

Implementation and evaluation of a blood products traceability procedure in a District General Hospital

Francis Ajeneye

ABSTRACT

Aim: The study evaluated poor traceability compliance of blood products within a District General Hospital (DGH) and explored why the wards traceability compliance varied across the DGH. The study also explored risk factors that lead to poor traceability of blood products within the DGH and implemented a suitable model to improve traceability compliance. **Method:** A quantitative approach was adopted. Data were collected using questionnaires, observations, and audit where data were extracted from the laboratory information management systems. A questionnaire was designed, piloted, and sent to all ward managers within the DGH, a descriptive statistic of the survey data was analyzed using statistical package SPSS (version 19, SPSS Inc., Chicago, IL, USA). **Results:** The wards with high transfusion episodes were more compliant than wards with fewer transfusion episodes in this study. Moreover, the low usage group had a significant lower compliance rate than the medium and high usage groups ($p < 0.001$), also the study provided an insight into the variety of services delivered to the end-users of transfusion services. It highlighted a lack of training tools; poor procedures for the return of labels and the challenges faced with the portering service. Poor communication between the laboratory and end-users was identified as another issue.

It was evident that although electronic tracking and paper-based methods improved traceability compliance, the cost of the two systems required further exploration. **Conclusion:** The finding from this study reiterated the importance of a trained transfusion practitioner, to provide support and training to the frontline personnel involved in the collection and transfusion of blood products within the DGH. The response to these problems led to the innovative use of the air tube system to send completed transfusion tags to the blood transfusion laboratory.

Keywords: Blood products, Blood safety, Blood Safety and Quality Regulations, Traceability

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INTRODUCTION

Traceability is defined by three distinct elements. These are: the initial prescription of blood components, the distribution slip and tag on the component stating the name of the recipient, and the return of the completed tag to the transfusion department when the procedure is completed. The prescription, distribution, and transfusion of blood components are complex processes within the transfusion chain, traceability compliance explores the quality management system of the process.

There is a lack of appreciation of the complexity of the traceability pathway. Traceability is poorly understood

and inadequately controlled in many cases. The level of safety, efficacy, and quality of blood products must be maintained and optimized on an ongoing basis. The only real test of effectiveness tends to be in live situations when an adverse event has occurred and needs to be handled urgently. In such situations traceability has often found to be wanting with long delays in tracing products and identifying recipients [1].

The developed countries are strengthening the blood safety infrastructure through the development of new tests and pathogen elimination techniques [2]. Many of these measures are the result of trends initiated by pharmaceutical manufacturers and in the healthcare sector although in general such processes have been restricted to, and focused on, developed countries [3].

Hemovigilance was launched in Europe in 1988 and the French established a Hemovigilance program in 1994. An incident in which the use of contaminated blood led to the import and distribution of contaminated plasma products to hemophiliacs in the United Kingdom undermined the government's ability to respond the threat and led to immeasurable damage to the National Blood Service. Although the European Blood Directive had indicated the need for hemovigilance, the idea did not immediately take off. Consequently, the Serious Hazards of Transfusion (SHOT) scheme was not launched until 1996.

The introduction of the European Union Directive in 2002 and Blood Safety and Quality Regulations (BSQR) [4] in 2005 brought a big change in the collection, storage, distribution, and traceability of blood products in the United Kingdom. The BSQR became law in 2005. The mandatory reporting at a national level of any undesirable events toward blood transfusion has been introduced in the United States since 1975. This concept was launched by European network in 1988 by Belgium, Denmark, France, Luxembourg, the Netherlands, Portugal, Spain, and Switzerland, with a simple objective of being able to share any alert that could involve any recipient, participation can either be mandatory or voluntary [5].

The International Society of Blood Transfusion (ISBT) and the International Haemovigilance Network had representation from 46 countries. Country presentations and a survey of participants demonstrated variable development of hemovigilance schemes worldwide, hindered in many countries by lack of resources. Other challenges included fragmented blood transfusion services, cultural fear of reporting adverse incidents (blame culture/fear of retribution), and lack of government commitment and support. Even within Europe and Canada, with relatively well-developed hemovigilance systems, there are very variable reporting rates from 0.2 to 7.07 reports per 1000 units transfused [6].

