportable to the HPRA.

Three errors occurred at the administration stage; 1 error at lab processing; 10 errors occurred at other stage and one error occurred at the prescription request form stage.

Respondents identified transfusion based on clinical decision not in conformity with guidelines in 7 reports. Transfusion based on incorrect or absent haematology results were identified in 5 reports. The remainder of the reports identified other factors (n=2) and one reported left the error category blank.

The majority of errors were cited as human error (n=14) and three reports cited system failure as the cause of the error. Human failure errors are as identified below:

- Knowledge - 7 reports
- Failure to adhere to policies and procedures - 6 reports
- Coordination and communication - 4 reports
- Slip – 1 report
- Other - 1 report

System failures included policies and procedures (n=1), culture (n=1) and other (n=1).

Inappropriate transfusions were most likely to involve doctors (n=14) and nurses (n=4). The majority of inappropriate transfusion errors occur in wards (n=10).

Case 2a Example of inappropriate transfusion

An elderly male patient with hemiarthroplasty was prescribed red cells on an incorrect Hb result. The bloods report in the patient's chart was that of another patient. The Hb result in the chart was 8.5 g/dl however the patient's actual Hb result was 10.8 g/dl. Red cells were requested for the patient based on the other patient's Hb result. Transfusion commenced but was quickly discontinued when the Consultant noticed the bloods report in the chart was for a different patient. The patient was not harmed. The case was discussed with the Consultant anaesthetist who ordered the unit. The consultant was fully aware of the risks associated with unnecessary transfusion. The error was classed as a human error with insufficient attention to detail on reviewing Hb result.

Transfusion of an incorrectly labelled unit (n=10)

The NHO received 10 reports of transfusion of an incorrectly labelled unit. All 10 reports were accepted and 7 reports were reported to the HPRA.

These events occurred most frequently at the blood transfusion laboratory processing stage (n=5). Errors also occurred at the stage designated laboratory processing other (n=2) the administration stage (n=1), initial clerking at hospital (n=1) and sampling (n=1).

Processing errors were identified in 6 reports accepted in 2021. Incorrect patient identifiers were identified in 2 reports. These events were a result of incorrect detail on Laboratory Information System (LIS) and incorrect details recorded on admission. Administration error and sampling error where the incorrect sample was processed were cited on one report respectively.

Human failure was more commonly attributed to these events with human failure cited in 10 reports and system failure cited in 2 reports. Human failures are as follows:

- Carrying out task incorrectly - (n=5)
- Verification errors - (n=3)
- Coordination and communication -(n=1)
- Failure to adhere to policies and procedures - (n=1)
- Other (n=1).

System failures included design (n=2) and other (n=1).

Nursing staff (n=10) and lab staff (n=9) were involved in transfusion of an incorrectly labelled unit events. These type of errors occurred more frequently in the lab (n=8) and ward (n=5) and less frequently on accident and emergency wards (n=3 reports).

Case 3a transfusion of an incorrectly labelled unit

A male orthopaedic patient was transferred from the Emergency department to the ward. When the patient was on the ward the nurses were made aware of an incorrect spelling on the patient's ID band. They informed the patient's doctor as the patient was prescribed red cells. The doctor contacted the lab to confirm details on LIS. The lab confirmed the name on the system and informed the doctor if the ID band was changed then a new sample would be required to be sent to the lab. As the details on LIS were what was on the ID band the doctor informed the nursing staff that they could give the unit. The nursing staff misunderstood that it was ok to change the ID band and continue with transfusion as the doctor did not specify to leave the ID band in place until the transfusion was complete. The error was discovered when further units were requested later that day from the laboratory. The HVO spoke to the people involved. The doctor was reminded to give clear instructions to the Nursing staff especially with regards to interactions they have with the lab to minimise any confusion or misunderstanding. The HVO informed the Nursing staff involved that to change the ID band made the initial transfusion sample invalid. The HVO also reiterated that any alerts they get using Blood track should be followed up with the lab. The implications of changing a patients ID band was discussed at the Interns weekly lecture. This case was captured as a human failure caused by failures in co-ordination and communication.

Transfusion of an incorrectly stored component (n=7)

The NHO received and accepted 7 reports related to the transfusion of an incorrectly stored component. 6 of these reports were reported to the HPRA.

Six errors were reported as occurring at the storage stage of the blood transfusion process. The seventh report identified the error as occurring at other. This error was a result of the blood not being scanned before it was put into the fridge so there was no cold chain record for the unit.

Human error was cited as the causative factor on all 7 reports with system errors cited on 6 reports. The types of human error cited on these reports included:

- Failure to adhere to policies and procedures - (n=1)
- Knowledge - (n=6)
- Coordination and communication - (n=2)
- Carrying out task incorrectly - (n= 1)
- Other - (n=1).

System errors were identified as issues with policies and procedures.

Four of these reports came from one location and were associated with the HSE cyber-attack. The four events occurred in the blood fridge room. The other events occurred on a maternity ward (n=1); lab (n=1) and on a ward (n=1). Staff involved in these events included nurses (n=6), doctors (n=4) and one lab staff member.

Case 4a transfusion of an incorrectly stored component and cyber attack

Red cells were ordered for a patient with hypotension and pleural effusion. A unit was rerouted from another hospital. Due to the cyber-attack manual temperature monitoring of blood fridges was conducted every two hours in the hospital sending the unit. The reporting hospital, who received the unit, deemed the manual check insufficient. The reporting hospital's policy was to manually check fridges every hour in the case of an electronic monitoring failure. The re-routed unit was added to the reporting hospital's stock and transfused. There was no ill effect on the patient. A medical scientist in the reporting hospital informed staff of the policy to check every hour. The original hospital changed their checking procedure. This case was captured as both a human failure and a system failure. The human failure was identified as knowledge and coordination and communication. The system failure was identified as policy and procedure.

Incorrect ABO group transfused if no reaction (n=5)

The NHO received 5 reports related to an incorrect ABO group transfused if no reaction. All 5 reports were accepted. Four of these reports were reported to the NHO.

All 5 errors occurred at the blood transfusion laboratory processing stage in the transfusion process.

Three of these reports were from the same hospital. Four reports stated that the incorrect component was issued. The other report stated that the error occurred because historical reports were not checked.

Human error was cited as the causative factor in all 5 reports. Failure in adhering to policy and procedure was attributed to the error in 4 reports. The other report cited that knowledge was a causative factor in the error that occurred.

All of these events occurred at the laboratory processing stage and involved laboratory staff.

Delay in giving product (n=4)

The NHO received 4 reports of a delay in giving product. All four reports were accepted by the NHO and none were reported to the HPRA.

All 4 reports cited human failure as a cause of error. The human failures identified by respondents include: failure to follow policies and procedures (n=2), verification (n=1) and communication and coordination (n=1). One report cited a system error-other as a contributory factor. The computers in the clinic were down and delayed presentation of the patient contributed to the delay in giving product.

Incorrect component/ product transfused (n=4)

The NHO received 4 reports related to incorrect component/product transfused and all reports were accepted. Two reports were reported to the HPRA.

The four errors all occurred at different stages in the transfusion process. Two events occurred at laboratory processing with one reported as other and the other at the blood transfusion stage, another report identified the stage of error as other and a final report stated that the error occurred at the prescription request stage.

All of the reports cited human failure as the cause of the error. System failure was not cited on any of the reports. Respondents considered failure to follow policies and procedures as the causative factor for the error in three reports. Carrying out task incorrectly was cited on one report.

Two reports involved processing errors; 1 report involved a prescription request error and the other report was an inappropriate transfusion. In the case of the inappropriate transfusion the incorrect haematology advice was received as to the appropriate product for administration.

Two of these errors occurred in laboratories; one on a ward and the other in A and E. Two of the errors involved doctors and two errors involved medical scientists.

Failure to administer product (n=3)

The NHO received 3 reports of failure to administer product and all reports were accepted. None of these reports are reportable to the HPRA.

Human error was cited as the error type on two reports. The other report did not cite any error type or error cause. Verification error was cited as the causative factor on one report and failure to follow policy and procedures was cited on two reports.

Failure to give CMV negative components (n=3)

The NHO received 3 reports where there was a failure to give CMV negative components. All three reports were accepted. One report was reported to the HPRA.

Two events occurred at the prescription request stage of the process and one at blood transfusion laboratory processing.

Human failure was cited as the cause of error on all three reports. One report cited that failure to follow policies and procedures led to the error; another report cited both failures to follow policy and procedure and knowledge as the causative factors of the error; the final report cited knowledge as the causative factor of the error.

The reports cited various errors that occurred. One report was caused by the failure to prescribe CMV negative components; another report cited that the special requirements were not requested and the final report stated that the incorrect component was issued.

The errors occurred in different locations one occurred in ICU, another in the laboratory and the final error occurred on a ward. The errors that occurred on the ward and ICU involved both doctors and nurses. The error that occurred in the laboratory involved a medical scientist.

Transfusion of an expired component (n=2)

The NHO received 2 reports of transfusion of an expired component. Both reports were accepted. One report was reportable to the HPRA.

One error occurred at the administration stage of the transfusion process. The other report identified the stage of the process where the error occurred as other.

One report cited human failure slip as the cause of the error. The other report cited both system and human failures as the cause of the error. This report cited failures in design as the system error and failures to follow policies and procedures and carrying out task incorrectly as human failure.

Both errors involved nursing staff and one also involved a medical scientist. One error occurred on a ward and the other in theatre.

Transfusion of other antigen incompatible RCC (if no reaction occurred) (n=2)

The NHO received two reports of transfusion of other antigen incompatible red cells (if no reaction occurred) and accepted both reports. Both reports were reported to the HPRA.

Both errors occurred at the blood transfusion laboratory processing stage of the transfusion process.

One report cited human failure as the cause of the event. The other report cited both human failure and system error as causative factors. Failure to adhere to policies and procedures, carrying out task incorrectly and other were identified on the reports.

Both errors occurred in laboratories and involved laboratory staff.

