GOOD CLINICAL PRACTICES TOWARDS SAFE BLOOD TRANSFUSION: PROCESS RE-ENGINEERING APPROACH

DR. SOMU G\textsuperscript{1}, DR. AKASH ANAND SHRIVASTAVA\textsuperscript{2}, DR. (COL) DAYANANDA M\textsuperscript{3}
Department of Hospital Administration,
Kasturba Medical College Manipal
Manipal University
Madhavanagar, Manipal -576104
INDIA
somu.g@manipal.edu

Abstract: Wrong blood transfusion is a medical negligence. Every hospital must have a strong policy to check incorrect blood transfusion and ensure that these policies are strictly implemented at the time of transfusion. Wrong blood transfusions can occur due to carelessness of the staff and shortcomings in verifying the blood bag to be transfused. Blame game and reasons can be avoided and wrong blood transfusion prevented by the formation of a short checklist consisting of the important details to be verified orally before initiating transfusion. This study aims at studying the blood transfusion process in a hospital and provides suggestion/s for streamlining the process of transfusion. The study also analyses near miss incidents, errors in transfusion process and also to streamline the same by using a process re-engineering approach. The methods adopted in carrying out this study were personal observations made at the blood-bank and ward level to know the practice of blood transfusion pre and post implementation of checklist. Adopting a process based root-cause analysis at the time of blood-bag issuing and transfusion. The study was carried out in a 2032 bedded tertiary care hospital. The design is prospective, observational conducted over a period of eight months in two phases. The data source was from safety incident reports and interviews conducted with the hospital staff concerned with blood transfusion. All the reports from Phase-one of the study were analyzed. Based on the observations, interventions in the form of “4C” checklist and work instructions were implemented in the hospital and then safety reports for Phase-two was analyzed. Results: The number of blood transfusion related safety incidents observed in Phase-two reduced markedly although the workload remained comparable during the two phases. An audit was conducted to corroborate the decline in transfusion related safety incidents. Further a declining trend in the reporting of incidents was seen through the subsequent phases. Conclusion: In conclusion the study findings demonstrate that improvement in quality of healthcare can be brought about by need based, focused intervention analysis and measurement, implemented in the form of “4C” checklist and work instructions which proved to be effective in reducing the number of human errors leading to wrong blood transfusions.

Keywords: Checklist, Human error, Process re-engineering, Work instructions, Near-miss, Blood transfusion
1. Introduction:
“Wrong blood transfusion is an error which no hospital/doctor exercising ordinary care would have made. Such an error is not an error of professional judgment but in the very nature of things a sure instance of medical negligence.”[1]

Every hospital must have a strong policy to check incorrect blood transfusion and see to it that these policies are strictly implemented at the time of transfusion. The recent testing facilities have lowered the incidence of transfusion-transmitted diseases to minimum; however, the incidence of adverse events due to human errors, ABO incompatibility, alloimmunization, bacterial contamination, and immunomodulation phenomena remain a matter of concern. [2]

2. Errors in Blood transfusion:
This study focused only on avoidable human errors related to ABO incompatible blood transfusion and no other hemolytic transfusion reaction.

Table 1. Transfusion related fatalities due to ABO incompatible blood transfusions. [3]

<table>
<thead>
<tr>
<th>Year</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>%</td>
<td>5</td>
<td>6</td>
<td>10</td>
<td>22</td>
<td>5</td>
</tr>
<tr>
<td>%</td>
<td>4</td>
<td>9</td>
<td>2</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>%</td>
<td>10</td>
<td>5</td>
<td>30</td>
<td>30</td>
<td></td>
</tr>
</tbody>
</table>

A popular management adage goes “If you can’t measure it you can’t manage it”. Thus, the importance of effective measurement in checking any error cannot be overstated.

The study encompasses measuring of errors in the blood transfusion process, which could lead to potential mismatch transfusions, analyzing errors and introducing focused interventions to bring down such errors such as adopting a process re-engineering approach. This intervention helps make the transfusion process safe with no room for error be it human or otherwise.

2.1 Near Miss

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 recognized before the transfusion took place. [4]

2.1.1. Definition

Definition of wrong blood in tube (WBIT) incidents: [5]

- Blood is taken from the wrong patient and is labeled with the intended patient’s details
- Blood is taken from the intended patient, but labeled with another patient’s detail

3. Aim of the study

To study the blood transfusion process and providing suggestions for streamlining the process of blood transfusion.

