OFFICE OF THE AUDITOR-GENERAL

Enhancing Accountability

PERFORMANCE AUDIT REPORT

ON

MANAGEMENT OF BLOOD TRANSFUSION SERVICES

BY THE

KENYA NATIONAL BLOOD TRANSFUSION SERVICE-PREDECESSOR TO KENYA TISSUE AND TRANSPLANT AUTHORITY

AUGUST 2022

VISION

Making a difference in the lives and livelihoods of the Kenyan People

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FOREWORD BY THE AUDITOR- GENERAL

I am pleased to present this Performance Audit Report on Management of Blood Transfusion Services by the Kenya National Blood Transfusion Service (KNBTS) - the predecessor to the Kenya Tissue and Transplant Authority (KTTA), which came into existence on 1 August, 2022 vide Legislative Supplement No. 61 and Legal Notice No. 142. My Office carried out the audit under the mandate conferred on me by Section 36 of the Public Audit Act, 2015. The Act mandates the Auditor - General to examine the economy, efficiency and effectiveness with which public money has been expended pursuant to Article 229 (6) of the Constitution of Kenya, 2010.

Performance, financial and compliance audits form the three-pillars of the audit assurance framework that I have established to give focus to the varied and wide scope of the audit work done by my Office. The framework is intended to provide a high level of assurance to stakeholders that public resources are not only correctly disbursed, recorded and accounted for, but their use results in positive impacts on the lives and livelihoods of the citizens. The main goal of our performance audit is to ensure effective use of public resources and promote service delivery to the citizens.

Our performance audits examine compliance with policies, obligations, laws, regulations, standards and whether the resources are managed in a sustainable manner. They also examine the economy, efficiency and effectiveness with which public resources have been expended. I am hopeful that corrective action will be taken in line with our recommendations in the report.

The report is submitted to Parliament in accordance with Article 229 (7) of the Constitution of Kenya, 2010 and Section 39 (1) of the Public Audit Act, 2015. I have also submitted copies of the report to the Principal Secretary, Ministry of Health; the Director Kenya Tissue and Transplant Authority; the Principal Secretary, The National Treasury and the Secretary, President's Delivery Unit.

CPA Nancy Gathungu, CBS
AUDITOR-GENERAL
24 August, 2022

LIST OF ABBREVIATIONS

ASBTS	-	African Society for Blood Transfusion Standards
CDC	-	Centre for Disease Control
EQA	-	External Quality Assurance
HTCs	-	Hospital Transfusing Committees
ICT	-	Information and Communications Technology
INTOSAI	-	International Organisation of Supreme Audit Institutions
ISA	-	International Standards of Auditing
ISO	-	International Standards Organisation
ISSAI	-	International Standards for of Supreme Audit Institutions
KEMSA	-	Kenya Medical Supplies Authority
KENAS	-	Kenya Accreditation Service
KNBTS	-	Kenya National Blood Transfusion Service
KTTA	-	Kenya Tissue and Transplant Authority
MDGs	-	Millennium Development Goals
MOH	-	Ministry of Health
NBTS	-	National Blood Transfusion Service
NCO	-	National Coordinating Office
NHS	-	National Haemovigilance Systems
OAG	-	Office of the Auditor- General
PEPFAR	-	U.S. President's Emergency Plan for AIDS Relief
RBTCs	-	Regional Blood Transfusion Centres
SAGA	-	Semi Autonomous Government Agency
SLIPTA	-	Stepwise Laboratory Quality Improvement Process Towards Accreditation
TTIs	-	Transfusion Transmissible Infections
UHC	-	Universal Health Care
WHA	-	World Health Assembly
WHO	-	World Health Organisation

DEFINITION OF TERMS

Blood: The red liquid that circulates in the arteries and veins of humans carrying oxygen and carbon dioxide to and from the tissues of the body.

Blood Bank: a place where supplies of blood or plasma for transfusion is stored.

Blood Centre: A facility that carries out all or part of the activities of donor recruitment, blood collection, testing for transfusion-transmissible infections and blood groups, processing into blood components, storage, distribution to hospital blood banks within a defined region and liaison with clinical services.

Blood Product or Component: Any therapeutic substance prepared from human blood that includes whole blood, blood components, and plasma derivatives. Whole blood is not commonly used in transfusion medicine.

Blood transfusion: Transfer of blood or a component of blood, such as red blood cells, plasma, or platelets, from one person to another to replace blood loss caused by injury, surgery or disease.

Crystalloids and Colloids: Intravenous replacement fluids that helps to avoid unnecessary transfusion.

Family/replacement blood donor: A person who gives a replacement unit of blood only when a family member or friend requires transfusion.

Haemovigilance: The set of surveillance procedures covering the entire blood transfusion chain, from the donation, processing of blood and its components, through to their provision and transfusion to patients and including their follow-up.

Haemorrhage: An escape of blood from a ruptured blood vessel.

Incinerator: An apparatus for burning waste material at high temperature until it is reduced to waste.

Septic shock: This a severe and potentially fatal condition that occurs when sepsis leads to life-threatening low blood pressure. Sepsis develops when the body has an overwhelming response to infection.

Voluntary non-remunerated blood donor: A person who donates blood of his or her own free will and receives no payment for it, either in the form of cash, or in kind which could be considered a substitute for money.

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EXECUTIVE SUMMARY

Background to the Audit

1. Transfusion of blood and blood products is a medical procedure performed for the treatment of patients with serious illness or emergencies that cannot be treated by other means. It is a life-saving and health improvement intervention hence an indispensable component of the health care system in the country.

2. The World Health Organization (WHO) Assembly resolution 28.72 of 1975 and the Regional Commonwealth Ministers of Health declaration of 1989 requires its member states to develop comprehensive, well-coordinated blood transfusion services based on voluntary non-remunerated blood donation. In 2010, the WHO Executive Board also adopted resolution EB126.R14 on the availability, quality and safety of blood products. The resolution notes that health-related Millennium Development Goals (MDGs) of reducing child mortality, improving maternal health and combating HIV/AIDS, malaria and other diseases could not be achieved unless significant attention was paid to the availability, safety and quality of blood products.

3. The WHO Blood Safety and Availability Status Report, 2013 stated that while the need for blood is universal, millions of patients requiring transfusion do not have timely access to safe blood, and there is a major imbalance between developing and developed countries in accessing safe blood.

4. In Kenya, at least 1,100 patients need blood or blood components each day. Sixty percent of the donated blood is used by expectant women and children due to birth-related complications, which include ante-partum and post-partum hemorrhages. Caesarean sections are on the rise, which account for half the births in both private and public hospitals, leading to increased demand for blood.

5. The mandate of the Kenya National Blood Transfusion Service (KNBTS), the predecessor to the Kenya Tissue and Transplant Authority (KTTA) which came into existence on 1 August 2022 vide Legislative Supplement No.61 and Legal Notice No. 142 amongst others, is to provide safe blood and blood products for all the citizens in an equitable and efficient manner. In this report, reference is made to KNBTS because the Authority was not in existence as at the time of the audit. The estimated annual national demand for blood in the country based on WHO guidelines is 500,000 units, with KNBTS collecting between 150,000 and 160,000 units annually.

Objective of the Audit

6. The objective of the audit was to assess whether the KNBTS ensures adequate supply of blood to hospitals for transfusion needs of patients. Specifically, the audit sought to establish the extent to which KNBTS:
    i. Supplies sufficient blood to hospitals for patients transfusing needs; and
    ii. Guarantees quality and safety of blood transfused to patients in hospitals.

Scope of the Audit

7. The audit team examined operations of KNBTS in 5 out of its 6 Regional Centres and in 10 out of its 18 Satellite Centres. This was in regard to donor recruitment and notification; blood collection; blood processing; blood banking and distribution; and haemovigilance. In addition, the Team examined KNBTS activities with regard to provision of blood services in 27 hospitals. The audit covered the period 2016/2017 to 2020/2021.

Summary of Audit Findings

8. The audit revealed that blood transfusion services in Kenya are not being effectively delivered. The findings are detailed below:

Inadequate Supply of Blood to Hospitals for Transfusion

9. The KNBTS is vested with the responsibility of ensuring supply of adequate and safe blood and blood products to transfusing hospitals for transfusion needs of all patients in hospitals. During the period 2016/2017 to 2018/2019, the audit revealed that KNBTS did not supply 46% of the blood requested on average in the 27 sampled hospitals. KNBTS supplied 26,950 out of 50,257 units requested. This not only poses a risk currently, but also on the future availability of blood for patients, considering that blood requests during the period gradually increased by about 6,000 units each year.

Lack of an Inventory System for Efficient Management of Blood and Blood Products

10. The KNBTS does not have a stock management system for blood and blood products for hospital blood banks. Consequently, there are no established re-order levels for efficient blood transfusion services. The hospitals therefore, order blood as and when needed. Lack of an efficient inventory system does not only affect the availability of blood and blood products as and when required for efficient service delivery, but may also result into wastage due to expiry of blood and blood components for lack of adequate stocking systems.

11. Failure to access blood when needed in hospitals is a major risk, considering blood is administered for treatment of patients with critical illnesses. This is especially for life threatening conditions like ante-partum and post-partum haemorrhages which

contribute to high mortality rates in maternal deaths or cases of emergencies like accident victims who require immediate blood transfusion.

12. Inability to supply adequate blood to hospitals is attributed to failure by KNBTS to meet WHO requirements for setting blood collection targets, its inability to meet its own collection targets, inadequate mobilization, recruitment and retention of blood donors, as well as inadequate resources for provision of blood transfusion services.

Failure to Meet the WHO's Standards for Blood Collection Targets

13. The WHO recommends that for a country to meet its blood and blood component requirements, it should collect a unit of blood from at least one per cent of its population every year. Kenya has a population of about 47.6 million people implying a target collection of about 476,000 units of blood per year. However, review of annual blood collection targets shows that KNBTS targeted an average of 201,250 units during the period 2016/2017 to 2019/2020 resulting in a below target of 274,750 (58% units) of the WHO requirements. The Management indicated that KNBTS does not base its blood collection targets either on the WHO requirement or blood needs in hospitals but rather on the available resources.

KNBTS does not Meet Its Own Blood Collection Targets

14. The KNBTS does not only fail to set its blood collection targets as per the WHO requirements or base its blood collection targets on the needs of hospitals, but also fails to meets its own set blood collection targets. Out of the total average collection targets of 201,667 units during the period 2016/2017 to 2018/2019, KNBTS failed to collect about 40,922 units of blood or an average of 20% of the set targets annually.

Inadequate Mobilization, Recruitment and Retention of Blood Donors

15. According to WHO standards, achievement of safe, secure and sufficient supply of blood and blood products is dependent upon voluntary non-remunerated blood donation. This requires strategies that ensure recruitment and retention of regular donors based on voluntary non-remunerated blood donors. However, KNBTS has not been able to recruit and retain regular voluntary non-remunerated donors. Instead, it has been relying on first time donors who cannot guarantee provision of adequate supply of safe blood. The data analysis undertaken on the blood donors during the period revealed that out of an average of 151,553 donors who donated blood during the period 2016/2017 to 2018/2019, only 9% were regular donors, 16% were repeat donors while majority, representing 76%, were first time donors who cannot be relied on to provide a steady and continuous supply of blood.

16. Inadequate regular donor recruitment is attributed to lack of an effective public awareness and donor education strategy. This has impacted on the effective recruitment and retention of voluntary donors, as well as inadequate donor notification, thus reducing on the possibility of regular repeat donors.

Inadequate Resources for Provision of Adequate Safe Blood and Blood Products

17. The KNBTS is expected to comply with national policies and strategies on blood transfusion. This is achieved by implementing standards that meet targets for the provision of safe blood and blood products. However, KNBTS does not have adequate number of qualified and experienced staff to perform its functions efficiently. For instance, there was an average shortage of 60% of staff requirements in 15 sampled blood transfusion Centres.

18. This was mainly attributed to non-renewal of contracts for staff employed on contract basis; under the President's Emergency Plan for AIDS Relief (PEPFAR) Blood Safety Program. Their contracts ended on 31 March, 2015 but had not been renewed as at the time of the audit in, 2020. This drastically reduced the number of staff available for blood transfusion services. Further, a rationalisation exercise that targeted at ensuring KNBTS has adequate staff has yet to be implemented.

19. Further, for KNBTS to be effective in implementing its mandate, it requires suitable infrastructure and facilities in all Centres where blood collection, testing, processing and storage of the blood and blood products takes place. KNBTS does not have adequate infrastructure including vehicles for blood transfusion services. Further, the available vehicles are not regularly maintained and lack adequate capacity for carrying out the blood drives.

20. Continuity in the supply of reagents, test kits and other consumables, as well as functional equipment in the Regional Blood Transfusion Centres (RBTCs) is critical to avoidance of interruptions in the processing of blood. However, due to lack of adequate reagents and breakdown of blood processing equipment, blood screening for the entire Country was being done in only 3 of the 6 RBTCs as at the time of the audit. This resulted in slow processing of blood, which affected the timely availability of blood. For instance, routine and emergency blood testing and grouping should take 24 hours and 6 hours respectively. However, the audit revealed that it took between 4 and 17 days for Satellite Centres to receive results sent to the Nairobi Regional Centre for Transfusion Transmissible Infections (TTI) screening. In some instances, it took up to a month for Satellite Centres to receive the blood samples results.

21. Delays in processing of blood does not only affect timely availability of blood but also poses the risk of the blood expiry while awaiting test results. Some of the Satellite Centres were noted to have held blood awaiting TTI screening results before being issued to the hospitals to a point of expiry.

Quality and Safety of Blood and Blood Products

22. The quality and safety of all blood and blood products must be assured throughout the process; from the selection of blood donors to the point of transfusion of patients at the hospitals. However, the audit revealed inadequacies which could compromise the quality and safety of blood transfused to patients. These include; lack of a centralized system for blood collection and processing, inadequate regular donors, lapses in the blood cold chain, inadequate donor recruitment practices, equipment gaps due to lack of preventive maintenance for equipment, inadequate staff, lack of adequate haemovigilance activities in hospitals, outdated policies and guidelines and lack of accreditation of KNBTS laboratories.

Failure to Embrace the Use of Blood Components as an Effective Way for Blood Transfusion

23. Blood is used most effectively if it is divided into components prepared from whole blood. This allows for one unit of whole blood to be used to meet the needs of more than one patient. Further, use of blood divided into components addresses a specific ailment in a patient, leading to effective use of blood. However, the audit revealed that KNBTS did not meet blood needs in hospitals due to its inability to meet its targeted component preparation. The hospitals therefore ended up using whole blood which was not effective, further aggravating blood insufficiency. The major challenges affecting component preparation are limited use of modern technology in component preparation, faulty manufacturing equipment in the RBTCs and lack of capacity in terms of human resources, equipment and training in Satellite Centres.

Appropriate Use of Blood and Blood Products for Efficient Blood Transfusion Services

24. The National Blood Transfusion Policy, 2001 requires KNBTS to promote the clinical use of blood and blood products, so as to ensure that they are appropriately used in hospitals. This requires KNBTS to develop policies and strategies to reduce the need for transfusion by minimising on unnecessary transfusions and ensuring safe and appropriate use of blood and blood products. Such strategies require the establishment of Hospital Transfusing Committees (HTCs) and National Haemovigilance Systems (NHS).

25. HTCs are the link between the transfusing hospitals and KNBTS. The committees should therefore be established in each hospital to implement the national policy and

guidelines on blood transfusion services. The committee should have authority within the hospital structure to regulate hospital policies on blood transfusion and ensure availability of the required blood and blood products at all times. However, the audit revealed that although the HTCs were in place, they were not functional. Consequently, KNBTS could not establish the blood and blood products need of the hospitals; issues pertaining to adverse reactions of patients; address the issue of appropriate clinical use of blood in hospitals; as well as monitor blood consumption.

Lack of Electronic Surveillance of Haemovigilance Activities in Hospitals

26. Surveillance procedures and haemovigilance systems are needed to monitor adverse events and known threats to blood safety and availability. This would enable informed decisions to be taken in response to challenges or threats faced. Effective haemovigilance enhances traceability of donated blood to the recipient and vice versa in a timely manner. However, the audit revealed that blood processes were not managed electronically. Consequently, information on adverse events was not readily available for prompt investigation and recall of the affected products to prevent further transfusion of the related blood products. Efforts towards enabling KNBTS achieve traceability of blood electronically made by the American Government PEPFAR through the Centre for Disease Control (CDC) faced licensing, technical and hardware challenges.

Lack of an Appropriate Legal and Supervisory Framework

27. The WHO recommends that a national blood system should be governed by a national blood policy and legislative framework to promote uniform implementation of standards and consistency in the quality and safety of blood and blood products. However, KNBTS lacked an appropriate legal and supervisory framework to monitor quality assurance controls for blood collection, testing, processing, storage and distribution in private transfusing hospitals as at the time of the audit. KNBTS in collaboration with the MOH developed a Bill in 2014, "The Kenya National Blood Transfusion and Transplant Bill, 2018" which, among others, sought to enable KNBTS provide technical support to private as well as national referral hospitals on best practices in blood transfusion. Subsequently, post audit, the Kenya Tissue and Transplant Authority came into existence on 1 August 2022 vide Legislative Supplement No. 61 and Legal Notice No.142.

Outdated Blood Polices and Guidelines

28. According to WHO standards, each country should have a well formulated national blood policy that addresses all issues that could affect the quality, safety, availability and accessibility of blood and blood products. The policy should be reviewed regularly, particularly when issues emerge that have implications for national blood programmes.

KNBTS has over the years developed guidelines, policies and procedures that govern activities on blood transfusion services. These guidelines and polices should be reviewed and updated after every 3 years, however, this has not been done. Consequently, a significant number of the critical polices and guidelines on blood transfusion services were outdated, with some dating as far back as 2001. The usage of these guidelines is, therefore, limited as majority are outdated and not aligned to the current health structures and emerging technologies.

Delayed Accreditation of Laboratories

29. Accreditation gives formal recognition that a particular organisation is competent to carry out its given responsibilities. In August 2018, KNBTS embarked on a programme to pursue ISO 15189:2012 accreditation, the most applicable standard for medical laboratories, through the Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) programme. However, as at the time of the audit, KNBTS had not completed the process. Delayed accreditation of KNBTS laboratories may hamper stakeholders' confidence in the safety of blood transfusion services being offered.

30. Further, KNBTS has participated in an External Quality Assurance (EQA) Scheme sponsored by donor partners since the year 2009 that was aiding in quality monitoring. However, this ceased in April 2020 when funding came to an end. As at the time of the audit, KNBTS had not participated in any EQA. Lack of regular independent monitoring of programmes may hinder the identification of performance gaps that would ensure KNBTS works towards improving safety and quality of blood and blood products.

The Blood Cold Chain Management Process was Inefficient

31. The condition under which blood and blood products are stored and transported have a direct impact on its safety, efficacy and availability. The blood cold chain is a system for storing and transporting blood and blood products within the required temperature range and condition from point of collection from donors to the point of transfusion to patients. Cold chain also involves a series of interconnected activities involving equipment, personnel and processes that are critical for the safe storage and transportation of blood. The audit revealed that KNBTS lacked sufficient storage facilities in the blood cold chain management process, as most of the equipment were broken down. Further, there were equipment gaps in the blood cold chain, as well as inadequacies in routine preventive maintenance of the available equipment.

32. Lack of proper maintenance of cold chain equipment resulted into inefficiencies in the cold chain process, especially in maintaining the required temperatures at the requisite levels. Lapses at any one point in the blood cold chain results in the collapse of the Chain.

Deviations from the specified temperature ranges and conditions during storage and transportation of blood and blood products seriously affects the viability of the constituents of blood, thus leading to reduced clinical benefits.

Conclusion

33. The Government has put in considerable effort in ensuring access to safe and quality blood services in Kenya by taking the service closer to the citizens. Currently, KNBTS has presence in 23 Counties. However, despite the gains achieved in blood transfusion services over the years, the audit established that the services were not being effectively delivered. According to WHO, access to sufficient, secure supply of blood and blood products and safe transfusion services is an essential part of any strong health system. Further, it is an important component of efforts towards achieving the goal of Universal Health Coverage (UHC).

34. The KNBTS has not been meeting the hospital blood needs as and when required. The blood collection targets set by KNBTS are not in line with the WHO requirements but are instead based on the available resources. There is therefore, no guarantee on availability of adequate blood to meet patients' needs in hospitals. Although KNBTS are in possession of records which indicate previous hospital blood needs that were yet to be met, these were not put into consideration when planning future blood collections.

35. There was limited public awareness initiatives on the importance and benefits of blood donation in the country. This impacted on the out reach to potential blood donors as the misconceptions on blood donations are not dealt with. This ultimately, impacts on the goal of achieving a pool of voluntary non-remunerated blood donors who would guarantee a safe and steady supply of blood.