Murphy and Kay [7] had previously looked at the extent of errors in many aspects of healthcare, including blood transfusion. Their review addressed issues of procedural errors and patient identification. The transfusion of

blood to the wrong patient has been identified as the most important hazard.

The mistransfusion of blood products typically results from errors made during bedside checks prior to the transfusion [8]; this study estimated mistransfusion to occur at a rate of 1 in 12,000 units. Similar results were reported by Sazama [9] in Quebec.

Mummert and Tourault [10] reviewed 150 transfusions associated fatalities from 1990 to 1992, they concluded that nearly one-third of the fatalities could have been prevented by adherence to proper standard operating procedure. Interestingly, a failure to follow procedures is also responsible for one-third of major air carrier accidents. Wiener and Nagel [11] stressed that the need for a model of human error to be used in conjunction with error data collection and classification. The management of error to limit adverse outcomes or unplanned effects is now recognised to be of fundamental importance in system design and training, Reason [12].

Moreover, they estimated that the incidence of mistransfusion was probably even higher due to the failure to recognize many errors. Another review by Ashford [1] noted that errors in the blood transfusion chain seem to occur at a rate of 1 in 1000 events and the data probably underestimated the magnitude of failures, not least because only one-third of errors have clinically significant consequences [13].

The I-TRAC system and its modified versions safe Track and I-TRAC Plus consist of a bracelet, a barcode wrist hand, and a handheld portable data terminal that identifies the patient and the blood pack through a scanner and downloads the information through a portable printer. The John Radcliffe Hospital, Oxford, UK has been a leader in the application of the bedside barcode technology to improve transfusion safety as described by Murphy and Kay [7]. A similar system was also installed at the Georgetown University Hospital in Washington [14]. Chan et al. [15] reported a simplified bar-coded method that reduced error rate in a hospital in Hong Kong. They found out that compliance within the hospital average 90%.

METHODS

Traceability compliance within our Trust was evaluated in two phases. In the first phase of this study, traceability compliance was calculated as the number of blood units successfully traced as a percentage of all blood products issued from the blood stock fridge. The second phase looked at the potential causes of poor compliance and risk factors associated. Data were collected through a questionnaire and structured observation tools. The structured observation tool was developed to evaluate the compliance at the blood collection point and bedside checking procedure on the wards.

Descriptive statistics were used to determine the mean and standard deviation of the compliance rate

for each ward. The wards were further categorized into three groups according to blood usage. The wards that transfused under 500 units were grouped as low users, medium users transfused 500–1200 blood units, and those that transfused over 1200 blood units were grouped as high users between 2005 and 2008.

Structured questionnaire for ward managers

A questionnaire was designed and piloted to ensure that respondents could understand the questions and the response format was suitable. It was divided into sections that covered various aspects of the transfusion chain, including user satisfaction and performance related to traceability compliance. The objective of the survey was to gather more information related to the following research areas:

- Training related to blood product collection and administration.
- Knowledge of traceability procedures.
- How traceability compliance can be improved within the Trust.
- Laboratory staff professionalism.
- Ward staff responsibilities related to traceability compliance.
- Ward staff opinion on traceability compliance.
- General considerations.

Questionnaires were posted to participants together with a self-addressed envelope for the return of the questionnaire. Reminders were sent a month later to maximize the response.

Structured observation tool

Due to a lack of access to the target population, a sample of 58 different transfusion episodes was observed. This represented about 10% of the average monthly transfusions on the wards. The study was entirely voluntary and personal information that could be used to identify participants was kept to a minimum. All wards involved in the collection and administration of blood products with more than two transfusion episodes per week were included. Participants included staff members who collected and administered blood products on the ward. The anonymity of the staff members observed was protected.

Survey of blood bank managers

This phase of the study aimed to provide information about the actual process of traceability and opinions from our consensus. The data gathered were also used in assisting with the choice of traceability processes implemented by the Trust.

Data were gathered through a self-administered questionnaire sent to blood bank managers working

in NHS Trusts in North East of London. It aimed to answer the question, “What variables are associated with traceability compliance in NHS Trust hospitals in North East of London.”