3.1. Objectives of the study:

- To analyze the near miss incidents during blood transfusions
- To identify the errors in the process of transfusion.
- To streamline the process by introducing checklist/work instructions for reducing errors.

4. Methodology:

The study was carried out in the blood bank and patient wards of a 2032 bedded tertiary level teaching hospital for a period of eight months. Study design was prospective; observational. The study was divided into two phases.
of four months each. During phase-one, the errors in transfusion were initially assessed and analyzed followed by implementation of process redesign in the form of checklist and work instructions. The second phase followed this and finally measuring the outcomes of the intervention. Analysis of safety reports regarding blood transfusion was carried out. Process based root-cause analysis was done at the time of issue and at ward level.

Data was collected from the Safety committee office, Medical Records Department and the Department of Immunohematology and blood transfusion. The data sources was in the form of
- Incident reporting safety and sentinel forms.
- Feedback regarding blood transfusion taken from blood bank and nursing staff.

4.1. Incident reporting
The hospital has a policy to report all patient safety related incidents through a Safety/sentinel form with the details of the incident. The staff involved in the incident initiates the form by filling the details of the affected party like name, hospital number, and ward along with the details of the initiator. The completely filled form is sent to the head of the department or the Nursing Superintendent depending on the department of the staff initiating the report (clinical or nursing). After perusal by the concerned authority the form is sent to the Chairman of the Safety Committee. The safety committee conducts a root cause analysis of the report and suggests ways to prevent further incidents. The safety related issues of the entire month are then compiled and presented in a Safety meeting attended by Medical Superintendent, consultants of various departments, Nursing in-charges, Operations team, Fire officer, Security in-charge and other staff.

For the study safety reports of eight months from January 2014 to August 2014 were analyzed.

The study was divided into two phases:
Phase 1: January 2014 – April 2014
Phase 2: May 2014 – August 2014

All the reports from Phase 1 of the study were analyzed. Based on the observations, interventions in the form of checklist and work instructions to the nursing staff were implemented in the hospital in the month of April and then the safety reports for the next four months were analyzed.

Meetings with all the stakeholders were called and initiatives to train the nursing staff focused on safe blood transfusion practices were taken.

5. Observations and Discussions
Process of blood requisition from the wards/Intensive Care Units and issue of blood component from the Blood Bank:

Step-1: Treating doctor decides the need for transfusion of blood component.
Step-2: Patient is explained about the need of transfusion and consent is taken.
Step-3: The treating doctor fills Blood requisition slip.
Step-4: Patient sample for grouping and cross-match is drawn and sent to Blood Bank with the requisition slip
Step-5: Requisition slip and sample of the patient are received at the counter in Blood Bank.
Step-6: All details are filled in the software and a Blood Bank Registration (BBR) number is generated.
Step-7: The sample of the patient is sent for cross match and grouping and other investigation.
Step-8: Blood bag of the same group is cross-matched, tested for compatibility and kept ready for issue.
Step-9: On receiving issue slip from the ward the blood is issued after checking for the details.

The errors were observed and identified during the processes Step-4 and Step-9.

5.1. Errors at ward:
Reasons for error at ward for sending WBIT for grouping/cross-match:

1. Two or more patients with ‘same name’ admitted in the ward.
2. The sample of one patient might be sent with the label of another patient (labelling error).
3. ‘Hospital number/IP number’ of the patient, not checked before labeling the sample.
4. Labeling of empty tube was done ‘before’ drawing the blood.

5.2. Near missed wrong transfusion in ward
Reasons for near missed wrong blood transfusions in ward:

1. Blood transfusion required by ‘more than one’ patient in the ward.
2. Proper ‘instructions not conveyed’ to the junior nursing staff by the in-charge and during patient hand-overs.
3. Patient ‘details not verified’ prior to starting blood transfusion.

5.3. Errors during blood bag issuing
Reasons for error during issuing of the blood product from Blood Bank:

1. The requisition slip of one patient might be sent with the cross-match sample meant for another patient.
2. Blood/blood product dispatched from the Blood Bank for one patient ‘wrongly labeled’ for some other patient.
3. ‘Failure’ of blood bank staff to cross-check the blood product before issue.