36. There were limited efforts by KNBTS to ensure that existing donors donated as frequently as possible. Failure to notify donors in good time decreases their confidence in the donation process and lowers their chances of donating repeatedly.

37. KNBTS has inefficiencies in blood collection, testing, processing and transfusion which may affect quality and safety of blood. Further, KNBTS is not leveraging on modern technology to maximize utilization of the available blood units.

38. Procurement processes for supplies were not responsive and precise to the urgent needs of the blood transfusion service. The KNBTS did not maintain buffer stocks and could, therefore, not guarantee that processes and procedures would not come to a standstill due to lack of crucial supplies, such as blood bags and reagents.

39. There were no proper schedules to ensure timely maintenance of equipment and motor vehicles which resulted to inefficiencies in blood transfusion service.

40. The existing haemovigilance system did not guarantee adequate surveillance of the entire transfusion chain and hence there was inadequate feedback for effective corrective measures.

41. The audit established that provision of safe and adequate supplies of blood is dependent on a well-organised blood transfusion service, with dedicated, well-trained manpower and resources for the service. According to the Policy Guidelines on Blood Transfusion in Kenya, 2001 the MOH was to create a self-sustaining financial mechanism that would run the blood transfusion service throughout the country. However, the financial mechanism is yet to be developed, which contributes to the above factors which are a hindrance to an efficient blood transfusion service.

Recommendations

42. Provision of safe and adequate supply of blood is dependent on a well-organised blood transfusion service, with dedicated well-trained manpower and resources for the service. This would require the Kenya Tissue and Transplant Authority (KTTA), the successor to KNBTS, to have adequate sustainable finances to carry out its functions including those related to blood transfusion services.

43. The Kenya Tissue and Transplant Authority should prioritise the blood donor recruitment function through the development of an all-inclusive nation-wide communication strategy that would help in sensitizing potential donors for increased voluntary blood donor recruitment and retention. The KTTA should fully implement the post-audit strategies on improving public awareness, information and education; increased media coverage on matters relating to blood; and increased public responsibility towards blood donations.

44. The Kenya Tissue and Transplant Authority should leverage on ICT in enhancing haemovigilance activities. This requires the national track and trace Blood Management Information System developed post-audit be put into optimal use. This will enhance traceability of blood, aid in receiving timely feedback from Hospital Transfusing Committees , as well as training and mentorship of transfusing clinicians. This would also contribute to improving appropriate utilization of blood and blood components in hospitals.

45. To ensure that blood is only used for deserving cases, thus easing on demand for blood, the KTTA should ensures clinicians are continuously trained and advised on prevention and early management of anaemia and the use of blood alternatives as far as possible. It is imperative for the KTTA to fast-track the development and implementation of the National Haemovigilance Framework in order to strengthen haemovigilance activities in the hospitals.

46. The Kenya Tissue and Transplant Authority needs to improve on donor notification and referral of TTI positive cases to care and treatment services. Further, the KTTA should ensure linkages are established with facilities to ensure that the deferred donors seek care and treatment as advised.

47. The Ministry of Health and the Kenya Tissue and Transplant Authority should consider developing a human resource policy for the later staff that addresses recruitment, retention, training and motivation of staff so as to ensure effective service delivery. Post-audit review indicates that KNBTS had requested the MOH for recruitment of 50 staff and also developed a capacity building framework for guiding training of health care workers on blood transfusion management. The MOH should fast-track staff recruitment and the KTTA should ensure adequate training for all staff in the blood service.

48. The Kenya Tissue and Transplant Authority should ensure that sufficient quantities of the required consumables for blood transfusion service are available. This can be done through replenishing new stock before the existing stock runs out, for enhanced efficiency in the blood service delivery. In addition, the KTTA should ensure that the forecasting and quantification committee set up post-audit, ensures security for stock and pipeline for reagents and other consumables.

49. The Kenya Tissue and Transplant Authority should improve on quality of blood products through modernisation of blood processing and component preparation. This will ensure optimal use of the scarce blood resources. Post-audit, Service through MOH has acquired four apheresis machines and other equipment for blood component preparation. The KTTA should therefore, ensure optimal utilisation of the equipment for efficient service delivery.

50. The Ministry of Health and Kenya Tissue and Transplant Authority should ensure prompt maintenance and replacement of motor vehicles and laboratory equipment. Major

laboratory equipment needs to be placed under maintenance service contracts and users trained on the basic preventive maintenance.

51. The Ministry of Health and the Kenya Tissue and Transplant Authority should fast track updating of outdated policies, guidelines and manuals on blood service delivery in the country for efficiency. Post-audit review indicates that three guidelines and manuals have been reviewed and others are being developed. However, there is still need for the KTTA to fast-track the content review and approval of the policies, guidelines and the manuals.

52. The Kenya Tissue and Transplant Authority should review and revive programmes geared towards attaining and maintaining international quality standards for accreditation of blood transfusion services. Post-audit review indicates that three out of the six KTTA Regional Blood Transfusion Centres have so far being accredited. There is need for the KTTA to fast-track accreditation of the remaining three Regional Blood Transfusion Centres and sustain the requisite standards for the three already accredited.

53. Post-audit review indicates various reforms have been initiated by the MOH on blood service delivery. The Office of the Auditor- General intends to carry out a follow up audit within a year of issuance of this report to assess whether the reforms including the creation of the Kenya Tissue and Transplant Authority have impacted on the blood service delivery and that sufficient, secure supplies of blood and blood products have been realised.

1.0 BACKGROUND TO THE AUDIT

Introduction

1.1 Transfusion of **blood and blood products** is a medical procedure performed for the treatment of patients with serious illness or emergencies that cannot be treated by other means. It is a life-saving and health improvement intervention and as such an indispensable component of the health care system in the country[1].

1.2 Blood transfusion is necessary for patients who are undergoing surgical procedures, have anaemia, sickle cell disease, bleeding disorders such as haemophilia, cancer treatment, maternal care and emergency care in case of accidents. Provision of sufficient and timely supplies of safe blood is therefore critical for saving lives of patients and improving their well-being. Safe blood transfusion reduces the risk of transmissible transfusion infections which include HIV, hepatitis viruses and other life-threatening infections that can be transmitted through unsafe blood.

1.3 The WHO Assembly resolution 28.72 of 1975 and the Regional Commonwealth Ministers of Health declaration of 1989 requires its member states to develop comprehensive, well-coordinated blood transfusion services based on voluntary non-remunerated blood donation.[2] Voluntary, non-remunerated blood donation is considered as the cornerstone of a safe and adequate national blood supply that meets the transfusion requirements of all patients.[3]

1.4 In 2010, the WHO Executive Board also adopted resolution EB126.R14 on the availability, quality and safety of blood products. The resolution notes that health-related MDGs of reducing child mortality, improving maternal health and combating HIV/AIDS, malaria and other diseases could not be achieved unless significant attention was paid to the availability, safety and quality of blood products.[4]

1.5 Demand for blood in the developed world is growing with longevity of life and increasingly sophisticated clinical procedures. Blood transfusion is most commonly used to support advanced medical and surgical procedures, including trauma, cardiovascular surgery, neurosurgery and transplantation.[5] Of the 118.5 million blood

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[1] Status of Blood Safety in the WHO African Region, Report of the 2010 Survey.
[2] Policy guidelines on blood transfusion in Kenya, 2001.
[3] WHA 58.13 of 2005 on blood safety.
[4] 63rd WHA Provisional Agenda Item 11.7.
[5] WHO, Access to Safe Blood Transfusion, 2008

donations collected globally, 40% of these are collected in developed countries, home to 16% of the world's population.[6] The most frequently transfused patient group and accounting for up to 76% of all transfusions is those over 65 years of age.

1.6 A report on the current status on blood safety and availability in the WHO African Region, 2013 stated that while the need for blood is universal, millions of patients requiring transfusion do not have timely access to safe blood and there is a major imbalance between developing and developed countries in accessing safe blood.[7]

1.7 The mortality rates in the WHO African Region are the highest in the world, with average regional estimates of an under-five years old mortality rate of 81.3 per 1,000 live births, and a neonatal mortality rate of 28 per 1,000 live births. Malaria incidence is 210 cases per 1,000 inhabitants. In terms of road traffic mortality, the incidence is 20 per 100,000 inhabitants. Lastly, 42% of the population in the WHO African Region suffer from anaemia. Majority of these patients require transfusion, but there is no timely access to safe blood or blood components. As a result, there are big discrepancies regarding access to safe blood in developing and developed countries.[8]

1.8 In the WHO African region, efforts to meet demand for blood are still affected by high prevalence of TTIs and considerable reliance on family or replacement donations.[9] Other factors include lack of policy commitment in some countries despite the development and adoption of national policies, low government funding leading to reliance on external funding, lack of skilled human resources with competitive career prospects for blood transfusion service staff, lack of adequate infrastructures and equipment, as well as the absence of a sufficient quality management system at each section of the blood safety chain, from blood donors to recipients.[10]

1.9 In Kenya, at least 1,100 patients need blood or a blood components each day. Sixty-percent of the donated blood is used by expectant women and children due to birth-related complications, which include anti partum haemorrhage and post-partum haemorrhage. Caesarean sections are on the rise, which account for half the births in both private and public hospitals leading to increased demand for blood. The Kenya

[6] https://www.who.int/news-room/fact-sheets/detail/blood-safety-and-availability
[7] Current Status on Blood Safety and Availability in the WHO African Region, 2013.
[8] Loua A (2018) Blood safety and availability in the WHO African region, 2018.
[9] Current Status on Blood Safety and Availability in the WHO African Region, 2013.
[10] Loua A (2018) Blood safety and availability in the WHO African region, 2018.

National Blood Transfusion Service[11] collects between 150,000 to 160,000 units of blood against an estimated national demand of 500,000, as per WHO guidelines.[12]

1.10 The KNBTS was established in the year 2000 under the MOH in line with recommendations from the WHO and resolutions of the World Health Assembly (WHA). The mandate of KNBTS - the predecessor to Kenya Tissue and Transplant Authority (KTTA), which came into existence on 1 August 2022 vide Legislative Supplement No. 61 and Legal Notice No. 142 amongst others, is to provide safe blood and blood products for all the citizens in an equitable and efficient manner. [13] In this report, reference is made to KNBTS because the Authority was not in existence as at the time of the audit.

Motivation for the Audit

1.11 The following factors motivated the Office to carry out the audit:

i. Prior to the year 2000, blood transfusion services in Kenya were hospital based and were run as part of hospital laboratory services. Family and replacement donations were the major sources of blood required for transfusion. Higher level hospitals struggled to meet their blood demand and managed their own stock levels while lower level hospitals were incapable and often referred patients requiring transfusions. The MOH could not meet the blood demand, offer adequate supervision, as well as ensure the quality and safety of blood. There were also challenges in the distribution of reagents and other supplies and it was difficult to dedicate staff and equipment for blood transfusion services.[14]

The centralisation of the blood service through KNBTS was a step forward towards attaining quality, safe and sufficient blood supply for patients throughout the country. It was therefore important to assess whether KNBTS has achieved the intended objective of improving blood transfusion services in the country by ensuring that patients receive sufficient, quality and safe supply of blood in hospitals as and when needed.

ii. The gap between demand and supply of blood is continuously widening as the population increases. Whole blood has a short shelf life of 35 days while its demand is always high, therefore, its supply should always be constant and this

[11] "The Kenya National Blood Transfusion Service" is interchangeably referred to as "the Service" in this Report.
[12] OAG Brief from KNBTS, 2019.
[13] Blood Service Update, 2020.
[14] East African Medical Journal Vol. 86 (Supplement) December 2009.

is not the case in most parts of the world. This is a particularly worrying trend in Kenya where the current blood collection figures are below the WHO's recommendations.[15] Kenya can only meet 52% of hospitals' blood needs.[16]

iii. An estimated Kshs.500 million was budgeted to procure equipment meant to improve the blood services at KNBTS between the financial years 2015/16 and 2019/2020. It was, therefore, important to assess the impact made on blood service delivery in the country.

iv. A report titled "Confidential inquiry into maternal deaths in Kenya 2017" identified obstetric haemorrhage as a leading cause of direct maternal death, part of which was associated with lack of blood.

v. Various media reports[17] highlighted issues on KNBTS not meeting the targeted levels of blood collection; cases of maternal deaths due to lack of blood transfusion; patients having to pay in order to be transfused with blood; [18]maternal mortality cases; challenges associated with the decentralized system where some hospitals collect own blood; and [19]cases of contaminated blood in blood banks.

[15] International Journal of Science and Research, Vol. III Issue 11, November, 2014.
[16] Medium Term Expenditure Framework for the period 2017-18 to 2019-20.
[17] The Standard Newspaper, 3 June, 2018.
[18] The Daily Nation Newspaper, 14 August, 2018.
[19] The Standard Newspaper, 23 October, 2017.

2.0 DESIGN OF THE AUDIT

Audit Objective

2.1 The objective of the audit was to assess whether KNBTS ensures adequate supply of blood to hospitals for transfusion needs of patients. Specifically, the audit sought to establish the extent to which KNBTS:

i. Supplies sufficient blood to hospitals for patients transfusing needs; and
ii. Guarantees quality and safety of blood transfused to patients in hospitals.

Scope of the Audit

2.2 The audit team examined operations of KNBTS in 5 out of its 6 Regional Centres and in 10 out of its 18 Satellite Centres with regard to donor recruitment and notification; blood collection; blood processing; blood banking and distribution; and haemovigilance. In addition, the Team examined KNBTS activities with regard to provision of blood services in 27 hospitals.

2.3 The period covered under the audit is five financial years; 2016/2017 to 2020/2021. However, not all requested information with regard to the various blood service activities for the period under review was provided to the audit team. Consequently, the audit review was limited to the information provided.

Methods Used in Gathering Audit Evidence

2.4 We conducted the audit in accordance with the International Standards of Supreme Audit Institutions (ISSAI) issued by the International Organization of Supreme Audit Institutions (INTOSAI) as well as relevant Supreme Audit Institution (SAI) standards and guidelines applicable to performance auditing. INTOSAI general auditing standards requires that the audit and the SAI must be independent, possess required competence and exercise due care to provide a guide on execution and reporting of audit findings.

2.5 To obtain information on the responsibilities and operations of KNBTS with regard to management of blood transfusion and how hospitals deliver blood transfusion services to patients, we interviewed senior management and staff at KNBTS and the hospitals' medical superintendents and officers in charge of laboratory units, as detailed in **Appendix 1.**

2.6 To obtain information on the goals, objectives and roles of KNBTS in the management of blood transfusion in Kenya, we reviewed the Kenya Health Policy 2014 - 2030, Health

Act, 2017 and Policy Guidelines on Blood Transfusion in Kenya, 2001 and other documents that are listed in **Appendix 2.** In addition, the team reviewed documents with regard to haemovigilance activities in the sampled hospitals.

2.7 The data collected was analysed by quantitative analysis which involved descriptive statistics and trend analysis. We also used qualitative analysis by way of analysing data collected during interviews and examination of relevant documents. The evidence collected is presented using tables and graphs, as appropriate.

Assessment Criteria

2.8 The audit assessed the management of blood transfusion services against criteria drawn from the statutory mandate and strategic goals of KNBTS. We also referred to recommended practices in accordance with the WHO Resolution requiring member countries to ensure availability, quality and safety of blood products. Details on the audit criteria are provided in the findings chapter and is also listed in **Appendix 3.**

3.0 DESCRIPTION OF THE AUDIT AREA

Legal Framework

3.1 The Constitution of Kenya, 2010 stipulates that every citizen has a right to life and the right to the highest attainable standard of health, including emergency treatment.

3.2 The MOH is responsible for providing the policy framework for blood services in the country. The KNBTS is under the Department of Curative and Rehabilitative Health Services, which is responsible for development of policies and guidelines for blood service delivery. The MOH Policy Guidelines on Blood Transfusion in Kenya, 2001 guides KNBTS in the provision of blood services.

3.3 The Public Health Act, 2017 in Section 85(3) vests KNBTS with the responsibility of developing a comprehensive and coordinated national blood service based on voluntary non-remunerated blood donations so as to guarantee availability of adequate and safe blood. Section 85(4) of the Act further vests the Service with the responsibility to superintend, regulate and provide blood transfusion services.

The Statutory Mandate of KNBTS

3.4 The KNBTS is mandated to provide safe and adequate blood and blood components in the Country. In 2001, Kenya's first blood policy guidelines were developed and launched by MOH. The first RBTC and National Coordinating Office (NCO) were established in Nairobi. Prior to this period, blood transfusion services were hospital based and were run as part of hospital laboratory services.

3.5 The Service is managed through the NCO in Nairobi, which also houses the KNBTS National Testing Laboratory, the 6 RBTCs and 18 Satellite Centres. The regional Centres are meant to decentralize the blood transfusion services and are charged with the responsibility of blood donor mobilisation, education, recruitment and retention; blood collection and donor care and laboratory testing of donated blood; blood component preparation; donor counselling and notification; blood banking and distribution; and haemovigilance.

3.6 Satellite Centres are for storage and distribution of blood. The National Testing Laboratory mainly conducts confirmatory testing for TTIs for RBTCs, quality assurance and reference checking. The National Testing Laboratory also serves as a backup testing facility for RBTCs.

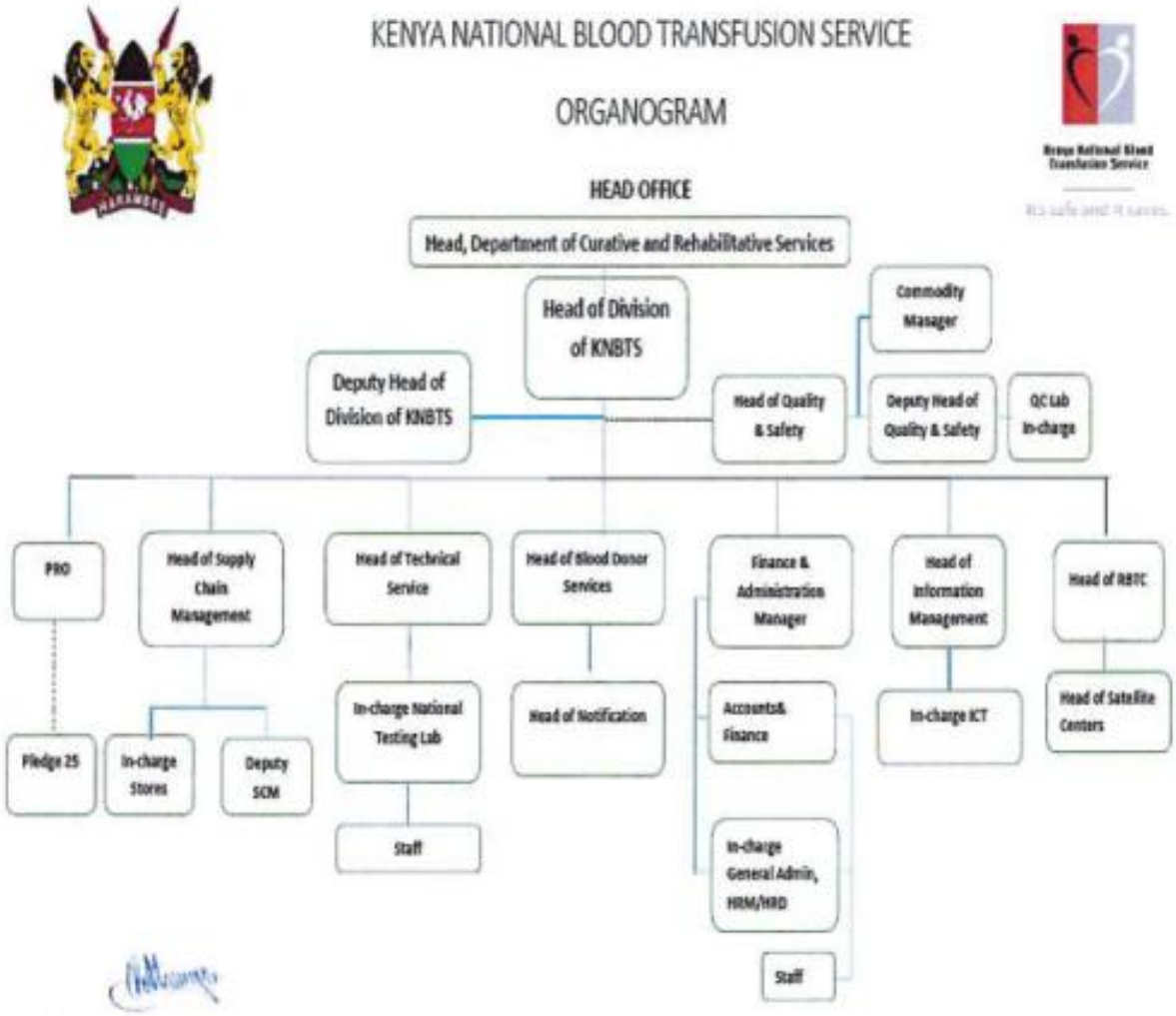
3.7 Strategic Objectives of KNBTS

i. Ensure the provision of adequate supplies of safe blood for the whole country.
ii. Ensure that each recipient receives the most appropriate therapy compatible with maximum possible safety.
iii. Ensure that blood is administered for genuine therapeutic needs only and with no financial motivation on the part of either the prescriber or the health institution.
iv. Improve and strengthen the procurement, supply, processing, distribution, and surveillance systems for blood transfusion through policy guidelines.
v. Establish a comprehensive and well co-ordinated National Blood Transfusion Service (NBTS) under the general guidance of the MOH.
vi. Establish a National Blood Transfusion Management Board, appointed by the Minister of Health, which will have wide representation to advise NBTS on the running and management of the services.
vii. Define the roles and responsibilities of all stakeholders, who will play their part in ensuring the proper running of the service.
viii. Ensure high standards of operations and safety through appropriate regulatory and supervisory mechanisms.
ix. Provide guidelines for a blood donor recruitment system through public education and advertising. This shall be based on voluntary non-remunerated potential blood donors.
x. Create a self-sustaining financial mechanism that would run the service throughout the country. The government will provide direct funding as well as create an enabling environment for NBTS to acquire funding from other sources, including local and international development partners and well-wishers. An agreed user fee will also be levied to recover part of the costs of providing safe blood products.
xi. Enact legislation providing a legal framework for the running of NBTS.
xii. Provide modality for manpower development, training and retention to satisfy the needs of the service.
xiii. Establish a system of data collection and management of blood transfusion, which will form part of the national comprehensive blood transfusion service surveillance system.
xiv. Ensure active basic, operational and developmental research into all aspects of blood transfusion.

