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Original Article

Documentation errors in transfusion chain: Challenges and interventions

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ABSTRACT

Background and objective: There are several steps in transfusion chain where accurate documentation is critical. This study was conducted to evaluate the frequency of documentation errors during transfusion process and to evaluate the effectiveness of interventions in error-management.

Methods /Material: This study was conducted at Aga Khan University, Pakistan during 2016–2018. Transcription and bedside documentation errors were identified from in-house computerized system and from medical charts. Raw WBIT rate was calculated for repeat blood samples and adjusted for frequencies of ABO-groups in our population accounting for silent WBIT. Rate of ABO-mismatched red cell transfusions was calculated for the annual totals of red cell transfusions. Chi-square was used for observing relationship among errors of various data sets.

Results: A total of 43 WBIT was identified during 54,219 repeat blood samples where blood group was already defined in blood bank information system. Annual unadjusted and cryptic WBIT rate was consistent at 0.8 and 0.6 per 1000 samples respectively during 2016–2018 (p 0.859). There were 1161 transcription errors (1.1 %) in blood group documentation in 105,064 blood samples received for arranging blood products. ABO-mismatched transfusion rate was 0.9 for 10,000 RBC transfusions in pre- and decreased to 0.4 in post-typing era. Overall, the compliance for completing checklist, correct ABO technique and appropriate ABO-interpretation was 88 %, 40 % and 24 % in the reviewed medical charts.

Conclusions: Sample labeling errors were not improved through training or counseling. Bedside ABO-typing and checklist prior to blood transfusion can control the ABO-mismatched transfusion if done timely and correctly.

1. Introduction

In 1818, Professor James Blundell experimented the very first blood transfusion in a woman who exsanguinated following severe post-partum hemorrhage [1]. Although this patient passed away, but his efforts established a new frontier in medicine. Furthermore, Dr. Karl Landsteiner's landmark discovery of ABO-blood groups in 1901, revolutionized the concept of safe blood transfusion. Today, non-infectious complications are the primary concern due to declining or low incidence of transfusion transmitted infections [2–4]. One of the most critical and potentially fatal transfusion reactions is administering ABO-mismatched red cells. This may be consequential to mislabeling of blood sample / blood unit, incorrect handling of blood units, or bedside error in correct patient's identification. Such transfusion errors were indicated very early. For example, The United States Food and Drug Administration (FDA) reported 256 transfusion-associated fatalities (during 1976–1985), of which ABO-mismatched transfusions accounted for 51 % of deaths [5]. In 1996, United Kingdom and Ireland launched Serious Hazard of Blood transfusion (SHOT) for collecting confidential information of transfusion related deaths and its serious complications [6]. Though voluntary, SHOT data (1996–2003) showed 1:100,000 ABO-incompatible transfusions with 1:1500,000 deaths [7]. This incidence was significantly reduced to 8 acute hemolytic transfusion reactions (AHTR) and 2 deaths during 2010–2016 [8], and no fatality in 2017 [9]. Global interest in hemovigilance initiated International Hemovigilance Network in 2009 and a national interest in 2013. While Safe Blood Transfusion Program (SBTP) in Pakistan is determined to improve blood safety [10], local data regarding

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documentation errors in blood transfusion is largely lacking except for a single centre report [11].

Located in Southern Pakistan, Aga Khan University Hospital (AKUH) blood bank was established in 1985 and was accredited by JCIA and CAP in 2006 and 2016 respectively. The blood bank has a computerized information system since its inception, and historical blood group-check was the only measure used to avoid ABO-mismatched transfusions. Wrong blood in tube (WBIT) was defined as the mismatch between current and recorded/historical blood group of the patient in question [12]. The incidence of ABO-mismatched transfusion (1:15785), its mortality (1:71033) [13] and WBIT (1:1789) [14] prompted initiation of bedside ABO-typing prior to blood transfusion in the hospital. Hands-on-training to perform and interpret ABO-group was provided to 1400 staff nurses through 50 teaching coordinators. Side-by-side, a pre-transfusion checklist was developed to ensure that the right patient received the right blood. Nurses' competency for transfusing blood and ABO- testing was maintained annually.

