

Quality Control in Screening for Infectious Diseases at Blood Banks

Isam Eldin Hassan Ali^{1*}, Dr. Abdelaziz M. Humd², Dr. Manal Mostafa², Hamza Abdallah³¹Lab Director, FMOH, Curative Director²Department of Clinical Hematology, Faculty of Medicine, Karary University, Khartoum, Sudan³Director of Virology Lab, MOHDOI: [10.36347/sjams.2022.v10i02.022](https://doi.org/10.36347/sjams.2022.v10i02.022)

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*Corresponding author: Isam Eldin Hassan Ali

Lab Director, FMOH, Curative Director

Abstract

Original Research Article

Background: It has long been recognized that blood bank institutions have an obligation to not only provide a safe product for patients, but also to protect the health and welfare of their donors and their staff. Quality control procedures are indispensable to ensure the reliability of the results provided by laboratories responsible for serological screening in blood banks. International recommendations on systems of quality management classify as a top component the inclusion of two types of control: (a) internal quality control (IQC) and (b) external quality control (EQC). **Methods:** A total of 300 donations were collected and screened for HBV, HCV, syphilis and HIV-1 using the enzyme inked immune sorbent assay. All initially reactive (IR) samples were retested in triplicate and, if repeatedly reactive (RR), consider as reactive. **Results:** The results showed that the sensitivity and specificity of the QCs in anti-B testing were 100% and 98.7%, respectively. The sensitivity and specificity of the QCs in testing, viral screening were all 99%. Therefore our QC products and methods are highly sensitive, specific, and reliable. Our study paves the way for the establishment of a uniform and standardized QC method for pre-transfusion compatibility testing in Sudan and other parts of the world. **Conclusion:** The implementation of screening for three viruses has improved blood safety in Sudan.

Keywords: blood bank, internal quality control (IQC), patients, blood safety.

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INTRODUCTION

The safety of blood and blood components continues to raise debate all over the world. In the past few decades, many measures have been introduced in order to reduce the risk of transmission of blood-borne viruses [1].

To improve blood transfusion safety, the World Health Organization (WHO) recommends an integrated strategy including establishment of well-organized blood transfusion services, prioritization of blood donation from voluntary non-remunerated donors, screening of donated blood for at least the four major transfusion-transmissible infections (TTI) with quality-assured assays, rational use of blood and implementation of effective quality control systems [2]. Selection of blood donors with low TTI risk followed by effective laboratory screening is the critical part of the process, since it has reduced the risk of transmission to very low levels in the past 20 years [3, 4].

Blood must be collected into single-use, sterile, FDA-licensed containers [5]. The blood should

be drawn from an area free of skin lesions, and the phlebotomy site should be properly decontaminated.

The risk of viral infection has emerged as the major cause of transfusion related morbidity and mortality like human immunodeficiency virus (HIV), hepatitis C virus (HCV), hepatitis B virus (HBV), etc.

Screening for transfusion-transmissible infections (TTIs) to exclude blood donations at risk of transmitting infection from donors to recipients is a critical part of the process of ensuring that transfusion is as safe as possible. Effective screening for evidence of the presence of the most common and dangerous TTIs can reduce the risk of transmission to very low levels [3]. Blood transfusion services should therefore establish efficient systems to ensure that all donated blood is correctly screened for specific TTIs and that only non-reactive blood and blood components are released for clinical and manufacturing use.

METHOD

Blood samples (300) from the 13 testing facilities and their screening results for hepatitis B

surface antigen (HBsAg), antibodies to hepatitis C virus (HCV), human immunodeficiency virus (HIV) and syphilis using EIAs were obtained. All the samples were then analysed for the three viral markers using 4(th) generational enzyme linked immunosorbent assay (ELISA) kit as the gold standard.

There are some blood banks screen for syphilis using rapid test. None of the blood banks use nucleic acid tests for confirmation of reactive samples. No blood banks repeat reactive TTIs samples testing. However, currently there are some blood banks counseling or referral system for those who found to be reactive.

RESULT

Blood banks has to ensure availability of a sufficient supply of high quality blood and blood components for transfusion with maximum efficacy and minimum risk to both donors and recipients in time.

The study was conducted in central Blood Bank on 300 blood donor using structured checklists guided by WHO standards about blood banking procedures: It was found that the refrigeration status was satisfactory reaching 80% in relation to standards. All blood banks use standardized procedures and have SOPs to perform testing.

The results showed that the sensitivity and specificity of the QCs in anti-B testing were 100% and 98.7%, respectively. The sensitivity and specificity of the QCs in forward blood typing, anti-A testing, viral screening and cross-matching were all 99%. Therefore our QC products and methods are highly sensitive, specific, and reliable. Our study paves the way for the establishment of a uniform and standardized QC method for pre-transfusion compatibility testing in Sudan and other parts of the world.

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