Participants were informed in writing that their participation was voluntary and anonymous. Nonrespondents were not followed up as it was felt that they should not have to justify their decision not to participate.

Hospitals with no blood bank services were excluded from the study. Twenty-five questionnaires were sent to blood bank managers who were invited to participate on a voluntary basis. A covering letter was attached to the questionnaire explaining that all data collected would be treated anonymously. The questions related to individual Trust traceability compliance and addressed issues, such as bed capacity, the availability of a satellite fridge, whether there was a tracking system in place, its cost and training.

RESULTS

The initial response was not satisfactory with a total of 10 out of 36 (28%) returns. Further telephone calls were made to ward managers and a further 20 questionnaires were returned with a final response rate of 30 out of 36 (83%). During the data analysis, the outstanding nonresponders returned their questionnaires, which were included in the final analysis.

Completed questionnaires were numerically coded to facilitate the analysis and organize the results. Descriptive statistics were used to evaluate the sample. The data were not normally distributed; the Kruskal–Wallis test, Spearman’s rank correlation coefficient, and the Mann–Whitney U test were used in the analysis.

Table 1 shows that not all respondents had a clear understanding of the procedures for sending transfused blood labels back to the laboratory. Nineteen percent of respondents did not agree that there were clear procedures for returning labels, although 56% of respondents agreed that they were informed about monthly traceability compliance. It was also evident that some respondents did not think that they should report damaged or destroyed labels. The transfer of patients between wards could be considered another risk factor for traceability compliance. Fifty percent of respondents in this study agreed.

Overall, the results obtained from the blood collection point and bedside check suggested that most of the time the ward staff did comply with checking procedures at the blood collection point and the patient’s bedside. However, full compliance was not achieved at the blood collection point. Seven percent of observed participants did not bring the prescription sheet for checking at the blood collection point, leading to the possibility of collecting the wrong blood. The transport box was not used by 18% of participants for blood collection, which increases the

Table 1: Ward managers' view of traceability compliance

Traceability compliance training (n = 36)	Agree	Disagree	No response
All my staff have been trained	27 (75%)	1 (3%)	8 (22%)
I have enough training materials	27 (75%)	1 (3%)	8 (22%)
I need more resources for training	27 (75%)	2 (6%)	7 (19%)
Some staff were trained on the job	28 (78%)	1 (3%)	7 (19%)
E-learning will help me do my job	5 (14%)	27 (78%)	3 (8%)
Locum untrained staff can collect blood products	3 (8%)	31 (86%)	2 (6%)
Knowledge			
I understand the importance of traceability compliance	30 (83%)	2 (6%)	4 (11%)
I understand the importance of returning labels	31 (86%)	2 (6%)	3 (8%)
Labels are returned immediately after transfusion	30 (83%)	3 (8%)	3 (8%)
We are given monthly feedback about ward compliance	17 (48%)	16 (44%)	3 (8%)
Improving traceability compliance			
Competency assessment can improve traceability compliance	26 (76%)	6 (16%)	3 (8%)
Methods of returning labels can be improved	20 (56%)	13 (36%)	3 (8%)
Too busy to send labels back to the laboratory	21 (59%)	12 (33%)	3 (8%)
Attitude and perceptions to lab staff			
I get prompt responses from the laboratory	32 (89%)	3 (8%)	1 (3%)
We are informed about missing labels	28 (78%)	5 (14%)	3 (8%)
We are given feedback about traceability compliance	20 (56%)	13 (36%)	3 (8%)
Staff courtesy and professionalism is good at all times	28 (78%)	5 (14%)	3 (8%)
Response time in answering telephone calls is acceptable	32 (89%)	3 (8%)	1 (3%)
Ward staff responsibilities			
The ward staff are responsible for returning compatibility labels	32 (89%)	2 (5%)	2 (6%)
The porters returned compatibility labels	12 (33%)	20 (56%)	4 (11%)
There are clear procedures for returning labels	26 (72%)	7 (19%)	3 (8%)
Labels are left on the transfusion bag and sent to the lab	11 (31%)	22 (61%)	3 (8%)
Transfused patients			
Patients are constantly transferred to a different ward	18 (50%)	15 (42%)	3 (8%)
Transfusion rarely takes place on the ward	19 (53%)	13 (36%)	4 (11%)
Wrong ward details on the labels and forms are common	14 (39%)	17 (48%)	5 (13%)
Ward staff attitude			
Ward staff know what to do if compatibility labels are misplaced	26 (72%)	7 (20%)	3 (8%)
Ward staff are regularly informed about traceability compliance	13 (36%)	20 (56%)	3 (8%)
Ward staff are encouraged to report lost or damaged labels	19 (53%)	14 (39%)	3 (8%)