This study aimed in determining the various documentation errors in the transfusion chain and evaluating the significance of bedside-ABO typing and the checklist in minimizing the frequency of ABO-mismatched red cell (RBC) transfusions.

2. Material and methods

2.1. Setting

This study was conducted at Aga Khan University Hospital (AKUH), Pakistan, a 700-bedded tertiary care academic institute with services for trauma and transplant patients. Its annual blood collection is approximately 40,000 units with facilities for component manufacturing, apheresis and stem cells collection. The hospital transfusion committee (HTR) monitors various clinical and managerial quality indicators and meets monthly to discuss transfusion related issues. Matters arising are discussed/resolved with chief medical officer (CMO) from time to time. HTR's performance is reviewed annually by the hospital leadership seeking recommendations for further improvement.

2.2. Transfusion protocols at hospital

2.2.1. Blood sampling for arranging blood

Blood samples are collected in EDTA tubes by staff nurses, phlebotomists or physicians and labeled with pre-printed labels, having two patient identifiers (full name and medical record number). Sample labeling is done at the bedside after confirming the identification verbally from the patient/attendant and cross checking from his/her wrist band as per institutional guidelines. There is no addition/correction of patients' information in sample's labeling or requisition once received in blood bank. There are regular teaching sessions for nurses/young doctors and phlebotomist for correct blood draw and labeling of the tube.

2.2.2. Historical ABO check in blood bank

Transfusion orders are made by clinicians through computerized physician order entry (CPOE). After receiving the sample, blood bank technologists perform the necessary technical work including historical check for blood group. Results of blood typing are added as individual reactions with anti-sera and red cells while blood group interpretation is made by the computerized system according to programmed dictionary. Entering blood group results for a wrong patient or changing blood group in the system is captured as a transcription error. In case of current vs. historical typing mismatch, a fresh sample is requested for re-typing.

2.2.3. RBC unit type and screening results confirmation before dispensing

The blood units are re-typed before dispensing. The blood bank information system (BBIS) does not allow releasing of reactive blood units to the patients. An ABO-bedside typing card with necessary accessories was issued with red cell units by the blood bank. As per institutional policy, ABO-card is sent for a patient's first RBC transfusion at the hospital while patients with known ABO-type and with a history of previous transfusions are exempted from bedside typing.

2.2.4. Bedside ABO typing

On receiving a blood unit, two nurses establish the identity of correct recipient, completes check list and performs bedside ABO-typing to ensure patient's readiness for transfusion. This test (Serafol ABO BioRad, Gmbh, Germany) is based on hemagglutination and the card has three reactions field; two are coated with dried monoclonal antibodies for A and B antigens and the third serves as an auto-control. One drop of recipient's blood and isotonic saline are added to all three fields, mixed and read. Agglutination in a field is a positive reaction while a positive auto control invalidates the results. Red cell transfusion is initiated only if there is no mismatch between the unit label and bedside ABO-card results. After completing the test, the nurse places the dried cards in a plastic pouch in the respective medical chart. As per institutional policy, there should be 100 % compliance for completing ABO-cards and checklists.

2.2.5. Structured training and appraisal

A staff is credentialed for performing a given task after at least six-month training under supervision. Additionally, competency assessment is conducted annually for all staff with a remediation of three months in case of failure. All information is electronically maintained and reviewed at the time of annual appraisal.

2.2.6. Mode of counselling

As per institutional policy, every human error such as wrong addressograph or an incorrect transfusion is logged electronically on an incident form. The in-charge conducts an inquiry reviewing the entire process including human factors, controlled/uncontrollable external factors, equipment performance, staffing, staff training and competences, staff contingencies etc. Counselling and training are provided as per shortfall identified and documented. All completed incident forms are reviewed and closed by CMO.

