



ROLE OF HORIZONTAL AND VERTICAL AUDITS IN QUALITY MANAGEMENT SYSTEM OF THE TRANSFUSION MEDICINE: AN EXPERIENCE OF TERTIARY LEVEL BLOOD CENTRE

Immunohematology

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KEYWORDS

INTRODUCTION

The main aim of modern transfusion services is to maintain an adequate, safe, and efficient supply of blood components for therapeutic use. Increasing pressure on both the supply and the demand for blood has focused attention on ensuring that appropriate clinical use is made of available blood components. The World Health Organization proposed the rational use of blood and blood products to reduce unnecessary transfusions and minimize the risks associated with transfusion⁽¹⁾.

Blood centers, hospital blood banks, and transfusion services need to embrace the quality philosophy to ensure a high degree of safe blood donation and transfusion practices to regulatory agencies, accrediting agencies, blood donors, physicians, patients and patient's families. A Quality Management System provides a framework for applying quality principles and practices uniformly across all blood bank operations, starting with donor selection and proceeding through transfusion outcomes. Assessments measure the state of a facility's quality program with respect to the applicable requirements at a single point in time. Blood Bank quality 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⁾

An Audit is a systematic investigation to determine if an organization's actual activities and practices are being performed according to its approved and written policies and procedures. Regular audit of blood and its component usage is essential to access the blood utilization pattern and set ideal policies in all the blood using specialties. Clinical audit is a management tool for the appraisal and justification of appropriateness and efficiency of transfusion therapy and an important part of the quality assurance program which can provide necessary information for improving transfusion medicine practice. Adequate documentation of evidence to support a rationale for blood transfusion is considered an essential part of transfusion medicine. More complete and appropriate documentation allows more transfusion episodes to be assessed in an audit. Transfusion is considered appropriate when it is used to treat conditions leading to significant morbidity and mortality and which cannot be prevented or managed effectively by other means⁽³⁾.

Quality audits are of two types: Horizontal and Vertical. Horizontal audit assesses the same process across different groups or departments, while a Vertical audit assesses all the activities in a given department. It can be an internal audit or an external audit. An internal audit reviews a specific facility process and determines by examining documents and records, interviews and observations – whether the facility is meeting applicable requirements and its own policies, processes and procedures.

An external assessment is the external inspection performed by the regulatory and accreditation organizations for the purpose of obtaining and maintaining the facility's license or accreditation.

AIMS AND OBJECTIVES

- To study the utility of Vertical quality audit and Horizontal quality audits as a quality improvement tool in blood bank.

- To determine the effectiveness of implemented Vertical and Horizontal audits in the blood bank.
- Compare and contrast between Vertical and Horizontal audits.

MATERIALS AND METHODS

This is a prospective study and will be conducted in the department of I.H.B.T at G.G. Hospital and Shri M.P. Shah Medical College, Jamnagar for a period of one year. The blood donor units to be audited were selected and the donor bag was followed as its actual work flow in the blood bank. Non-conformities observed during these audits will be analysed for their root cause which will be followed by corrective actions/preventive actions.

Study Setting And Design

The present study is an observational study and data collected prospectively, for vertical audits and horizontal audits that were conducted at I.H.B.T department, G.G. hospital and Shri M.P. Shah Medical College, Jamnagar. The primary goal of the study is to look at procedures as they span many functions or departments. The study aims to check all the activity procedures in the blood bank starting from blood donation to the dispatch of components to the particular patients. It is essential to maintain and improve the quality of the blood bank.

Study Size And Sample Size

This will be a prospective observational time bound study over a period of one year.

Study Population

After applying inclusion and exclusion criteria, all patients admitted at G.G. Hospital, Jamnagar and the inhouse donors and camp donors at blood bank, G.G. hospital, Jamnagar will be included for the study.

Inclusion Criteria

All the patients requiring blood transfusion admitted at G.G. hospital, Jamnagar and the inhouse and blood donation camp donors at blood bank, G.G. hospital Jamnagar for the period of one year will be included in this study.

Exclusion Criteria

Patients admitted outside G.G. hospital for the above mentioned time period will be excluded from the study.

METHODOLOGY

In this study, the donor units will be traced through all the process and procedures it undergoes from the start of the donation till the issue of the unit, through the departments it passes including the red cell serology area, component separation and storage area and the Transfusion Transmitted Illness Laboratory (TTI). The nature and percentage of non-conformities will be observed during this and their root cause analysis with corrective actions/preventive actions will be done.

DATA ANALYSIS

The non conformities observed will be categorized into that in Donor area, Component separation and storage area, Red cell serology area, TTI area, procedural/technical, operator related, Software system related and documentation related. The data collected will be entered in the MS Excel and will be analysed by calculating the proportion of

non conformities in the different areas of the blood bank.

RESULTS

Maximum non-conformities encountered were documentation related non-conformities 29 (27.10%) followed by operator related non-conformities 25 [23.36%], other non-conformities 22 [20.56%], software system non-conformities 20 [18.70%] and procedural or technical non-conformities 11 [10.28%] in decreasing order of frequency in Vertical audit. While in Horizontal audit the maximum non- conformities encountered were procedural/technical non-conformities 6 [46.2%], followed by other non-conformities 4 [30.70%]. All three were 1 [7.7%] documentation non-conformities, operator related & software system non-conformities in decreasing order of frequency.

In vertical audit, maximum non- conformities observed were in donor area were 33(30.84%) followed by red cell serology area 31(28.97%), Component separation area 23(21.50%), Component storage area 11(10.28%), Other areas and TTI area were 05(4.67%) and 04(3.74%) in decreasing order of frequency.

While in Horizontal audit, maximum non-conformities observed were in Red cell serology area were 05(38.46%) followed by Component Storage area 03(23.08%) and Donor area 02(15.38%) and Component Separation area 02(15.38%) and TTI area 01(7.7%) in decreasing order of frequency.

CONCLUSION

Vertical quality audits help to know feasibility of traceability and highlight pitfalls as well as non-conformities in a Blood Bank. There are distinct advantages of Horizontal and Vertical audits respectively and both the systems should be used in a manner which is complimentary in order to bring about continuous quality improvement.