

Seven hundred and fifty-nine (759) chances to learn: a 3-year pilot project to analyse transfusion-related near-miss events in the Republic of Ireland

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Background The National Haemovigilance Office has collected and analysed reports on errors associated with transfusion since 2000. A 3-year pilot research project in near-miss event reporting commenced in November 2002.

Materials and Methods Near-miss reports from 10 hospital sites were analysed between May 2003 and May 2005. The Medical Event Reporting System for Transfusion Medicine was used to collect and analyse the data. Root cause analysis was used to identify causes of error.

Results A total of 759 near-miss events were reported. Near misses are occurring 18 times more frequently than adverse events causing harm. Sample collection was found to be the highest risk step in the work process and was the first site of error in 468 (62%) events. Of these, 13 (3%) involved samples taken from the wrong patient. Medical staff were frequently involved in error. The general wards and emergency department were identified as high-risk clinical areas, in addition, 78 (10%) events occurred within the transfusion laboratory. Three specific human and two system failures were shown to have been associated with the errors identified in this study.

Conclusions This study confirms that near-miss events occur far more frequently than adverse events causing harm. Collecting near-miss data is an effective means of highlighting human and system failures associated with transfusion that may otherwise go unnoticed. These data can be used to identify areas where resources need to be targeted in order to prevent future harm to patients, improving the overall safety of transfusion.

Key words: haemovigilance, MERS-TM, near-miss, transfusion safety.

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Background/introduction

The National Haemovigilance Office (NHO) was established in 1999 to collect and analyse serious adverse events and reactions associated with transfusion in the Republic of Ireland. During the 5-year period from 2000 to 2004, approximately 875 000 blood components were issued from the

Irish Blood Transfusion Service (IBTS) and a total of 778 reports of adverse events/reactions were received by the NHO [1]. Of these, 428 (55%) were adverse events, 13 involving ABO-incompatible red cell transfusions. This correlates to a risk of receiving an ABO-incompatible red cell transfusion at 1 : 49 169 units issued, suggesting that significant risks of error continue to be associated with transfusion which outweigh other more publicized risks such as viral infection. Similar findings have been reported through other haemovigilance systems [2].

Much work has been done to analyse adverse events in transfusion. Adverse event reporting systems, however, are reactive and by the time lessons have been learned,

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the patient has been exposed to harm. Also, as adverse events occur relatively infrequently it is difficult to gather enough aggregate data to generate statistically significant information on patterns and trends in error and their root causes.

It has been well established in many industries that data collected from near-miss reporting systems can offer numerous advantages over adverse event reporting [3]. Firstly, near-miss events occur far more frequently than adverse events [4], providing sufficient numbers of events for analysis. They can also be reported and studied without the patient being exposed to harm, as the distinguishing feature of a near-miss event is the 'recovery step' preventing harm. Despite these obvious benefits, near-miss reporting systems in medicine have been slow to develop.

Much of the research in the area of establishing transfusion-related near-miss event reporting systems has been done in the USA. Data relating to near-miss events in transfusion has been published through the use of a system called the Medical Event Reporting System for Transfusion Medicine (MERS-TM) [5]. Although some European systems publish near-miss data annually, no data has yet been published in the Republic of Ireland. A 3-year pilot research project to collect and analyse transfusion-related near-miss events was established in 2002.

Materials and methods

A project coordinator (PC) based at the NHO with a nursing and haemovigilance background was appointed to coordinate the project.

Hospitals were selected for inclusion in the project on the basis of haematologist agreement and the existence of an established haemovigilance programme within the hospital. Four consultant haematologists with responsibility for eight hospitals (10 hospital sites) agreed to contribute to the project. Each hospital site varied in demographics and specialties. The hospital size ranged from a large 850-bed teaching hospital issuing 19 023 units from their transfusion laboratory per year to a small 68-bed regional hospital issuing 276 units per year. Each hospital involved in the project has a haemovigilance officer (HVO) in post who is responsible for reporting serious adverse events and reactions to the NHO and they agreed to coordinate the near-miss reporting process within their individual sites.