Blood or blood product given to the wrong patient if no reaction (n=1)

The NHO received one report where blood was issued to the wrong patient. This report was accepted and reported to the HPRA.

This error occurred at the laboratory processing stage in the blood transfusion laboratory and involved laboratory staff.

The respondent cited human failure as the cause of this error. Failure to adhere to policies and procedures, carrying out task incorrectly and coordination and communication were identified as the human failures that led to this error.

A medical scientist had not written the order in daily request log at time of issue. A second Scientist issued units to wrong patient.

Incorrect RhD group transfused if no reaction (n=1)

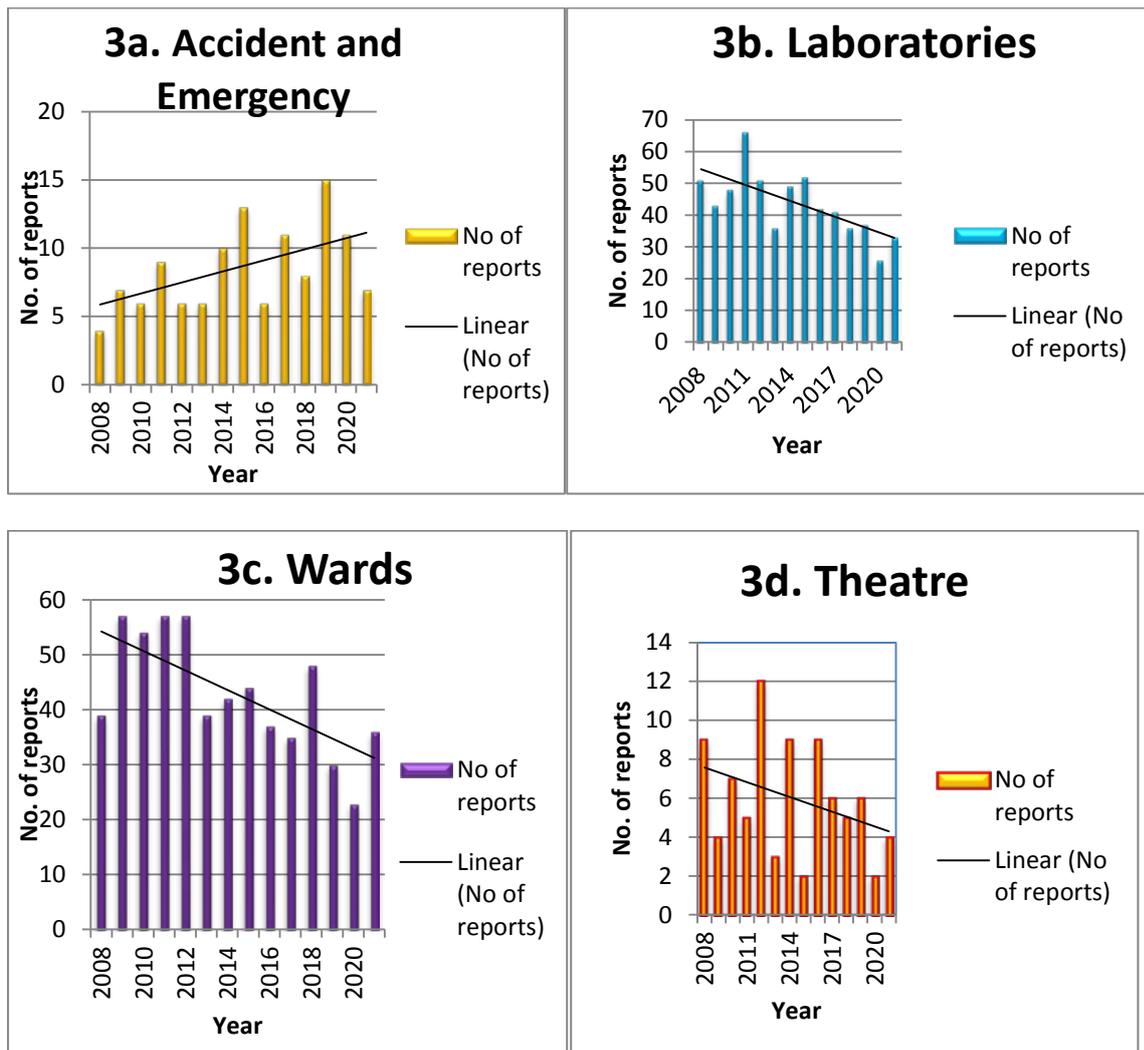
The NHO received one report of an incorrect RhD group transfused if no reaction. This report was accepted and reported to the HPRA.

The error occurred in the laboratory at the blood transfusion laboratory processing stage and involved a laboratory staff member. .

This error was attributed to human failure with the cause of the error considered to be a slip.

Analysis of errors by location

Laboratories and wards are the locations where a greater number of reported SAE occur. The number of SAE reports increased in all locations in 2021 from 2020 with the exception of Accident and Emergency departments. Despite the increase in SAE reports in 2021 the NHO has reported a downwards trend in the number of reports received from most locations with the exception of Accident and Emergency departments and day wards. Unfortunately there is no denominator data available for the number of transfusions undertaken in each of these areas.



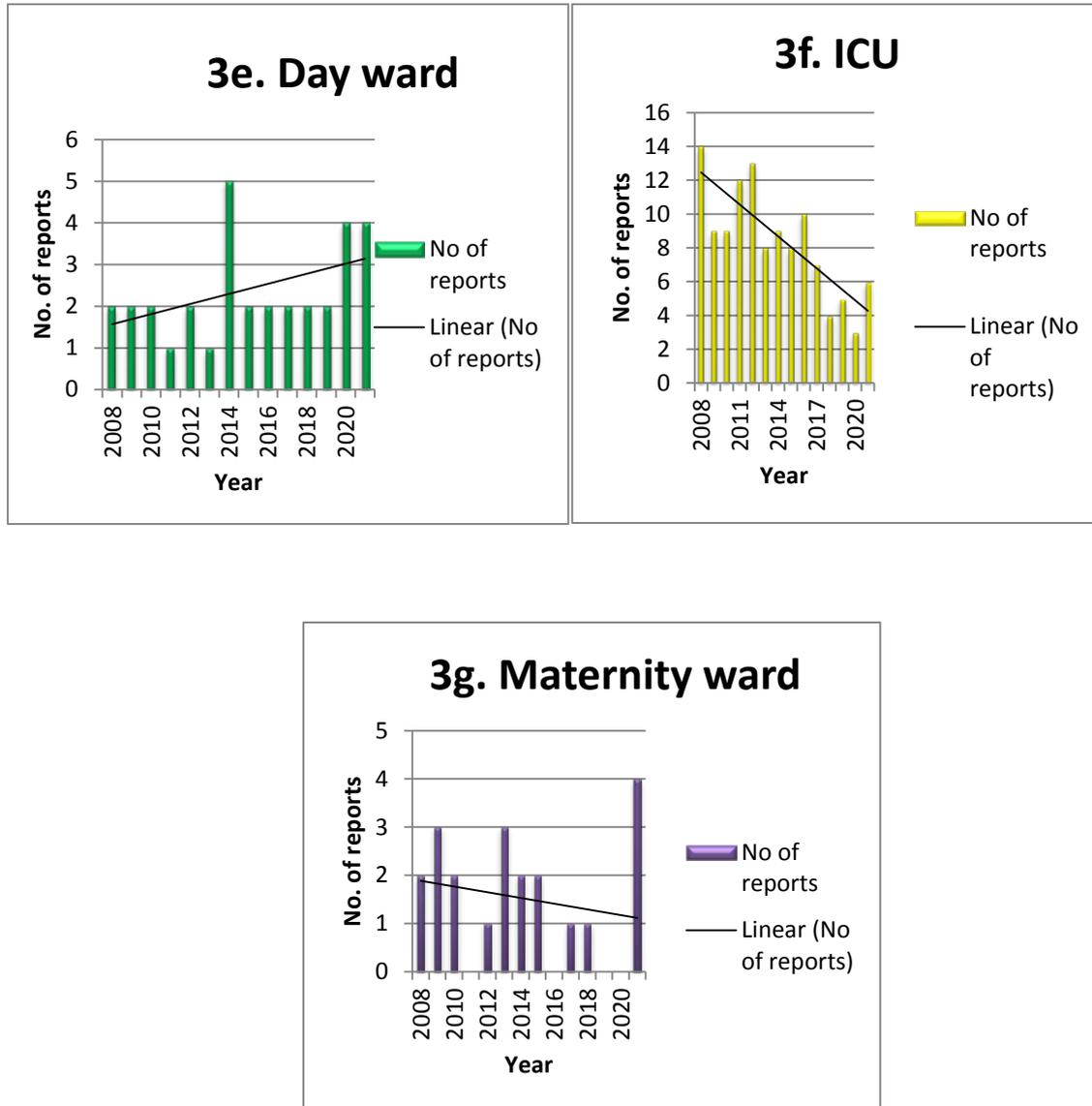


Figure 5: Trends of SAE reports from different department

Who is involved in Serious adverse Events?

The data suggests that doctors, nurses and lab staff remain the target groups for training and education as these staff groups were involved in events reported to the NHO in 2021 (see figure 6). None of the reports received by the NHO identified other staff members, e.g. porters or phlebotomists, involvement in SAEs in 2021.

There is no denominator data available to determine the number of transfusion samples taken by different staff groups. Determining the amount of transfusion samples taken by each staff group may enable establishments to decide whether staff groups such as nurses and doctors need more targeted training and education or whether health care assistant phlebotomists should take all transfusion samples.