2.3. Data collection for this study

Following documentation errors were observed during the study:

1 Wrong addressographs: The mis-collected samples were identified as WBIT and the details were obtained from online incident forms. This was also one of the quality indicators for the blood bank.
2 Blood group editing errors: The recipients' blood groups edited in the computerized system was recorded as transcription error. This information was recorded with patient name and medical record number, date at which change was made, blood group before and after editing and the name of technologist making the change. Each blood group is re-checked by a senior technologist prior to issuing blood unit.
3 Blood unit handling errors: Releasing a reactive or wrong blood unit was considered as a handling error.
4 Bedside documentation errors: ABO-mismatched transfusions data was obtained from incident forms as filed by blood bank. Failure to document bedside ABO and completing checklist by the transfusion nurse was considered as bedside documentation error. This data was not computerized and therefore was obtained by reviewing a cohort of medical charts. First, the data was retrieved from the blood bank information system to identify patients who received red cells transfusions and were typed for bedside ABO-groups during last three years (2016–2018). Patients who had ABO- mismatched transfusions were studied in detail for their demographics, location and outcomes. Two hundred medical charts were reviewed to

determine the attributes of ABO-cards (technique, result interpretation and nurse traceability) and the checklists for completion.

2.4. Data analysis

Data was entered and analyzed in Microsoft excel 2010. Documentation errors during blood grouping and screening were expressed as % of total samples received for blood grouping prior to transfusion. Annual WBIT rate was determined exclusively on repeat samples to comply with Dzik WH et al. calculation [15] and was expressed as 1:n where 'n' is the number of patients receiving ≥ 2 red cell transfusions. This rate was adjusted for ABO frequencies for Pakistani population to account for "silent" WBITs that remained cryptic because of chance matching of ABO-type. Hence silent WBIT rate was obtained by multiplying the unadjusted rate with a correction factor of 1.4. This factor was calculated through 1/1-Q where $Q = (0.23)^2 + (0.35)^2 + (0.33)^2 + (0.09)^2$ representing frequencies of blood groups A, B, O and AB respectively as per our own blood bank data for blood donors.

Rate of mismatched red cell transfusions before (during 2014–2015) and after (during 2016–2018) bedside typing was simply calculated as a percentage of mismatched transfusions over annual totals of red cell transfusion. The observed number of attributes required for successful completion of ABO-cards and checklists was expressed as the percentage compliance of total reviewed charts where 100 % was considered as the threshold.

Pearson Chi-square (two-tailed) was used to evaluate significance of relationship between documentation errors over a period of years using Statistical package for Social Sciences version 24 (Chicago, USA). A p-value < 0.05 was the threshold of significance.

3. Ethical approval

The study was conducted after approval from ethical review committee of Aga Khan University (#4886-Path-ERC-17) and conformed to standards as described in declaration of Helsinki. Being a retrospective study, informed consent was not required as per institutional ERC.

4. Results

4.1. Sample collection errors

A total of 43 WBIT was identified during 54,219 repeat blood samples where blood group was already defined in blood bank information system. Annual unadjusted and cryptic WBIT rate was consistent at 0.8 and 0.6 per 1000 samples respectively during 2016–2018 (p-value 0.859) (Table 1). High output areas like ER, OR and ICU were mainly responsible for wrong addressographs. Interventions like monthly educational flyers and sensitization of personnel for correct blood draw failed as the number and turnover of health personnel (nurses/interns/ residents) was too large for error-control simply by education or counseling.

4.2. Transcription errors

For three years (2016–2018), a total of 105,064 tubes were received for arranging blood products (table1). Technologists made 1161 transcription errors in documenting blood group representing 1.1 %. Blood group was revised for 208 patients for various reasons (Table 2). Continuous monitoring of transcription errors as a quality indicator with identification and counseling of concerned technologists led to the decline of these errors from 1.6 to 0.6 % in the last three years (p-value < 0.001). Annual appraisal of technologists might also be a contributing factor for this reduction. It was observed that this kind of intervention was effective in a controlled environment like blood bank.