Extensive training was carried out at each participating site over a period of 6 months, prior to the commencement of data collection. This training was targeted at the key stakeholders including HVOs, management, nursing, medical, laboratory and portering staff. The training was aimed at raising awareness of the project and ensuring all staff understood the importance of error detection and reporting, in addition to knowing what and how to report near-miss events within their hospital. The fact that all near-miss reports received

during the period of the study would be confidential and anonymous and that patient, hospital and staff identifiers would be removed from the forms prior to entry onto the database was emphasized at all training sessions. Management were supportive of the project and all staff understood that the data collected would be used to improve weaknesses identified in the transfusion chain rather than blaming individuals for error.

The definition of a near-miss event agreed for the purpose of the project was 'any error which might have occurred, but didn't, as it was detected and corrected before administration took place'.

Medical Event Reporting System for Transfusion Medicine

The MERS-TM [5,6] was used to collect and analyse the data. MERS-TM is a Web-based event reporting system specifically designed to collect, classify and analyse events that could compromise the safety of transfused blood. It is designed to collect data on adverse events causing harm, actual events without harm, near-miss events, and 'dangerous situations', but for the purpose of the project was only used to collect near-miss event data.

Calculating the risk index of an event

The risk was calculated using the risk assessment index (RAI) tool (Table 1) provided by MERS-TM. The risk is based on the probability of a particular event type recurring, the probability of it causing patient harm, whether or not the unit involved in the event had been issued from the transfusion service at the time of discovery and the type of recovery from the event (planned or unplanned). The RAI was used to calculate whether an event was high, medium or low risk guiding the PC in the level of investigation particular events required [7].

Root cause analysis

Following receipt of a report from the hospital-based HVO (via post or email), the PC selected events requiring root cause analysis (RCA).

Root cause analysis was carried out on events that were calculated as posing a significant risk to either the patient or the organization, new or unusual events, or when a particular type of event recurred frequently. Root causes for each event were determined using MERS-TM methods and taxonomies following completion of the event investigation by the PC.

Using the Eindhoven Classification System, there are 20 different possible root cause codes which can be assigned to an event, and these are grouped under four headings: Human Failures, Organizational Failures, Technical Failures and Patient-Related Failures [8]. Definitions of the root cause codes included in this study are given in Table 2.

Table 1 Risk assessment index tool

Quantified estimate of severity of Pt harm (QES)		Quantified estimate of probability of recurrence (QEP)					
		Extremely high 0-99	Very High 0-9	High 0-75	Medium 0-50	Low 0-25	Very low 0-10
Extremely high	0-99	1-0	0-9	0-7	0-5	0-2	0-1
Very high	0-90	0-9	0-8	0-7	0-4	0-2	0-1
High	0-75	0-7	0-7	0-6	0-4	0-2	0-1
Medium	0-50	0-5	0-4	0-4	0-2	0-1	0-05
Low	0-25	0-2	0-2	0-2	0-1	0-1	0-02
Very low	0-10	0-1	0-1	0-1	0-05	0-02	0-01

Calculation of risk index:

Product issued	Add 0-2
Unplanned recovery	Add 0-1

Determination of investigation type:

$\geq 0-5$	Root cause analysis
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Recommended action:

$> 0-5$	Monitor ^a
$\geq 0-5$ and $\leq 0-7$	Monitor and consider change ^a
$> 0-7$	Monitor and propose change ^a

^aExternal report if appropriate.

RAI, risk assessment index; QES \times QEP = risk index.

Table 2 Definition of root cause codes

Code	Category	Definition
Human errors		
HSS	Human slip	Failures in performance of highly developed skill
HRV	Human rule-based verification errors	Failures in the correct and complete assessment of a situation
HRI	Human rule-based intervention errors	Failures resulting from faulty task planning and execution
Organizational errors		
OK	Transfer of knowledge	Failures resulting from inadequate measures taken to ensure that site-specific knowledge or information was transferred to all new or inexperienced staff
OM	Management priorities	Failures relating to internal management decisions in which safety was not given priority

Results

The total number of near-miss events reported and analysed over the 2-year period between May 2003 and May 2005 was 759. There was a marked increase in reporting from year 1 to year 2, with 280 reports being received in year 1 (mean reporting rate = 23 events per month) and 479 in year 2 (mean reporting rate 40 events per month). During the same period 87 468 blood components were issued between the 10 sites, corresponding to a reporting rate of nine near-miss events per 1000 units issued.

The incidence of reports received by the NHO involving transfusion errors from all sites nationwide is approximately 0-5 per 1000 units issued [9], suggesting that near-miss events occur 18 times more frequently than adverse events causing harm.