incidence of storage and wastage error (Table 2). There was also non-compliance with the bedside checking procedure by ward staff. Seventeen percent of observed staff did not check the patient’s identification against the blood transfusion request form. The patient’s notes were not used in the bedside checking procedure by 14% of observed staff and the blood pack was not checked against the form by another 14%.

This stage of the study took place from 2005 to 2008. At that time the Trust had implemented a paper-based traceability method and transfusion labels were transported by porters (referred to as Method 1).

In the period between 2005 and 2008 (Table 3), low usage groups had an average compliance of 68.5%. Medium usage groups had an average compliance of 73.8 and high usage groups had an average compliance of 80.2%. Moreover, the low usage group had a significant lower compliance rate than the medium and high usage groups ($p < 0.001$) using the independent T test.

An analysis given in the column of year (2005–2008) in Table 4 showed that although there was a steady increase (50–80%) in overall percentage compliance from 2005 to 2007, in 2008 it fell to 65%. The overall average traceability compliance for all wards for 2005–2008 was 69% with a standard deviation of 13.5. The transfusion department’s approach was to target noncompliant wards, personnel through incident reporting and cascade training to affected wards.

Table 5 shows that 44% of the Trusts had a bed capacity of 401–500, similar to our Trust Demographic data were not normally distributed; hence, the Kruskal–Wallis test was used to compare the relationship between bed capacity and average traceability compliance. The

number of beds on the wards did not influence compliance ($p = 0.64$; median 0.62).

All respondents confirmed that they transferred blood products to other sites or hospitals, however, the transfer of blood products to satellite hospitals did not influence traceability compliance ($p = 0.44$).

Seventy-five percent of respondents said they had a paper-based tracking system, while 25% said they were using electronic tracking. The analysis showed that there was no relationship between electronic tracking and traceability compliance ($p = 0.52$; median = 0.25). It was evident that although electronic tracking and paper-based methods improved traceability compliance, the cost of the two systems required further exploration.

Regarding the percentage of staff trained in the collection of blood products, 50% said the percentage was 51–75%, while the other half assessed it to be 76–100%. The Trusts with most trained staff had better traceability compliance as Spearman’s correlation showed there was a positive correlation between training and traceability compliance but not clinically significant ($r = 0.48$; $p = 0.06$).

Eighty-one percent of respondents said that their hospital had transfused less than 5000 red cell units in the past year. Twelve percent reported transfusing more than 5000 red cell units and 6% did not know the number. There was positive correlation between transfused units and traceability compliance ($r = 0.54$; $p = 0.03$).

Ninety-four percent of respondents said that average traceability compliance was greater than 75%. At the same time, few Trusts were working toward improving their compliance which suggested that both tracking methods (paper and electronic) improved traceability compliance.

Table 2: Structured observation tool (blood collection point and bedside checking)

Question	Compliant	Noncompliant
Blood collection procedure		
Patient’s prescription chart brought to the collection point	56 (97%)	2 (3%)
Blood pack ID checked against report and labels	57 (97%)	1 (3%)
Procedure for blood collection followed as stated by the standard operating procedures	54 (83%)	4 (17%)
Transport box used to collect unit	48 (82%)	10 (18%)
Bedside checking procedure		
Patient’s notes brought to the bedside	50 (86%)	8 (14%)
Patient’s ID checked against the form	48 (83%)	10 (17%)
Blood pack ID checked against the patient’s ID wristband	50 (86%)	8 (14%)
Checking procedures carried out by two qualified nurses	56 (97%)	2 (3%)
Patient confirms all details	56 (97%)	2 (3%)
All identification correct	56 (97%)	2 (3%)
Starting time of transaction recorded	54 (93%)	4 (7%)