Table 1
Documentation errors in labeling, blood grouping, screening for transfusion purpose for 2016-2018.

Year→	2016	2017	2018	*P*-value
Wrong blood in tube (WBIT)				
Total WBIT(n)	13	15	15	0.859
*Repeat samples(n)	17,639	19,756	16,824	
**Cryptic WBIT rate (1: n)	1900	1844	1570	
Blood groups' editing for samples received for transfusion				
Total edits (n)	557	402	202	< 0.001
*Total tests performed (n)	35,096	35,235	34,733	
**Editing rate (1: n)	63	88	172	
Errors in handling blood units				
Total edits (n)	1	0	0	0.368
*Total blood units issued(n)	63,711	63,754	63,609	
**Editing rate (1: n)	63,711	0	0	
Wrong red cell transfusion				
Wrong red cell transfusion(n)	1	1	1	0.999
*Total of transfused RBCs(n)	22,797	22,792	23,896	
**Wrong transfusion rate (1: n)	22,797	22,792	23,896	

* represents denominator for the given documentation error.
** n is expressed.

Table 2
Reasons for blood group revision in patients receiving transfusion during 2016-2018 (n = 228).

Reason for revising blood group	n
Identification of correct Rh group	100
Identification of correct subgroups or rare groups	9
Discrepancy in current and historical group	119

4.3. Blood unit handling errors

In 2016, the screening results were accidently edited for a unit resulting in transfusing a hepatitis B reactive blood product to the patient. This incident led to the removal of manipulation/editing option once screening results were released by the instrument. Table 1 shows edits rate for screening.

4.4. Transfusion errors

Table 1 summarizes the total RBC transfusions and ABO-mismatched transfusion rate. ABO-mismatched transfusion rate was 0.9 for 10,000 RBC transfusions (data not shown) in pre- and decreased to 0.4 in post-typing era. During post-bedside typing period (2016–2018), a total of 69,485 RBC units were transfused. Of these, only 22 % represent the first-ever red cell transfusions. Bedside ABO typing was performed during transfusion of 15,266 red cell units.

4.5. Root cause analysis of incorrect red cells transfusions

During 2016–2018, three wrong red cell transfusions were reported (Table 3) and all were exclusively in ER. WBIT was the sole reason for two of the three errors. Review of bedside- ABO cards showed the incorrect technique of testing.

4.6. Bedside ABO-typing and time-out

The blood bank information system identified 268 patients for whom ABO-cards were dispensed during October to December 2018. Medical charts in record room were available for 211 (79 %) patients only, including 34 charts from emergency room. Review showed that ABO-cards and time-out forms were filed in 109 (52 %) and 185 charts (87 %) respectively. Fig. 1 summarizes the observations during clinical audit. Overall, the compliance for completing checklist, correct ABO

Table 3
Morbidity and mortality associated with ABO-incompatible transfusions (2016-2018).

Year	Age in Years /Sex	Underlying pathology	Location of patients	Blood group of recipients	Blood group of transfused units	Volume received (ml)	Reason for error	Morbidity	Mortality
2016	32/M	RTA*	ER	Oh+	O+	250	Technical error by blood bank	Acute tubular necrosis	Nil
2017	74/F	DLBCL**	ER	O+	B+	250	WBIT	Nil	Nil
2018	27/F	Ectopic pregnancy	ER	B+	A+	300	WBIT	Acute tubular necrosis	Nil

* RTA: Road traffic accident.
** DLCBL: Diffuse large B-cell lymphoma.

technique and appropriate ABO-interpretation was 88 %, 40 % and 24 % respectively in the reviewed medical charts.