The Organisational Structure of KNBTS

3.8 The Service is headed by the Director who is the Chief Executive Officer of the Service and reports to the Head, Department of Rehabilitation and Curative Services. The Director is assisted by the Head of Regional Blood Transfusion Centre, Nairobi. **Figure 1** shows the organisational structure for KNBTS.

Figure 1: KNBTS Organisational Structure



Approved By Head KNBTS

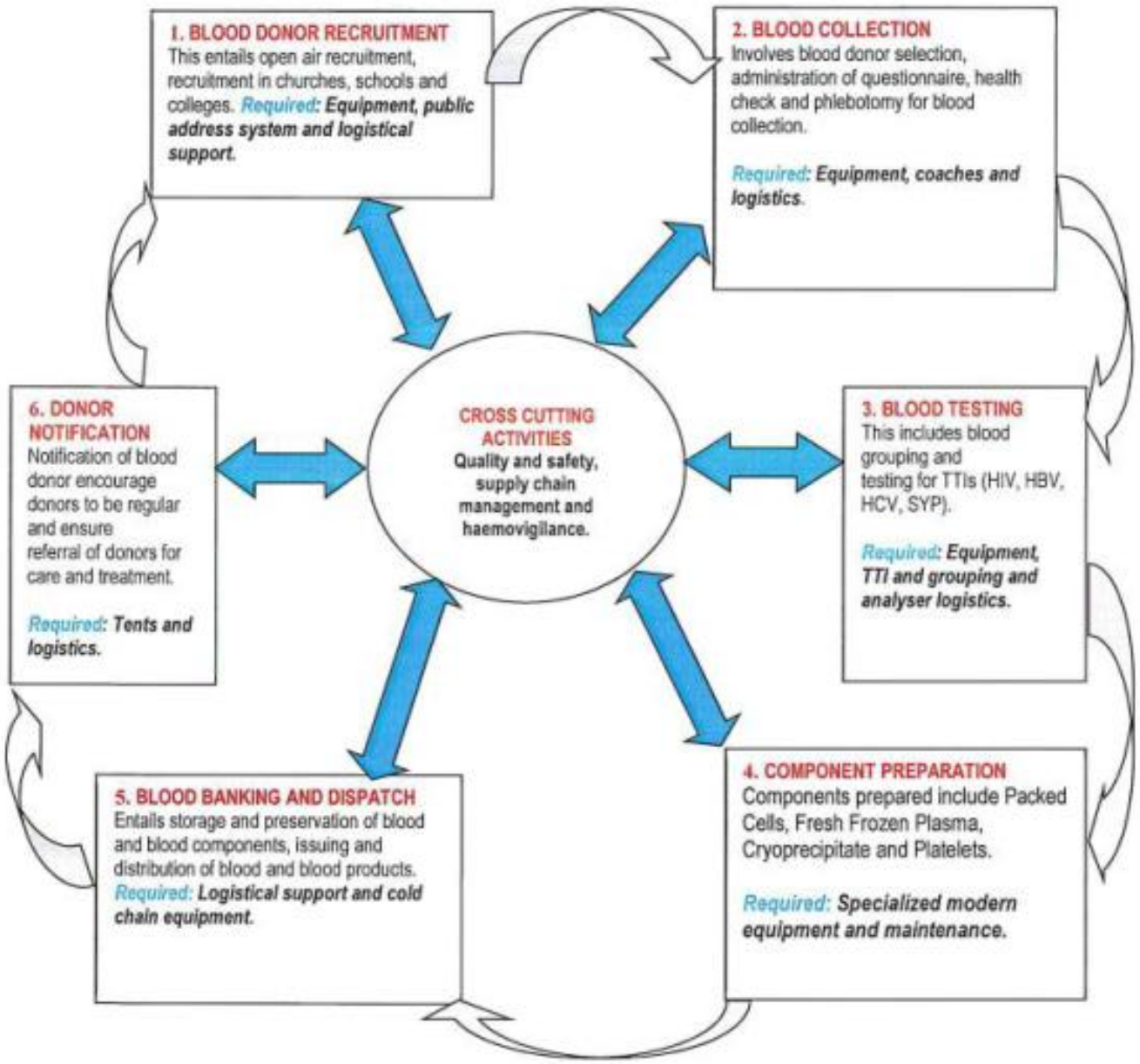
Confidential controlled document

FRM POL 001 REVISION 00 EFFECTIVE DATE: 1st Nov 2018

Process Description for Blood Management

3.9 The Blood Management Cycle commences with blood donor recruitment, progressing through to donor notification. This cycle is broken down into six major processes, namely; blood donor recruitment, blood collection, blood testing, component preparation, blood banking, dispatch and donor notification, as illustrated in **Figure 2** and as explained in the succeeding paragraphs:

Figure 2: The Blood Management Cycle



Source: Adapted from KNBTS Brief to OAG dated 12 July, 2019

I.Donor Recruitment Process

Potential donors are pooled from a low risk population. A low risk population is considered as one whose blood has low probability of having TTIs such as HIV, hepatitis B and C virus and syphilis. Risk profiling of the population also considers sexual exposure, prevalence of malaria and historical genetics data. High school students are the largest population in this category. The three approaches used to appeal and categorize potential donors in the recruitment process are:

i. One on one appeals through social media platforms. Once potential donors are identified, the responsible KNBTS recruitment team get the relevant information concerning the potential donors;
ii. Institutional campaigns which involve the use of advertising materials such as posters, fliers and brochures that communicate to donors with respect to their culture, language, age, sex and other variables as found necessary; and
iii. Emergency cases where KNBTS recruitment team go through the media and call for mass donation of blood from the general public at specific donation locations.

In all the three approaches KNBTS staff ultimately interact with donors at an individual level.

There are also donor recruitment partners who get involved in actual donor mobilisation. They play a role in the recruitment process by creating awareness through social media platforms and short text messages. Once recruiting is finalised, it is the responsibility of KNBTS to organise and have pre-donation talks and plan for the donation exercise.

Pre-donation talks are given before potential donors donates blood. The importance of the health talks is to give the potential donors all the necessary information on the donation exercise and clarify any areas of concern.

II.Blood Collection

Blood collection is either done in KNBTS or outside facilities through outreaches. Blood is collected from both voluntary and non-voluntary donors. In voluntary blood donations, the donor gives blood out of their own free will. Family or replacement donations are considered non-voluntary as such blood donations are a result of requests made by hospitals to relatives or friends of a patient.

Regular donors are individuals who donate blood annually, in which male donors donate four times and the female counterparts three times. These type of blood donors guarantee a regular, safe pool of blood donors. On the other hand, repeat donors are individuals who donate blood on a randomized pattern and can forego donating in a period of time. First time donors are individuals who have only donated blood once, therefore, cannot be depended on for a steady supply of blood.

In outreaches, the number of teams to be engaged in a particular blood collection exercise is determined by the targeted units of blood to be received. An ideal team can collect 50 – 60 units of blood in a day and it comprises of 7 members. These include; 2 medical laboratory technologists, 2 nurses, a driver, a support staff and a blood donor recruiter. medical laboratory technologists are responsible for conducting phlebotomy and other related activities like haemoglobin screening, one of them also plays the role of the in-charge. Nurses conduct health talks, donor selection, pre-donation counselling and notification, donor care and phlebotomy. Support staff keep donor records, maintain order and clean the facility where blood donation takes place. The driver is required for mobile blood drives while the blood donor recruiter carries out outreach and mobilisation of donors.

To ensure blood and blood donor safety, a questionnaire is administered to a potential donor to enable KNBTS team identify whether there are risks that may deter it from getting blood from a potential donor. This questionnaire helps to eliminate donors who may have health conditions such as asthma, bleeding conditions or diseases and risks such as unknown status of sexual partners, accidental needle injuries and tattoos. This makes it crucial for selected potential donors to provide factual information.

Physical examination of donors is also carried out to ensure that they are in good health. Donors are required to consent before donating and are observed during and after donation to ensure their safety. After donation, a post donation talk is given to donors where they are advised on what to do after donating blood. Male donors can donate blood every three months while female donors can do so every four months.

Single bags are used for collecting whole blood; double bags help prepare packed red blood cells; triple bags assist in preparing packed red blood cells for adults and children, platelet concentrate, fresh frozen plasma and cryoprecipitate while quadruple bags assist in preparing packed red blood cells for adults and children, platelets and cryoprecipitate.

III.Blood Testing

All donated whole blood undergoes the blood grouping process and screening for evidence of infection, prior to the release of blood and blood components for clinical use. After collection, blood is delivered in two different test tubes; (purple and red each for carrying out blood grouping and testing for TTIs respectively). Screening of all blood donations for HIV, Hepatitis B & C and Syphilis infections is mandatory. For samples that test positive for TTIs, a second test is done and if the results show otherwise, the donor is recalled to have another sample drawn which is then tested again. The process for blood grouping tests is also repeated for such cases. Safe blood is released to hospitals for transfusion while infected blood is discarded through incineration process. The testing unit gives feedback indicating reasons why the blood is discarded.

IV.Component Preparation

Once blood is collected from the Satellite Centres, samples are taken to the RBCTs for testing and processing. Blood test results from the samples of the donated blood inform KNBTS as to whether the donated units will be processed or discarded or the donor should be recalled for a repeat test.

For proper utilization of blood, components are prepared from whole blood for specific therapeutic purposes. Separation of blood into components allows one unit of whole blood to be used to meet the needs of more than one patient, by providing the required component only.

The main components prepared are red blood cells used in treatment of anaemic patients; platelets that are administered to bleeding patients with low platelet count; and fresh frozen plasma given to patients with low blood clotting factors.

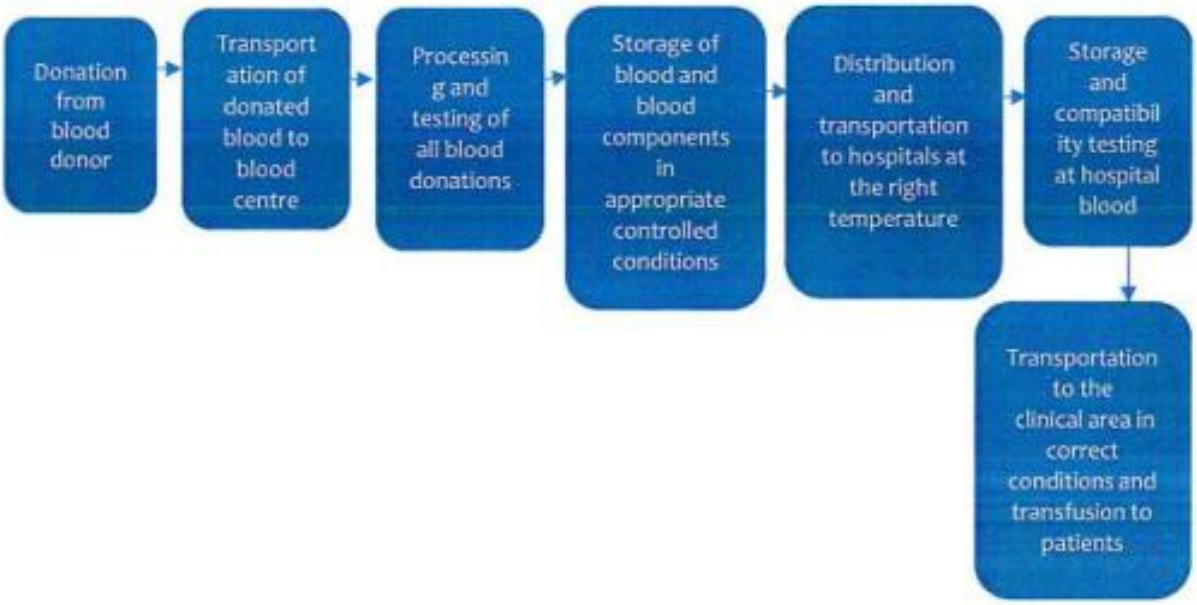
V.Blood Banking and Dispatch

Storage, preservation, issuance and distribution of blood and blood components requires an effective blood cold chain. The blood cold chain system ensures storage and transportation of blood and blood products within the requisite temperature range and conditions, from the point of collection from the blood donors to the transfusion point to the patient, as shown in **Figure 3**.

After collection, blood units are packed in cool boxes and should be delivered to the laboratory within six hours, where blood components are stored in their prescribed temperatures (platelets stored at 20-24°C, whole blood stored at 2-10°C,

cryoprecipitate [20]at 1-4°C, fresh frozen Plasma at 2-8°C, packed cells 2-10°C). Blood should be transported at temperatures below 10 degrees Celsius and samples below temperatures of 15 degrees Celsius. Units of platelets should be prepared within 4 to 5 hours of collection as they expire after 6 hours.

Figure 3: Key Elements in the Blood Cold Chain



Source: Adapted from WHO Aide-Memoire for National Blood Programmes, 2011

Hospitals make blood requests to the nearest blood Centres using requisition book issued by KNBTS. Requisition is done in triplicate where KNBTS retain the original copy. In the issuance voucher, hospitals are required to indicate their maximum and minimum quantity of blood needs. Blood is issued by blood group and component type. During issuance, a print-out giving details of the package is generated and blood is packed. During the next requisition, KNBTS staff check whether the print-out was stamped to ensure safe delivery. Hospitals indicate the quantity of blood in stock. KNBTS is charged with the responsibility of delivering blood to respective hospitals.

[20] *Cryoprecipitate is used to prevent or control bleeding in people whose own blood does not clot properly. This includes; patients with serious but rare hereditary conditions such as Haemophilia A, who lack factor VIII and Von Willebrand disease in people who lack Von Willebrand factor.*

VI.Donor Notification

After donating blood, counselling services are provided to blood donors, as well as their test results for previous donation. Information at this level should be provided promptly, accurately, confidentially and in a manner that alleviates anxiety and promotes understanding. For reactive cases, notification is done verbally while for non-reactive cases, donors are notified in writing. In cases that require follow-up, donors are referred to appropriate clinical services for further investigations, diagnosis, treatment, care and support.

Donor notification and counselling is thus part of a continuum of care and support that involves both the blood transfusion service and the wider health-care system. Therefore, it plays an important role in preventing further transmission, contributing significantly to the containment of epidemics and the reduction in the disease burden on the national health system.

During notification, donor cards are issued after four weeks for those who undertook their first donation. Message alerts are also sent to remind donors when they are due for the next blood donation.

VII.Quality and Safety Assurance

KNBTS has in place a quality manual and standard operating procedures for use by all the blood Centres in handling, collection, testing, processing, storage and distribution of blood and blood components. KNBTS also participates in external quality assurance through accreditation assessments, regulatory agencies' inspections and health and safety inspections.

VIII.Supply Chain Management

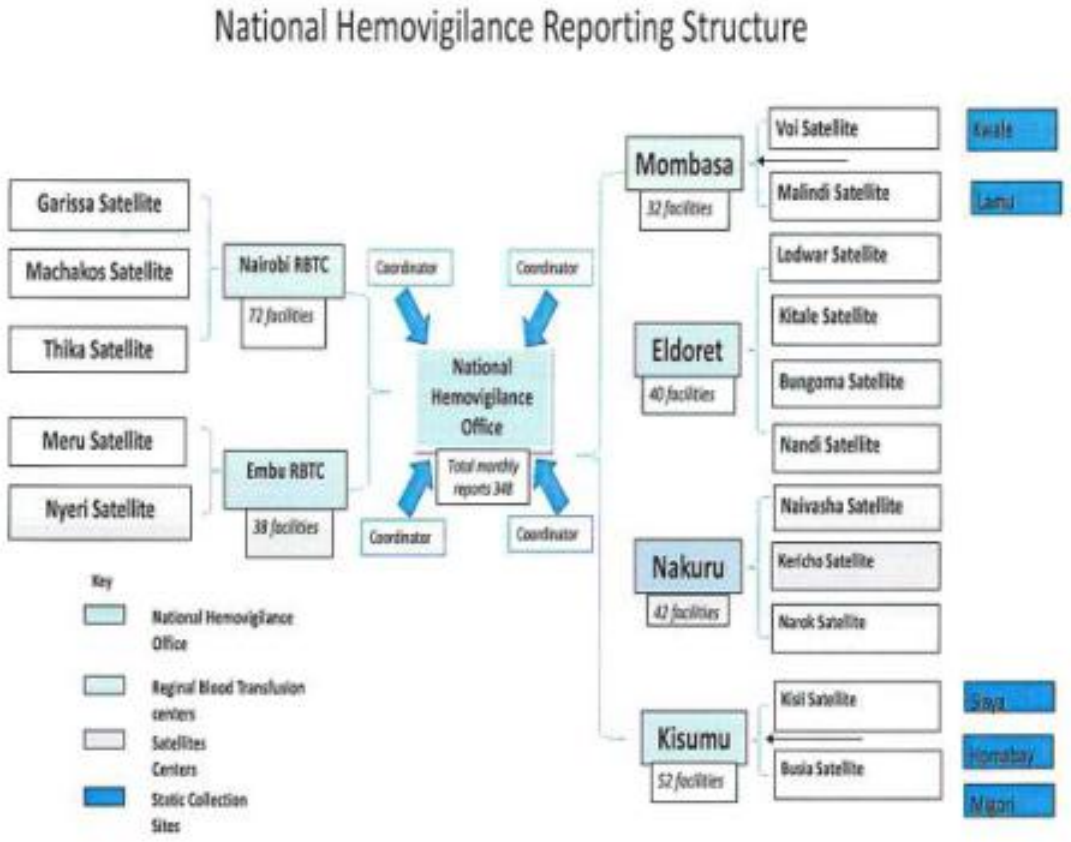
KNBTS develops annual work plan that prioritise the most critical needs. Requisitions made within the work plan are approved by the Principal Secretary, MOH. The requisitions go through the normal procurement process at the Ministry. As a department, KNBTS provides specifications for items or commodities they need, which are then approved by the Principal Secretary. Thereafter, the procurement personnel start the tendering process of awarding the tender. Some procurement procedures may be done at the MOH while others may be done at the Kenya Medical Supplies Authority (KEMSA). During all stages of tendering process there are representatives from KNBTS. Supply of commodities to regional or Satellite Centres is either done from KNBTS or KEMSA.

IX. Haemovigilance

This is a term used to depict the end to end process of monitoring blood transfusion activities from the donation through processing of blood and its components, to their provision and transfusion to patients and follow-up of the clinical outcomes thereafter. It includes the monitoring, reporting, investigation and analysis of adverse events related to the donation, processing and transfusion of blood and taking actions to prevent their occurrence or recurrence. This is a nationally coordinated structure that gives analysed reports periodically.

The KNBTS National Haemovigilance Reporting Framework, shown in **Figure 4,** enables transfusing facilities to provide feedback on blood services in the hospitals. The structure of reporting and data starts at primary service delivery points in transfusion facilities, up to the national level at KNBTS.

Figure 4: The Hemovigilance Reporting Structure



Source: Adapted from KNBTS Brief on Haemovigilance

Hospitals' management appoint a haemovigilance officer who undertake blood safety surveillance and monitoring activities in the hospital and provides feedback in form of monthly reports to the HTC and KNBTS. Such feedback includes matters pertaining to adverse reactions of patients, need for blood and blood products, peer reviews and training of clinicians on matters pertaining prescription of blood.