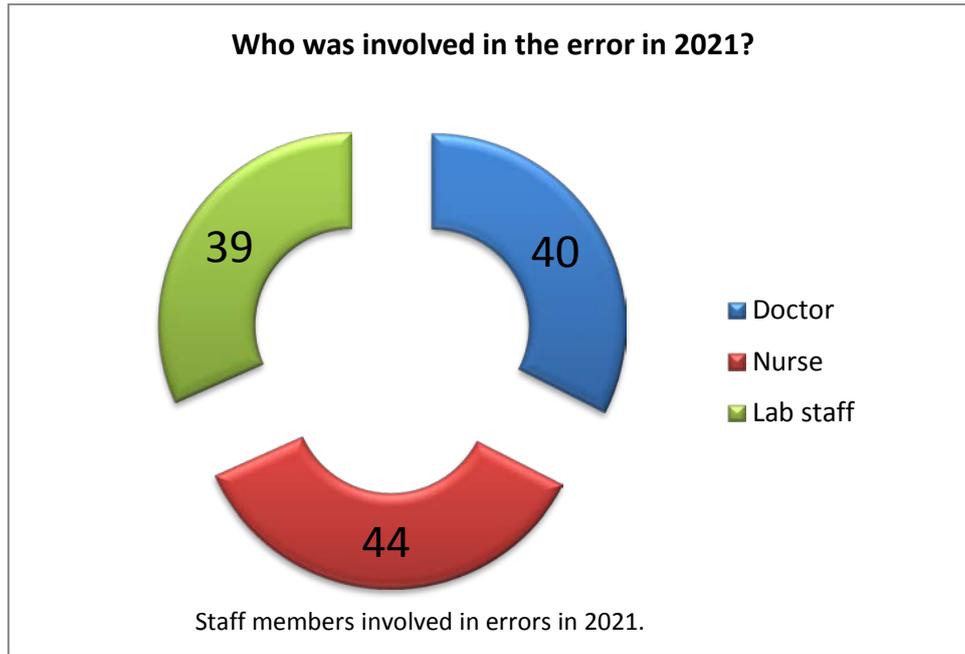


Figure 6: Staff members involved in serious adverse events in 2021

Why did the errors occur?

Human error remains the most common cause of error cited by respondents in reports accepted by the NHO. In 2021 human error was cited 86 times and system error was cited 21 times on the reports accepted.

| Types of Human Error | No. of reports (n=87) 2019 | No. of reports (n=67) 2020 | No. of reports (n=90) 2021 |
|--|----------------------------|----------------------------|----------------------------|
| Failure to adhere to policies and procedures | 60 | 33 | 48 |
| Knowledge | 19 | 19 | 24 |
| Co-ordination and communication | 14 | 14 | 13 |
| Carrying out task incorrectly | 18 | 12 | 13 |
| Other | 7 | 9 | 9 |
| Verification | 25 | 7 | 3 |
| Slip | 9 | 3 | 5 |
| Monitoring | 4 | 1 | 1 |
| Patient related | 2 | 1 | 1 |

Table 4: Types of human error identified on SAE reports in 2021

Failure to adhere to policies and procedures remains the most common causative factor cited on reports accepted by the NHO. There was an increase in the number of reports that cited knowledge as a causative factor in 2021. Issues with co-ordination and communication and carrying out tasks incorrectly persist and were the third most common cause of events in 2021.

While we know that staff have failed to follow policies and procedures in many of the events reported it is difficult to determine why staff continue to fail to adhere to policies and procedures that are in place. Understanding why staff has failed to follow established policies and procedures could help the NHO and HVOs to determine whether system and or environmental adjustments could help staff to better follow best practice when carrying out tasks.

The slight increase in reports that identify issues with knowledge among staff may suggest that staff require further training or refresher training in particular aspects of transfusion.

Issues with coordination and communication could be addressed by examining all aspects of the transfusion process to see if improvements in communication and coordination need to be addressed.

Serious Adverse Reactions (SARs)

The NHO received 133 serious adverse reaction reports in 2021 and accepted 124 reports. 78 SAE reports were reportable to the HPRA. The breakdown of SAR reports can be seen in figure 7 below.

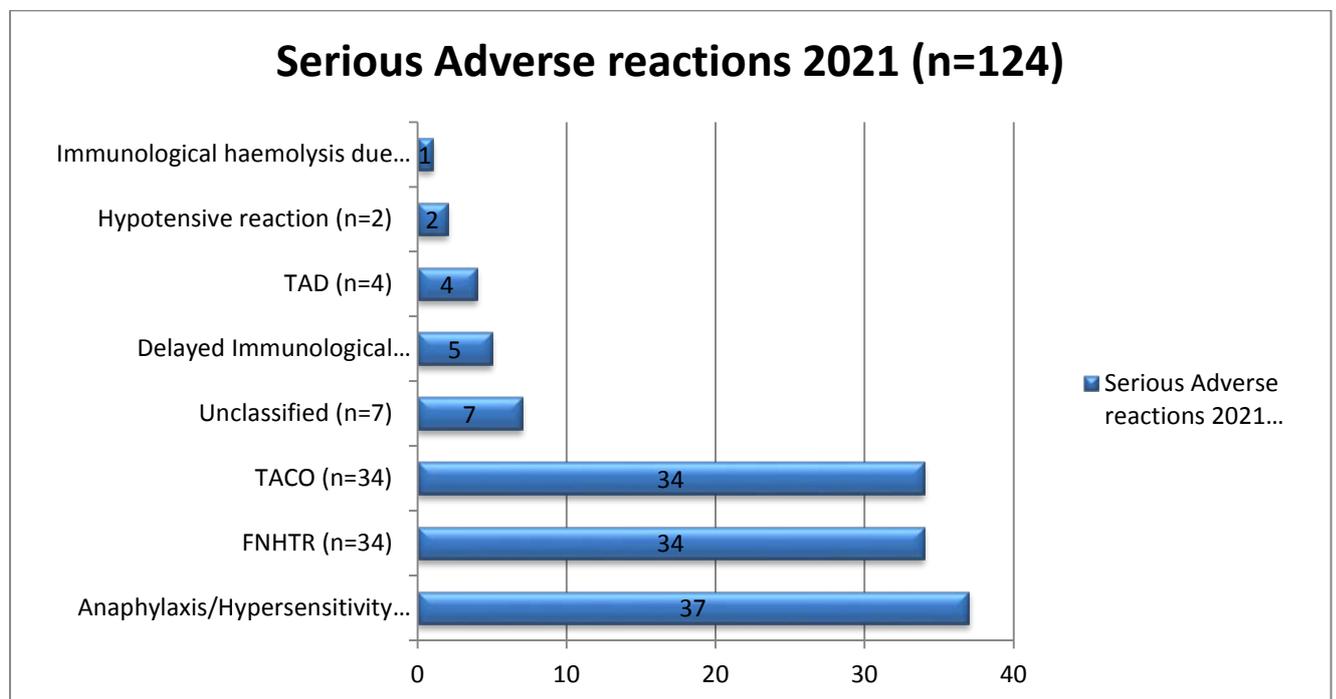


Figure 7: SAR reports accepted by the NHO in 2021.

Febrile, Allergic and hypotensive reactions (FNHTR) (n=80)

The NHO received 80 reports related to FNHTR, Anaphylaxis/Hypersensitivity reactions or hypotensive reactions and accepted 73 reports. The majority of patients made a complete recovery (n=62), some patients had minor sequelae (n=10) and one report had no clinical outcome recorded.

The table below shows the classification of such reactions.

| | <u>1 = Mild</u> | <u>2 = Moderate</u> | <u>3 = Severe</u> |
|-------------------------------------|---|---|--|
| <u>FNHTR</u> | A temperature $\geq 38^{\circ}\text{C}$ and a rise between 1 and 2°C from pre-transfusion values, but no other symptoms/signs | A rise in temperature of 2°C or more, or fever 39°C or over and/or rigors, chills, other inflammatory symptoms/signs such as myalgia or nausea which precipitate stopping the transfusion | A rise in temperature of 2°C or more, and/or rigors, chills, or fever 39°C or over, or other inflammatory symptoms/signs such as myalgia or nausea which precipitate stopping the transfusion, prompt medical review AND/OR directly results in, or prolongs hospital stay |
| <u>Anaphylaxis/Hypersensitivity</u> | Transient flushing, urticaria or rash | Wheeze or angioedema with or without flushing/urticaria/rash but without respiratory compromise or hypotension | Bronchospasm, stridor, angioedema or circulatory problems which require urgent medical intervention AND/OR, directly result in or prolong hospital stay, or anaphylaxis (severe, life-threatening, generalised or systemic hypersensitivity reaction with rapidly developing airway and/or breathing and/or circulation problems, usually associated with skin and mucosal changes) |
| <u>Hypotensive</u> | | Isolated fall in systolic blood pressure of 30 mmHg or more occurring during or within one hour of completing transfusion and a | Hypotension, as previously defined, leading to shock (e.g. acidaemia, impairment of vital organ function) without allergic or inflammatory symptoms. Urgent |

| | | | |
|--|--|---|-------------------------------|
| | | systolic blood pressure 80 mmHg or less in the absence of allergic or anaphylactic symptoms. No/minor intervention required | medical intervention required |
|--|--|---|-------------------------------|

Table 4: Classification of reactions

Anaphylaxis/Hypersensitivity Reactions (n=37)

The NHO received 42 reports related to anaphylaxis/hypersensitivity reactions and accepted 37 of these reports. 20 anaphylaxis/hypersensitivity reactions were reported to the HPRA.

The majority of anaphylaxis/hypersensitivity reaction reports accepted by the NHO in 2021 were for adults. The NHO accepted 25 reports of reactions in adults and 12 reports of reactions in children. 59% of paediatric anaphylaxis/hypersensitivity reactions accepted in 2021 occurred in adolescents age 12-17.