5. Discussion

The study showed several documentation errors in transfusion chain. The silent WBIT rate was 0.6 per1000 repeat blood samples and stayed consistent during 2016–2018. Transcription errors reduced from 1.6 to 0.6 % with repeated training of technologists. Bedside ABO-typing and check lists were effective in reducing the rate of ABO-mismatched transfusions from 0.9 per 10,000 RBC units in pre- to 0.4 in post-typing era.

Correct blood sampling/labeling is the first step related to transfusion safety. Though definitions for WBIT and policies for blood sampling differ worldwide, mis-collected tubes are frequently identified in the laboratory setting. This is extremely important in relation to transfusion as WBIT can be potentially fatal for a patient who receives ABO-incompatible transfusion due to a blood unit arranged according to the blood type of mis-collected tube. Silent WBIT rate in this study was 1 in 1628 repeat samples which is not-so-good performance when compared to WBIT rate of 1:1986 in 190,406 repeat blood in a large multi-center international study [15]. The report considered a WBIT rate of > 1:1000 as the worst performance. It also highlighted the significance of using national patient identification systems in Sweden and Finland which was associated with very low estimates for WBIT. Blood banks at United States and European countries reported WBIT rate ranging from 1:1303 to 1:3448 though definitions and calculations differ [12]. A recent report from India reported an incidence of 1: 3602 in 61,237 repeat samples for ABO grouping. Though appropriate training of medical staff and phlebotomist is critical in correct blood sampling, we found that these were ineffective in preventing WBIT by itself. To counteract human errors, robust electronic devices e.g. barcode system or RFID for patient identification may reduce WBIT rate. For example Kaufman RM et al. in 2018 observed a crude WBIT rate of 1:10,110 during manual patient identification in contrast to only 1:35,806 during electronic identification ($p < 0.0001$) and a fivefold decrease in adjusted WBIT rate [16]. 'Group check' sample or requiring second sample to confirm blood group may increase WBIT detection and minimize sampling errors [17]. In our institute, we are acquiring hardware system for scanning barcode on wrist band for patient identification at the time of blood draw and when transfusing the patient. The policy of blood grouping every patient admitted in the hospital is also under consideration.

Editing of a blood group is a serious issue. Technologists' editing was high at 1.6 % in 2016 but decreased to 0.6 % in 2018. The introduction of new blood bank information system in 2016 and difficulties in entering the results faced by technologists resulted in these errors. Continuous training of technologist resulted in decline of editing in blood grouping. Similarly, human errors in releasing a sero-reactive unit were eliminated through interfacing of instruments with BBIS eliminating the possibility of editing/manipulating the screening results.

Final bedside check for establishing the correct blood unit for the intended recipient is another element of transfusion safety. In fact, this is last opportunity to evade ABO-incompatible transfusions or human errors. One of the ways of establishing recipient identification is doing bedside ABO-typing prior to blood transfusion. This method was described as early as 1990 [18]; however, its reliability was questioned soon after its inception [19,20]. Bedside check for ABO group can detect up to 93 % of ABO- incompatibilities and this sensitivity increased to 99.6 % by adding data matching check [21]. These two controls were probably the reasons underlying low incidence of ABO-incompatible