The HTCs ensure the implementation of the blood transfusion guidelines, conduct blood use audits and monitor blood safety in the hospitals. An example of guidelines in hospitals are those meant to enhance appropriate and clinical use of blood at hospital level. Appropriate utilization ensures administration of blood and blood products on a need basis. Clinical use indicates the use of blood and blood products for specific clinical indications and desired outcomes and not use of products beyond what is required.

Sources of Funding

3.10 Blood service in the country has been jointly funded by the government through the MOH and donor partners since the year 2001. The total funds expended on blood service delivery for the period 2017/2018 to 2020/2021 amounted to Ksh.2.1 billion as shown in **Table 1.**

Table 1: Funds Spent on Blood Service Delivery Between 2017/2018 and 2020/2021

Financial Year	Recurrent Expenditure (Ksh)	Development Expenditure (Ksh)	Total Expenditure (Ksh)
2017/2018	258,826,564	175,000,000	433,826,564
2018/2019	252,025,351	154,000,000	406,025,351
2019/2020	266,265,096	175,280,000	441,545,096
2020/2021	224,964,357	600,000,000	824,964,357
Total Expenditure	**1,002,081,368**	**1,104,280,000**	**2,106,361,368**

Source: OAG analysis of KNBTS funding

4.0 FINDINGS OF THE AUDIT

I. Inadequate Supply of Blood to Hospitals for Transfusion

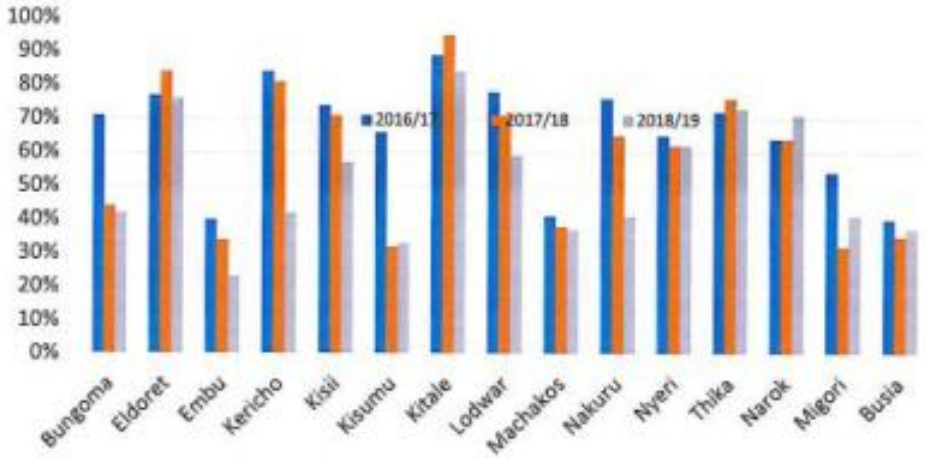
4.1 Blood transfusion is a key part of modern healthcare. It is the responsibility of the national blood programme to provide adequate supply of blood for all patients requiring transfusion and to ensure the safety and quality of blood and blood products for clinical use. The Service is vested with this responsibility in the 540 transfusing hospitals in the country. Analysis of data for the period 2016/2017 to 2018/2019 on blood requested by the hospitals in 15 out of 27 Centres indicated that KNBTS was not able to supply on average 46% of the blood requested for by the hospitals. This is shown in **Table 2** and **Figure 5** and further detailed in **Appendices 4** and **5**.

Table 2: Average Monthly Blood Requests and Supply for the Period 2016/2017 - 2018/2019

Financial Years	Average Monthly Blood Requested	Average Monthly Blood Issued	Deficit	Issued as a Percentage of Requested	Deficit as a Percentage of Requested
2016/2017	10,927	7,216	3,711	66%	34%
2017/2018	16,645	9,222	7,423	55%	45%
2018/2019	22,685	10,512	12,173	46%	54%
Cumulative Average	**50,257**	**26,950**	**23,307**	**54%**	**46%**

Source: OAG analysis of blood requests and issuances

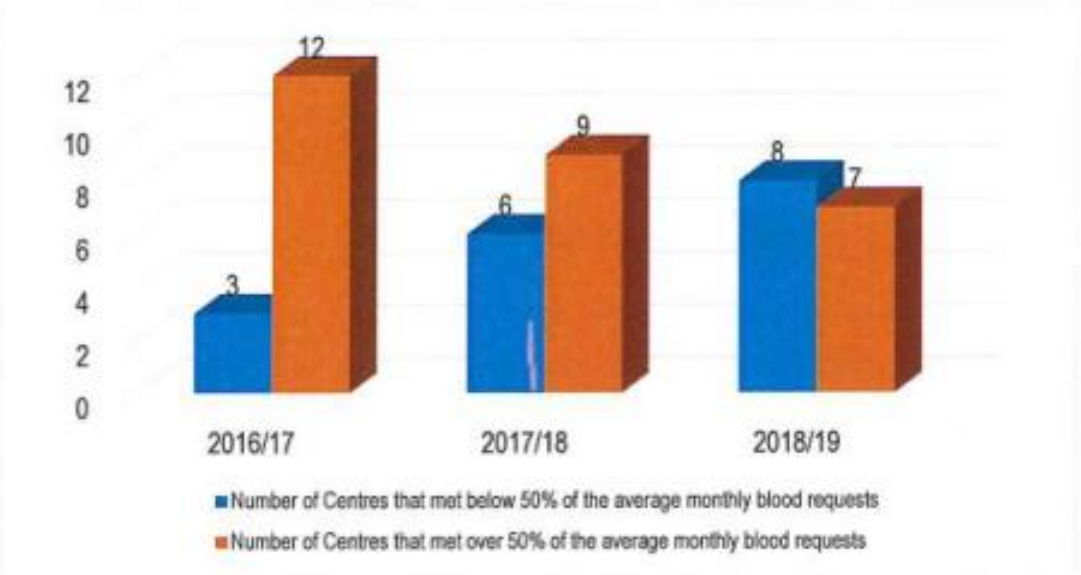
Figure 5: Average Percentage of Monthly Blood Requests Met by Each Centre



Source: OAG analysis of average monthly blood requests met

4.2 Further analysis shows that there was a gradual decrease in the number of centers that met 50% of the hospitals' blood requests from the 15 Centres sampled during the period. This is evidenced by the gradual increase in number of Centres that could not meet 50% of the monthly blood requests from hospitals during the same period as shown in **Figure 6**. There is risk of blood not being available to the patients s evidenced by the increase in average monthly blood requests from 10,927 units in 2016/2017 to 22,685 units in 2018/2019 as detailed in **Appendix 4.**

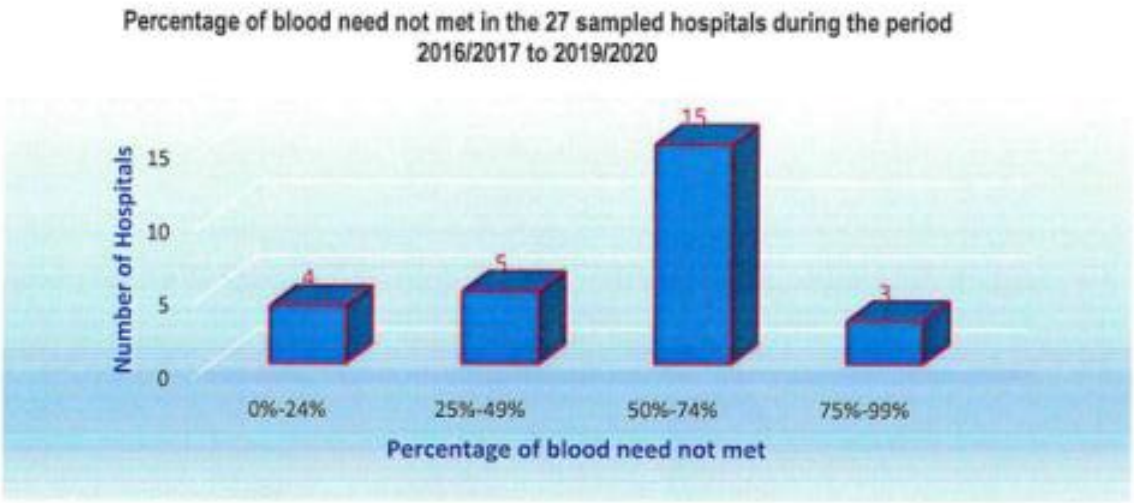
Figure 6: Number of Centres that Met Over or Below 50% of the Blood Requests



Source: OAG analysis of blood mothly blood requests met in 15 Centres

4.3 Analysis of interview responses from the 27 hospitals sampled detailed in **Appendix 5,** for the period 2016/2017 to 2019/2020 revealed that 3 hospitals did not receive up to 90% of their blood requests. Another 15 hospitals did not receive up to 73% of their blood requests, while 5 hospitals did not receive up to 40% of their blood request. Only 4 hospitals received over 80% of their blood requests. This is illustrated in **Figure 7.**

Figure 7: Extent of Blood needs not Met in 27 sampled hospitals



Source: OAG analysis of extent of blood need not met in 27 hospitals

II. Lack of an Inventory System for Efficient Management of Blood and Blood Products

4.4 Blood Transfusion services should comply with national policies and strategies to ensure they implement standards and meet targets for provision of safe blood and blood products. One of the ways to perform this function efficiently is to have an efficient inventory management system for optimal blood stock and minimal wastage.

4.5 The KNBTS does not have an electronic stock management system for blood and blood products for hospital blood banks. Hospitals make orders as and when blood is needed, since there are no established limits of re-order levels for efficient blood transfusion services. This could be evidenced by empty freezers at the Bungoma District Hospital, St. Damiano Mission Hospital and Kangundo District hospital as shown in **Figure 8** and elaborated in **Table 21**. The sampled hospitals hardly had any stock to deal with emergency cases, as they mostly had nil or no stock of blood units.

Figure 8: Depleted Blood Stocks in Various Hospitals

Source: OAG Photos taken by the audit team during physical verification between 28 February and 18 March, 2020

4.6 Lack of an efficient inventory system does not only affect the availability of blood and blood products as and when required for efficient service delivery, but may also result into wastage due to expiry of blood and blood components due to lack of adequate stocking systems. Analysis of data provided in the KNBTS CDC Technical Report for April 2018 to June 2018 showed that, hospitals in the Upper Eastern, Nairobi, Lower Eastern, Coast and Rift Valley regions discarded 2% of the components issued during this period.

4.7 Failure by hospitals to access blood when needed is a major risk as it puts the lives of patients with critical illnesses at greater risk of loss. Some illnesses can be life threatening, this include; anti-partum haemorrhage and post-partum haemorrhage which contribute to high mortality rates in maternal deaths or cases of emergencies like accident victims who require immediate blood transfusion.

4.8 The inability to supply adequate blood to hospitals is attributed to KNBTS failure to meet WHO requirements for setting blood collection targets coupled by its inability to meet its own collection targets as a result of inadequate mobilization, recruitment and retention of blood donors. There are also inadequate resources for provision of blood transfusion services.

III. Failure to Meet the WHO's Standards for Blood Collection Targets

4.9 The WHO recommends that for a country to meet its blood and blood component requirements, it should annually collect a unit of blood from at least one per cent of its population. Kenya has an approximate population of 47.6 million translating in an annual target of 476,000 units of blood to be collected. However, review of KNBTS annual blood collection targets reveals a shortfall of an average of 58% over the five-year period against the WHO requirements as shown in **Table 3**.

Table 3: KNBTS Annual Targets Compared With WHO's Requirement

Financial Year	National Blood Targets (Units of Blood)	WHO Recommended Target (Units of Blood)	Shortfall (Units of Blood)	Percentage Shortfall
2016/2017	205,000	476,000	(271,000)	57%
2017/2018	200,000	476,000	(276,000)	58%
2018/2019	200,000	476,000	(276,000)	58%
2019/2020	200,000	476,000	(276,000)	58%
Annual Average Shortfall				**58%**

Source: OAG analysis of KNBTS targets compared to WHO's

4.10 Further analysis of the KNBTS annual targets on blood collection revealed that it does not consider the needs of the hospitals in arriving at the targets. Analysis of the set targets for 12 Centres show that the set targets were below the hospitals' blood requests during the period by 27% to 74%, as indicated in **Table 4**.

Table 4: Shortfall in Monthly Collection Targets in Relation to Hospitals' Requests

Year	Centres	Average Monthly Collection Target by KNBTS	Average Monthly Blood Requests by Hospitals	Shortfall in Blood Collection Targets	% Shortfall
2016/2017	Nyeri	848	1,161	313	27%
	Thika	672	989	317	32%
	Eldoret	1,520	2,560	1,040	41%
2017/2018	Machakos	1,200	1,608	408	25%
	Kisii	1,200	1,744	544	31%
	Nakuru	1,200	1,929	729	38%
2018/2019	Kisumu	1,000	2,010	1,010	50%
	Kisii	1,000	2,188	1,188	54%
	Bungoma	450	1,057	607	57%
	Kericho	500	1,285	785	61%
	Machakos	1,100	3,384	2,284	67%
	Embu	1,000	3,787	2,787	74%
The unit of measure is blood units					

Source: OAG analysis of KNBTS shortfall in monthly collection targets

4.11 Interview with staff in the Nyeri Satellite Centre revealed that over time, the Centre has established that, to meet the regional needs for blood and blood products, it should target to collect 14,400 units of blood on annual basis. However, for the period 2016/2017 to 2018/2019 the Satellite's annual collection target set by KNBTS was on an average of 9,592 units of blood which was 33% below the needs of the region by as indicated in **Table 5**.

Table 5: Nyeri Satellite Blood Target Vs KNBTS Set Target

Financial Year	Actual Target (Based on actual blood need)	Yearly Targets Set by KNBTS	Yearly Target deficit (Units)	Percentage of Blood Units not Targeted
2016/2017	14,400	10,176	4,224	29%
2017/2018	14,400	10,800	3,600	25%
2018/2019	14,400	7,800	6,600	46%
Average	**14,400**	**9,592**	**4,808**	**33%**
The unit of measure is blood units				

Source: OAG analysis of Nyeri Satelite's blood target

4.12 The Service management indicated that it does not base its blood collection targets on the WHO requirement nor blood needs by hospitals, but instead on the available resources.

IV. KNBTS does not Meet Its Own Blood Collection Targets

4.13 Further analysis indicated that KNBTS did not also meet its own blood collection targets despite being below the WHO requirement and the hospitals needs. **Table 6,** indicates average annual shortfall on blood collections for the period 2016/2017 to 2018/2019 by 40,922 units of blood representing 20% of the targets annually.

Table 6: Blood Collection Targets Compared with Actual Collection

Year	Units of Blood Collected	Targeted Collection	Shortfall in Collection	% Short fall
2016/2017	167,100	205,000	37,900	18%
2017/2018	150,859	200,000	49,141	24%
2018/2019	164,275	200,000	35,725	18%
Average	**160,745**	**201,667**	**40,922**	**20%**
The unit of measure is blood units				

Source: OAG analysis of KNBTS blood collection

4.14 As a result of failure to set blood collection targets as per the WHO requirement, not basing own collection targets on the blood requests by the hospitals and not meeting its own set targets, KNBTS could not supply adequate blood for transfusion needs in hospitals.

V. Inadequate Mobilization, Recruitment and Retention of Blood Donors

4.15 According to WHO standards, achievement of self-sufficiency in blood and blood products, based on voluntary non-remunerated blood donation, is an important national policy direction. This requires a strategy that ensures recruitment and retention of regular donors to be put in place. The donors should be based on voluntary non-remunerated blood donors from low risk populations as a base for safe and adequate supply. However, KNBTS has not put in place measures to recruit and retain regular voluntary non-remunerated donors, but instead relies on first time donors who cannot guarantee provision of adequate supply of safe blood.

4.16 Analysis of data in 19 out of 27 sampled Centres revealed that out of an average of 151,553 donors who donated blood during the period 2016/2017 to 2018/2019, only 9%

were regular donors, 16% were repeat donors while majority representing 76% were first time donors. This is summarised in **Table 7** and detailed in **Appendix 6.** Relying on first time blood donations does not ensure a steady and continuous supply of blood.

Table 7: Source of Blood Donations

Financial Year	Total Number of Blood Donors	Percentage Donations from First Time, Regular and Repeat Donors		
		First Time	Regular	Repeat
2016/2017	153,639	77%	8%	15%
2017/2018	144,648	77%	8%	15%
2018/2019	156,373	73%	10%	18%
Averages	**151,553**	**76%**	**9%**	**16%**

Source: OAG analysis of documents on source of donated blood

4.17 Further, interviews with staff in 5 out of the 15 sampled Centres revealed that on average, regular donations accounted for 6% repeat donations 8% and first-time donors 86%. First time donors mainly comprise of students with a small proportion being family replacement donations as indicated in **Table 8.**

Table 8: Categories of Blood Donors

	RBTC/Satellite	First	Regular	Repeat
1	Kisumu	95%	3%	2%
2	Kitale	97%	2%	1%
3	Eldoret	85%	10%	5%
4	Kitui	80%	1%	19%
5	Machakos	74%	13%	13%
	Average donation from each donor category	86%	6%	8%

Source: OAG analysis of categories of blood donors

4.18 Collection of blood from first time donors is associated with a significantly higher prevalence of TTIs hence an increase in the amount of blood discarded. Over 50% of blood discarded in the Embu, Kisumu and Nairobi Centres during the period under review was as a result of testing positive with TTIs, as shown in **Table 9.** This indicates that over reliance on first time donors is riskier and could affect blood sufficiency in hospitals.

Table 9: Discarded Blood Due to Transfusion Transmissible Infections

Financial Year	Centre	Total Discards	Discards Due to TTIs	% Discards Due to TTIs
2016/2017	Embu	431	325	75%
	Kisumu	695	686	99%
2017/2018	Kisumu	640	640	100%
	Nairobi	1,067	593	56%
2018/2019	Embu	646	371	57%
	Kisumu	700	670	96%
The unit of measure is blood units				

Source: OAG analysis of blood discards

4.19 Inadequate regular donor recruitment is attributed to lack of an effective public information and donor education strategy for creating public awareness for effective recruitment and retention of voluntary donors. KNBTS management attributed lack of public awareness to donor withdrawal. Prior to 2015, planning for advocacy and public education was done through Partners who were funded by donors. These partners included; the Kenya Red Cross, Hope Worldwide Kenya and Pledge 25. With donor funding withdrawal, public awareness and information dissemination regarding blood related services in the Country could not be adequately undertaken.

4.20 Lack of adequate regular donor recruitment is also attributed to inadequate donor notification. According to WHO standards, donors should be managed in a way that ensures high standards of care and assures them of the concern of the blood transfusion service, for their health and well-being. Post-donation counselling should be provided as soon as practicable, after test results are available. This is aimed at educating donors on the interval between donations, special instructions in case of adverse events, specific instructions depending on their job, as well as nutritional or medical advice to deferred donors.

4.21 However, analysis of documents for donor notification indicates that there was no effective donor notification, including for TTI reactive cases. During the period 2016/17 to 2018/2019, only 30,314 out of 396,994 of those who donated blood in 14 out of 27 Centres were notified, as shown in **Table 10** and further detailed in **Appendix 7.**

Table 10: Number of Donors Notified or Not Notified of their Results

Financial Years	Total Number of Donors	Total Number of Donors Notified	Total Number of Donors Not Notified
2016/2017	136,773	12,233	124,540
2017/2018	127,188	7,797	119,391
2018/2019	133,033	10,284	122,749
Totals	**396,994**	**30,314**	**366,680**
Percentage of donors notified		**8%**	
Percentage of donors **not** notified			**92%**

Source: OAG analysis on donor notification

4.22 For positive cases, the donor should be notified within 24 days of receipt of test results. However, only 1,923, representing 16%, from the total 11,987 positive cases recorded were notified, as summarised in **Table 11** and detailed in **Appendix 8.**

Table 11: Notification of Donors who Tested Positive for TTIs Infections

Financial Years	TTI Positive Cases	TTI Positive Donors Notified	% Donors Not Notified	TTI Positive Donors Not Notified	% Donors Not Notified
2016/2017	4,170	755	18%	3,415	82%
2017/2018	3,947	689	17%	3,258	83%
2018/2019	3,870	479	12%	3,391	88%
Totals	**11,987**	**1,923**	16%	**10,064**	84%
Percentage of positive donors **notified**			16%		
Percentage of positive donors **not notified**					84%

Source: OAG analysis of notification of donors who tested positive for TTI

4.23 Some of the reasons that hindered effective donor notification include lack of dedicated funds for the exercise, airtime to call donors for results, transport to go back to potential donors and donor cards. More details are as indicated in **Appendix 9.**

4.24 Failure to notify donors reduces the possibility of them becoming regular donors. Further, failure to notify donors about their confirmed TTI test results on a timely basis hinders further investigations, diagnosis, treatment, care and support for these donors and may also containment of further transmissions.