Apheresis platelets were most commonly associated with anaphylaxis/hypersensitivity reactions.

| Unit type | No. of reports (n=37) |
|----------------------------|-----------------------|
| RCC | 6 |
| Apheresis platelets | 23 |
| Pooled platelets | 8 |
| SD plasma | 0 |

Table 5: The number of reports and units involved in anaphylaxis/hypersensitivity reaction reports 2021

Steroids and anti-histamines were the treatments most commonly administered to patients with anaphylaxis/hypersensitivity reactions.

| Treatment given | No. of reports (n=37) |
|-----------------------|-----------------------|
| Anti-pyretic | 7 |
| Antibiotics | 2 |
| Steroids | 28 |
| Fluids | 7 |
| No treatment | 0 |
| Anti-histamine | 35 |
| Nebuliser-inhaler | 6 |
| Diuretics | 0 |
| Oxygen | 9 |

Table 6: Treatments given to patients with anaphylaxis/hypersensitivity reactions 2021

It is recommended if anaphylaxis is suspected to give adrenaline to the patient. Antihistamines are recommended for less severe reactions. The effect of steroids is delayed by several hours, will have no immediate effect, and should only be used to prevent a late recurrence. Steroid use may further immunosuppress already immune-compromised patients and increase the risk of side effects such as infection (SHOT, 2022).

It is noted that 62% of anaphylaxis/hypersensitivity reactions reported to the NHO in 2021 are linked to apheresis platelet components. The IBTS intends to introduce additive solution and pathogen reduction for this component which will likely impact the number of this type of reaction reported in the future.

Case 5: A two year old female patient with neuroblastoma received one unit of pooled platelets and developed an anaphylaxis/hypersensitivity reaction approximately 50 minutes after transfusion commenced. The patient developed hypertension (132/102), substernal discomfort and falling O2 saturation (88%). The patient received O2, antihistamines and steroids and made a complete recovery within 30 minutes. The transfusion committee decided that in the future this patient would receive pre-medication with hydrocortisone and piriton.

Febrile non-haemolytic transfusion reactions (FNHTRs) (n=34)

The NHO received and accepted 34 FNHTR reports in 2021. 11 FNHTR reports were reported to the HPRA. Two of the reports involved paediatric patients aged between 5 and 11 years. The remaining 32 reports involved adult patients.

Red cells were more commonly associated with FNHTR reports.

| Unit type | No. of reports (n=34) |
|----------------------------|-----------------------|
| RCC | 30 |
| Apheresis platelets | 3 |
| Pooled platelets | 1 |
| SD plasma | 0 |

Table 7: Unit types associated with FNHTR in 2021

Anti-pyretics are the most commonly administered treatment to patients with suspected FNHTR. However, in 9 incidences antibiotics were administered and in 6 instances anti-histamines were administered.

| Treatment given | No. of reports (n=34) |
|-------------------|-----------------------|
| Anti-pyretic | 25 |
| Antibiotics | 9 |
| Anti-histamine | 6 |
| Fluids | 5 |
| Steroids | 2 |
| No treatment | 1 |
| Oxygen | 0 |
| Nebuliser-inhaler | 0 |
| Diuretics | 0 |

Table 8: Treatments administered to patients with FNHTR in 2021

Case 6: A 59 year old male patient with MDS received one unit of red cells for anaemia. The patient developed shivers 90 minutes after transfusion commenced and the rate was slowed down by the medical team. 20 minutes later the patient's temperature rose from 36.8° to 39.1 °. The transfusion was stopped temporarily and the patient was observed. Eventually the decision was made to discontinue the transfusion completely. The patient was administered antibiotics and anti-pyretics. The patient made a complete recovery. The hospital transfusion committee decided that this patient did not require special requirements as they had received a subsequent transfusion without any issues.

Hypotensive reactions (n=2)

The NHO received 2 reports of Hypotensive transfusion reactions in 2021. Both reports were accepted and both reports were reported to the HPRA.

One report was related to an elderly male patient (>70 years) with prostate cancer who received a red cell component for anaemia. The patient's blood pressure dropped from BP 90/55 to 74/36. The patient was admitted to the high dependency unit (HDU) and was administered antibiotics, steroids and fluids. The patient suffered minor sequelae and their blood pressure returned to normal after 6 hours.

The remaining report was for an infant male cardiac patient (1-12 months) who received apheresis platelets. This patient's BP dropped to 60/30. The infant was admitted to ICU and administered fluids and vasopressin. The patient's BP rose to 80/40 within one hour.

Pulmonary complications

The emergence of Covid 19 in 2020 complicated the identification of pulmonary complications associated with transfusion. Both TACO and TRALI can be mistaken for worsening COVID-19

pneumonitis, especially in ventilated and sedated patients, where the clinical presentations can be multifaceted and complicated. Similarly, disseminated intravascular coagulopathies can be encountered in the ITU environment with and without plasma transfusions. All these conditions present with hypoxia, pulmonary oedema and (eventually) acute respiratory distress syndrome. At best, a differential diagnosis might depend upon chronology: an abrupt decline in the patient's condition shortly after a transfusion might favour TRALI over the complications of COVID-19 infection [Seifner et al., 2021].

Transfusion related Acute Lung Injury (TRALI)

The NHO did not receive any reports associated with TRALI in 2021.

Transfusion Associated Circulatory Overload (TACO)

The NHO accepted 34 TACO reports in 2021 and 33 of these reports were reported to the HPRA. The majority of TACO patients were over the age of 50, 50% of TACO patients were 70+ and 26% of patients were aged between 51 and 70.

| Age of patient | No. of reports (n=34) |
|---------------------|-----------------------|
| Elderly (>70 years) | 17 |
| 51-70 years | 9 |
| 31-50 years | 2 |
| 18-30 years | 1 |
| 12-17 years | 2 |
| 5-11 years | 2 |

Table 9: Age of patients with TACO in 2021

Case 7: A 79 year old male patient with bladder cancer, myeloproliferative syndrome, ischemic heart disease, urinary sepsis, congestive cardiac failure, atrial fibrillation and a leg ulcer was prescribed one unit of red cells for anaemia. Weight of patient was between 60-69kgs. This patient had not received any other components in the previous 24 hours and had a pre transfusion Hb of 8.1. The patient had not received a diuretic prior to or during transfusion. Rate of transfusion was 3-4 hours and the volume transfused was between 100-150mls. Approximately 1 hour and 20 minutes after transfusion commenced the patient began to experience symptoms consistent with TACO. Dyspnoea, falling O2 sats (89%), rising pCO₂, tachycardia, hypertension and an audible wheeze were observed. The patient's chest X ray revealed a small amount of pleural fluid present. Transfusion was discontinued. Minor sequelae were recorded for this patient. Bipap ventilation and diuretics were administered. The patient had a complete recovery 5 hours and 30 minutes post administration of O₂ and diuretics. The hospital transfusion committee recommended that this patient should receive furosemide prior to any future transfusion.

Careful assessment of transfusion recipients is advised. In susceptible patients at risk from TACO (elderly or paediatric patients, patients with severe anaemia, and patients with congestive heart

failure or renal disease) transfusion should be administered slowly and consideration given to the use of a diuretic.

Following the principles of patient blood management and avoiding transfusions in non-bleeding anaemic patients should reduce the number of transfusions and potentially reduce the incidence of TACO.

Transfusion Associated Dyspnoea (TAD) (n=4)

The NHO received 4 reports related to transfusion associated dyspnoea in 2021. All four reports were reported to the HPRA. 3 cases involved elderly patients aged 70+ and the remaining case involved a patient aged between 18 and 30 years. Three of the patients were male and one was female. Three of the cases involved red cells and the fourth involved apheresis platelets.

Case 8: An 18 year old sickle cell disease patient received two units of red cells and began to develop symptoms consistent with TAD approximately 1 hour and 30 minutes after commencing transfusion. Symptoms included stridor, falling O2 saturation and decline in level of consciousness, difficulty breathing and disorientation. The patient received oxygen and an IV bolus of adrenaline. The patient made a complete recovery. On review it was decided that this patient will require chlorphenamine and hydrocortisone prior to red cells in future.

Haemolytic Transfusion Reactions (n=6)

The NHO received 6 haemolytic transfusion reaction reports. One report was related to Immunological haemolysis due to other allo-antibody (Acute < 24 hrs) and this case was not reported to the HPRA.

The other 5 reports were related to Immunological haemolysis due to other allo-antibody (Delayed > 24 hrs). Two of these cases were reported to the HPRA. Both of these reports involved elderly patients over the age of 70 years of age. These reactions were associated with red cells.

Transfusion Transmitted Infections (n=1)

The NHO received one report related to transfusion transmitted infections. This report was not accepted by the NHO.

Near Miss reports

Definition:

A 'near miss' event refers to any error which if undetected, could result in the determination of a wrong blood group or transfusion of an incorrect component, but was recognised before the transfusion took place. (SHOT UK, 2020)

Since 2010, it is mandatory to report all near miss events occurring in the **Hospital Blood Bank (HBB)** to the National Haemovigilance Office (NHO). The NHO submits these reports as serious adverse events (SAE) to the Health Products Regulatory Authority (HPRA), who in turn submits an annual report to the European Commission.

The NHO received 31 Near Miss Reports in 2021 from 15 sites, 20 reports were accepted.

11 reports were not accepted; 5 of these reports were related to clinical errors; 1 report was related to plasma and 5 of the Near Miss reports received at the NHO were transfused events and were captured as SAEs.

There has been a decrease in the number of reports accepted in 2021 from previous years see Figure 9. The reasons for this are unclear. It is possible that haemovigilance and improvements in transfusion processes have helped to remove the root cause of some incidents. However, it may also be likely that incidents are not being reported.

Near misses can occur many times before an actual harmful event occurs. It is very important that Near Misses are documented so that the NHO can establish whether any trends are occurring and so that we can work to help prevent SAEs from occurring. Learning from Near Miss events is essential to improving patient safety.