Table 3: Average traceability compliance for usage groups 2005–2008

Usage group	Traceability compliance
Low	68.5%
Medium	73.8%
High	80.2%

Table 4: Compliance as percentage of units issued for all wards 2005–2008

Year	Compliance as a % of all units issued n = 24	Standard deviation
2005	49.6	(17.7)
2006	65.9	(15.4)
2007	82.3	(9.9)
2008	64.8	(14.4)

Table 5: Demographics of the 16 NHS Trusts surveyed

	Frequency (n=16)	%
Bed capacity		
1–100	1	(6.3)
101–200	2	(12.5)
401–500	7	(43.8)
>500	6	(37.5)
Trusts with satellite fridges		
Yes	13	(81.3)
No	3	(18.7)
Transferring blood to other sites		
Yes	16	(100)
Tracking system in place		
Paper tracking	12	(75)
Electronic tracking	4	(25)
Cost of tracking system in place		
Medical Laboratory Assistant	9	(56.3)
Not known	7	(43.7)
Hospital staff trained in the collection of blood		
51–75%	8	(50)
76–100%	8	(50)
Red cell units transfused in the last 12 months		
>5000	13	(81.3)
<5000	2	(12.4)
Unknown	1	(6.3)
Average traceability compliance		
<75%	1	(6.3)
>75%	15	(93.7)
Feedback mechanism to users		
Yes	13	(81.3)
No	3	(18.7)
Audit of the transfusion process		
Yes	13	(81.3)
No	3	(18.7)

DISCUSSION

Pagliari and Rebullia [16] highlighted that the main elements of a quality approach for preventing identification errors include having a transfusion safety officer, regular training, competent staff, system reengineering, and standard operating procedures. Similarly, Steinbrook [17] identified the factors associated with good levels of compliance as the appointment of a hospital transfusion practitioner, electronic prescribing, having a medical laboratory assistant in clinical units, timely feedback and reinforcing success. In the light of these studies there are ongoing initiatives in the Trust to develop better testing and assessment of competency for both clinical and laboratory staff. The major changes made within the traceability procedure had improved our compliance to 100% as shown in Figures 1 and 2.

The University of Iowa, USA also evaluated a similar system and found out that they captured error almost 10 times better than the manual process. Despite the advantages of the barcodes systems, traceability compliance did not improve significantly (Nichols et al. [18]). The bar codes on wristbands can be blurred and difficult to read. Bar code-based system requires that the wrist and unit can be scanned each time, in urgent situations and make the process be clumsy.

Tracesoft blood tracking system was designed to scan in and out blood pack to be delivered to the wards. It was designed to search for blood packs and location and also consists of a central server giving a web view activity, which provide controlled access to blood fridges

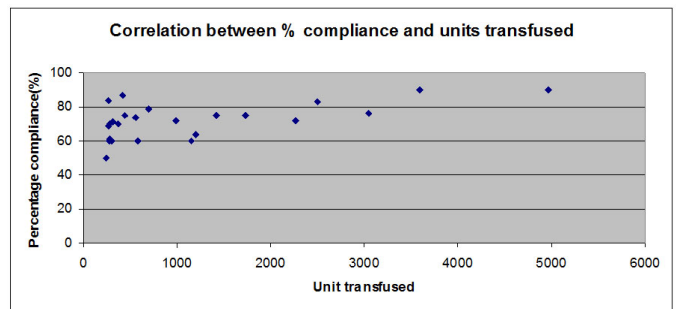


Figure 1: Correlation between traceability percentage compliance and units transfused.

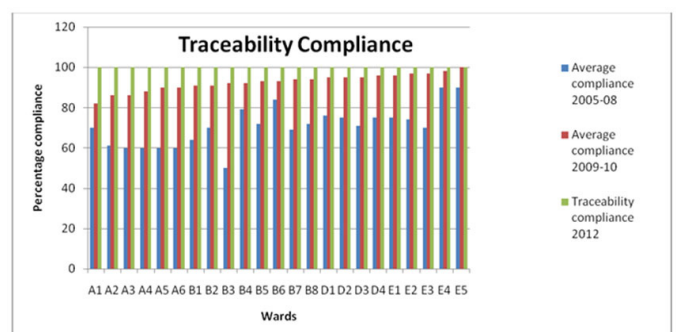


Figure 2: Comparison of ward traceability compliance using Methods 1 and 2.

and bedside software. All kiosks and bedside devices and linked with the central server in a real time thereby providing a view of all product movement.