VI. Inadequate Resources for Supply of Adequate and Safe Blood and Blood Products

4.25 The Service should comply with national policies and strategies to ensure that they implement standards and meet targets for the provision of safe blood and blood products. To perform its functions efficiently, the Service should have adequate number of qualified and experienced staff in all the areas for efficient blood transfusion services. Further, according to the African Society for Blood Transfusion (ASBTS), for which Kenya is a signatory, KNBTS should have sufficient, trained and competent personnel to perform its activities.

4.26 However, analysis of staff status indicated that out of 374 staff required in 15 sampled Centres, only 152 were in post. This indicates a deficit of 222 staff equivalent to 60% deficit. Further, some Centres had staff deficits of up to 81% in, as indicated in **Table 12**.

Table 12: Staff Deficit in Fifteen Centre's as at February 2020

	RBTC/Satellite Centre	Staff Requirement	Staff in Post	Deficit	Percentage of Deficit
1	Eldoret	63	34	29	41%
2	Kitale	12	7	5	42%
3	Nakuru	36	19	17	47%
4	Kisii	26	13	13	50%
5	Kitui	12	6	6	50%
6	Bungoma	18	8	10	56%
7	Malindi	7	3	4	57%
8	Kisumu	43	18	25	58%
9	Naivasha	6	2	4	66%
10	Thika	12	4	8	67%
11	Kakamega RBTC	24	8	16	67%
12	Mombasa	35	11	24	69%
13	Machakos	31	9	22	71%
14	Embu	33	7	26	78%
15	Nyeri	16	3	13	81%
	Total	**374**	**152**	**222**	**60%**

Source: OAG analysis of staff status

4.27 Further, paragraph 3.2.2 of the ASBTS, 2019 require that the personnel, including volunteers, performing specific tasks shall be qualified on the basis of education, training and experience and shall have the requisite knowledge and skills. However, analysis of the staff in post indicates that 11 out of the 15 Centres, had over 50% of donor

services staff seconded from the counties, with Kitui and Malindi Centres relying on the Counties for its staff compliment. This has implication on the availability and safety of blood. Such Centres could not base their planning for activities on the entire number of staff seconded from counties.

4.28 In addition, no regard was given to skills and knowledge or qualification of seconded staff as KNBTS has no control over the staff they receive, but accept them as they are irrespective of their qualifications in blood transfusion services. **Table 13** shows the status of staff in 11 sampled Centres.

Table 13: Staff Seconded from Counties

	RBTC/Satellite Centre	Staff in Post	Staff Seconded by National Government	Staff Seconded by County Governments	Percentage Seconded from Counties
1	Kisumu	18	13	5	28%
2	Embu	7	5	2	29%
3	Kitale	7	5	2	29%
4	Eldoret	34	18	16	47%
5	Naivasha	2	1	1	50%
6	Kisii	13	6	7	54%
7	Machakos	9	4	5	56%
8	Thika	4	1	3	75%
9	Bungoma	8	1	7	88%
10	Kitui	6	0	6	100%
11	Malindi	3	0	3	100%
Total		**111**	**54**	**57**	**60%**

***Source: OAG analysis of staff status* as at February 2020**

4.29 Lack of adequate staff has a direct effect on availability of blood. For instance, a minimum number of seven staff are needed for effective planning and carrying out of donor recruitment services. However, staff status as at January 2019 in 21 Centres revealed that none of the Centres had the ideal number of staff required for carrying out donor services, as shown in **Table 14** and detailed in **Appendix 10.**

Table 14: Number of Staff Carrying Out Donor Services as at January 2019

Number of Centres	Number of staff in place	Deficit	% Deficit
8	6	1	14%
3	5	2	29%
3	4	3	43%
5	3	4	57%
2	1	6	86%
The ideal number of staff for donor recruitment is 7			

Source: OAG analysis of staff requirement for carrying out donor services

4.30 Review of WHO Blood Donor Selection Guidelines, 2012 indicate that inadequate staff can also contribute to wastage of blood when collection is done from unsuitable donors. WHO considers effective utilisation of available blood supply as crucial, and one important way for effective utilisation is to minimise discard of blood. However, analysis of blood collected in 15 out of the 27 KNBTS Centres, for the period 2016/2017 to 2018/2019, showed that out of a total collection of 412,575 units, 19,366 units or 5% of the blood collected was discarded, as shown in **Table 15**.

Table 15: Blood Units Discarded

Financial Year	Total Blood Units Collected	Total Blood Units Discarded
2016/2017	141,732	6,789
2017/2018	132,210	6,432
2018/2019	138,633	6,145
Totals	**412,575**	**19,366**
Percentage of Blood Discarded		5%

Source: OAG analysis of amount of blood units discarded

4.31 The discard of the units of blood was mainly attributed to TTIs prevalence and underweight or overweight blood units representing 62% and 29% of the blood discards, respectively. This is indicated in **Table 16 and Appendices 11, 12 and 13** which shows detailed analysis of the blood collected, blood discarded and reasons for the discards.

Table 16: Reasons Why Blood was Discarded

Financial Years	Total Units Discarded	Reasons for Discarding Part of the Blood Units Collected						
		TTI	Under Weight/ Over Weight	Expiry	Blood Clot	Cold Chain	Processing	Any Other
2016/2017	6,789	4,105	1,878	68	45	6	24	338
2017/2018	6,432	4,019	2,049	151	36	6	22	159
2018/2019	6,145	3,920	1,758	163	11	0	11	282
Total	**19,366**	**12,044**	**5,685**	**382**	**92**	**12**	**57**	**779**
Average percentage discard for each reason		62%	29%	2%	0%	0%	0%	4%

Source: OAG analysis of reasons for discarding blood

4.32 Interviews in Kisumu, Mombasa, Voi, Kisii and Kitui Centres revealed that when less than the recommended number of staff handle large pools of donors, it can result to inadequate elaborate pre-donation talks, as well as inadequate blood donor monitoring during donation sessions. This contributes significantly to collection of blood from unsuitable donors, including those who are TTI positive. Further, some blood units develop blood clots due to inadequate monitoring of blood flow rate during blood collection which increased the number of discards.

4.33 One of the reasons for inadequate staff is the failure to implement the recommendations of the Ministry Capacity Assessment and Rationalisation Report done in April 2015. The Report recommended reassessment of KNBTS staff requirements to adequately provide for effective management of the standards associated with the blood transfusion services by the MOH. However, interviews with KNBTS Management revealed that the recommendations were not implemented. Further, KNBTS had a total of 142 staff employed on contract basis under the PEPFAR whose contracts ended on 31 March, 2015 but had not been renewed as at the time of the audit. This drastically reduced the number of staff available for blood transfusion services.

4.34 Further, for KNBTS to be effective in implementing its mandate, it requires adequate infrastructure and facilities in all Centres where blood collection, testing, processing and storage takes place. In the Centres visited, KNBTS did not have its own infrastructure, but were mainly hosted by hospitals, with limited space for blood donor services. This affected efficient delivery of blood transfusion services by KNBTS as the facilities were not ideal for blood transfusion services.

4.35 Availability of transport during blood drives, to ensure that sessions are conducted as planned, was a challenge. For instance, though 13 out of 15 sampled Centres had been allocated motor vehicles, only 9 of the Centres had their vehicles operational. In addition, none of the vehicles had the capacity to accommodate up to 7 people and equipment needed for blood drives. This was mainly attributed to lack of regular repairs and maintenance of vehicles.

4.36 A review of documents for the period 2016/2017 and 2017/2018 revealed that regular vehicle repair and maintenance was not being carried out. As a result, the vehicles were broken down and grounded in the yards, as shown in **Figures 9, 10 and 11**. For instance, in Kisii Satellite Centre a vehicle inspected in March 2018 was yet to be repaired as at the time of the audit. In Nyeri Satellite Centre, a Nissan double cabin had been grounded since 2016 while Toyota double cabin had been lying in the yard due to the need for major mechanical intervention. The Centre relied on borrowed vehicle from Embu Level 5 Hospital, which was also in poor mechanical condition.

Figure 9: The only Vehicle for Malindi Satellite Centre had Stalled

Photo taken by auditors on 27 February, 2020

Figure 10: Two Vehicles Allocated to Machakos Satellite Centre had Stalled

The two Stalled vehicles allocated to Machakos Satellite Centre; photo taken by the auditors on 17 March, 2020.

Figure 11: Photo of a Stalled Vehicle at Kisumu RBTC

Kisumu RBTC had five vehicles as at the time of the audit; three were non-operational while two required major service and new tyres- Photo taken by auditors on 05 March, 2020.

4.37 **Figure 12** shows the vehicle used for blood collection at the Thika Satellite Centre with a capacity of only 2 passengers and yet the minimum number of staff required for a blood drive is 7 staff.

Figure 12: Vehicle Used for Blood collection at Thika Satellite

Photo taken by auditors during physical verification on 18 March, 2020

4.38 Fuelling for the available vehicles was also noted to be a challenge. Review of documents on blood drives conducted in the financial years 2016/2017 and 2018/2019 indicated that some of the reasons for cancellation of blood donation activities in 14 out of the 27 KNBTS Centres was lack of fuel.

4.39 As a result of inadequate logistical support, there were instances where Centres opted to use public transport, mostly "Tuk Tuk", for blood collection sessions which are not ideal as blood is a sensitive commodity.

VII. Break Down of Equipment and Lack of Reagents for Processing of Blood

4.40 Continuity in the supply of reagents, test kits and other consumables, and functional equipment in the Regional Blood Transfusion Centres are critical in order to avoid interruptions in processing of blood and hence its supply. However, as at the time of the audit, interviews with staff in the 15 sampled Centres revealed that due to lack of reagents and breakdown of blood processing equipment, blood screening for the entire Country was being done in only 3 of the 6 RBTCs namely; Nairobi, Kisumu and Eldoret.

4.41 Further, interviews at Embu, Nyeri and Nakuru RBTCs revealed that lack of reagents and auxiliary equipment had led to underutilisation of the modern blood processing machines at the Centres. This slowed down on the processing of blood, thereby affecting its availability in a timely manner. For instance, at Embu Regional Centre, a machine for automating blood grouping purchased 6 months before the time of the

audit, was yet to be operationalised due to lack of reagents. The machine has the capacity to process 200 samples of blood per day, in comparison with the machine currently in use that could only process 80 samples per day.

Figure 13: Underutilized Blood Processing Equipment

Photos of underutilized blood processing equipment in Embu and Nakuru RBTCs, taken by the auditors on 28 October and 11 November, 2019, respectively.

4.42 Delays in repairing blood processing equipment and lack of reagents resulted in delays in blood processing. Ideally, routine blood testing and grouping should take 24 hours, while emergency blood testing and grouping should take 6 hours. However, review of records in Embu and Naivasha Centres for the period March 2018 to October 2019 revealed that it took 4 to 17 days for the Centres to receive results from the Nairobi RBTC for TTI screening. Review of records in Kisumu, Mombasa, Kisii, Kitui, Eldoret and Machakos Centres revealed that from December 2019, it took up to a month for the Centres to receive results for blood samples taken for screening in Nairobi RBTC, which ultimately affected blood supply in the hospitals.

4.43 Delays in blood processing does not only affect the timely availability of blood but also blood may expire while awaiting test results. For instance, some of the Satellite Centres held blood awaiting TTI screening results, to its expiry before being issued to the hospitals. **Figure 14** shows unscreened blood which was awaiting screening results.

Figure 14: Unscreened Blood Awaiting TTI Results

Unscreened stock of blood awaiting screening results while there are nil stocks of screened blood at Bungoma Satellite-Photos taken by the audit team during physical verification on 12 March,2020

Figure 15: Shows unscreened blood that expired due to delayed screening results

Photos showing Expired blood at Kisii and Machakos satellites; taken by auditors on 06 and 17 March, 2020, respectively

VIII. Erratic Supply of Blood Bags for Collection of Blood and Blood Products

4.44 Blood bags are used for the reliable collection, separation, storage and transport of blood. Without blood bags, blood cannot be collected from donors. Ideally, the bags should be supplied to Regional and Satellite Centres from KNBTS headquarters. Interviews with KNBTS management revealed that procurement of blood bags is done by the MOH, through the Kenya Medial Supplies Authority (KEMSA). However, the management indicated that there were no timelines for delivery of the supplies resulting to erratic supply of the blood bags to KNBTS. This ultimately affected supplies to blood collection Centres. As a result, supply of blood bags to KNBTS Centres was not always synchronised with the blood collection targets set by KNBTS.

4.45 Nyeri Satellite Centre requires 1,200 blood bags per month, however, during the month of October 2019, the Centre received only 86 blood bags from KNBTS headquarters. As at 31 October, 2019 there were no blood bags at the Satellite. Consequently, voluntary or family replacement donors could not donate, but were indefinitely deferred. Kisumu RBTC had an annual blood collection target of 18,240 and 13,200 for the years 2016 to 2017 and 2018 to 2019 respectively. However, KNBTS did not supply adequate blood bags to match the target collections resulting in deficits of between 24% to 43% during the period as indicated in **Table 17**.

Table 17: Blood Bags Supply at Kisumu Regional Blood Transfusion Centre

Year	Blood Bags Need as per KNBTS Yearly Blood Collection Target	Total Blood Bags Supplied During the Year	Shortages of Bags	Percentage Blood Bags Need Not Met
2016	18,240	13,864	4,376	24%
2017	18,240	10,624	7,616	42%
2018	13,200	9,828	3,372	26%
2019	13,200	7,545	5,655	43%

Source: OAG analysis of blood bags supply in Kisumu RBTC

4.46 As a result of inadequate staff, logistical support and erratic supply of blood bags, KNBTS could not achieve its planned blood collection targets, thus affecting sufficiency of blood supply. Analysis of blood donor recruitment in 19 out of the 27 KNBTS Centres for the financial years 2016/17 to 2018/19, revealed that on average out of targeted 876 monthly recruitment sessions, 357 or 41%, were not conducted due to lack of or inadequate logistical support and erratic supply of blood bags. This is detailed in **Appendix 14.**

IX. Quality and Safety of Blood and Blood Products

4.47 The quality and safety of all blood and blood products must be assured throughout the process; from the selection of blood donors through to their administration to the patient. This can only be achieved through a well organised, nationally co-ordinated blood transfusion service that ensures supply of safe blood; by establishing a stable base of regular, voluntary donors, as the prevalence of blood borne infections is lowest in this group.

4.48 Further, there is need to ensure quality assured screening of donated blood for TTIs, blood grouping and compatibility testing. Use of blood components instead of whole blood can further enhance quality, as each component can be quality assured before use. There is also need to reduce unnecessary transfusions through effective clinical use of blood, including the use of simple alternatives to transfusion such as crystalloids and colloids[21], wherever possible.

4.49 Document review and interviews with KNBTS management, staff in the 15 sampled Centres and laboratory staff in 27 hospitals revealed inadequacies which may compromise quality and safety of blood being transfused to patients. These include lack of a centralized system for blood collection and processing, inadequate regular donors, lapses in blood cold chain, inadequate donor recruitment practices, equipment gap, lack of preventive maintenance for equipment, inadequate staff, lack of adequate haemovigilance activities in hospitals, outdated policies and guidelines and lack of accreditation of KNBTS laboratories.

4.50 KNBTS only achieved 57% blood component preparation. This was attributed to inadequate equipment and unavailability of the required type of blood bags. For instance, Embu RBTC had targeted to convert 80% of the blood collected into blood components. However, as at the time of the audit, the Centre had not prepared any blood components for two months due to lack of blood bags for collection and separation of blood for component preparation. Therefore, the Centre only supplied whole blood to hospitals. Consequently, patients who only required a specific blood component(s) ended up being transfused with whole blood, which further aggravated the blood insufficiency in hospitals.

[21] Intravenous replacement fluids that helps to avoid unnecessary transfusion.

4.51 Interviews conducted at KNBTS Centres on preparation of blood components indicated that 7 out of 15 sampled Centres had inadequate multiple blood bags and the requisite equipment, as indicated in **Table 18**. This affected the amount of blood that was converted into blood components. For instance, between January and December 2019, Eldoret RBTC supplied only 56% of the requests made for Fresh Frozen Plasma. Thika Satellite Centre prepared only Packed Red Cells and therefore, could not supply the requests made by hospitals for Platelets. No components were prepared at Kitui Satellite Centre during the period January 2017 to September 2019.

Table 18: Reasons for Not Meeting Blood Component Targets

	RBTC / Satellite Centre	Deficiencies
1	Eldoret	Has only one machine for platelet preparation
		No freezer for Fresh Frozen Plasma
		No blood collection mixers
		Has only one blood weighing balance
		Only one functional centrifuge, and other faulty
2	Kisumu	Lack of assorted blood bags
		No refrigerated centrifuge for preparing platelets
3	Kitale	Lack of assorted blood bags
4	Kisii	Lack of assorted blood bags
5	Kitui	Lacks equipment for component preparation
6	Machakos	Constrained by blood bags received
7	Thika	Prepared Packed Red Cells only

Source: OAG analysis of reasons for Centres not meeting blood component targets

4.52 Further, physical verification of blood availability in 24 out of the 27 sampled hospitals indicated that there were blood components that were out of stock at the time of the audit. **Table 19** shows the count of hospitals that did not have the particular blood components.

Table 19: Blood Components not in Stock

Blood Component	No. of Hospitals Without
Packed Red Cells	8
Fresh Frozen Plasma	15
Cryoprecipitates	22
Platelets	13

Source: Physical verification of blood components stocks

X. Appropriate Use of Blood and Blood Products for Efficient Blood Transfusion Services

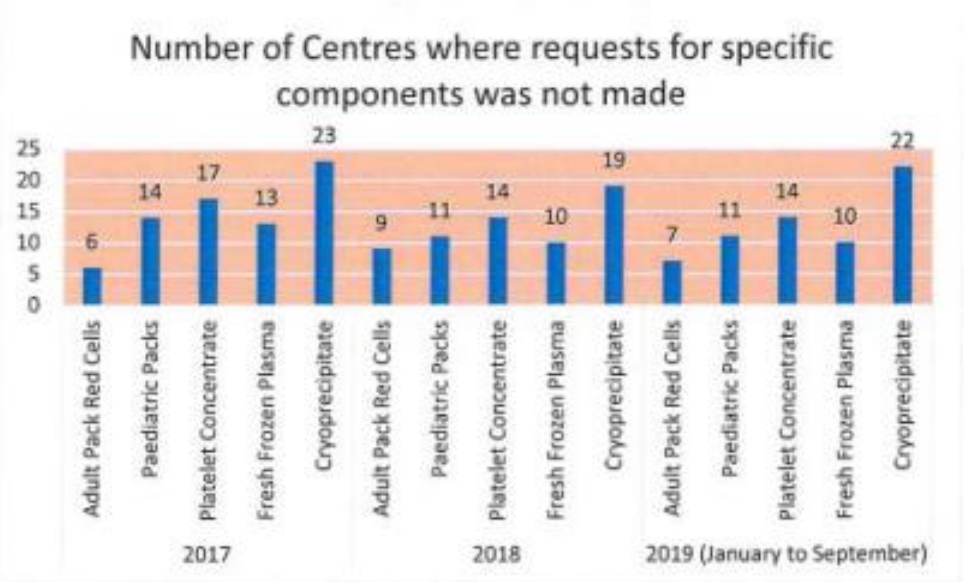
4.53 The National Blood Transfusion Policy, 2001 requires KNBTS to promote clinical use of blood and blood products so as to ensure that they are appropriately used in hospitals. This requires the Service to develop policies and strategies to reduce the need for transfusion, minimise unnecessary transfusions and ensure safe and appropriate use of blood and blood products. Such strategies include the establishment of Hospital Transfusing Committees (HTCs) and National Haemovigilance Systems (NVS).

4.54 HTCs are the link between transfusing hospitals and KNBTS. They should be established in each hospital to implement the National Transfusion Policy and guidelines. The Committees should have authority within the hospital structure to determine hospital policy, in relation to transfusion and ensure availability of the required blood and blood products at all times. The Committees monitor usage of blood and ensure appropriate clinical use of blood, as well as training all hospital staff involved in blood transfusion services. Hospital Transfusing Committees should also monitor investigation of severe adverse effects or errors associated with transfusion, take any corrective and preventative action required and report on the clinical use of blood through the haemovigilance system, to the National Committee.

4.55 However, the audit revealed that as much as the Committees were formed, they were not functional. The Committees would enable KNBTS establish the needs and indications of blood and blood products at specific hospitals, help with issues pertaining to adverse reactions of patients, address the issue of appropriate clinical use of blood in hospitals, monitor blood consumption and reduce wastage of blood and blood products.