Reported events per hospital site

There was significant variation in reporting rates between the hospital sites. Reporting rates did not correspond to hospital bed size or units transfused (Table 3).

Table 3 Reported events per hospital site: breakdown of reporting rates per hospital bed size and units transfused

Hospital	Near-miss events reported (over 24 months)	Bed size	Near-miss events reported per 50 beds	Units transfused (over 24 months)	Near-miss events per 100 units transfused
A	225	850	13	38 046	0.6
B	102	206	24	5902	1.72
C	119	209	28	2956	4
D	109	146	37	2698	4
E	65	472	7	16 968	0.4
F	37	180	10	5656	0.7
G	44	94	23	1316	3
H	38	406	5	13 038	0.3
I ^a	19	99	10	336	6
J	1	68	0.7	552	0.2

Hospital ^a I (with the highest report rate per 100 units transfused), may have had a falsely high result as the majority of near-miss events in this site relate to one specific type of failure unique to the patient setting.

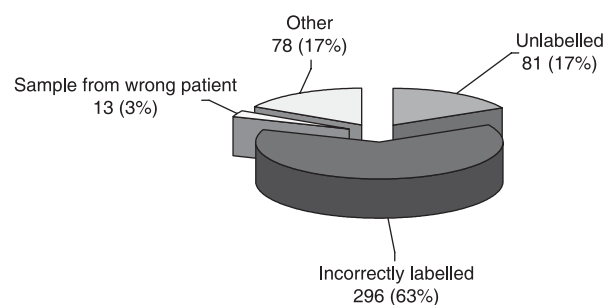
Consequent events (discovery information)

The majority of events 406 (53%) were discovered at the sample-handling step in the laboratory during crosschecking of details on the request form and sample tube. However, in 184 (24%) events the error was discovered only after the product was issued and in 60 (33%) of these events, the discovery was made by chance (unplanned recovery).

Antecedent events (first site of error)

Sample collection was the step in the work process where the majority of events first occurred. It was the first site of error in 468 (62%) cases. A further breakdown of sample collection errors is given in Fig. 1.

Prescription/request was also highlighted as a potentially high-risk step in the work process, being the first site of error in 63 (8%) events. In addition, 41 (5%) events first occurred at some point after issue from the laboratory but before administration; these included events in which the wrong unit was collected from site of storage.

**Fig. 1** Breakdown of sample-collection errors ($n = 468$).

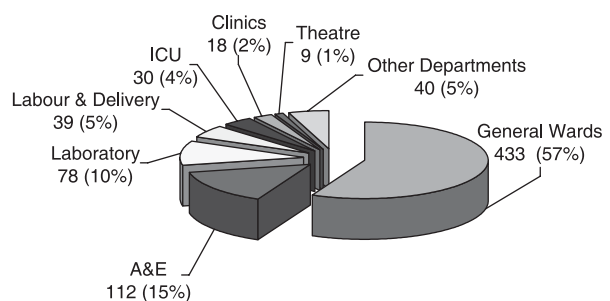
In 488 (64%) events the patient was subjected to a second venipuncture in order to obtain a repeat sample. Most of the events involving repeat sampling were as a result of errors made at sample collection.

Staff involved

Medical staff were most frequently involved in error. Four hundred and twenty-two (55%) events concerned errors involving doctors, the majority of which relate to errors associated with sample collection. Nursing staff were involved in 222 (29%) events, laboratory staff in 90 (12%), phlebotomy staff in 41 (5%) and clerical staff in 15 (2%). 'Other' grades of staff were involved in the remaining 44 (6%) events.

Where events are occurring (high-risk clinical areas)

Other than the general ward areas (including haematology/oncology units) where the majority of transfusion activity took place, the accident and emergency (A&E) department and the transfusion laboratory were the two departments where significant numbers of near-miss events occurred (Fig. 2).

**Fig. 2** Breakdown of events by clinical area ($n = 759$).

Recovery data

In 179 (24%) of the 759 events reported, recovery was unplanned, i.e. the error was simply discovered and harm to the patient prevented by chance. In 580 events (76%) recovery was planned, i.e. the error was detected and harm to the patient prevented by a planned barrier, such as a checking step in the work process. Hospitals with higher percentage of events involving unplanned recovery were also found to have a high percentage of high-risk events (Tables 4 and 5).