In 1991, Albert Einstein College of Medicine in the United States evaluated the BloodLoc system. In this system, an alphabetic code taken from the patient's bracelet must be used to access the assign unit. The same system was also implemented in Dartmouth-Hitchcock Medical Centre in New Hampshire and Gaetano Pini orthopaedic Institute in Milan, Italy [19].

Dzik [20] and Sandler et al. [14] reported radiofrequency technology (RFID), a method using a frequency of 13.56 MHz. The radiofrequency blood bag tags integrated into the blood bank computer system. The tags were used in combination with the radiofrequency patient's wristbands with a built-in radiofrequency reader. Radiofrequency has several advantages in comparison to bar coding for patient's safety applications. Radiofrequency technology chips can hold more data than a bar code and can include more data, such as allergies, blood needs a special, requirements. Second, RFID did not require the use of light beams with a bar code and RFID chips are interrogated simply by proximity to an electric reader.

Turner et al. [21] recorded 51 units prior to and after the designation of the barcode patient identification. In their study, 7 (14%) of the total patients have been queried to perform identification first, practically by saying their first and last names, to ensure that the right patient get the procedure. Six (12%) patients were not able to wear their ID bands during the identification check. Since the introduction of this computer code technology, the process of identifying patients by asking them to state their first and last names were implemented. Turner's team noted a significant figure of 49 (96%) patients having a similar data on their blood bag. However, this barcode technology does not drive the staff to perform all the important steps. They could just falsify their documentation, recording coverage of everything when these were not actually done. Only 41% of compliance was noted, owing mainly to the substandard checking.

Davies et al. [22] incorporated the concepts of the bar code technology. This involved units from the blood bank amounting to 50 products, another 20 from the theatre and 10 units more from the cardiac recovery unit (CRU). Records that were penned revealed a ratio of 42 to 50 (or 84%) from the blood bank units, 8 of 20 (40%) from theatres, and from the CRU refrigerators 1 of 10 (10%) patients brought to the refrigerator. After the electronic system introduction, the figures were set to 19 of 20 (95%; $p = 0.43$), 18 of 20 (90%; $p = 0.002$), and 5 of 5 (100%; $p = 0.002$), respectively.

The findings from this study also reiterated the importance of a transfusion practitioner who can provide support and training to personnel involved in the collection and transfusion of blood products. Their role is also to ensure that training and the delivery of healthcare meet acceptable standards. The research highlighted

that wards where there are trainers provide a higher traceability compliance than wards without a trainer.

We found out that wards that carried out many transfusions performed better than those that only carried out a few. This information enabled enhanced training to be provided in the poorly performing wards.

The study provided an insight into the variety of services delivered to the end-users of transfusion services. It highlighted a lack of training tools; poor procedures for the return of labels and the challenges faced with the portering service. Poor communication between the laboratory and end-users was identified as another issue. The response to these problems led to the innovative use of the air tube system and greater incident reporting at every stage of the transfusion process.

The initial survey provided a baseline from the problems that can be encountered at the blood collection point and in the bedside checking procedure. The issues that were identified included incomplete documentation brought to the blood collection point and untrained personnel collecting blood products at the blood collection point. The problem of blood product collection was addressed by providing security locks on the blood fridges to deter untrained staff collecting blood products, in greater number of cases this had been effective. It has become mandatory that two nurses must check blood products administered on the wards.

This finding from this research had enabled the development of a tool (Objective Structure Clinical Examination) covering knowledge, skills, performance, and products for all frontline staff involved in blood collection, distribution, and the administration.