4.56 The HTCs would also ensure training of clinicians; to prescribe the required blood components to patients so as to ensure appropriate use of blood by hospitals. This would avoid cases where blood components are prepared but no requests are placed for the components by hospitals. For instance, review of KNBTS annual progress reports for April 2017 to March 2018 to Centre for Disease Control (CDC) and April 2017 to September 2018 to PEPFAR revealed low demand for blood components by transfusing hospitals as one of the major challenges in blood component production. Analysis of data in the 23 out of the 27 KNBTS Centres, for the period January 2017 to September 2019 showed that not all Centres had requests for various blood components from hospitals, as shown in **Figure 16**. Further, Cryoprecipitate stood out as one of the components that is hardly requested for by hospitals.

Figure 16: Centres that had no Requests for Blood Components



Source: OAG analysis of blood component requests

4.57 Review of documents on component preparation, as detailed in **Appendix 15,** showed that during the period January 2017 to September 2019; 9 out of 23 Centres had prepared blood components but there were no requests for them from hospitals. **Table 20** shows a summary for various components that had been prepared but no requests made. Failure to use the prepared blood components in hospitals lead to wastage and contributes to blood insufficiency.

Table 20: Prepared Blood Components that were not Used

Component	Period			
	2017	2018	2019*	Cumulative
Adult Pack Red Cells	3,247	29,336	4,407	**36,990**
Platelet Concentrate	324	386	0	**710**
Fresh Frozen Plasma	888	3,376	0	**4,264**
Pediatric Packs	0	2,131	382	**2,513**
Cryo-precipitate	0	0	82	**82**
Total Units Prepared	**4,459**	**35,229**	**4,871**	**44,559**

* Coverage Period is nine Months; January to September

Source: OAG analysis of documents on blood components

XI. Lack of Electronic Surveillance of Haemovigilance Activities in Hospitals

4.58 Surveillance procedures and haemovigilance systems are needed to monitor adverse events and known threats to blood safety, availability and for informed decisions to be taken in response to new challenges or threats. Effective haemovigilance enhances traceability of donated blood, that is from donor to recipient and vice versa in a timely manner. This is essential to ensure the ability to recall at-risk products, to identify recipients of non-conforming products that may require additional follow-up and to fully investigate adverse events. Therefore, there is need for an efficient system for tracking the donated blood throughout the transfusion pathway, to capture details at each stage and maintain necessary linkages.

4.59 However, interviews with KNBTS Management revealed that currently, the system for tracking blood is manual. This is done through unique identification numbers assigned to each blood bag traceable from the donor to the blood recipient. However, the manual system is not effective as it takes long to track the path of a unit of blood, from the source to the recipient, unlike when it is electronic.

4.60 Interviews with KNBTS staff in Mombasa, Kisumu, Voi, Kitui, Machakos, Thika, Kisii and Eldoret Centres revealed that blood processes were not managed electronically due to lack of internet connectivity. As a result, information on adverse events was not readily available for prompt investigation. Consequently, recall of at-risk products to prevent further transfusion of related blood products may not be done in good time.

4.61 Efforts towards enabling KNBTS achieve tracing of blood electronically were made by the American Government Presidents Emergency Plan for Aids Relief (PEPFAR) through the Centre for Disease Control (CDC) by procuring the e-PROGESA[22] Blood Establishment Computerized System (BECS) software. The Software is designed to trace blood from the donor to the recipient, including tracking blood requests, issuances, as well as blood stock levels in hospitals. Though the software had been in use for 5 years in six Regional Centres as at the time of the audit, it was yet to be fully utilised due to technical and hardware challenges. This included non-payment of the annual maintenance fee. Further, connectivity to various blood transfusion Centres had not been realised due to inadequate funding to support the software operation.

4.62 Further, CDC procured a system for linking all KNBTS facilities to hospitals and within its Centres, at a cost of Ksh.6 (six) million. However, as at the time of audit linkage had

[22] *It is a web-based software for blood centres, which scalable and can be used from a single site up to nation-wide centralised organisation.*

only been done in the regional Centres. Consequently, Satellites and hospitals were yet to be connected to the system. As a result, it was not possible to optimally utilize the system due to limited resources and lack of requisite licenses to operate it. The MOH Annual Performance Report for the period 2017/18 indicated that lack of funding to support recurrent monthly internet bills had hampered the roll out of the system to the identified sites.

XII. Lack of an Appropriate Legal and Supervisory Framework

4.63 The WHO recommends all activities related to blood should be coordinated at the national level, through effective organization and integrated blood supply networks. The national blood system should also be governed by a national policy and legislative framework to promote uniform implementation of standards and consistency in the quality and safety of blood and blood products.

4.64 The Service however, lacked an appropriate legal and supervisory framework to monitor quality assurance controls for blood collection, testing, processing, storage and distribution in private transfusing hospitals at the time of the audit . The Service, in collaboration with MOH, developed a Bill in 2014, "The Kenya National Blood Transfusion and Transplant Bill, 2018" which seeks among other things to enable KNBTS provide technical support to private, as well as national referral hospitals on best blood transfusion practices. Subsequently, post audit, the Kenya Tissue and Transplant Authority came into existence on 1 August 2022 vide Legislative Supplement No. 61 and Legal Notice No.142.

4.65 Interviews conducted and document reviews indicated that due to the drastic shortage in blood supply, hospitals were making efforts to enhance blood availability for their patients. For instance, Nakuru Provincial General Hospital (NPGH) had plans to introduce a blood donation Centre, while Nyeri County Referral Hospital had plans to set up a donation and processing Centre. This trend may in the long run revert to the hospital-based blood banking, which is contrary to the WHO standards that requires a country to have a centralized system for blood transfusion services. A centralised system ensures standardisation of all blood processes in order to avoid compromise on the safety and quality of blood.

4.66 Further, due to an increasing shortage of blood for transfusion in hospitals, County Governments were seeking alternative ways of ensuring sufficiency of blood in hospitals. This is evidenced by the Case Study of Kakamega County below.

Case Title: Kakamega County Move to Salvage its Blood Crisis

The Kakamega County Blood Transfusion Centre (KCBTC) was formerly a satellite of KNBTS Kisumu Regional Blood Transfusion Centre (KRBTC) until 2016. The need for the County to set up own blood centre was prompted by the unmet blood needs in hospitals within the county. This was due to delays in receiving results for blood samples sent to Kisumu RBTC for screening purposes, which meant that though there was blood in the then Satellite, it could not be issued to hospitals for transfusion services.

In 2015, the Kakamega County General Hospital (KCGH) experienced increased maternal and child mortalities due to lack of blood supply in the hospital. In one instance, the hospital recorded 15 child mortalities over a weekend. During this period, there were about 200 units of blood at the satellite awaiting results for samples that had already been sent to Kisumu RBTC for testing.

Due to the strained health care delivery and rising mortality cases as a result of blood shortage in the County, the Ministry of Health Kakamega County, proposed to partner with KNBTS through its satellite in a move to enhance the blood service in the County. The Memorandum of Understanding (MOU) dated July 2016, proposed a partnering of all the activities of the satellite on a ratio of 40:60 (KCBTC: KNBTS). This was aimed at ensuring that no patient lost their life due to lack of blood. However, KNBTS did not commit to the MOU and in 2016 KNBTS withdrew all its staff, the stock of reagents for blood grouping and cross matching plus the vehicle from the satellite centre. As a result, the County Government of Kakamega had to come in fully to ensure that the blood service did not come to a stand-still. This defeats the purpose for centralizing blood services in the country through KNBTS, that was intended to ensure quality, safety and sufficiency of blood supply for patients throughout the country.

Source: Interview and document review at Kakamega Blood Transfusion Centre

XIII. Outdated Blood Polices and Guidelines

4.67 According to WHO standards, the public health importance of blood safety issues necessitates that each country should establish a sustainable national blood programme, with a well formulated national blood policy and plan, a national blood transfusion service, legislative and regulatory mechanisms and a structured process for policy making. National blood policies should address all issues that could affect the quality, safety, availability and accessibility of blood and blood products. The policy should be reviewed regularly, particularly when new issues emerge that have implications on the national blood programme.

4.68 The Service is in-charge of the national blood transfusion programme and has over the years developed guidelines, policies and procedures that govern blood transfusion services. These guidelines and polices should be reviewed and updated after every 3

years, however, this had not been done as at the time of the audit since its roll out. Consequently, a significant number of the critical polices and guidelines on blood transfusion services were outdated, with some dating as far back as 2001.

4.69 The policies and guidelines include: guidelines for the appropriate use of blood and blood products, 2007; hemovigilance manual for transfusing facilities in Kenya, 2008; National Strategy on blood donor mobilization 2005; national standards for blood transfusion services in Kenya, 2001; policy guidelines for blood transfusion in Kenya, 2001; and manual for supervision of hospital transfusion laboratories in Kenya, 2008.

4.70 Consequently, the usage of the guidelines was limited since majority were outdated and not aligned to the current health structures and emerging technologies.

XIV. Delayed Accreditation of Laboratories

4.71 Accreditation gives formal recognition that a particular organisation is competent to carry out its given responsibilities. In August 2018, KNBTS embarked on a programme to pursue ISO 15189:2012 accreditation, the most applicable standard for medical laboratories, through the Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) Programme. The programme was introduced by WHO Regional Office for Africa in 2009, to provide an interim pathway for measuring, monitoring and recognising improvement toward achieving ISO 15189 standards. The standard evaluates a laboratory's Quality Management Systems; technical competence; and ability to provide reliable and accurate test results.

4.72 The Service first enrolled 6 Regional Centres, the National Testing Laboratory and its headquarter administrative division to the SLIPTA Programme with an aim of gradually mentoring all its Centres for accreditation. The audit revealed that prior to this, KNBTS had made efforts of acquiring laboratory accreditation as per the Africa Society for Blood Transfusion Programme. However, due to financial constraints the accreditation process was abandoned.

4.73 In September 2019, KNBTS through partner support paid assessment fee for four of its six regional facilities in Kisumu, Nakuru, Eldoret and the National Testing Laboratory. Embu and Mombasa regional facilities were however omitted due to the lean number of human resources and lack of funds to pay for the assessment fee respectively. The external assessment based on ISO 15189:2012 was conducted by the national accreditation body, Kenya Accreditation Service (KENAS) in October and November 2019.

4.74 Several non-conformities were raised and KNBTS was accorded a timeline to act on the identified areas and submit evidence of the actions taken. According to KNBTS Management, most of the non-conformities had been addressed as at time of the audit, except those with financial implications.

4.75 Further, KNBTS participated in an External Quality Assurance (EQA) Scheme sponsored by donor partners since the year 2009 that was aiding in quality monitoring. However, this ceased in April 2020 when funding came to an end. As at the time of the audit, KNBTS had not participated in any EQA since 2020.

4.76 Lack of regular independent monitoring programmes may hinder the identification of performance gaps that would ensure KNBTS works towards improving safety and quality of blood and blood products. Delayed accreditation of KNBTS laboratories may also hamper stakeholders' confidence in the safety of blood services offered.

XV. Storage and Transportation of Blood and Blood Products

4.77 The condition under which blood and blood products are stored and transported have a direct effect on their safety, efficacy and availability. The blood cold chain is a system for storing and transporting blood and blood products, within the required temperature range and conditions from the point of collection from donors to the point of transfusion to patient. The blood cold chain involves a series of interconnected activities involving equipment, personnel and processes that are critical for the safe storage and transportation of blood from collection to transfusion. The three main processes involved include; storage, packing and transportation of blood and blood products. It also includes the maintenance of blood cold chain equipment. It is important that every step of the chain is monitored as the blood cold chain should not be broken at any point. **Appendix 16** details equipment used in the blood cold chain.

4.78 Interviews with KNBTS management revealed that the blood cold chain did not have sufficient storage facilities. Therefore, if KNBTS were to collect the ideal amount of blood units, there would be no sufficient storage space. Further, interviews with KNBTS staff in the sampled 15 of the 27 Centres revealed equipment gaps in the blood cold chain, as indicated in **Table 21.** There were also inadequacies in routine preventive maintenance of the available equipment.

Table 21: Equipment Deficiencies in the Blood Cold Chain

RBTC / Satellite Centre	Deficiency	Purpose of the Machine/Equipment
Mombasa	Faulty cold room	Ideal for bulky storage of blood components.
Mombasa, Eldoret, Thika and Embu.	No automatic power back up	Ensure continuous power supply in case of power failure.
Mombasa and Embu	There was no air conditioner	Maintaining ideal temperatures.
Kisumu, Machakos and Bungoma.	Lack of gadgets for remote temperature monitoring	Provide alerts in case of temperature fluctuations.
Kisii and Bungoma.	Cool boxes did not have temperature monitors.	To ensure that blood is transported within the appropriate temperature range.

Source: OAG analysis of equipment used in the blood cold chain

4.79 Interview with staff in the Nyeri Satellite Centre revealed that during transportation, the Centre packed blood samples in cartons instead of cool boxes. Further, there were delays in delivery of blood samples to the testing Centre by the courier company. Such lapses in the blood cold chain compromise the safety and usefulness of blood.

4.80 Review of documents in Mombasa RBTC revealed the following lapses in the cold room; some equipment was not functional either because they needed replacement of some parts or repairs, as indicated in **Table 22.**

Table 22:Status of Cold Chain Equipment at Mombasa Regional Blood Transfusion Centre

	Equipment	Condition	Requirement	Service Contract
1	Air conditioners (15)	2 working	13 not working	No
2	Cold room	Not working	Replacement of compressor	No
3	Generator	Not working	Servicing, battery and changeover switch needed replacement.	No
4	Refrigerator double door	Not working	Needs fan and gas	No
5	Refrigerated Centrifuge (2)	Not working	Needs motherboard	No
6	Freezer	Not working	Needs repair	No
7	Centrifuges (2 Roto Silenta)	Not working		No

Source: OAG analysis of equipment for the blood cold chain in Mombasa RBTC as at February 2020

4.81 In Embu RBTC, one of the freezers had not been in operation since 2014, a period of about six years. The Regional Centre relied on a freezer provided by the County Government. A standby generator for Nakuru RBTC installed in 2002 had been non-functional for a year. In the event of power outage, the Centre's cold storage facilities could only maintain the required temperature for two hours. Consequently, blood had to be to be transferred to the nearest hospital cold storage.

4.82 Lack of proper maintenance of cold chain equipment resulted to an inefficient and unreliable cold chain process, especially in maintaining the required temperature levels. Temperature fluctuations can affect the quality of blood and blood components stored, as shown in the **Table 23**.

Table 23: Effects of Temperature Fluctuation on Blood Quality

Blood Type	Ideal Storage Temperature	Effects of Temperature Fluctuations
Whole blood	+2 °C to +6 °C	Its oxygen-carrying ability is greatly reduced, therefore, compromises the quality of blood transfused to patients.
Fresh Frozen Plasma	−20 °C or lower	Essential clotting factors deteriorate and diminish in quantity and greatly reduce the clotting activity of the plasma, therefore, compromising the quality the component.
Cryoprecipitate	+1 °C to +6 °C	Reduced Factor VIII.
Platelet Concentrates	+20 °C to +24 °C BUT with continuous agitation.	Lower temperatures adversely affect platelet functionality and viability.

Source: OAG analysis of effects of temperature fluctuations on blood quality

4.83 Failure at any point in the blood cold chain could compromise the quality of blood and blood products. Deviations from the specified temperature ranges and conditions during storage and transportation of blood and blood products can seriously impact on its viability of the constituents of blood, thus leading to reduced clinical benefits. It can also increase the risk of bacterial proliferation in blood components during storage. Further, it may result to potentially life-threatening transfusion reactions, such as septic shock or even death.

4.84 Gaps identified in performance of equipment in the blood cold chain was mainly attributed to lack of preventive maintenance due to lack of sservice ccontracts. All

equipment needs regular maintenance, as recommended by the manufacturer, for efficient and effective functioning. However, interviews with KNBTS management revealed that though KNBTS had a quality manual to guide on maintenance and replacement of equipment, maintenance was mostly done when funds were available.

4.85 Review of documents revealed instances where most equipment in the regional Centres were not working for lack of preventive maintenance and repairs. For instance, in Mombasa RBTC, out of the 39 equipment available, only 31% were operational as shown in **Appendix 17**.

5.0 CONCLUSION

5.1 The Government has put in considerable effort in ensuring access to safe and quality blood services in Kenya by taking the service closer to the citizens. Currently, KNBTS has presence in 23 Counties. However, despite the gains achieved in blood transfusion services over the years, the audit established that the services were not being effectively delivered. According to WHO, access to sufficient, secure supply of blood and blood products and safe transfusion services is an essential part of any strong health system. Further, it is an important component of efforts towards achieving the goal of Universal Health Coverage (UHC).

5.2 The KNBTS has not been meeting the hospital blood needs as and when required. The blood collection targets set by KNBTS are not in line with the WHO requirements but are instead based on the available resources. There is therefore, no guarantee on availability of adequate blood to meet patients' needs in hospitals. Although KNBTS are in possession of records which indicate previous hospital blood needs that were yet to be met, these were not put into consideration when planning future blood collections.

5.3 There was limited public awareness initiatives on the importance and benefits of blood donation in the country. This impacted on the out reach to potential blood donors as the misconceptions on blood donations are not dealt with. This ultimately, impacts on the goal of achieving a pool of voluntary non-remunerated blood donors who would guarantee a safe and steady supply of blood.

5.4 There were limited efforts by KNBTS to ensure that existing donors donated as frequently as possible. Failure to notify donors in good time decreases their confidence in the donation process and lowers their chances of donating repeatedly.

5.5 KNBTS has inefficiencies in blood collection, testing, processing and transfusion which may affect quality and safety of blood. Further, KNBTS is not leveraging on modern technology to maximize utilization of the available blood units.

5.6 Procurement processes for supplies were not responsive and precise to the urgent needs of the blood transfusion service. The KNBTS did not maintain buffer stocks and could, therefore, not guarantee that processes and procedures would not come to a standstill due to lack of crucial supplies, such as blood bags and reagents.

5.7 There were no proper schedules to ensure timely maintenance of equipment and motor vehicles which resulted to inefficiencies in blood transfusion service.

5.8 The existing haemovigilance system did not guarantee adequate surveillance of the entire transfusion chain and hence there was inadequate feedback for effective corrective measures.

5.9 The audit established that provision of safe and adequate supplies of blood is dependent on a well-organised blood transfusion service, with dedicated, well-trained manpower and resources for the service. According to the Policy Guidelines on Blood Transfusion in Kenya, 2001 the MOH was to create a self-sustaining financial mechanism that would run the blood transfusion service throughout the country. However, the financial mechanism is yet to be developed, which contributes to the above factors which are a hindrance to an efficient blood transfusion service.

6.0 RECOMMENDATIONS

6.1 Provision of safe and adequate supply of blood is dependent on a well-organised blood transfusion service, with dedicated well-trained manpower and resources for the service. This would require the Kenya Tissue and Transplant Authority (KTTA), the successor to KNBTS, to have adequate sustainable finances to carry out its functions including those related to blood transfusion services.

6.2 The Kenya Tissue and Transplant Authority should prioritise the blood donor recruitment function through the development of an all-inclusive nation-wide communication strategy that would help in sensitizing potential donors for increased voluntary blood donor recruitment and retention. The KTTA should fully implement the post-audit strategies on improving public awareness, information and education; increased media coverage on matters relating to blood; and increased public responsibility towards blood donations.

6.3 The Kenya Tissue and Transplant Authority should leverage on ICT in enhancing haemovigilance activities. This requires the national track and trace Blood Management Information System developed post-audit be put into optimal use. This will enhance traceability of blood, aid in receiving timely feedback from Hospital Transfusing Committees , as well as training and mentorship of transfusing clinicians. This would also contribute to improving appropriate utilization of blood and blood components in hospitals.

6.4 To ensure that blood is only used for deserving cases, thus easing on demand for blood, the KTTA should ensures clinicians are continuously trained and advised on prevention and early management of anaemia and the use of blood alternatives as far as possible. It is imperative for the KTTA to fast-track the development and implementation of the National Haemovigilance Framework in order to strengthen haemovigilance activities in the hospitals.

6.5 The Kenya Tissue and Transplant Authority needs to improve on donor notification and referral of TTI positive cases to care and treatment services. Further, the KTTA should ensure linkages are established with facilities to ensure that the deferred donors seek care and treatment as advised.

6.6 The Ministry of Health and the Kenya Tissue and Transplant Authority should consider developing a human resource policy for the later staff that addresses recruitment,

retention, training and motivation of staff so as to ensure effective service delivery. Post-audit review indicates that KNBTS had requested the MOH for recruitment of 50 staff and also developed a capacity building framework for guiding training of health care workers on blood transfusion management. The MOH should fast-track staff recruitment and the KTTA should ensure adequate training for all staff in the blood service.

6.7 The Kenya Tissue and Transplant Authority should ensure that sufficient quantities of the required consumables for blood transfusion service are available. This can be done through replenishing new stock before the existing stock runs out, for enhanced efficiency in the blood service delivery. In addition, the KTTA should ensure that the forecasting and quantification committee set up post-audit, ensures security for stock and pipeline for reagents and other consumables.