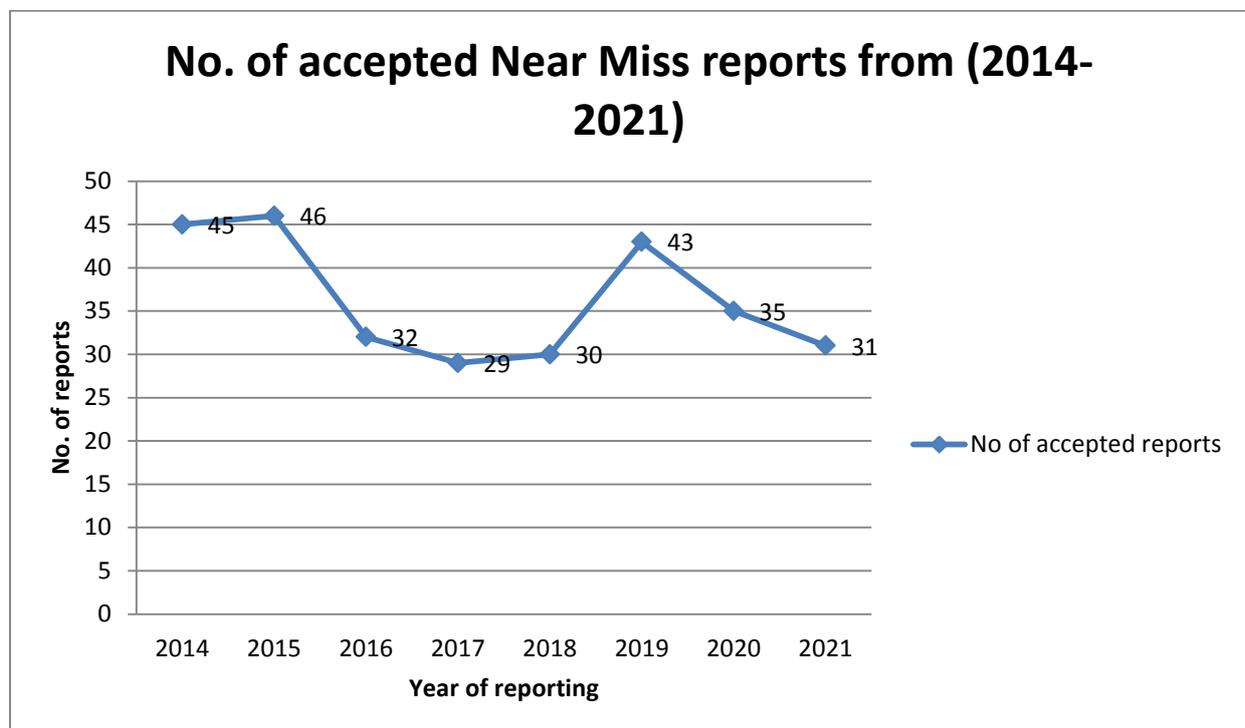


Figure 8: Trend of Near Miss reporting from 2014 to 2021

Human Errors versus system Errors

Human error was the most commonly cited causative factor on Near Miss reports received in 2021, (n = 17) reports. System errors were cited as the primary causative factor in 2 reports. One report cited other as the primary causative factor.

System errors may be overlooked by respondents when completing reports. When examining why an event occurred it is important to ask if anything could have been changed to prevent the error from occurring. Issues with staffing, resourcing, materials etc. could impact events that occur and should be noted on reports submitted to the NHO.

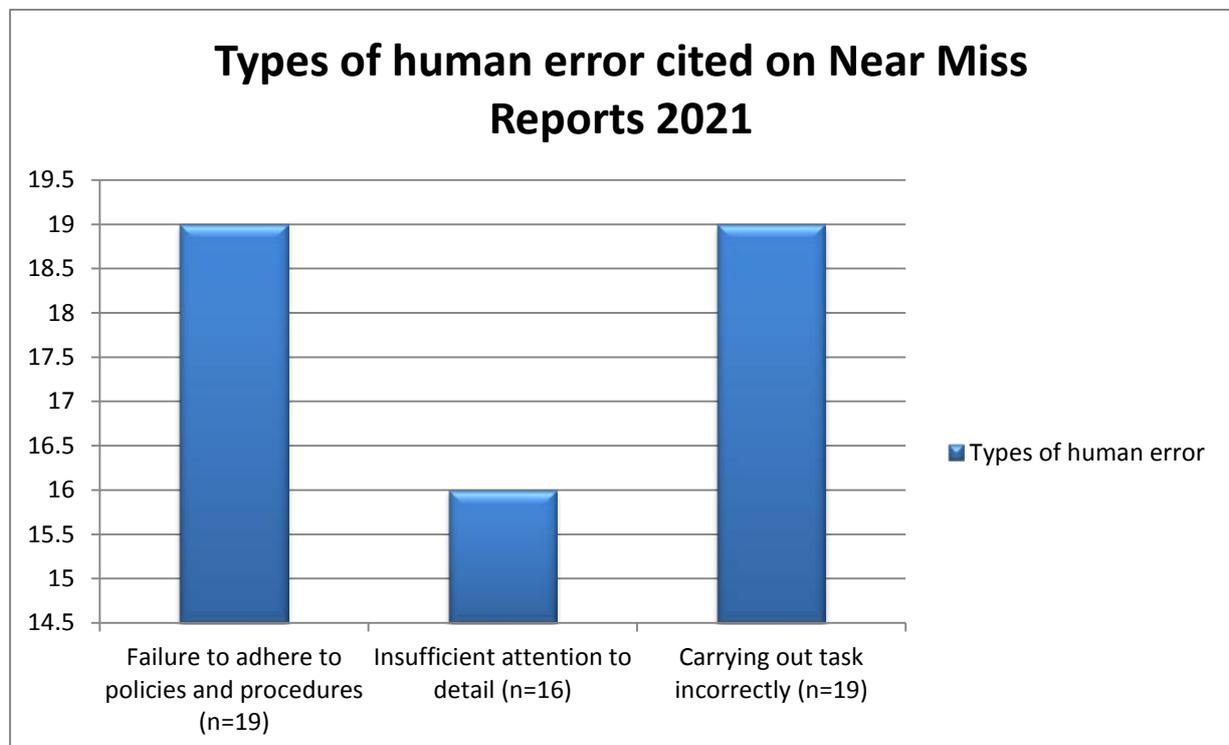


Figure 9: Types of human error identified on reports in 2021

Deviations occurred in different stages of the transfusion process. The most common stage of deviation cited in reports was other.

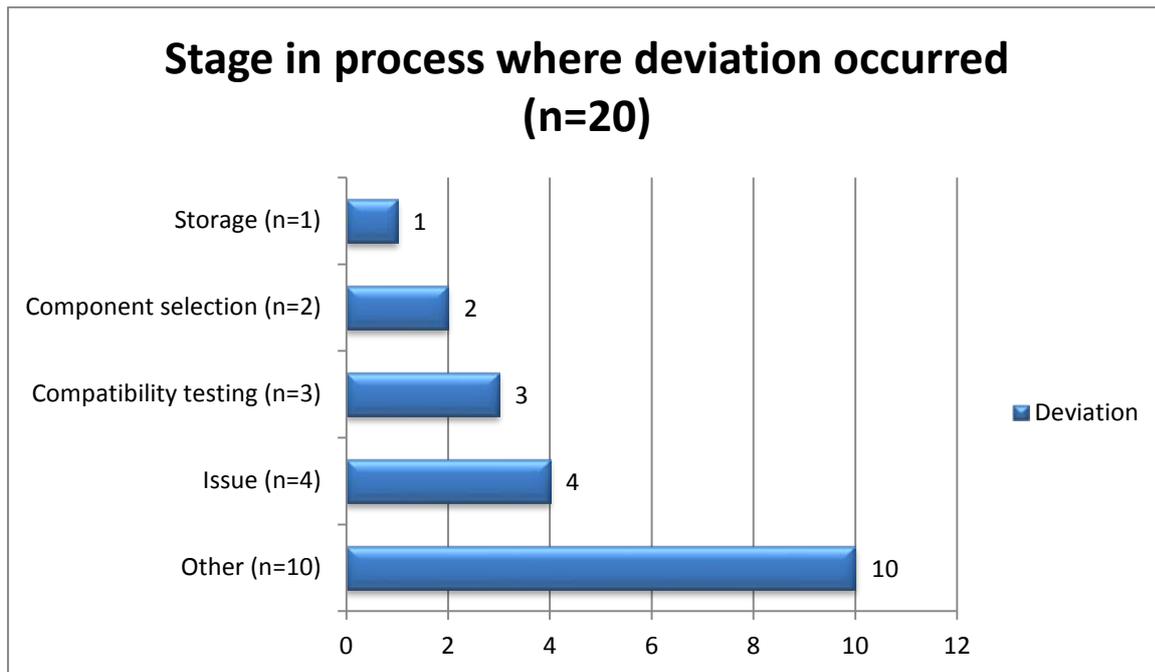


Figure 10: Stage in process where errors occurred in 2021

Deviations classified as other (n=10)

- Details on sample and request form did not match (n=5)
- Details on hospital system from previous admission are different or incorrect to details on wristband (n=2)
- Patient details entered incorrectly on LIS (n=3)

Deviations classed as Issue (n=4):

- Patient's name was too long for the label (n=1)
- Patient's surname was incorrectly added on to LIS (n=1)
- Compatibility label for paediatric Split 2 was placed on Split 3 and vice versa (n=1).
- ABO incompatible unit released due to transposition of compatibility labels (n=1)

Deviations classed as Compatibility testing, (n=3):

- Results read by eye using the laboratory light without using a light box (n=1).
- Further antibody investigations not completed (n=2)

Deviations classed as component selection, (n=2)

- Special requirement (irradiation) missed for crossmatch (n=1)
- During the cyber-attack satellite blood fridges were checked daily by Haemovigilance Staff to check inventory and expiry, this was not usual practice of Haemovigilance staff. One morning the inventory was checked in one of the satellite fridges and the expiry date of a unit was read incorrectly. The unit was due to expire the previous

night at 23:59. The fridge was checked again next morning and it was noted that the unit had expired at midnight. The unit was immediately returned to the Blood Bank for disposal. There was no delay in the patient receiving any blood, no additional units were required. Retraining of staff completed (n=1).

