Feasibility Of Blood Bank Data Management System (Bdms) In Record Keeping And Prevention Of Near Miss Events: An Experience At Tertiary Care Center

Maitrey D Gajjar*, Rajeshkumar V Sonani, Nidhi Bhatnagar***, Shweta Gupta**, Suryakant Patel******

*Professor & Head, ** Resident, *** Associate Professor at Dept. of IHBT, Civil Hospital, Ahmedabad,
******Managing Director at Easy Software, India

Abstract : Introduction and Aim-Objective: Regulatory authority and voluntary accreditation organization require particular records and documents to be maintained for the operation of the blood bank. It can be accomplished using blood bank data management (BDMS) software in a less labor-intensive manner as compared to manual methods provided that the technical staff is properly trained. Many of the near miss events could be prevented with the use of blood bank software ensuring better patient safety. Hemovigilance scheme though not yet well established in our country which requires robust data management and compilation can be easily retrieved from the software. We present below reports on the effectiveness of Blood Bank Data Management System in strengthening of Blood Transfusion Services. The main aim of the study was to compare computer software with traditional hand-written documents for record management and evaluate BDMS in prevention of near-miss events. Materials and Methods: A comparative study between record keeping by conventional registers and Blood bank Data Management System (BDMS) software was done for period of six months from September 2011 to February 2012. Each of the entry was duplicated in both during this study period. Each of the technicians using the software was asked to rate the user friendliness of the system using an objective method of scoring to prevent any bias. The time taken to enter each donor/patient data manually and on software was also compared. Results: All mandatory registers were electronically maintained. The time taken for the each register was significantly less by the software. The inventory of consumables was excellently managed. Also, the equipment records required to be maintained were available at the click of a mouse. 6 out of 15,220 samples were found to contain Wrong Blood In Tube (WBIT) based on traceability system of prior sample received of the same patient which could have been undetected with manual methods and 4 out of these 6 would have resulted in fatal Hemolytic Transfusion Reaction. Apart from this, two-way traceability of blood products was maintained. 30 out of 35 technicians rated the software as "Excellent" with respect to user friendliness. Conclusion: BDMS is a reinforcing tool in the data management and prevention of near miss events leading to improved safety in Blood transfusion Services.[Gajjar M et al NJIRM 2013; 4(3) : 66-69]

KEY Words: Software, Data management, Near miss events

Author for correspondence: Dr. Rajeshkumar V Sonani, Address:B-2 Ward, Dept of IHBT, Civil Hospital, Asarwa, Ahmedabad 380016 Gujarat, India, Email : rajsonani18@gmail.com

Introduction: Regulatory authorities require certain records to be maintained for the licensing and functioning of the blood bank.[1] Voluntary accreditation organizations also require more or less similar manner of documentation.[2] Compared with manual hand-written registers, computer software is a valuable tool for such documentation because it reduces the likelihood of human errors often encountered during clerical work. A near miss event is defined as an error or deviation from standard procedure or policy that is discovered before the start of the transfusion. Various safety checks as an integral part of data entry in the software beginning from the patients sample receiving to the issue of blood components and two-way traceability has prevented near miss events during our study period of six months. Moreover, the increased blood safety in Europe after implementation of Hemovigilance, has created the need of the day to take up this initiative in our country as well.[3] National Blood Transfusion Council (NBTC) is also planning to incorporate hemovigilance into National Blood Policy.[4,5] For an effective hemovigilance scheme, robust data management and compilation is necessary[6] which is facilitated by computer software. We present below reports on the effectiveness of Blood Bank Data Management System in strengthening of Blood Transfusion Services.

Aim and Objective: The aim of this study was to compare reports generated from computer software with conventional hand-written registers

and evaluate the effectiveness of the software in prevention of near-miss events.

Materials And Methods: A comparative study between record keeping by conventional registers and Blood bank Data Management System (BDMS) software was done for period of six months (September 2011 to February 2012) prior to implementation of the software as the sole tool for record maintenance in our blood bank. Each of the entry was duplicated in both during this study period. The same sets of technicians were doing both the entries to avoid any bias in the results. All the Standard Operating Procedures (SOPs) of the blood bank were strictly followed in each and every process. The entire staff was well-trained for entry in the software prior to initiating the study and constant support was provided by the software developer for any troubleshooting. The software along with the server had undergone off-site and on-site validation for each step that was performed prior to putting it in use. The software had provisions for electronic user login and authentication password of each individual as well as hierarchy of administration rights from the Medical Director in the descending order. Along with the routine blood bank work, the software was also used to maintain inventory of consumables like reagents, blood bags, kits for Transfusion Transmitted Infections (TTIs) testing, etc as well as the blood bank equipment details.

For the maintenance of records, a printout of data was taken containing all relevant data mandatory by the Drugs and Cosmetics Act, 1940 and the amendments thereof, and also the documents/registers required by NABH (National Accreditation Board for Hospitals and Healthcare Providers) so that any required information can be retrieved in minimal amount of time.

There were multiple check points in data entry at various levels starting from sample receiving to issue of components as well as starting from donor registration to transfer of components to stock inventory after completion of required testing as mandated by the Drugs and Cosmetics Act. Examples of check points include alerts to the user when ABO and Rh grouping do not match with previous and current samples, unable to move components from quarantine to stock until all Transfusion Transmitted Infections (TTIs) are non-reactive and all tests for ABO/Rh including weak D for donors are complete, unable to issue ABO-Incompatible components such as Whole Blood (WB), Red Cell Concentrate (RCC) or Fresh Frozen Plasma (FFP), unable to issue components until segment number entered at the time of donation matches.

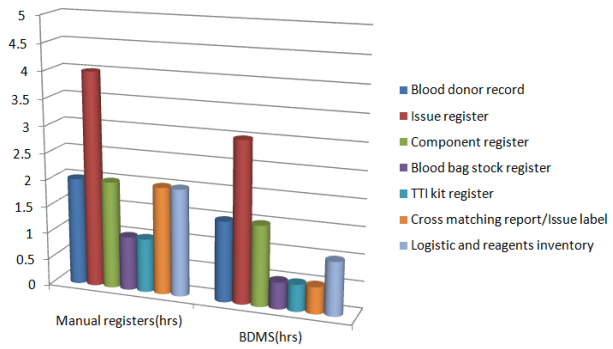
Each of the technicians using the software was asked to rate the user friendliness of the system vis a vis the manual record maintenance using scoring system based on objective questions.

The time taken to enter each donor/patient data manually and on software was also compared.

Results: Following registers (required by the licensing authority that is Food & Drug Administration- FDA[1]) were maintained with ease from the data entered in the software:

1. Blood donor register
2. Issue register
3. Master records of blood and its components
4. Blood bag stock register
5. Register for Transfusion Transmitted Infections (TTIs) kit stock
6. Cross matching register/reports
7. Logistics and reagents inventory records

Figure 1. Time (in hours) required by Manual method and BDMS for maintenance of records/registers required by regulatory authorities



6 out of 15,220 samples were found to contain Wrong Blood In Tube (WBIT) based on traceability system of prior sample received of the same patient which could have been undetected with manual methods and 4 out of these 6 would have resulted in fatal Hemolytic Transfusion Reaction because of ABO Incompatibility. Prior to issue, based on segment number entry, 2 incorrect unit although of same ABO group was identified which also prevented near miss events from occurring. 30 out of 35 technicians rated the software as "Excellent" with respect to user friendliness. 3 rated "Good" and 2 rated "Average".

And also, master record of blood and components can be retrieved from the default data of BDMS without any additional time.

Discussion: Although during the study period of six months, a total of only 8 near miss events were prevented, these mishaps could be fatal as it would end as serious ABO hemolytic transfusion reaction. Clerical error, considered the most common cause of hemolytic transfusion reaction[7], can be reduced by eliminating manual errors. The occurrence of Wrong Blood In Tube (WBIT) is quite similar to other study done for five years elsewhere.[8]

As with any service based industry, a harmonious work atmosphere and smooth operations, ensures optimal productivity, having the BDMS in our setup was like a boon which helped greatly in the efficiency of services. An added benefit was having the staff which was happy and relaxed after managing the huge workload of 150-200 samples for blood grouping, 100 compatibility testing, 70-100 blood collections with 90% component separation daily.

The time taken in the inventory management of blood and/or blood components as well as reagents and/supplies can also be reduced by the software. Two way traceability of the software (from components made from the donor unit to recipients of each component and patient receiving components from different donors) is a feature that enables for the less labor intensive investigation in case of allo-immunization or development of transfusion transmitted infections in multiply transfused patients. Donor recall for reactive test results and donation after 3 months of last donation is easily accomplished through search filters of the software. Voluntary donors are better retained as messages can be sent by default from the system on their birthdays/anniversaries.
Once blood grouping of the patient is complete, the software automatically gives choices about component selection resulting in better following of First In First Out (FIFO) policy, especially useful in inventory management of platelets. The software also alerts about insufficient stock and expiry date of all consumables resulting in better inventory control.

Problem of loss of records because of system breakdown due to power failure or virus was taken care of by continuous backup of the records and provision of power back up and anti-virus guard for the system. Rare possibility of server failure is the only disadvantage being noted.

Conclusion: BDMS is a reinforcing tool in the data management and prevention of near miss events leading to improved safety in Blood Transfusion Services.

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Conflict of interest: Suryakant Patel has disclosed financial relationship with Easy Software. The other authors have no conflicts of interest.

Funding: None