6.8 The Kenya Tissue and Transplant Authority should improve on quality of blood products through modernisation of blood processing and component preparation. This will ensure optimal use of the scarce blood resources. Post-audit, Service through MOH has acquired four apheresis machines and other equipment for blood component preparation. The KTTA should therefore, ensure optimal utilisation of the equipment for efficient service delivery.

6.9 The Ministry of Health and Kenya Tissue and Transplant Authority should ensure prompt maintenance and replacement of motor vehicles and laboratory equipment. Major laboratory equipment needs to be placed under maintenance service contracts and users trained on the basic preventive maintenance.

6.10 The Ministry of Health and the Kenya Tissue and Transplant Authority should fast track updating of outdated policies, guidelines and manuals on blood service delivery in the country for efficiency. Post-audit review indicates that three guidelines and manuals have been reviewed and others are being developed. However, there is still need for the KTTA to fast-track the content review and approval of the policies, guidelines and the manuals.

6.11 The Kenya Tissue and Transplant Authority should review and revive programmes geared towards attaining and maintaining international quality standards for accreditation of blood transfusion services. Post-audit review indicates that three out of the six KTTA Regional Blood Transfusion Centres have so far being accredited. There is need for the KTTA to fast-track accreditation of the remaining three Regional

Blood Transfusion Centres and sustain the requisite standards for the three already accredited.

6.12 Post-audit review indicates various reforms have been initiated by the MOH on blood service delivery. The Office of the Auditor- General intends to carry out a follow up audit within a year of issuance of this report to assess whether the reforms including the creation of the Kenya Tissue and Transplant Authority have impacted on the blood service delivery and that sufficient, secure supplies of blood and blood products have been realised.

7.0 APPENDICES

Appendix 1: List of Officers Interviewed

Position of the Interviewee	Purpose of the Interview
Director, KNBTS	To obtain information on the general position of blood transfusion in Kenya.
Screening, Monitoring and Evaluation Manager	To understand the processes for blood donation, screening, storage and transfusion.
Quality and Safety Manager	To obtain information on the measures put in place by KNBTS in ensuring safety and quality in the blood process.
Laboratory Technologists	To understand the process of blood testing and blood component preparation.
Nurses	To understand the process for donor recruitment and notification.
Finance Officer	To obtain information on KNBTS funding.
Medical Superintendents	To obtain information on the general position of the blood service in their respective hospitals.
Hospital Laboratory Manager	To obtain information on hospitals' blood needs, how the needs are met and the challenges faced in meeting hospitals' blood needs.

Appendix 2: Documents Reviewed

Document	Information Needed from the Document
The Health Act, 2017	Requirements for the blood service in the country.
The Kenya Health Sector Strategic and Investment Plan 2014 to 2018	To understand the goals, strategies and action plans guiding health in the country.
The Ministerial Strategic and Investment Plan 2014 to 2018	To obtain information on operations of the MOH.
The MOH Policy Guidelines on Blood Transfusion, 2001	To obtain information on the management of the blood services in the country.
The Constitution of Kenya, 2010	To assess whether the MOH and KNBTS are delivering blood services as required by the Constitution.
The Haemovigilance Manual for Hospital Transfusion Services in Kenya	To understand the management of blood transfusion services at hospital level.
WHO Guides and Aide-Memoires	Universal requirements for blood transfusion services.
World Health Assembly Resolutions	Universal requirements for blood transfusion services.
The WHO Status Report on Blood Safety and Availability, 2016	To understand the challenges facing blood service delivery in the WHO African Region.
WHO Guide for the Stepwise Laboratory Improvement Process Towards Accreditation in the African Region	To understand the process towards accreditation of public health laboratories.

Appendix 3: Audit Criteria

Audit Sub Objective	Audit Criteria	Source of Criteria
To assess the extent to which KNBTS is able to supply sufficient blood to hospitals for patients' transfusing needs.	The MOH is responsible for providing the policy framework for blood services in the country. KNBTS is charged with the responsibility of developing a comprehensive and coordinated national blood service based on voluntary non-remunerated blood donations so as to guarantee availability of adequate and safe blood. Voluntary, non-remunerated blood donation is considered as the cornerstone of a safe and adequate national blood supply that meets the transfusion requirements of all patients. Ensuring the safety and availability of blood and blood products is an essential public health responsibility.	The Executive Order No. 1/2018 The Public Health Act, 2017 in Section 85(3) WHA 58.13 of 2005 on blood safety WHO | National blood policy; African Society for Blood Transfusion Standards, 2019
To assess the extent to which KNBTS is able to guarantee quality and safety of blood transfused to patients in hospitals.	i. The WHO Strategic Framework for Blood Safety and Availability states that a well organised, nationally co-ordinated blood transfusion service ensures supply of safe blood by establishing a stable base of regular, voluntary, unpaid blood donors as the prevalence of bloodborne infections is lowest among this group. ii. The WHO Handbook on Clinical Use of Blood states that: iii. The quality and safety of all blood and blood products must be assured throughout the process from the selection of blood donors through to their administration to the patient. iv. The need to ensure quality assured screening of the donated blood for TTIs, blood grouping and compatibility testing. v. Use of blood components instead of whole blood in enhancing quality as each component can be quality assured before use. vi. Need to reduce unnecessary transfusions through effective clinical use of blood, including the use of simple alternatives to transfusion (crystalloids and colloids), wherever possible. vii. Good laboratory practice in all aspects of blood grouping, compatibility testing, component preparation and the storage and transportation of blood and blood products.	WHA Resolution EB 126/R14 of January 2010 WHO Handbook on Clinical Use of Blood, 2002

Appendix 4: Average Monthly Blood Requests, Issuances and Deficits

Centre	2016/2017			2017/2018			2018/2019		
	Average Monthly Blood Requested	Average Monthly Blood Issued	Deficit	Average Monthly Blood Requested	Average Monthly Blood Issued	Deficit	Average Monthly Blood Requested	Average Monthly Blood Issued	Deficit
Bungoma	255	182	73	822	360	462	1,057	444	613
Eldoret	2,560	1,977	583	2,894	2,420	474	3,042	2,299	743
Embu	844	337	507	2,292	779	1,513	3,787	855	2,932
Kericho	215	181	34	576	465	111	1,285	544	741
Kisii	937	689	248	1,744	1,230	514	2,188	1,243	945
Kisumu	1,209	794	415	2,438	786	1,652	2,010	656	1,354
Kitale	177	157	20	278	264	14	450	377	73
Lodwar	94	73	21	211	150	61	291	173	118
Machakos	1,205	497	708	1,608	616	992	3,384	1,238	2,146
Nakuru	953	723	230	1,014	660	354	1,929	800	1,129
Nyeri	1,161	751	410	627	388	239	816	504	312
Thika	989	708	281	852	646	206	980	719	261
Narok	12	8	4	102	65	37	302	214	88
Migori	81	44	37	741	235	506	521	213	308
Busia	235	95	140	447	159	288	645	236	409
Grand Total	**10,927**	**7,216**	**3,711**	**16,645**	**9,222**	**7,423**	**22,685**	**10,512**	**12,172**
Overall Percentage of Blood Request Met		**66%**			**55%**			**46%**	
Overall Percentage of Blood Request **Not** Met			**34%**			**45%**			**54%**

Appendix 5: Percentage of Blood Needs Met During the Period 2016/2017 to 2019/2020

	Name of Hospital	% of Blood Need Met	% Blood Need not Met
1	St Elizabeth Mission Hospital Mukumu	90%	10%
2	Kakamega County General Teaching and Referral Hospital	90%	10%
3	Kitale County Hospital	80%	20%
4	Butere County Hospital	80%	20%
5	St Damiano Mission Hospital	75%	25%
6	Coast General Teaching and Referral Hospital	70%	30%
7	Thika Level 5 Hospital	70%	30%
8	Mary Help the Sick Mission Hospital	65%	35%
9	Jaramogi Teaching and Referral Hospital	60%	40%
10	Bungoma District Hospital	50%	50%
11	Kitui County Hospital	50%	50%
12	Machakos Level 5 Hospital	50%	50%
13	Cherang'any Nursing Home	50%	50%
14	Kisii County Teaching and Referral Hospital	50%	50%
15	Moi Teaching and Referral Hospital	50%	50%
16	Malindi Sub-County Hospital	50%	50%
17	Port Florence Community Hospital	50%	50%
18	Moi County Referral Hospital Voi	50%	50%
19	Kisumu County Hospital	50%	50%
20	Ruiru Sub County Hospital	40%	60%
21	Kangundo District Hospital	35%	65%
22	Mbagathi Hospital	33%	67%
23	Nakuru Provincial General Hospital	30%	70%
24	Mama Lucy Kibaki Hospital	27%	73%
25	Iten County Referral Hospital	25%	75%
26	Port Reitz Sub County Hospital	25%	75%
27	Kilifi County Hospital	10%	90%

Appendix 6: Source of Blood Donations

		2016/2017				2017/2018				2018/2019			
			Types of Blood Donors (%)				Types of Blood Donors (%)				Types of Blood Donors (%)		
	CENTRES	Total Blood Donors	First Time	Regular	Repeat	Total Blood Donors	First Time	Regular	Repeat	Total Blood Donors	First Time	Regular	Repeat
1	Bungoma	4,959	4,008	78	873	5,022	3,844	187	991	5,600	3,975	200	1,425
2	Eldoret	22,087	21,211	876	0	2,2384	22,076	298	10	23,333	22,386	737	210
3	Embu	9,475	9,475	0	0	9,939	9,764	152	23	11,471	11,471	0	0
4	Kericho	4,846	4,653	24	169	5,797	5,561	33	203	6,657	5,366	64	1,227
5	Kisii	12,347	8,028	2,109	2,210	10,073	6,501	1,494	2,078	11,989	6,969	1,437	3,583
6	Kisumu	10,570	10,570	0	0	8,805	8,805	0	0	8,627	8,627	0	0
7	Kitale	4,582	3,685	102	795	4,525	3,653	112	760	5,029	4,273	108	648
8	Lodwar	1,909	1,421	43	445	2,025	1,445	19	561	2,173	1,808	94	271
9	Machakos	10,882	8,886	14	1,982	11,388	8,267	1,340	1,781	11,055	7,555	22	3,478
10	Malindi	1031	624	1	406	639	376	26	237	2,839	1,819	58	962
11	Meru	5,668	2,829	1,728	1111	4,950	4,496	86	368	7,345	6,731	227	387
12	Mombasa	7,962	6,989	333	640	9,956	9,790	134	32	8,217	5,341	1,274	1,602
13	Nairobi	19,567	11,875	809	6,883	16,281	10,036	64	6,181	14,668	9,982	174	4,512
14	Naivasha	697	539	1	157	976	697	0	279	1,213	964	3	246
15	Nakuru	11,789	6,492	2,594	2,703	10,412	3,423	3,453	3,536	11,683	4,046	4,016	3,621
16	Nyeri	8,841	6,189	654	1,998	5,879	4,135	255	1,489	7,095	5,463	175	1,457
17	Thika	9,223	6,963	853	1,407	8,748	5,193	1,661	1,894	9,823	3,907	2,895	3,021
18	Voi	4,595	1,746	2,139	710	4,322	1,204	2,658	460	4,562	1,095	3,114	353
19	Garissa	2,609	1,959	146	504	2,527	1,864	213	450	2,994	2,059	342	593
	Totals	153,639	118,142	12,504	22,993	144,648	111,130	12,185	21,333	156,373	113,837	14,940	27,596
Percentage Donations from each type of Donor			77%	8%	15%		77%	8%	15%		73%	10%	18%

Appendix 7: Number of Donors Notified or Not Notified

	CENTRES	2016/2017			2017/2018			2018/2019		
		Number of Blood Donors	Number of Donors Notified	Number of Donors Not Notified	Number of Blood Donors	Number of Donors Notified	Number of Donors Not Notified	Number of Blood Donors	Number of Donors Notified	Number of Donors Not Notified
1	Eldoret	22,087	3,480	18,607	22,384	2,731	19,653	23,333	2,816	20,517
2	Embu	11,471	1,249	10,222	9,939	147	9,792	11,471	707	10,764
3	Kericho	4,846	298	4,548	5,797	247	5,550	6,657	298	6,359
4	Kisii	12,347	1,611	10,736	1,0073	1,493	8,580	11,989	1,699	10,290
5	Kisumu	10,570	646	9,924	8,805	256	8,549	8,627	699	7,928
6	Kitale	4,582	285	4,297	4,525	221	4,304	5,029	350	4,679
7	Lodwar	1,909	4	1,905	2,025	17	2,008	2,173	14	2,159
8	Machakos	10,882	70	10,812	11,388	167	11,221	11,055	75	10,980
9	Mombasa	7,962	448	7,514	9,956	961	8,995	8,217	1,394	6,823
10	Nairobi	19,567	216	19,351	16,281	227	16,054	14,668	443	14,225
11	Naivasha	697	78	619	976	0	976	1,213	155	1,058
12	Nakuru	11,789	3,111	8,678	10,412	951	9,461	11,683	672	11,011
13	Nyeri	8,841	7	8,834	5,879	36	5,843	7,095	181	6,914
14	Thika	9,223	730	8,493	8,748	343	8,405	9,823	781	9,042
	Totals	136,773	12,233	124,540	127,188	7,797	119,391	133,033	10,284	122,749
Percentage of donors notified			9%			6%			8%	
Percentage of donors not notified				91%			94%			92%

Appendix 8: TTI Positive Donors Notified or Not Notified

	Centre	2016/2017				2017/2018				2018/2019			
		Number of Blood Donors	TTI Positive Cases	Positive Cases Notified	Positive Cases Not Notified	Number of Blood Donors	TTI Positive Cases	Positive Cases Notified	Positive Cases Not Notified	Number of Blood Donors	TTI Positive Cases	Positive Cases Notified	Positive Cases Not Notified
1	Eldoret	22,087	475	96	379	22,384	399	69	330	23,333	360	60	300
2	Embu	11,471	325	63	262	9,939	245	14	231	11,471	371	32	339
3	Kericho	4,846	215	115	100	5,797	275	7	268	6, 657	290	15	275
4	Kisii	12,347	262	46	216	10,073	231	121	110	11 ,989	310	80	230
5	Kisumu	10,570	686	46	640	8,805	640	26	614	8, 627	670	75	595
6	Kitale	4,582	137	6	131	4,525	114	3	111	5 ,029	131	5	126
7	Lodwar	1,909	186	0	186	2,025	186	17	169	2 ,173	59	14	45
8	Machakos	10,882	328	41	287	11,388	471	123	348	11 ,055	334	0	334
9	Mombasa	7,962	218	184	34	9,956	287	188	99	8 ,217	145	93	52
10	Nairobi	19,567	818	17	801	16,281	593	9	584	14, 668	443	25	418
11	Naivasha	697	33	20	13	976	41	0	41	1, 213	80	2	78
12	Nakuru	11,789	164	43	121	10,412	189	87	102	11, 683	202	35	167
13	Nyeri	8,841	109	0	109	5,879	117	1	116	7 ,095	139	5	134
14	Thika	9,223	214	78	136	8,748	159	24	135	9 ,823	336	38	298
	Total	**136,773**	**4,170**	**755**	**3,415**	**127,188**	**3,947**	**689**	**3,258**	**133 ,033**	**3 ,870**	**479**	**3, 391**
Percentage of TTI Positive Donors Notified				**18%**				**17%**				**12%**	
Percentage of TTI Positive Donors Not Notified					**82%**				**83%**				**88%**

Appendix 9: Reasons that Hindered Effective Donor Notification

	Name of RBTC or Satellite Centre	Reasons for Inadequate Donor Notification
1	Mombasa, Voi, Machakos and Nyeri.	Lack of air time to call donors for results.
2	Mombasa, Machakos, Thika and Embu.	Lack of transport to go back to potential donors.
3	Mombasa	Lack of donor cards.
4	Kisumu, Kitale, Eldoret, Kitui and Bungoma.	The Centres had no mandate to notify school donors; most donors constitute students who are below age of consent.
5	Kisumu, Kitale and Thika.	Most donors did not to go back for their results.
6	Kitui and Eldoret.	Notified only those who went back for their results.
7	Machakos	The Centre had inadequate staff.
8	Bungoma	The Centre did not have dedicated funds for the exercise.
9	Nakuru	Withdrawal of the donor partner who was funding recruitment of blood donors.

Appendix 10: Availability of Staff for Donor Services as at January 2019

	Name of RBTC or Satellite Centre	Total in Place	Deficit	Number Seconded/ PEPFAR Project	Remarks	Percentage of Staff Seconded
1	Nairobi	6	1	2		33%
2	Nakuru	6	1	0		0%
3	Mombasa	6	1	0		0%
4	Kisumu	6	1	4	2 nurses seconded.	67%
5	Kisii	6	1	3	1 nurse seconded and 1 support staff seconded.	50%
6	Embu	6	1	2		33%
7	Eldoret	6	1	2	1 support staff seconded.	33%
8	Kitale	6	1	1		17%
9	Machakos	5	2	2	1 nurse seconded and 1 support staff seconded.	40%
10	Bungoma	5	2	5	2 Laboratory Technologists and 2 nurses seconded.	100%
11	Nyeri	5	2	2		40%
12	Kericho	4	3	2	1 Laboratory Technologist seconded.	50%
13	Voi	4	3	3	1 Laboratory Technologists Seconded and support staff seconded.	75%

	Name of RBTC or Satellite Centre	Total in Place	Deficit	Number Seconded/ PEPFAR Project	Remarks	Percentage of Staff Seconded
14	Meru	4	3	4	2 Laboratory Technologist seconded and 1 nurse seconded.	100%
15	Garissa	3	4	0		0%
16	Malindi	3	4	3	1 nurse seconded, 2 Laboratory Technologists seconded.	100%
17	Lodwar	3	4	3	1 Nurse seconded and 2 Laboratory Technologists seconded.	100%
18	Busia	3	4	3	1 nurse seconded and 2 Laboratory Technologists seconded.	100%
19	Migori	3	4	3	2 Laboratory Technologists and 1 nurse seconded.	100%
20	Thika	1	6	0		0%
21	Naivasha	1	6	0		0%

Appendix 11: Blood Discards and Reasons for Discards

2016/2017										
	RBTC or Satellite Centre	Total Blood Units Collected	Total Blood Units Discarded	Reasons for Discarding Part of the Units Collected						
				TTI	Under Weight / Over Weight	Expired Blood	Blood Clot	Cold Chain	Processing	Any Other
1	Bungoma	4,959	353	238	115					
2	Eldoret	22,087	1,027	475	341	4		6	23	178
3	Embu	11,471	431	325	84	22				
4	Kericho	4,846	269	215	44	3				7
5	Kisii	12,347	309	262	44		1			2
6	Kisumu	10,570	695	686	7	2				
7	Kitale	4,582	178	159	19					
8	Lodwar	1,909	186	186						
9	Machakos	10,882	407	328	79					
10	Mombasa	7,962	218	218						
11	Nairobi	19,567	1,512	818	588		30			76
12	Naivasha	697	64	33	29	1			1	
13	Nakuru	11,789	341	164	150					27
14	Nyeri	8,841	177	109	63	5				
15	Thika	9,223	622	214	315	31	14			48
	Total	141,732	6,789	4,105	1,878	68	45	6	24	338
Average percentage of blood discarded			5%							
Average percentage discard for each reason				60%	28%	1%	1%	0%	0%	5%

Appendix 12: Blood Discards and Reasons for Discards

2017/2018										
	RBTC or Satellite Centre	Total Blood Units Collected	Total Blood Units Discarded	Reasons for Discarding Part of the Units Collected						
				TTI	Under Weight/Over Weight	Expired Blood	Blood Clot	Cold Chain	Processing	Any Other
1	Bungoma	5,022	101	67	34					
2	Eldoret	22,384	1,040	399	571	33		6	22	9
3	Embu	9,939	462	245	195	22				
4	Kericho	5,797	344	275	61	2				6
5	Kisii	10,073	294	231	60	1				2
6	Kisumu	8,805	640	640						
7	Kitale	4,525	128	114	14					
8	Lodwar	2,025	191	191						
9	Machakos	11,388	685	471	201	1				12
10	Mombasa	9,956	298	287	11					
11	Nairobi	16,281	1,067	593	443		31			10
12	Naivasha	976	68	41	27					
13	Nakuru	10,412	397	189	112					96
14	Nyeri	5,879	232	117	105	10				
15	Thika	8,748	485	159	215	82	5			24
		132,210	**6,432**	**4,019**	**2,049**	**151**	**36**	**6**	**22**	**159**
Average percentage of blood discarded			5%							
Average percentage discard for each reason				62%	32%	2%	1%	0%	0%	2%