Table 4 Breakdown of recovery data per hospital site

Hospital	Near-miss events reported per 100 units transfused			Percentage of events with unplanned recovery
	Planned recovery	Unplanned recovery		
A	225	192	33	15%
B	102	71	31	30%
C	119	104	15	13%
D	109	90	19	17%
E	65	52	13	20%
F	37	16	21	57%
G	44	30	14	32%
H	38	20	18	47%
I	19	9	10	53%
J	1	1	0	0%

Hospital sites F, H & I were the three sites with the highest number of events caught by unplanned recovery.

Table 5 Breakdown of high-risk events per hospital

Hospital	Number of high-risk events reported out of total number of events reported	Percentage of high risk per hospital
A	17 out of 225	7.5%
B	5 out of 102	5%
C	7 out of 119	6%
D	4 out of 109	1%
E	3 out of 65	5%
F	3 out of 37	8%
G	0 out of 44	0%
H	13 out of 38	12%
I	4 out of 19	21%
J	0 out of 1	0%

Hospital sites F, H & I were also the three sites with the highest number of high risk events.

Breakdown of risk index of events

Of the 759 events reported, 59 (8%) were considered to be high risk, 151 (20%) medium risk and 549 (72%) low risk. The majority of events reported were low risk, posing very low risk of harm such as single digit/spelling errors on samples. The types of medium-risk events seen varied greatly, but relate to errors with more serious potential for harm such as failure to take either mother or baby grouping samples post delivery or patients almost receiving unnecessary transfusions due to failure to verify most recent laboratory results prior to prescribing.

All of the events categorized as high risk were events with high potential for harm and almost half of these (28) were associated with errors made at the sample collection step in the work process. Twenty-six of these relate to wrong blood in tube (WBIT) events [10]. Thirteen of the WBIT events involved the sample being taken from the wrong patient and a further 13 involved the sample being taken from the correct patient, but being labelled with another patient's details. Medical staff were involved in 19 of these events. Eleven of these events involved remote labelling of the sample away from the bedside and 12 involved failure to verify patient identity at the bedside. Eleven high-risk events occurred within the transfusion laboratory.

Laboratory high-risk events ($n = 11$)

Five events were associated with sample testing. These included two events involving errors in performing Rh(D) typing, two events where patients' grouping results were entered onto the computer incorrectly and one event where a sample containing a weak antibody was reported as antibody negative. Four out of the 11 laboratory-based high-risk events (36%), occurred during on call hours and involved laboratory staff doing cross call cover.

Root causes of error

Although there were errors involving all four of the categories (defined earlier in this paper), three significant types of human failure and two significant types of organizational failure emerged from the aggregate data (Fig. 3). The specific failures identified are presented in Tables 6 and 7.

Discussion

Based on this study, the frequency of reported near-miss events related to the transfusion process in the Republic of Ireland is 18 times higher than that of actual adverse events causing harm. However, the true incidence of near-miss events is likely to be much higher as it is clear from the variation in reporting rates between similar sized sites transfusing similar volumes, that some sites were more likely to

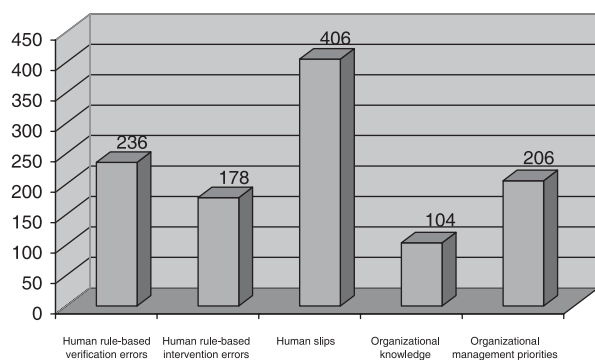


Fig. 3 Root causes.

report events than others. Certain sites may have falsely perceived that it was only important to report the more serious events and failed to see the usefulness of reporting the low-risk events. Busy clinical workloads may also explain differences in reporting rates, as small to medium sized sites tended to have higher reporting rates. Lack of time to attend the training and information provided by the project coordinator

was also identified as a problem. We found that informing staff about the project and explaining/emphasizing the usefulness of reporting near-miss events alone, was not a successful means of encouraging reporting from nurses and doctors. This may be due to the high turnover of staff in these two groups or it may be that we failed to convince these staff that reporting near-miss events could actually improve patient safety and system weaknesses. The culture of reporting varied between sites and between different grades of staff. Doctors in particular have been found to have a poor reporting culture [11].