This also encourages personal development plan, annual competency, validation of staff and also keeping with the requirement of the GMS contract (Department of Health [23]). It had also be a good evidence for the progression through the knowledge and skill framework along the side with the Agenda for Change implementation (Department of Health [24]). It was also clearly identified that supervision and training from a practitioner with skills in transfusion is an essential requirement. The ward with a trainer provided a high standard of care, compared to some wards without a trainer. The wards with high transfusion episodes were more compliant than wards with fewer transfusion episodes.

It became evident that traceability compliance varied from one Trust to the other and various strategies were being deployed to attain full compliance. Technology has been introduced by many Trusts, but in this case there was neither the time nor the money to investigate it fully. This may not be so much of a problem; the study by Murphy and Kay [7] observed that most tracking systems could be overridden and concluded that such systems could only assist in reducing errors and augment existing hospital tracking system. Chan et al. [15] also concluded from their study that additional training in transfusion medicine would be beneficial by physicians in all specialities. This was based on their findings from the survey conducted

which demonstrated lack of knowledge of transfusion medicine across all specialities and all training levels.

Bolton-Maggs and Cohen [6] explained that the errors made in the basic transfusion process is very disappointing despite the national initiatives and standards introduced in the last 10 years, they highlighted the importance of the essential steps in the transfusion process. In addition, communication failures arising between clinical and laboratory staff, sharing care between hospitals or between the hospitals and the community remains a concern.

Radiofrequency technology remains a promising technology, and has an advantage in managing inventory and preventing overstocking of blood products. The RFID Tracking in Paediatric Transfusion had successfully implemented by using a High Frequency RFID system in managing product products inventory [25]. Swedberg concluded in his studies that more research is required in bigger hospitals with trauma centres. Coustasse et al. [26] also suggested that RFID provided improvement in the quality of care and efficiency but the initial cost, security, and privacy appear to be a challenge in the adoption of this technology in Transfusion Medicine. As RFID gains acceptance in Transfusion Medicine significant impact is expected with regards to patient safety.

The full impact of traceability compliance will only become clearer when more rigorous, large-scale studies are conducted that take into consideration all possible variables.

CONCLUSION

The finding from this study reiterated the importance of a trained transfusion practitioner, to provide support and training to the frontline personnel involved in the collection and transfusion of blood products within the DGH. This information enables us to scale up training in the low performing areas of the district general hospital. This study ensure the rapid adoption of traceability compliance by wards in the Trust and improve the attitude of stakeholders to patient safety.

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Author Contributions

Francis Ajeneve – Conception of the work, Design of the work, Acquisition of data, Analysis of data, Interpretation of data, Drafting the work, Revising the work critically for important intellectual content, Final approval of the version to be published, Agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved

Guarantor of Submission

The corresponding author is the guarantor of submission.

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Trust Clinical Governance approved this study.

Conflict of Interest

Author declares no conflict of interest.

Data Availability

All relevant data are within the paper and its Supporting Information files.

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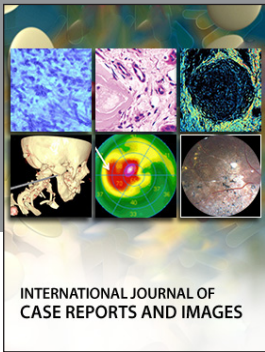
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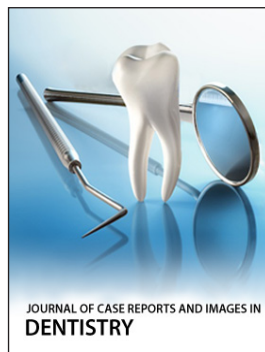
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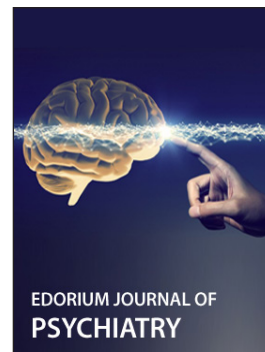
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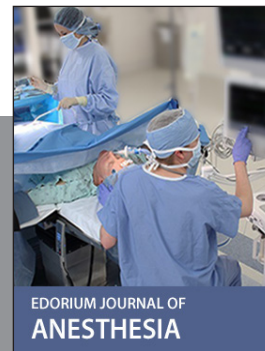
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