Wrong Blood in Tube (WBIT)

Definition:

- Blood is taken from the wrong patient and is labelled with the intended patient's details
- Blood is taken from the intended patient, but labelled with another patient's details

58 WBIT reports were received by the NHO in 2021.

56 WBIT reports were accepted by the NHO in 2021.

Types of error that occurred

- 45 WBIT events were due to the sample taken from intended patient but labelled with another patient's details.
- 11 WBIT events were due to the sample taken from wrong patient but labelled with intended patient's details.

| | No. of reports 2019 (n=46) | No. of reports 2020 (n=71) | No. of reports 2021 (n=56) |
|--|-------------------------------|-------------------------------|-------------------------------|
| Sample taken from the intended patient but labelled with another patient's details | 61 | 36 | 45 |
| Sample taken from the wrong patient but labelled with intended patient's details | 10 | 10 | 11 |

Table 9: Table illustrating the trend in the type of error that occurred between 2019 and 2021

WBIT reporting trends

The number of WBIT reports received in 2021 decreased from 71 in 2020 to 56 in 2021. It is likely that Covid infection control measures contributed to the increase in reports in 2020. 7 reports received reported new Covid Infection measures as a causative factor. The data suggests that measures may be taken to prevent errors in the event of future disruptions to the health service.

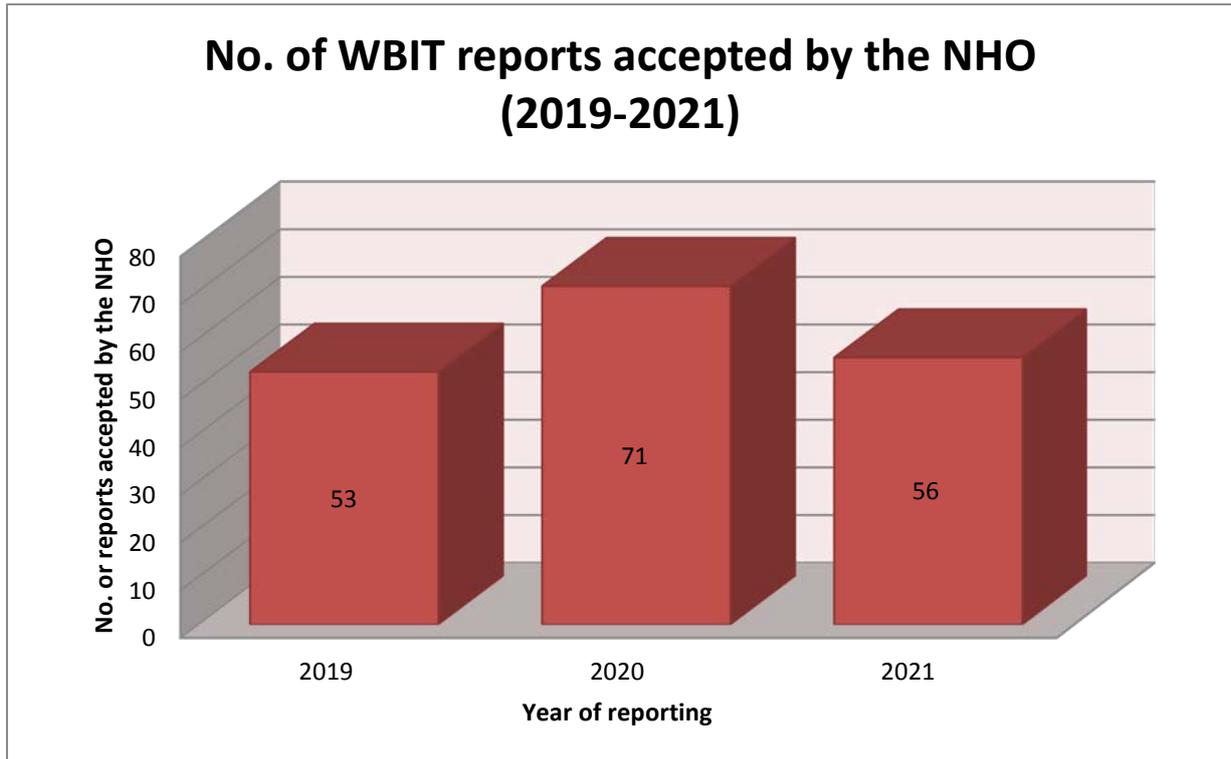


Figure 11: The number of WBIT reports received by the NHO from 2019 to 2021

Who was involved in the error?

Doctors, nurses and midwives were most commonly involved in WBIT errors. The data suggests that training and education should remain focussed on these staff members.

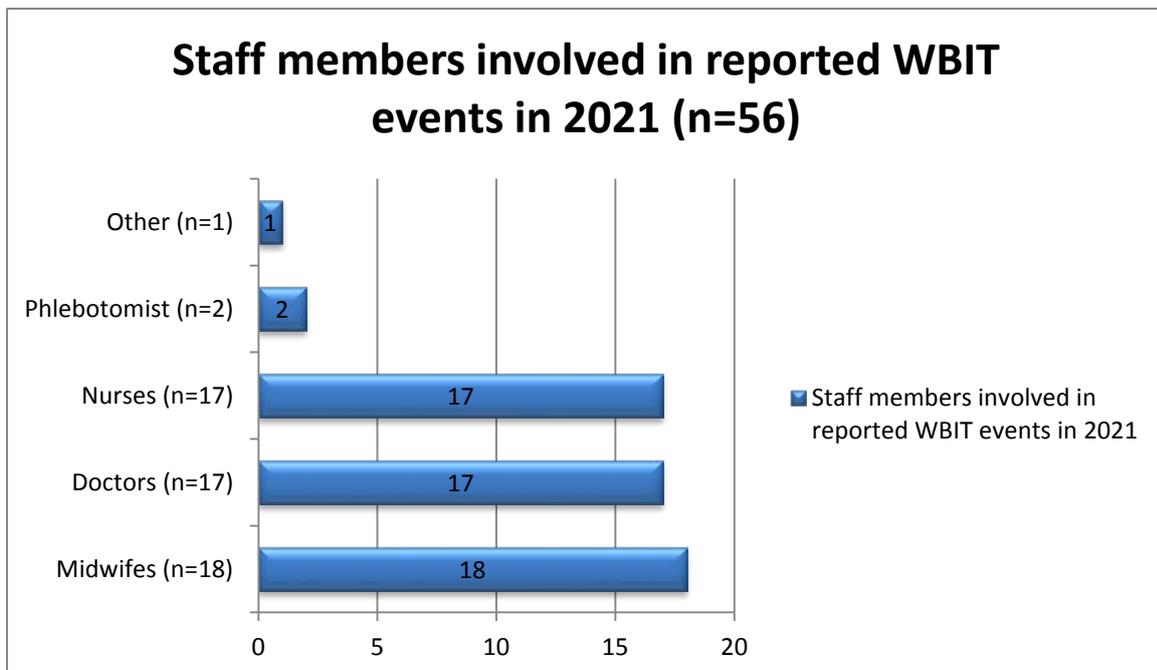


Figure 12: Staff member involvement in WBIT events reported to the NHO in 2021

What happened?

Despite clear guidelines outlining the importance of positive patient identification (PPI) in blood transfusion safety current WBIT data suggests that PPI may not be undertaken every time a blood transfusion sample is obtained. Remote labelling of samples and patients not being identified at the phlebotomy stage made up 50% of WBIT events reported to the NHO in 2021.

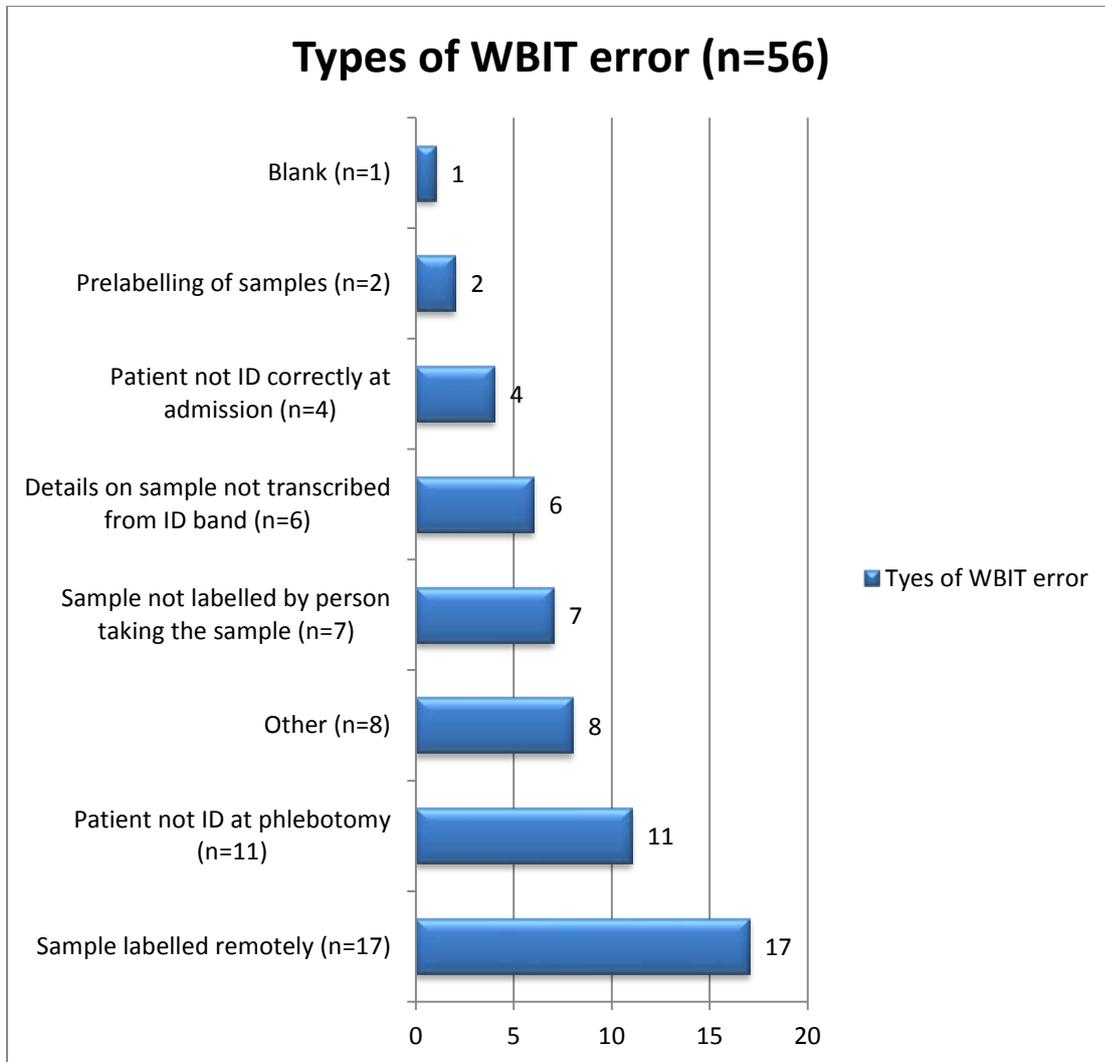


Figure 13: The different types of errors identified on WBIT reports in 2021

Where did the error occur?