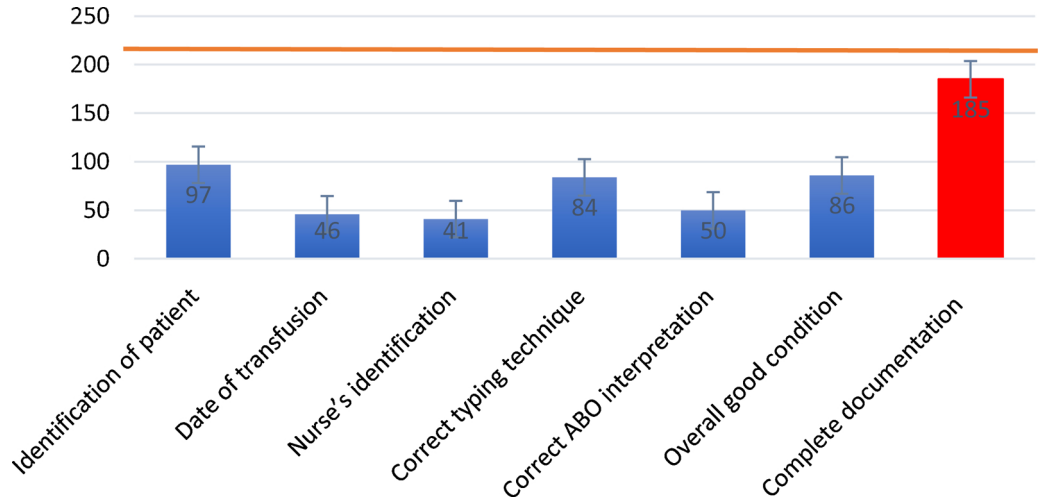

Fig. 1. Compliance of completing bedside-ABO typing (blue bars) and checklist (red bar) in 211 medical charts. Red bar indicates 100 % threshold for compliance.

transfusions in France since 2003. Various ABO-card systems have been described and validated for their performance [22] but the key element is appropriate training and experience of transfusion nurses in timely performing bedside ABO-typing [20,23]. Our study observed filing of ABO-cards in 52 % of medical charts only. This might be due to discarding of ABO-cards after performing test for curtailing risk of infection. Overall performance was better in completing checklist then filing the ABO-cards. As an intervention, bedside typing results were scanned and uploaded in CPOE in 2019 and monitored as a quality indicator of blood bank performance. Within the same year, colored educational flyers depicting ABO-group results were placed on various nursing stations. A 2017- survey following SHOT recommendations for using bedside checklist showed that 41 % Trusts/health boards had already implemented the checklist while 29 % planned to do so. It is imperative to know if such implementation was successful in minimizing human factors for error-reduction. In our study, we found a better documentation compliance with checklist than with ABO-cards. Since both controls were started at the same time, it is difficult to analyze the performance of each separately. We believe that ABO-control and checklist assisted in reduction of human error for preventing ABO-incompatible blood transfusion. However, two ABO-incompatible transfusions in 2017 and 2018 occurred despite bedside ABO-typing raising concerns regarding nurses' competencies to perform and interpret blood group. Electronic capturing of data indicates an improved compliance in test performance ranging from 80 % in ER to 95 % in ICU and 100 % in other service lines (March data 2020, data not shown).

5.1. Limitations and strengths

The study identified several human errors in documentation within the transfusion chain that can be detrimental with serious consequences for the blood recipients. However, the study was limited in its scope as it was a single institutional and might not reflect the practices at other blood banks in the country.

6. Conclusions

Wrong blood in tube cannot be minimized by training or counseling of health care providers. Robust electronic interventions are needed to counteract such human errors. Bedside-ABO typing and completing checklist prior to blood transfusion can be effective only if done timely and correctly.

Authorship

BM conceive the idea, supervise research and wrote the manuscript. AKS and MWS wrote part of the manuscript. NS conducted audit of medical charts and contributed in data collection and analysis. FK and NA critically reviewed the paper.

Ethical approval

The study was conducted after approval from ethical review committee of Aga Khan University (#4886-Path-ERC-17) and conformed to standards as described in declaration of Helsinki

Being a retrospective study, informed consent was not required as per institutional ERC.

CRediT authorship contribution statement

Bushra Moiz: Conceptualization, Methodology, Formal analysis, Writing - original draft, Visualization, Supervision, Project administration. **Arsalan Kabir Siddiqui:** Writing - review & editing. **Nazish Sana:** Investigation, Writing - original draft. **Muhammed Wahhaab Sadiq:** Writing - review & editing. **Farheen Karim:** Conceptualization, Methodology, Resources, Writing - review & editing. **Natasha Ali:** Writing - review & editing, Methodology.

Declaration of Competing Interest

Authors declare no conflict of interest

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