Barriers to error

The human check carried out at the laboratory 'sample handling' step was identified as a vital checking step in error detection. It is interesting that this check appears to work so well when other human checks, such as the bedside check later in the transfusion process, have such a high incidence of failure. This could be due to the fact that the sample-handling check is much less complex than the final bedside check and therefore, may be easier for staff to comply with.

Table 6 Breakdown of significant Human Failures identified (some events involved more than one type of failure)

Human skill-based slips (HSS) (<i>n</i> = 406)	Human rule-based verification errors (HRV) (<i>n</i> = 236)	Human rule-based intervention errors (HRV) (<i>n</i> = 178)
Forgetting to complete tasks/ inattention to task/mind slips	Failure to verify patient or product ID at the bedside	Remote labelling/ checking away from patients bedside
Spelling/digit errors on samples	Failure to carry out crosschecks correctly or at all	Prelabelling of samples
Failure to label samples (unlabelled samples sent to lab for processing)	Failure to verify most recent test results prior to prescribing	Failure to adhere to prescription/requesting guidelines
	Failure to check historical records in laboratory	Attaching addressograph labels to samples
	Failure to check prescription prior to commencing transfusion	Failing to bring written ID when collecting units from site of storage
		Taking samples from patients not wearing any ID bands

Table 7 Breakdown of significant Organizational Failures identified (some events involved more than one type of failure)

Management priorities (OM) (<i>n</i> = 206)	Organizational knowledge (OK) (<i>n</i> = 104)
Failure to replace staff on sick/annual leave	Failure to provide haemovigilance training for clinical staff prior to working in clinical areas
Absence of systems for provision of medical record numbers out of hours and at weekends leading to the use of supplementary numbering systems for transfusion	Absence of systems for providing haemovigilance training for agency/locum staff
Absence of systems for provision of electronically generated ID bands	Failure to provide protected time for staff to attend training
Limited/absent phlebotomy services to clinical areas	Failure to provide ongoing training programmes for laboratory staff involved in cross-call cover.
Failure to introduce automated systems where available	
Failure to provide resources for upgrading/replacing outdated IT systems.	
Absence of interface between laboratory and clinical computer systems.	

The project has highlighted the important role that 'recovery data' provide in detecting weak points in the transfusion chain. It is clear that safety barriers in some hospitals are more effective than others. This study shows that hospitals with higher numbers of errors caught 'by chance' instead of by planned checks in the work process were the same hospitals with higher than average numbers of high-risk events. This indicates that there is a higher risk of potential patient harm in sites where barriers to error are weak or missing. This finding supports recent research suggesting that using near-miss data to enhance protective barriers increases our capacity to get the right blood to the right patient [12].

High-risk steps in the work process

As other studies have identified [13–17] sample collection was found to be a high-risk step in the work process. The majority of serious errors associated with sample collection in our study were made by medical staff (19 out of 26 WBIT events involved sample collection errors made by doctors). It seems that large numbers of pretransfusion samples are currently being taken by medical staff. This may be partly due to the limited phlebotomy services available in many of our hospitals; however, the sample collection step has been also associated with error in countries where phlebotomists and nurses take the majority of samples [10]. It is likely that the inherent weaknesses in the sample-collection process are the key, rather than the grade of sampler.

We found high rates of re-sampling were required as a result of errors at the sample-collection step. Repeat sampling wastes time and resources, in addition, it can cause critical delays in transfusion and subjects the patient to the unnecessary discomfort of having a sample taken twice.

Prescription/request was also identified as a high-risk step. Medical staff at undergraduate level receive minimal training in blood transfusion and knowledge in this area can often be derived from senior colleagues, who may be using outdated transfusion protocols [18].

Apart from the general wards, where the majority of transfusions took place, the A&E department and the transfusion laboratory were identified as high-risk clinical areas on the basis that these were the other clinical areas where the highest numbers of near-miss events occurred. This project highlighted that phlebotomy services are absent in many of our A&E departments – an area where a high number of patients have blood samples taken, often in challenging conditions. Medical and nursing staff in A&E are frequently the only staff available to carry out sampling, adding to their workload significantly.