Wards were the most common locations for WBIT events to occur followed by Maternity/Labour wards.

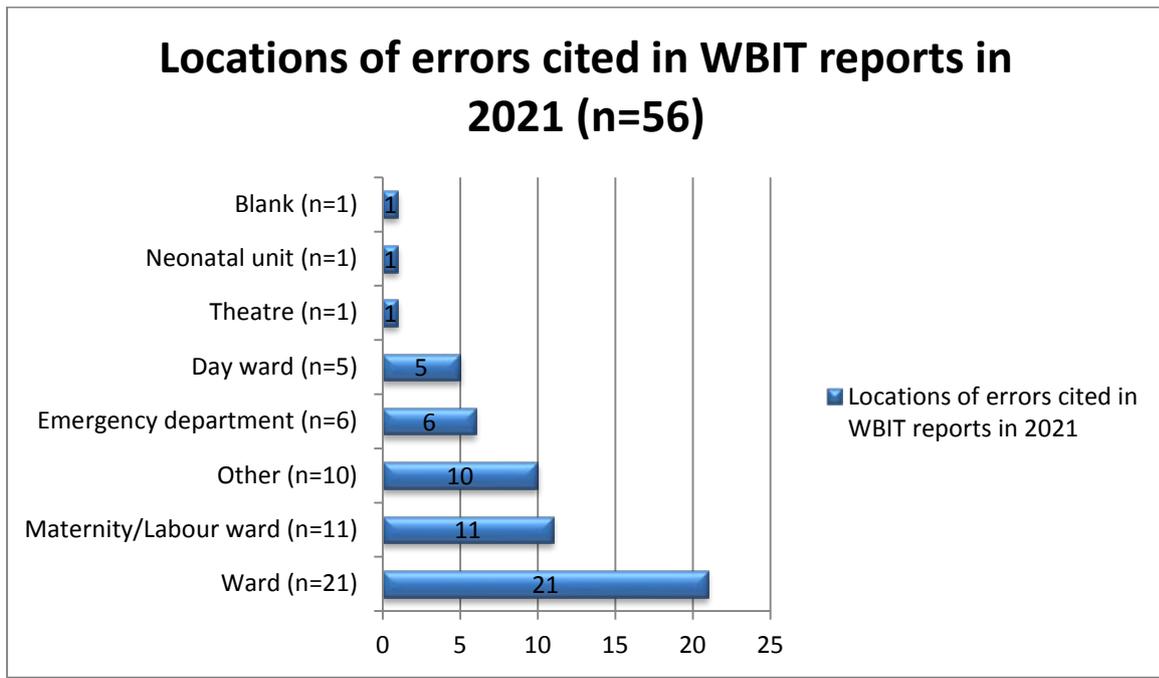


Figure 14: The different locations where wrong blood in tube events occurred as reported to the NHO in 2021

Human error v’s system error and WBIT reports

Human error remains the most common form of error cited by respondents on WBIT reports. In 2021 human error was cited 175 times whereas system error was cited only 25 times in the reports accepted by the NHO.

It is difficult to establish from the details provided in the reports whether human factors may play a greater role in causing events than are identified in individual reports. Greater detail on reports focussing on environmental factors such as how busy the working environment is, whether printers are working and whether correct resources are in place should be considered for every event.

Failure to adhere to policies and procedures is the most common human error reported to the NHO followed by carrying out a task incorrectly. Similar to the data obtained from the near miss and SAE reports it is difficult to understand why staff fails to comply with established policy and fail to carry out tasks incorrectly. Further investigation into the reasons why staff fails in these cases may enable the NHO to address these issues. Encouragingly the NHO received only 2 WBIT reports where the error was associated with knowledge deficits (see Figure 15).

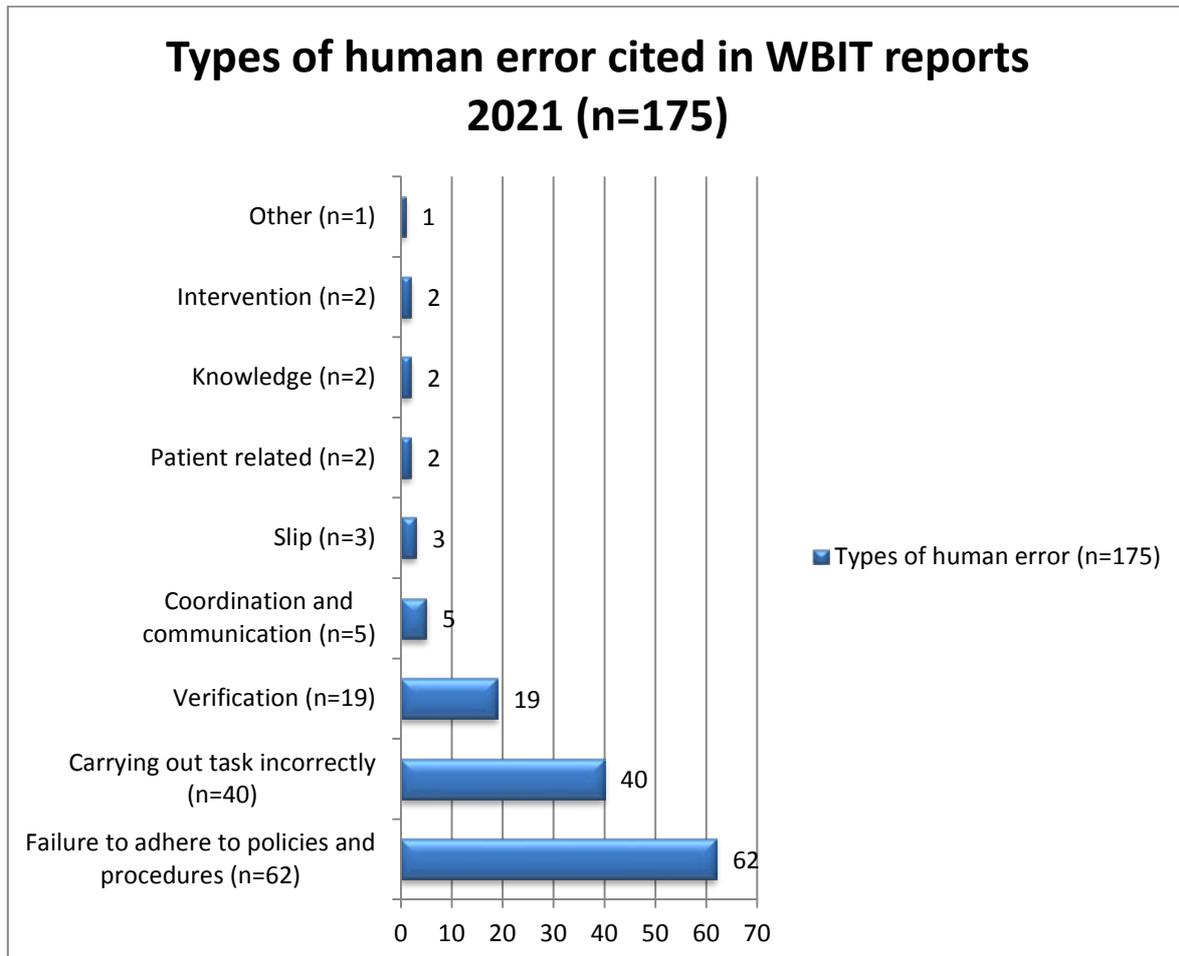


Figure 15: Different categories of human error cited on reports received by the NHO in 2021