6. Process re-engineering:
Based on root cause analysis of safety reports, feedback of nursing and blood bank staff, interview with various stakeholders and observation of workflow at the user level (wards) as well as at the dispatch level (Blood Bank) it was found that most of the errors took place in the wards.

Although a blood transfusion form in accordance with guidelines from a national organization on AIDS control with eighteen entries like name and address of patient, IP number with blood group, blood unit received from Blood bank, donor’s ID number and reasons for transfusion etc. was made available in the wards it failed to check the human error likely to take place before starting transfusion. In order to circumvent this problem a very short yet comprehensive checklist was required to be designed which would prevent wrong blood transfusion yet not add to the existing paperwork for the nursing staff.

A “4C” checklist was designed with just four elements that could be orally or mentally reviewed by the nursing staff before beginning transfusion.

- Confirm
- Converse
- Consent
- Cross match report

According to this checklist the nurse was first supposed to confirm the identity of the patient with the ‘Hospital Number’ assigned to him and not with his name alone. The issue slip, blood bag and the cross match slip would be tallied only with the hospital number of the patient. It was stressed that conversing with a conscious and oriented patient was very essential before beginning transfusion. This would further ensure the correct
identity as the patient would himself know whether the doctor had advised him/her blood transfusion. Keeping the element of conversation in the checklist would also stress on the basic and essential yet easily missed component of patient involvement in treatment.

Consent of the patient is of utmost importance and any checklist should have this element as a necessity, for it is not only ethical but also a medico-legal requirement in ensuring consent for the transfusion process. Checking of cross match report will ensure that the patient is transfused the correct bag of blood. Hence by having a checklist which it was easy to remember and non-cumbersome in implementing the checklist.

Specific work instructions were given to the nursing personnel at the ward level to prevent any errors during labeling of the samples being sent for cross match and blood grouping before blood transfusion. These work instructions developed were specific step-by-step instructions, from checking the identity of the patient, drawing and labeling of the blood sample to sending the correct blood sample for investigation.

The work instructions would not only serve as a ready reckoner for the nursing staff but would also help in training the newly recruited staff. The Work instructions were as follows:
1. Check the doctor’s order and confirm that the patient requires blood transfusion (BT).
2. Check the grouping/ cross match requisition slip for the ‘Hospital Number’.
3. Check for consent.
4. Select the appropriate vacutainers (lavender for grouping, red for cross match).
5. Go to the bedside with the ‘patient file’, vacutainers and requisition slip.
6. Talk to the patient and confirm if the doctor had advised blood transfusion or not.
7. Draw the sample and label after drawing the blood.
8. Send the blood sample for investigation to blood bank.

The above mentioned “4C” checklist and work instructions for sending the sample for investigations were implemented in the tertiary care hospital at the end of Phase 1 in the month of April and the outcome was measured in the next four months (i.e. during phase-two of the study).

7. Results

Table 2.- Showing the comparison between the two phases

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Phase-1</th>
<th>Phase-2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total no. of safety incidents reported</td>
<td>34</td>
<td>13</td>
</tr>
<tr>
<td>Transfusion related incidents</td>
<td>7</td>
<td>2</td>
</tr>
<tr>
<td>Transfusion related incidents reported from Blood banks</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>Transfusion related incidents reported from wards</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Near missed wrong blood transfusion</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Wrong blood in tube</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Wrong labeling of blood product</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Safety reports initiated by nursing staff</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Safety reports initiated by other staff</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>No. of blood components issued</td>
<td>9,873</td>
<td>9066</td>
</tr>
<tr>
<td>No. of cross match samples received</td>
<td>14,951</td>
<td>15399</td>
</tr>
</tbody>
</table>
The number of blood transfusion related safety incidents reduced from seven in Phase-1 to two in Phase-2. There were two incidences of ‘near miss’ events of wrong blood transfusion during Phase-1 which was eliminated during Phase-2. The incidences of wrong labeling of sample/blood bag were reduced from five during Phase-1 to two during Phase-2 (post implementation). There was a single incident of issue of blood product under incorrect label in Phase-1 which was not seen during Phase-2.

The difference in the number of cross-match samples received for testing by the blood bank during Phase 1 (14,951) and Phase 2 (15,399) remained insignificant. The number of blood bags issued during the two phases was also comparable (i.e. 9873 during Phase-1 and 9066 during Phase-2). Total number of safety incidents too had shown a decline from 34 in Phase-1 to 13 in Phase-2. The number of Safety incident reporting from nursing personnel in the wards also decreased from two in Phase-1 to zero during Phase-2.