Findings within the transfusion laboratory

Although the majority of events were detected within the transfusion laboratory reflecting raised levels of awareness

within this area, we found that 57 (73%) of the 78 events that occurred within the transfusion laboratory were discovered and reported after the blood had been issued, by staff working outside the transfusion laboratory. The transfusion laboratory is traditionally viewed as an area where the risk of error is low. Previous studies have shown that most transfusion events occur outside the laboratory [19]; however, this study suggests that significant system and human failures exist in the transfusion laboratory. We highlighted several possible reasons for this. Laboratory IT systems (LIS), were often poorly designed, setting humans up for error. Automated alerts on computers were frequently absent or designed so that they could be easily over-ridden. None of the laboratory computer systems in the contributing sites were fully interfaced with the hospital systems. This frequently led to situations where vital data relating to transfusion was not transferred over from one system to the other and was missed. In addition, the practice of staff from other laboratory disciplines performing cross-call cover in transfusion in the absence of formal training systems was identified in some sites. Where ongoing training programmes for on-call staff were provided, systems for evaluation and assessing competencies were often poor or absent.

System and human errors identified

The root causes of error highlighted by this study indicate the presence of both systematic human and organizational failures. Part of the reason for the human errors found may actually be ascribed to the organizational components such as environment and/or systems within which staff operate [12,20].

One of the major obstacles in establishing best practice and compliance in the hospitals studied was the difficulty in gaining access to staff for training, in particular medical staff. There is no standardized system in place for ensuring that medical or other grades of staff are given protected time for attending transfusion/haemovigilance training.

The study demonstrated a clear correlation between high-risk events and two particular practices; failing to check patient identification at the bedside and remote labelling of samples in areas such as the nurse's station. Both of these practices pose a significant risk of ABO-incompatible transfusion to the patient.

Strict adherence to sample collection and labelling procedures has shown to result in a decrease in erroneous blood grouping [21], but this requires an ongoing monitoring system to ensure compliance. Data provided through ongoing surveillance by HVOs can monitor transfusion practice but investment in automated blood sampling and administration systems would enforce compliance and eliminate or reduce the chances of human error [12,22].

Changes to practice as a result of contributing to the near-miss project

Contributing to the project has already prompted practical as well as cultural changes in some of the sites. Phlebotomy services have been extended in one site, in addition to improved provision of training for medical staff at hospital level. Similarly in another site, nurses working in the A&E department have now received phlebotomy training. Feedback from other sites confirms that transfusion documentation has been improved and updating/introduction of certain guidelines which were previously outdated or absent have been introduced as a result of data produced by the project. There has been extension of the hours of work in one medical record department to include some weekend cover so that patients admitted out of hours can have medical record numbers assigned on admission.

Other sites are currently in the process of using this data to introduce solutions to prevent future error, based on the findings of this study.

On a national level, this data can be used to support funding for improvements such as the expansion of phlebotomy services to provide full-time services during routine hours, including the provision of phlebotomy service to A&E. All hospitals should have access to medical records and systems for the provision of new medical record numbers on a 24-h basis to eliminate the need for supplementary numbering systems for transfusion.

The introduction of automated blood tracking/administration systems and upgrading or replacing of LIS systems in addition to the provision of a 'live' interface between computers in the clinical areas and laboratory would allow staff access to the most recent laboratory results.

More generally, the results suggest that haemovigilance and best transfusion practice should be included as part of training for medical staff at undergraduate level and protected time should be made available for staff (including medical staff) to attend haemovigilance/transfusion training at hospital level. Training for all hospital blood bank staff is now mandatory under the provisions of EU Directive 2002/98/EC [23] and formal ongoing training programmes for medical scientists of all grades providing cross-call cover in transfusion, should be provided in every hospital transfusing blood.

Conclusions

The near-miss data obtained through this research have provided hospitals within the Republic of Ireland, new and clear evidence that seemingly low risk, recurring errors are in fact signals that more serious underlying latent defects in our transfusion process exist. It is evident that near-miss reporting should be a part of all adverse event reporting systems as every near-miss analysed provides unique opportunities

to learn by allowing identification of the specific defects or weaknesses that exist and need to be addressed. It is vital that funding and support from management is provided to implement the suggested solutions in order to improve the safety of the transfusion process and prevent future harm to patients.

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