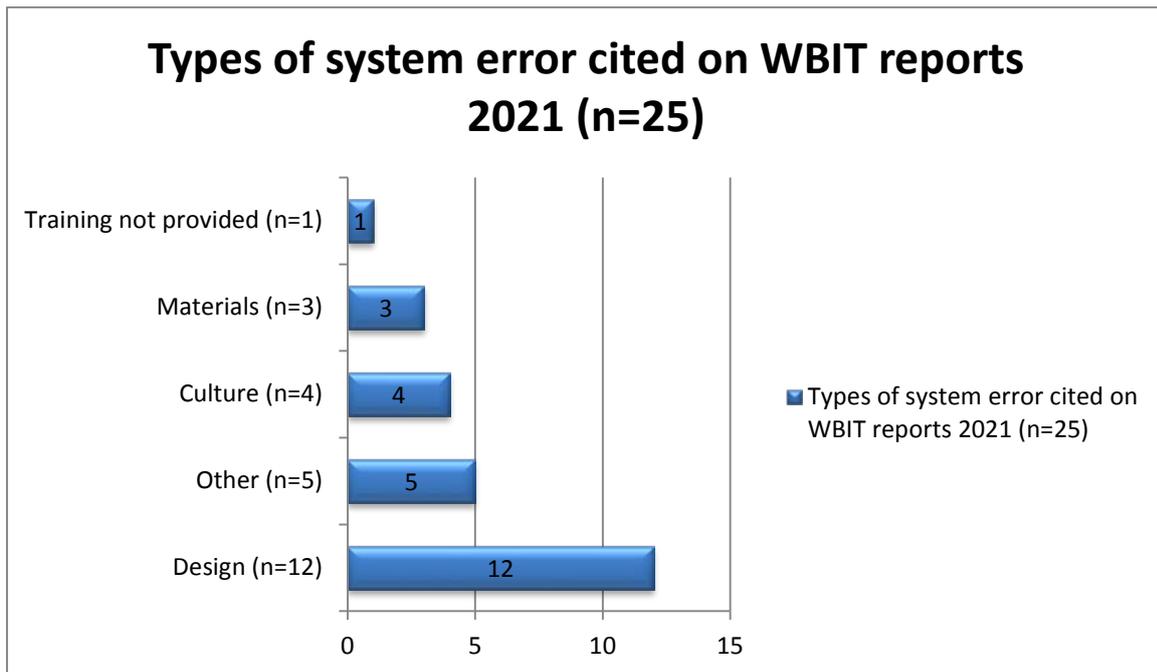


Figure 16: Classification of system errors cited on WBIT reports in 2021

Electronic Blood Track System (EBTS) and WBIT events

- In 40/58 (69%) of events EBTS was in use in the blood establishment.
- In 10/58 (17%) of events EBTS was in use in the blood establishment but not used at the time of the event.
- In 29/58 (50%) of events EBTS was in use at the blood establishment and was used at the time of the event.
- In one event EBTS was in use at the blood establishment but it is not clear whether it was used at the time of the event.

Reasons given for not using Blood Track varied. In three instances no reason is given. Other reasons include see below:

- SN could not locate printer when using PDA
- PDA was not charged
- HSE cyber-attack meant that there was no Wi-Fi available
- User trained but did not use the system
- EBTS was not suitable for cord sampling
- Intern was new to hospital and was unsure where BT was in surgical ward and was under pressure
- Blood Track was not used

Reasons given for the WBIT event occurring despite the use of Blood Track also varied. Common themes included the patient wearing the wrong wristband (n=5); EBTS was not used to label specimen or affixed to request form (n=3).

Maternal and Newborn Clinical Management System (MNCMS) and WBIT events

In 5/58 events MNCMS was in use in the blood establishment

In 2/58 events MNCMS was in use at the blood establishment but not used at the time of the event

In 3/58 events MNCMS was in use at the blood establishment and used at the time of the event.

Both events that occurred when MNCMS was in use at the establishment but not used at time of event were a result of the malware attack on the HSE. Electronic systems were not in use at these sites because of the cyber-attack.

The three events that occurred while using MNCMS gave various reasons:

- Remote labelling
- Patient not identified correctly at the phlebotomy stage combined with a labelling error
- Sample not labelled by person taking the sample. Also Patient not identified correctly at phlebotomy / sample labelling. Failure to check the sample label against the ID Band at time of labelling.

Human factors identified in reported WBIT events

Qualitative analysis of details provided using thematic coding identified human factor themes that have been identified as causative factors in the WBIT events that were reported.

Busy workloads

19 reports identified busy work environments, staff shortages and/or high volume workloads as causative factors in the WBIT events that occurred.

Wristband issues

8 reports identified issues with wristbands as a causative factor in the WBIT events reported.

- Two reports cited that faded wristbands caused staff members to scan wristbands from charts. The staff scanned wristbands from the wrong charts.
- One report cited that a linear barcode on the wristband was in situ which was not compatible with EBTS causing the doctor to scan a wristband affixed to the chart. The wristband was for a different patient.
- In four instances wristbands were not applied to patients on admission. Staff either had to scan wristbands affixed to charts or place wristbands on patients which were not the correct wristbands for the patients.

Printer Issues

Issues with electronic identification system printers were cited in 6 reports. Issues included:

- Printer failures or printers not working in (n=4).

- 1 report stated that the staff member was unable to locate the printer.
- The final report stated that the staff member had to print labels remotely but did not give a reason why.

In all cases staff members had to print off labels away from the bedside which contributed to the error reported.

HSE Cyber attack

On 14th of May 2021 the HSE suffered a major ransom-ware attack which caused HSE IT systems nationwide to be shutdown. Hospitals reported that they could not access electronic files; electronic databases such as LIS and Blood Track were also affected. This disruption contributed to a number of errors that were reported to the NHO in 2021. Despite the major disruption to services the NHO received a small number of reports related to the cyber-attack.

The NHO received 6 SAE reports which cited the cyber-attack as a contributory factor in the error that occurred. Storage errors due to insufficient temperature monitoring as a result of the REES temperature monitoring system being unavailable was cited in 4 reports. Failure to give an irradiated component as a result of being unable to check patient's history on LIS was cited in 2 reports.

The NHO received 4 Near Miss reports associated with the cyber-attack. Deviations in Storage were cited on 2 reports; Issue on 1 report and other on the remaining report. Two near miss reports were caused when staff failed to verify labels on units correctly. EBTS is used routinely to alert staff of incompatibilities and expiration dates. In one case a sample was handwritten incorrectly because EBTS was unavailable. The Near Miss report related to storage was a result of incorrect fridge monitoring because the REES temperature monitoring system was unavailable due to the cyber-attack.

The NHO received 3 WBIT reports which cited the cyber-attack as a contributory factor in the error that occurred. All three cases occurred at the sampling stage of the transfusion process and were a direct result of EBTS or MNCMS being unavailable due to the cyber-attack. In all three cases the sample was taken from the wrong patient and labelled as per the intended patient's details. The NHO also received a WBIT notification that details on a request form were incorrect as a result of EBTS being unavailable due to the cyber-attack. This case was not accepted as the NHO do not collect WBIT cases where details on the request form do not match the details on the sample.

Near miss case 1: Issue

A patient's details were entered incorrectly on the LIS. Units were issued. The error was discovered on the ward during pre-transfusion checks. Medical Scientist misinterpreted sample takers handwriting. Sample was handwritten as Bloodtrack PDA could not be used due to the Cyber-attack. Medical Scientist did not confirm patient details on iPMS before entering details on LIS as they were unaware iPMS was working again the day before. Unit was returned to lab and a repeat group and crossmatch sample processed. This error was captured as Other – system failure.

Near Miss case 2: Storage Error

During the cyber-attack the satellite blood fridges were checked daily by Haemovigilance Staff to check inventory and expiry, this was not usual practice of haemovigilance. One morning the inventory was checked in one of the satellite fridges and the expiry date of a unit was read incorrectly. The unit was due to expire at 23:59 the previous night. The unit was immediately returned to the Blood Bank for disposal. There was no delay in the patient receiving any blood, no additional units were required. Retraining of staff was completed.

SAE case 1: Storage error

The Rees Temperature Monitoring System in one hospital was offline due to HSE Cyber Attack. Blood fridges were manually monitored and temperatures recorded every two hours. At a later date a MS from another hospital (where units had been re-routed to) advised that temperature monitoring should occur every hour. There was a risk of temperature fluctuations going unnoticed when only recording every 2 hours. A total of 6 units RCC that were rerouted to the other hospital were discarded. 2 x Patients transfused during this time frame but no reactions recorded.

Recommendations

The recent cyber-attack and the Covid 19 pandemic have highlighted the need for strong IT security and tighter mitigation strategies in the event of future disruptions to the health service. Further investigation into the impact of the pandemic on WBIT events could provide transfusion practitioners with more information as to how we can make transfusions safer for Irish patients in the event of future disruptions to service.

Current reporting practices are very good at informing the NHO what happened in SAEs but information is scant as to why these events are occurring. Without understanding why events occur and collecting information regarding human factors it is difficult for the NHO to identify changes that could be made to existing systems. We need to better understand why staff is not following policies and procedures. Are staff not being compliant, could they be too busy and distracted or is there an issue with the policies that are in place? It is recommended that respondents include information regarding resourcing, issues with materials, IT systems etc. on all reports.

The NHO received 18 reports of failure to give an irradiated component. The data suggests that training and reminders to doctors of the implications of not providing details of special requirements on a request form may be appropriate. Prompts on request forms and laboratory information systems may also reduce the number of cases where there is a failure to give an irradiated component. Patient alert cards and a national database for special requirements could further reduce the occurrence of these errors.

The NHO received 15 reports of inappropriate transfusions. Transfusion based on clinical decision not in conformity with guidelines was cited in 7 reports. The data suggests that doctors and nurses may require further training or education on transfusion guidelines. Transfusions based on incorrect or absent haematology results were identified on 5 reports. Reminders or prompts to check haematology results may reduce the number of cases of inappropriate transfusions. Wards remain target locations for education and training with regard to inappropriate transfusions.

WBIT reports indicate that positive patient identification is not carried out every time a transfusion takes place. In 2 cases staff members have scanned wristbands attached to charts. Removal of wristbands from patient charts may encourage staff to carry out positive patient identification and prevent remote sample labelling. Issues with electronic identification systems need to be addressed. Printer failures or printers not working contribute to remote labelling. Printers should also be easily accessible in designated areas so that all staff is able to locate them. Finally WBIT data indicates that busy workloads are a factor in 19/58 (33%) of WBIT events. Sufficient staff resourcing or rostering may help reduce the number of WBIT events in future.

References:

Seifner, A., Fox, A.W. Why Does the Precautionary Principle Suffice for Blood Regulation? *Pharm Med* **35**, 281–286 (2021). <https://doi.org/10.1007/s402>

Shotuk.org. 2022. [online] Available at: https://www.shotuk.org/wp-content/uploads/myimages/Interactive_SHOT-REPORT-2020_V2.1.pdf [Accessed 21 September 2022].

S Narayan (Ed) D Poles et al. on behalf of the Serious Hazards of Transfusion (SHOT) Steering Group. The 2020 Annual SHOT Report (2021).