6.1. Post intervention Audit
Based on the observations made from review of Safety/Sentinel reports an audit was undertaken to corroborate the findings. The audit was conducted over two months after phase-2. This audit comprised direct observation of the transfusion process as well as interviews held with the nursing personnel. The compliance to checklist was observed.

6.2. Audit Results
Number of blood component transfusions observed as part of the Audit: 120
Number of blood transfusions observed in ward: 98
Number of blood transfusions observed in critical areas (ICU, OT and post-op wards): 22

The parameters that were looked for were the components of the 4C checklist consisting of:
- Confirm - Hospital number
- Converse
- Consent
- Cross match report

It was observed whether the staff administering transfusion confirmed the hospital number of the patient, communicated with the patient, checked for consent and the cross match report before starting transfusion.

The report of the audit according to the parameters reviewed is as follows:
6.1.1. Confirm-hospital number
To reduce the number of safety incidents associated with transfusions it was suggested that the patient be identified by name as well as Hospital number to reduce incidents arising out of same name of two or more patients. Number of transfusions in which patient identity of the patient was confirmed by checking the Hospital number before starting transfusion: 93 (77.5%).

6.1.2. Converse
It was decided by the auditing team that following components should be present in the conversation:
1. Introducing oneself.
2. Asking the patient’s name.
3. Confirming whether the doctor has advised a transfusion (the patient would know if his signature was taken on the consent form by the treating physician).
4. Informing the patient that the blood transfusion would now be started.

Table-3 Showing the compliance to Converse

<table>
<thead>
<tr>
<th>Component</th>
<th>Number</th>
<th>Total</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Introducing oneself</td>
<td>13</td>
<td>120</td>
<td>10.83</td>
</tr>
<tr>
<td>2. Asking the patient’s name</td>
<td>80</td>
<td>120</td>
<td>66.67</td>
</tr>
<tr>
<td>3. Confirming whether advised</td>
<td>12</td>
<td>120</td>
<td>10.00</td>
</tr>
<tr>
<td>4. Informing the patient that the blood transfusion would begin</td>
<td>82</td>
<td>120</td>
<td>68.33</td>
</tr>
</tbody>
</table>

6.1.3. Consent
A patient’s consent is mandatory and legally binding. The consent is taken by the treating doctor on the consent form, signed by the patient himself/herself, the doctor and a witness (usually a relative of the patient). For non-emergency cases admitted in wards consent is taken during rounds. For patients posted for surgery it is taken before surgery for transfusion if any to take place during the post-operative period. Nurses check for consent form completeness in the patient file before starting transfusion. During the audit it was observed that 110 (91.97%) consent forms were checked out of the 120 transfusions.

6.1.4. Cross match report
The patient folder contains the cross match report. As part of the checklist the nursing staff is supposed to check the blood bag with the cross match report. This ensures that the blood bag received from Blood bank is compatible with the recipient’s blood. The number of Blood cross-match reports checked before starting transfusion was 112 (93.33%).

It was observed during the audit, the 3rd and 4th “C” of the 4C checklist was being adhered most of the time (i.e. 91.97% and 93.33% respectively). Communication between staff and patient needed gross improvement with staff introducing themselves only in about 10% of the transfusion observed.

7. Conclusion:
It is demonstrated from this study that improvement in quality of healthcare can be brought about by need based, focused intervention and that analysis and measurement of errors are pivotal in reducing human errors.

Analysis of safety and sentinel incident reports bring to light various reasons for WBIT and ‘near miss’ wrong blood transfusions. Therefore focused interventions in the form of checklist and work instructions which was implemented proved to be effective in reducing the number of human errors leading to wrong blood transfusions. The study also shows that the reporting
of incidents also decreased probably due to repeated interviews on the staff by the research team. Though this intervention could not reduce the numbers to zero, which is always desirable, making this practice as a continuous process would achieve the desired result.

An Audit for the compliance of checklist conducted later demonstrates that the “Converse” component needs to be improved upon probably by ongoing training to the nursing personnel. By introducing a simple mental checklist of four components to check just before the start of transfusion reduced the number of safety incidents markedly. Further reduction in safety incidents can be achieved by establishing and ensuring good communication amongst the hospital personnel and patient needs.

Reference:


