

A Study of the Utility of Vertical Quality Audits in a Blood Transfusion Centre as a Quality Improvement Tool: Comparison and Differences between Vertical and Horizontal Audits

Killol N DESAI^a, Parth S BHATT^b, Alpesh Kumar MARU^b, Riyaz Ahamed SHAIK^c

^aDepartment of Pathology, Nootan Medical College and Research Centre, Visnagar, Gujarat, India

^bDepartment of Pathology, Dr N D Desai Faculty of Medical Science and Research, Nadiad, India

^cDepartment of Family and Community Medicine, College of Medicine, Majmaah University, Majmaah 11952, Saudi Arabia

ABSTRACT

Introduction: Blood transfusion services is the important part of the modern healthcare system without which efficient medical care is not possible. Blood bank quality audits become an important assessment tool to check the efficiency of the quality system in terms of realization of quality policy, fulfilment of designed targets and implementation of quality system documents.

Aims: To study the utility of vertical quality audits as a quality improvement tool, to compare vertical and horizontal audits and explore the differences between them.

Methods and Materials: The study duration was three years and two months, from November 2018 to December 2021. We conducted an observational prospective study of vertical and horizontal quality audits in a transfusion centre of our tertiary care hospital as per ISO 9001:2000 and National Accreditation Board for Hospitals & Healthcare Providers (NABH) guideline.

Results: The most common non-conformities in vertical audit were related to documentation (80%). The donor area was the most common area of blood bank from where non-conformities were observed in vertical audit (60%). The most commonly observed non-conformities in horizontal audit were related to procedural or technical aspects (42.8%). The donor area was the most common area of blood bank from where non-conformities were observed in horizontal audit (57.14%).

Address for correspondence:

Dr Alpesh Kumar Maru, Associate Professor

Department of Pathology, Dr N D Desai Faculty of Medical Science & Research, Nadiad, India Email: drmaru28@gmail.com

Article received on the 9th of May 2022 and accepted for publication on the 18th of June 2022

Conclusions: Quality audits verify compliance and therefore, they are driving continuous quality improvement in a blood bank. Vertical audit is a retrospective process and helps to identify near miss events and errors performed by blood bank staff. Horizontal audits are cumbersome to conduct as compared to vertical audits.

Keywords: vertical audit, horizontal audit, audit plan, audit process, audit analysis.

INTRODUCTION

Blood transfusion services is the important part of modern healthcare system without which efficient medical care is not possible (1). The AABB standards for blood banks and transfusion services have accepted performance requirements necessary for providing quality systems in transfusion medicine (2). Blood bank quality audits become an important assessment tool to check the efficiency of the quality system in terms of realization of quality policy, fulfilment of designed targets and implementation of quality system documents (2). Every hospital/blood transfusion centre develops a system of audit that is appropriate to its needs (3). The audit is based on set guidelines, but in fact consists of determining the difference between the given directions and what has actually been done (4). Audit is defined in ISO 9001:2000 as “a systematic, independent and documented process for obtaining evidence and evaluating objectively the extent to which audit criteria are fulfilled” (5).

There are two main types of blood bank quality audit (5): 1) vertical audit: start to finish audits are described as vertical audit, which examines one function; and 2) horizontal audit, which follows a process from start to end; this type of audit would look at procedures as they support the process itself and is likely to span many functions or departments.

Study aims and objectives

- To study the utility of vertical quality audits as a quality improvement tool
- To compare vertical and horizontal audits and explore the differences between them

Need of study

A more comprehensive prospective audit is required to understand whether the transfusion services are being appropriately used for indications of blood use.

Change or impact of the present study

The study results will provide a good opportunity for finding strategies in improving blood bank services with appropriate and safe use of blood.

The novelty of study

In our study we used vertical audits as a quality improvement tool and horizontal audit as per the National Accreditation Board for Hospitals & Healthcare Providers (NABH) guideline (6, 7). We have also compared the two types of audits and explored the differences between them. This was the first time that an audit of blood bank services has been carried out in our blood bank and thus, our results represented the starting point from which the use of medical technology should be improved. □

MATERIALS AND METHODS

The study duration was three years and two months, from November 2018 to December 2021. We conducted an observational prospective study of vertical and horizontal quality audits in a transfusion centre of our tertiary care hospital as per ISO 9001:2000 (5) and NABH guideline (6, 7).

Inclusion criteria

For both vertical and horizontal audits, we audited all processes and their related routines and NABH related documentation in blood bank.

Exclusion criteria

For vertical audit: donations performed as a part of either therapeutic phlebotomy or apheresis procedures.

For horizontal audit: not applicable.

The audit plan (5)

All audit activities were conducted as per the internal audit plan drawn by the quality manager. Vertical quality audits were conducted every month. We audited 1% of collected units per

month. Horizontal quality audits were conducted annually.

The audit process

Vertical audit as per ISO 9001:2000 guideline (5) – The blood donor units to be audited were initially randomly selected every month. The donor bag was followed as its actual work flow in the blood bank vein to vein as follows (8-10):

- Completeness of donor forms
- Adequacy of phlebotomy and collection
- Within time component separation
- Proper TTI assessments
- Issue and transfusion of appropriate components
- Proper disposal of TTI positive components
- Proper documentation check in blood request/cross match form and register updates such as cross match register, blood issue register and master register
- Proper protocols followed in case of bag return

Horizontal audit as per NABH guideline (6, 7) – It focused on the individual tasks at hand rather than the process flow:

- Organization and management (Clause 1)
- Accommodation and environment (Clause 2)
- Personnel (Clause 3)
- Equipment (Clause 4)
- External services and supplies (Clause 5)
- Process control (Clause 6)
- Identification of deviations and adverse events (Clause 7)
- Performance improvement (Clause 8)
- Document control (Clause 9)
- Records (Clause 10)
- Internal audit and management review (Clause 11)

Analysis procedure (5)

Horizontal quality audit non-conformities were further classified in major non-conformities and minor non-conformities.

Non-conformities encountered during the study period with both audits were divided into three types: 1) procedural/technical non-conformities; 2) documentation (entry related and typographical) non-conformities; and 3) others (organization and management, personnel related, equipment related and all other not falling under the prior four categories.)

Also, non-conformities were categorised according to the area in which they have been encountered: donor area; component separation area; red cell serology area; TTI area; component storage area; and others, including the central documentation area, common storage area, washing areas, etc.

All collected data were plotted in Excel 2015, then master chart was prepared and further obtained parameters were evaluated accordingly. □

RESULTS

Vertical audit

During the study period the total number of donations was 3888. In the years 2018, 2019, 2020 and 2021, the total numbers of donations were 77, 670, 1066 and 2075, respectively (Table 1). From November 2018 to December 2021, the total number of donor units that were evaluated was 52. In the years 2018, 2019, 2020 and 2021, the total numbers of donor units which were evaluated were 2, 12, 14 and 24, respectively (Table 2). We evaluated 1% of the total donor collection every month. From November 2018 to December 2021, the total number of identified non-conformities (NCs) was five. In the years 2018, 2019, 2020 and 2021,

TABLE 1. Total number of donations during the study period

Year	2018	2019	2020	2021
Months				
January	0	42	50	178
February	0	13	43	115
March	0	32	66	238
April	0	30	67	61
May	0	75	96	146
June	0	58	227	263
July	0	52	155	65
August	0	48	43	211
September	0	104	45	384
October	0	19	95	354
November	60	85	84	142
December	17	35	96	118
Total	77	670	1066	2075

TABLE 2. Monthly number of units evaluated and non-conformity observed during vertical audit

Year	2018		2019		2020		2021	
Months	No. of donor units evaluated	No. of donor units with NCs	No. of donor units evaluated	No. of donor units with NCs	No. of donor units evaluated	No. of donor units with NCs	No. of donor units evaluated	No. of donor units with NCs
January	0	0	1	0	1	0	2	0
February	0	0	1	0	1	0	1	0
March	0	0	1	0	1	0	2	0
April	0	0	1	0	1	1	1	0
May	0	0	1	0	1	0	2	0
June	0	0	1	0	2	0	3	1
July	0	0	1	0	2	1	1	0
August	0	0	1	0	1	0	2	0
September	0	0	1	0	1	0	4	0
October	0	0	1	0	1	0	4	1
November	1	0	1	1	1	0	1	0
December	1	0	1	0	1	0	1	0
Total	2	0	12	1	14	2	24	2

TABLE 3. Non-conformity observed during vertical audit

Sr. No.	Non-conformities	Areas	Types	Frequency
1	Donor registration and consent form	Donor	Documentation	Three times
2	Platelet concentrate was prepared after six hours of collection of the blood	Component separation	Procedural/technical	One time
3	Antibody screening was not entered	Red cell serology area	Documentation	One time

Year	2018	2019	2020	2021
Major	1	1	1	2
Minor	0	1	1	0
Total NCs	1	2	2	2

TABLE 4. Major and minor non-conformities (NCs) observed during horizontal audit

the total numbers of observed NCs were 0, 1, 2 and 2, respectively (Table 2). The most commonly seen non-conformities were related to documentation (80%). The donor area was the most common area of blood bank from where NCs were observed (60%) (Tables 3 to 7).

Horizontal audit

During the study period, a total number of four horizontal audits were conducted in our transfusion centre (Table 4). As per Table 5, we observed different NCs during the horizontal

audit according to clauses. From November 2018 to December 2021, the total number of observed NCs was seven. In the years 2018, 2019, 2020 and 2021, the total numbers of observed NCs were 1, 2, 2 and 2, respectively (Tables 5 and 6). The most common NCs were related to procedural or technical aspects (42.8%). The donor area was the most common area of blood bank from where NCs were observed (57.14%) (Tables 7 and 8). Out of all non-conformities, five were major and two minor NCs (Table 4). □

Sr. No.	NABH clause	NCs	Major/Minor	Areas	Types
2018					
1	3.5	Training of basic life support (BLS) and using emergency medicines not done	Major	Donor	Others
2019					
1	6.2.1.4b	Disinfection protocol not being followed in the blood bank – donor area	Minor	Donor	Procedural/technical
2	2.3	Eye wash facility was not available in Red Cell Serology and TTI lab	Major	TTI test area	Others
2020					
1	6.2.1.3	The QC of CuSo4 was done, but not documented	Minor	Donor	Documentation
2	3.3	Job description in the personnel files was not up to date.	Major	Other (record keeping)	Procedural/technical
2021					
1	4.2	Hemocue, did not have any validation records.	Major	Donor	Documentation
2	4.5	Platelet agitator was not calibrated for number of oscillations <i>per</i> minute.	Major	Component storage area	Procedural/technical

TABLE 5. List of non-conformities (NCs) observed during horizontal audit

Main clause category No.	Main clause title	Year wise repeatability of NCs according to main clause category No.			
		2018	2019	2020	2021
1	Organization and management	0	0	0	0
2	Accommodation and environment	0	1	0	0
3	Personnel	1	0	1	0
4	Equipment	0	0	0	2
5	External services and supplies	0	0	0	0
6	Process control	0	1	1	0

TABLE 6. Year wise repeatability of non-conformities (NCs) according to main clause category number observed during horizontal audit

Types of NCs	No. of NCs in vertical audit	No. of NCs in horizontal audit
Procedural or technical NCs	1 (20%)	3 (42.8%)
Documentation-related NCs	4 (80%)	2 (28.6%)
Other NCs	0	2 (28.6%)

TABLE 7. Comparison of type of non-conformities (NCs) in vertical and horizontal audits

NCs related to blood bank areas	Present study vertical audit (%)	Present study horizontal audit (%)	Vuk T <i>et al</i> study (%)
Donor area	3 (60%)	4 (57.14%)	37.2%
Component separation area	1 (20%)	0	37.8%
Red cell serology area	1 (20%)	0	4.7%
TTI area	0	1 (14.29%)	5.2%
Component storage area	0	1 (14.29%)	5.8%
Other areas	0	1 (14.28%)	9.3%

TABLE 8. Comparison of non-conformities (NCs) according to blood bank area in vertical and horizontal audits

DISCUSSION

1. Vertical audit

The purpose of conducting regular vertical audits was to detect non-conformities, record, analyse and resolve them and their inclusion during the charting up of the quality improvement plan.

In the present study, the most commonly observed NCs were related to documentation (80%), while those related to procedural or technical aspect accounted for 20% of NCs.

The majority of repeated NCs were related to documentation (80%), including improper antibody screening entry, donor consent form with non-availability of address, contact phone number and occupation were maximum.

Root cause analysis and corrective actions for vertical audit non-conformities

Documentation related non-conformities – The most commonly observed NCs were related to documentation (specifically to entries and typography), which would affect proper documentation and, in turn, would lead to difficulty in donor tracing for repeat donation or TTI intimation. In the present study, NCs like incomplete donor consent forms with non-availability of address, contact phone number, email ID and wrong donor form entry were found. Among them, non-availability of either donor's address or occupation was a frequently identified NC. The donor form entry is mandatory for completeness of master register. It is one of the most important registers according to Drugs and Cosmetics Act of 1940 for Blood Banks (11). The root cause for wrong donor form entry of the unit number of donations was due to random error by a newly joined doctor. This NC could lead to wrong donor identification and totally wrong documentation for that blood unit. The corrective action taken against this NC was training and orientation session conducted by senior doctors. The non-conformity regarding antibody screening was solved by giving a proper orientation to all documentation procedures. In our transfusion centre, we need an indigenously developed in-house online system which is utilized for all blood bank activities and processes (vein-to-vein) (10). Hence, the online register forms the backbone of the transfusion services.

Procedural/technical non-conformities – One incident during vertical audit revealed that plate-

let concentrate was prepared after six hours of collection. The root cause analysis for the delay in platelet separation was found to be due to a delay in receipt of blood bag from blood donation camp. The corrective action taken against this non-conformity was to arrange an extra vehicle at the site of blood donation camp.

2. Horizontal audit

It incorporates a detailed check of all aspects of the quality management system of blood bank for checking the existence of SOP's, process documentation such as worksheets that need to be filled in were fully and correctly completed, checking the training records and that any policies described in the Quality Manual, for instance process control policies, were being fully implemented. The most commonly encountered NCs were related to procedural or technical aspects (42.8%). The donor area was identified as the blood bank area from where most NCs were observed (57.14%) (Tables 7 and 8). Out of all non-conformities, 5 non-conformities were major non-conformities and 2 were minor non-conformities (Table 4).

Root cause analysis and corrective actions for horizontal audit non-conformities (6, 7)

Procedural or technical non-conformities – Every year, the entire blood bank staff is required to undergo basic life support, training at least once a year. However, the horizontal audit found that they were still not able to manage a mock drill situation effectively. Staff retraining was undertaken and proper orientation to BLS was ensured. On one occasion, the personnel files were found incomplete and not up-to-date. The same was intimated to the human resources department and their updating at regular interval was emphasized. Several critical types of equipment like centrifuge machine and Platelet agitator were being routinely calibrated by the company personnel. However, the traceability certificate of the master equipment (tachometer-revolution counter) used to calibrate our equipment was not available during the horizontal audit. At that time, we immediately called the company personnel to do the same. We found that the eye wash facility was not available in Red Cell Serology and TTI lab. We took immediate action and ensured availability of eye wash facility. We found that the disinfection protocol was not

being followed in the blood bank donor area. Training and orientation session conducted by senior doctors was the corrective action taken against this non-conformity.

Documentation related non-conformities – No verification records were found before putting Hemocue into use during the horizontal audit. As haemoglobin estimation is an important part of donor selection, improper verification of the Hemocue may lead to false haemoglobin estimation and donor may get falsely selected or rejected for blood donation. The root cause for validation records of Hemocue was represented by the fact that staff members were not aware of the validation process. The corrective action taken against this non-conformity consisted of training and orientation sessions conducted by senior doctors. In another scenario, we have found that the QC of CuSo4 was done, but not documented. It was due to random error by a newly joined doctor.

In Tables 7 and 8 we showed the comparison between vertical and horizontal audits. Kantharaj A and Chandrashekar S (10) had undertaken a study in Manipal Hospital, Bangalore, Karnataka, India, from 2011 to 2013, to monitor the element of safety by vein-to-vein vertical audits. Monthly vertical audits were used to trace a unit from the time of collection to its transfusion or disposal. They had concluded that frequent vertical audits helped monitor blood safety and provide better compliance with adherence to requirements in transfusion services. Kumar A *et al* (12) observed problems related to blood requisition forms, which were also not properly filled. Similarly, donor deferral registers were not properly maintained. This is probably due to misunderstanding that the filling of requisition forms and maintenance of donor deferral register is not an important activity. Therefore, they are given less attention. Vuk T *et al* (13) had conducted a study at the Croatian Institute of Transfusion Medicine (CITM), from 2003 to 2010, in which they had done error tracking in 6,20,107 total donations. They have encountered different errors and typed them on the basis of the medical event reporting system for transfusion medicine (MERS-TM). This study shows that comprehensive management of errors, including near miss ones, can generate data on the functioning of transfusion services, which is a precondition for implementation of efficient corrective and pre-

ventive actions that will ensure further improvement of the quality and safety of transfusion treatment. Vuk T *et al* (13) analysed all complaints with the root cause and their corrective actions, and concluded that systematic recording and analysis of complaints provided a basis for problem identification, implementation of corrective and preventive actions and improvement of product and service quality, and thereby, customer satisfaction. Ardenghi D *et al* (14) performed a study in the Service of Immunohematology and Transfusion Medicine (SIMT), Italy, from 2005 to 2006, to identify near miss errors and non-conformances which could affect patient safety in terms of blood transfusion. They did root cause analysis and corrective action for the same to reduce or eliminate the risk to patients. From the study, the authors concluded that computerized delivery of the request for blood components and automation of pre-transfusion blood tests improved the quality of blood bank and patient's safety. Jovanović R (15) had undertaken a study that aimed to evaluate the quality control system in blood transfusion service by regular blood bank audits, and concluded that audits were used not only to determine further quality management activities but also to build the basis for excellent relations with product and service users.

While none of the above-mentioned studies is truly comparable with the present study in terms of design and assessed parameters, they do assess indicators in the context of continuous quality improvement. Hence, the findings of our study and those of studies used for comparison would help to highlight the importance of regular monitoring for early error detection and effective error management. It has been emphasized enough that effective error management not only increased customer satisfaction but also decreased measurable and non-measurable costs incurred by the instillation.

Problems relevant to the study field

No studies similar to ours have been previously conducted in any blood bank. Without proper and detailed quality audit we cannot improve our transfusion services. We have less blood collections in our blood bank. So, as time passes, more and more collections will be received and follow-up study will be done. □

CONCLUSION

Based on the observations made in the present study, the following conclusions may be drawn:

1. Quality audits verify compliance and are therefore driving continuous quality improvement in a blood bank.

2. Vertical audit – By conducting a vertical audit it is much easier to determine if there is a problem between different processes of a blood bank, such as donor counselling to donor collection, serology test to separation of blood products, separation to cross matching and dispatch of blood products to particular patients. Vertical quality audits help to know feasibility of traceability and non-conformities in blood bank. Vertical audit is a retrospective process which helps to identify near miss events and errors made by blood bank staff. Vertical audits mainly keep a close eye over blood bank process from donation to dispatch of blood unit, registers and compatibility of blood bank.

3. Horizontal audits – They look at procedures as they support the process itself and are

likely to span many functions or areas of blood banks. Horizontal audits are cumbersome to conduct as compared to vertical audits. Horizontal audits require extensive planning, more manpower and are time consuming as compared to vertical audits.

4. Vertical and horizontal audits should be carried out in all blood banks on a regular basis as they are complementary to each other and together cover all aspects of a blood bank functioning. □

Conflicts of interest: none declared.

Financial support: none declared.

Authors contribution: All authors have contributed equally.

Acknowledgements: I acknowledge this research and express my thanks to my mentor and guide respected Dean for the continued support and encouragement. I offer my sincere appreciation for the learning opportunities provided by the research committee of the institute.

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