Appendix 13: Blood Discards and Reasons for Discards

	2018/2019									
	RBTC or Satellite Centre	Total Blood Units Collected	Total Blood Units Discarded	Reasons for Discarding Part of the Units Collected						
				TTI	Under Weight/Over Weight	Expired Blood	Blood Clot	Cold Chain	Processing	Any Other
1	Bungoma	5,600	133	50	83					
2	Eldoret	23,333	806	360	360	30			11	45
3	Embu	11,471	646	371	239	36				
4	Kericho	6,657	364	290	58	16				
5	Kisii	11,989	373	310	60	1				2
6	Kisumu	8,627	700	670	19	2	2			7
7	Kitale	5,029	133	131	2					
8	Lodwar	2,173	59	59						
9	Machakos	11,055	449	334	112					3
10	Mombasa	8,217	165	145	10					10
11	Nairobi	14,668	615	443	137	7	3			25
12	Naivasha	1,213	137	80	55					2
13	Nakuru	11,683	636	202	276					158
14	Nyeri	7,095	303	139	130	32	2			
15	Thika	9,823	626	336	217	39	4			30
Totals		**138,633**	**6,145**	**3,920**	**1,758**	**163**	**11**	**0**	**11**	**282**
Average percentage of blood discarded			4%							
Average percentage discard for each reason				64%	29%	3%	0%	0%	0%	5%

Appendix 14: Recruitment Sessions Conducted or Not Conducted

		2016/2017			2017/2018			2018/2019		
		Target Average Monthly Recruitment Sessions	Average Monthly Recruitment Sessions Conducted		Target Average Monthly Recruitment Sessions	Average Monthly Recruitment Sessions Conducted		Target Average Monthly Recruitment Sessions	Average Monthly Recruitment Sessions Conducted	
1	Bungoma	14	8		12	9		12	12	
2	Eldoret	20	33		24	19		24	17	
3	Embu	20	10		12	7		12	9	
4	Kericho	12	4		12	3		12	3	
5	Kisii	20	14		20	11		20	14	
6	Kisumu	20	15		20	8		20	10	
7	Kitale	16	8		12	5		12	6	
8	Lodwar	12	5		10	6		10	5	
9	Machakos	25	15		25	11		25	14	
10	Malindi	12	2		12	1		12	4	
11	Meru	12	6		12	6		12	9	
12	Mombasa	20	14		20	14		20	9	
13	Nairobi	23	21		23	18		23	15	
14	Nakuru	20	11		22	15		20	19	
15	Nyeri	16	10		16	6		16	7	
16	Thika	14	6		12	5		12	4	
17	Voi	14	8		12	7		12	8	
18	Garissa	12	3		12	2		12	3	
Total Average Sessions		302	193		288	153		286	168	
Percentage of Target Average Monthly Recruitment Sessions Conducted				64%			53%			59%
Percentage of Target Average Monthly Recruitment Sessions Not Conducted				36%			47%			41%

Appendix 15: Centres that Prepared Components but Had no Corresponding Requests

Period	Component	Centre	Number of Units Prepared
2017	Adult Pack Red Cells	Mombasa	3,247
	Platelet Concentrate	Mombasa	324
	Fresh Frozen Plasma	Mombasa	888
2018	Adult Pack Red Cells	Nairobi	11,013
		Nakuru	9,437
		Nyeri	5,157
		Voi	3,729
	Platelet Concentrate	Nakuru	369
		Nyeri	17
	Pediatric Packs	Kisumu	1,299
		Kitale	4
		Nakuru	405
		Nyeri	423
	Fresh Frozen Plasma	Kisumu	101
		Voi	3,275
2019 (January to September)	Adult Pack Red Cells	Migori	4,407
	Pediatric Packs	Machakos	382
	Cryoprecipitate	Kisumu	60
		Nairobi	22

Appendix 16: Equipment Used in the Blood Cold Chain

Category of Equipment	Specific Equipment Required	Purpose for the Equipment
Equipment for movement of blood	Blood transport boxes, ice packs and temperature monitoring devices.	
Quarantine equipment	Blood bank refrigerator(s)	To hold blood undergoing processing before it is released for use.
	Blood plasma freezer(s)	For storing plasma components and cryoprecipitate or serum.
Equipment for holding available blood stock	Blood bank refrigerator(s)	To hold blood available for issue.
	Blood plasma freezer(s)	For storing plasma components and cryoprecipitate or serum.
	Platelet agitator(s)	For storing platelet concentrates.

Appendix 17: Status of Equipment at Mombasa Regional Blood Transfusion Centre

Status of Equipment at Mombasa RBTC as at 25 February 2020				
	Name of Equipment	Condition	Requirement	Service Contract
1	Etimax 3000 (TTI Testing)	Working	Needed Automatic Voltage Switcher	Irregular service
2	Water Pump	Working	But required servicing and plumbing works	No
3	Echo Lumena (Blood Grouping)	Working	Required reagents antiseras	Yes
4	Distiller	Working	Awaiting free flow of water	Yes
5	Platelet Agitator	Working	Required servicing	No
6	RPR Shaker	Working	Required servicing	No
7	Freezer	Working		No
8	Water Bath	Working		No
9	Microscope	Working		No
10	Weighing balance for reagents and components	Working		No
11	Air conditioners (15)	2 working 13 Not Working		No
12	Cold room	Not working	Replacement of compressor	No
13	Generator	Not working	Required servicing, battery, and changeover switch replacement	No
14	Tube sealer	Not working	Required repair	No
15	Refrigerator double door	Not working	Required fan and gas	No
16	Rotina Centrifuge	Not working	Vibration dumpers needed replacement	No
17	Blood collection mixer	Not working		No
18	Weighing Scale	Not working	Required replacement	No
19	Refrigerated Centrifuge (2)	2 Not working	Required motherboard	No

Status of Equipment at Mombasa RBTC as at 25 February 2020				
	Name of Equipment	Condition	Requirement	Service Contract
20	Freezer	Not working	Required repair	No
21	Water Bath	Not working	Mother board faulty	No
22	Incinerator	Not working	Required replacement of the compressor	Always repaired by the Coast General Hospital
23	Centrifuges (2 Roto Silenta)	2 Not working		No

Summary:

The total number of equipment was 39.

Out of the 39 equipment, 2 were on service contract while 37 were not. In addition, 12 of the 39 equipment were working while 27 were not working.

Appendix 18: KNBTS Management Comments on Audit Findings and Recommendations

Note: The Annexures referred to under KNBTS Response and Auditor's Comments columns are documents that KNBTS provided to support their responses to the OAG's Management Letter. These documents are not attached to this report as most of them are bulky, but they are available in the Office for reference.

Audit Finding	KNBTS Response	Auditors' Comments
Paragraph 4.1 – 4.3 ***Inadequate Supply of Blood to Hospitals for Transfusion*** **4.1** Analysis of data for the period 2016/2017-2018/2019 on blood requested by the hospitals in 15 out of 27 Centres shows that KNBTS was not able to supply on average 46% of the blood requested by the hospitals.	**The management agreed with the finding** The management response indicated that with improvement in systems, in the Financial Year 2020/2021 the deficit has reduced to 32%.	• The action being taken by KNBTS to improve supply of blood to hospitals is commendable and reduction of deficit to 32% during 2020/2021. However, there is need to observe the trend for a reasonable period of time hence the need for follow-up. • During a future follow up audit, the Office will be able to establish whether over time KNBTS have been able to reduce on its blood supply deficit. Our finding remains as reported.
Paragraph 4.4 – 4.8 ***Lack of Inventory system for efficient management of blood and blood products***	**The management agreed with the finding** The management response indicated that since 2020 KNBTS has:	• **Annexure 2** on Appointment of a Technical Working Group to facilitate Development and Implementation of a National Blood Surveillance Strategy and a

Audit Finding	KNBTS Response	Auditors' Comments
4.5 KNBTS does not have a stock management system for blood and blood products for the hospitals' blood banks. Hospitals make orders as and when the blood is needed since there are no established limits of re-order levels for efficient blood transfusion services.	i. Developed a monitoring and evaluation system that provides monthly and quarterly data. ii. Established a National Monitoring and Evaluation Working Group to guide development of efficient management systems. iii. Developed an inventory management tracking tool that is filled monthly – Facility Consumption Data and Request that is reviewed monthly. iv. Developed a national track and trace Blood Management Information System that leverages ICT to digitize blood transfusion services that is currently under deployment. The BMIS *once deployed in the hospitals will enable requisition of blood from blood establishments and enable visibility of stocks and establishment of minimum stock levels.*	Monitoring and Evaluation Framework; and, **Annexure 4 & 5a** on digitizing blood transfusion services in the country are evidences presented of measures being taken by MOH in improving KNBTS inventory system for managing blood and blood products. • The Blood Management Information System has various modules ranging from donor self-registration portal and also allows blood test results to be relayed online; an inter-collaboration module where facilities can share blood needs; a vendor module that allows transfusing Centres to register and report what they receive and what they transfuse; among other modules. The National Referral Hospitals have been instructed to get into the system. Faith Based hospitals have also requested that their major hospitals be deployed into the

Audit Finding	KNBTS Response	Auditors' Comments
		system in order to enhance the vein to vein blood management. • **Annexure 5b** shows there is still need for MOH and KNBTS to fast track full utilization of BMIS in all blood establishments and transfusing facilities. • During a future follow up audit, the Office shall establish whether the measures put in place have improved efficiency in KNBTS inventory system for managing blood and blood products. Our finding remains as reported.
Paragraph 4.9 – 4.14 ***Failure to meet KNBTS and WHO's Standards for Blood Collection Targets*** **4.9** The World Health Organisation recommends that for a Country to meets its blood and blood component requirements, it should collect a unit of blood from at least one per cent of its population every year. Kenya has a population of about 50 million people and therefore should target	**The management agreed with the finding** The management indicated that: i. There has been improved blood collection through strengthened partnerships with institutions **(Annexure 6 and Annexure 7 shows Reports on blood drives conducted in October 2021).**	• Actions being taken by MOH and KNBTS towards realization of WHO recommendation for blood collection is commendable. • Collection targets for the financial years 2021/2022 were based on WHO requirements. In each collecting Centre collection targets

Audit Finding	KNBTS Response	Auditors' Comments
to collect about 500,000 units of blood each year. However, review of blood collection targets shows that KNBTS was short of WHO requirement by an average of about 60%.	ii. In the calendar year 2021, the KNBTS has had the highest blood collections in the Service at 283,000 units.	were based on 1% of the county population. **(Annexure 8).** • During a future follow up audit, the Office shall establish; whether KNBTS will have attained consistency in setting collection targets on the basis of WHO standards. Whether KNBTS will have realized the targets. The finding remains as reported.
4.14 The management admitted that KNBTS does not base its blood collection targets either on the WHO requirement or blood needs by the hospitals but rather on the resources available.	**The management agreed with the finding** The management response indicated that targets for FY2021/2022 are based on WHO requirements **(Annexure 8)**	
Paragraph 4.15 - 4.24 ***Mobilization, Recruitment and Retention of Donors*** **4.15** KNBTS has not been able to recruit and retain regular voluntary non-remunerated donors, but has mainly been relying on first time donors who cannot guarantee provision of adequate supply of safe blood. **4.16** Analysis of data in 19 out of 27 Centres shows out of an average of 151,553 donors who donated blood during the period 2016-2017 to 2018-2019, only 9% were regular	**The management agreed with the finding** The response indicated that since 2020, the management has invested in developing a long-term mobilization and recruitment and retention strategy for donors through: i. Development of a donor mobilization, recruitment and retention strategy **(Annexure 9).** ii. A national scheduled and coordinated calendar of blood drive activities is in place to increase the number of regular blood donors.	• The action being taken by MOH and KNBTS is commendable. • KNBTS has developed a strategy for donor mobilization, recruitment and retention. A Youth Blood Donation Technical Working Group has been appointed by the Accounting officer with an aim of ensuring that youths become potential pools of regular donors when they leave school. The Media Council of Kenya have also been involved and

Audit Finding	KNBTS Response	Auditors' Comments
donors, 16% were repeat donors while majority representing 76% were first time.	iii. Identification of post-secondary school youth as potential pools of regular donors and therefore established a youth Blood Donation Technical Working Group appointed by the Accounting Officer **(Annexure 10)**. iv. On notification of donor (4.24), the Blood Management Information System has an automated notification module, and the Accounting Officer has approved procurement of a sender ID and bulk SMS for donor recruitment and for notification of donors **(Annexure 11)**. v. To strengthen donor recruitment and notification, the management has ensured provided internet access in all Regional Blood Transfusion Centres and all Satellites **(Annexure 12)**.	reporters trained who will be engaged in featuring stories on blood matters. The aim is to improve public awareness, information and education; increase media coverage on matters relating to blood; and increase public responsibility towards blood donations. • During a future follow up audit, the Office shall conduct a follow up audit to establish whether the strategies have enhanced mobilization, recruitment and retention of voluntary non-remunerated blood donors. The finding remains as reported.
Paragraph 4.25 – 4.39 ***Resources Needed for Supply of Adequate and Safe Blood and Blood Products*** **4.26** Analysis of staff status indicates that out of 374 staff needed in 15 of the Centres, only 152 were in position. This shows a deficit of 222 staff or an average shortage of 60% of	**The management agreed with the finding** i. The management response indicated that since 2020, KNBTS has since made requests for more personnel and there exist an on-going engagement with the Ministry. ii. In order to strengthen personnel at the Transfusion Satellites and understanding	• The action being taken by MOH and KNBTS in ensuring adequate, qualified and experienced in order to ensure efficient blood transfusion services is commendable.

Audit Finding	KNBTS Response	Auditors' Comments
staff requirements in these Centres. In some of the places like Embu, Nyeri, Machakos, Thika, Mombasa and Kakamega, the shortages were 67% - 81%. **4.27** Paragraph 3.2.2 of the African Society for Blood Transfusion Standards for 2019 require that the personnel (including Volunteers) performing specific tasks shall be qualified on the basis of education, training and experience, shall have the requisite knowledge and skills. Analysis of the staff in position indicates that in 11 out of the 15 Centres, 7 had over 50% of donor services staff seconded from the counties with Kitui and Malindi having 100% of the staff seconded from the Counties.	that transfusion of blood is a hospital-based treatment is a County function, the management engaged the Counties to develop a formalized coordination framework. An Intergovernmental Framework on Coordination of Blood Transfusion Services was approved at the Health Sector Inter-Governmental Consultative Forum on 11th November 2021 **(Annexure 13).** Within this arrangement Counties have dedicated County Blood Transfusion Officers and also have increased staffing to Satellites. iii. The KNBTS developed a capacity building framework in 2021 and has invested in training of health care workers on blood management. This has included on-line training and in-person staff training **(Annexures 14, 15 and 16).**	• KNBTS made a request for additional 50 staff to be recruited in the service. In the meantime, there has been some internal re-organisation where staff have been moved across transfusion sites by the MOH. A capacity building framework has been developed to guide on training of health care workers on blood management. • During a future follow up audit, the Office shall establish whether KNBTS acquired and sustained adequate and qualified staff for blood delivery service. The finding remains as reported.
4.34 For KNBTS to perform effectively, it requires suitable infrastructure and facilities in all Centres in which blood collection, testing, processing and storage of blood and blood products takes place. However, in the Centres visited, KNBTS does not have its own infrastructures but were mainly housed by the hospitals with very limited space for		There was no response for this finding. The finding remains as reported.

Audit Finding	KNBTS Response	Auditors' Comments
the blood donor services. This also affect efficient delivery of blood transfusion services by KNBTS as these facilities may not be ideal for such services.		
4.35 Availability of transport during blood drives that would ensure that sessions are conducted as planned was also a challenge where for instance though 13 out of 15 Centres had been allocated motor vehicles, only 9 of the Centres had operational vehicles and none had an ideal capacity of at least 7 people needed for the blood drives and capacity to accommodate donation equipment. This was mainly attributed to lack of regular repairs and maintenance of vehicles where review of documents for the period 2016/2017 and 2017/2018 revealed that regular vehicle repair and maintenance was not carried out and as a result broken down vehicles were lying in Centres yards.	**The management agreed with the finding** The management response indicated that since 2020, the management have invested in vehicle repair, replacement and ensuring functionality through: i. Procurement of 10 long chassis 4-wheel drive (7 passenger carrying capacity). ii. Grounded vehicle on process of repair as per attached approved request, having now received the reports from different County based Ministries of Works. iii. All vehicles uses fuel cards which is automatically topped up every month end. **(Annexure 17 – approved distribution plan for the vehicles)**	• The action taken being taken by MOH and KNBTS to ensure efficient transport during blood drives is commendable. • Centres that have received new vehicles include Nyeri, Thika, Kisii, Machakos, Kericho, Bomet, Kitale, Naivasha and Nairobi. • During a future follow up audit, the Office shall establish whether KNBTS sustains an efficient transport system to ensure that blood sessions are conducted as planned. The finding remains as reported.
Paragraph 4.40 – 4.43 ***Breakdown of Equipment and Lack of Reagents for Processing Blood***	**The management agreed with the finding**	• The action being taken by MOH and KNBTS to ensure timely and uninterrupted processing of blood

Audit Finding	KNBTS Response	Auditors' Comments
4.40 As at the time of the audit, interviews with staff in the 15 sampled Centres revealed that due to lack of reagents and breakdown of blood processing equipment, blood screening for the whole country was being done in only 3 Centres namely Nairobi, Kisumu and Eldoret. **4.42** Delays in repairing of blood processing equipment, lack of reagents results in delays in processing of blood. For instance, ideally routine blood testing and grouping should take 24 hours while emergency blood testing and grouping should take only 6 hours. However, review of records between March 2018 and October 2019 in Embu and Naivasha Centres revealed that it took between 4 and 17 days to receive results sent to Nairobi for TTI screening. Review of records in Kisumu, Mombasa, Kisii, Kitui, Eldoret and Machakos Centres revealed that from December 2019 it took up to a month to receive results for blood samples sent for	Management response indicated that since 2020: i. The management invested in additional equipment for blood processing, banking and grouping increasing the national banking capacity by 100%. ii. The management has developed a system of quarterly reporting of the status of all plant and equipment by the bio-medical Engineer for continued functionality. iii. On finding 4.40, a forecasting and quantification committee in KNBTS has been set up to ensure stock and pipeline security for reagents and consumables. Forecasting has been done up to 2023 to allow pipeline and avoid stock outs and requisitions done on time. iv. Testing equipment has been repaired and machines are currently under service contracts. Testing is currently being carried out in all the KNBTS Testing sites that is National Testing Laboratory (Nairobi), Eldoret RBTC, Nakuru RBTC, Kisumu RBTC, Mombasa RBTC and Embu RBTC. v. Management response noted that KNBTS has reduced the Turn-around-time (time for results to be received) from up to one	and blood products is commendable. • A forecasting and quantification committee has been set up to ensure stock and pipeline security for reagents and other consumables. • Gaps in plant and equipment have been worked on and serviceable items have been put on contract. • Cold rooms, generators and incinerators in various Centres have been repaired and serviced and are currently under service contracts. • Respective Bio-Medical Engineers are expected to report on a quarterly basis on the status of all plant and equipment to ensure continued functionality. • The turn-around time for blood testing has reduced to an average of 30 hours across the counties.

Audit Finding	KNBTS Response	Auditors' Comments
screening in Nairobi which ultimately affected blood supply in hospitals.	month to less than 48 hours. This has been through procurement of a sample referral and transportation, through Postal Corporation of Kenya was contracted to be delivering samples, reagents and consumables to the testing sites. Results are relayed immediately via internet since the regions and Satellites are connected. **Annexure 18** – Approved distribution list of equipment and plant in 2021 (purchased by World Bank) **Appendix 19** – Quarter 2 Turn Around Time FY 2021/2022 report **Appendix 20** – Forecasting and Quantification committee appointment **Appendix 21** – a data illustration of current turnaround times that are monitored monthly and quarterly	• During a future follow up audit, the Office shall establish whether the measures taken have enhanced timely processing of blood and blood products. The finding remains as reported.
Paragraph 4.44 – 4.46 ***Erratic Supply of Blood Bags for Collection of Blood and Blood Products*** **4.44** Blood bags are the basic necessity without which no blood can be collected from the donor. The bags should ideally be supplied to Regional and Satellite Centres	**The management agreed with the finding** The management response indicated that since 2020, the management has ensured a steady supply of blood bags through KEMSA and these have been distributed to regions and Satellites.	• The action taken by MOH and KNBTS to ensure a steady supply of blood bags to regions and Satellites is commendable. • A forecasting and quantification committee has been set up to ensure stock and pipeline security

Audit Finding	KNBTS Response	Auditors' Comments
from the KNBTS headquarters. Interviews with KNBTS management revealed that procurement of blood bags is done by the MOH through the Kenya Medial Supplies Authority (KEMSA). The management however noted that there lacked timelines for the supplies delivery and this results to erratic supply of blood bags to KNBTS which ultimately affect supplies to the Centres. As a result, supply of blood bags to KNBTS Centres is not always concurrent with the blood collection targets set by KNBTS.		for reagents and other consumables. • During a future follow up audit, the Office shall establish whether the measures taken have ensured steady supply of blood bags and other commodities to RBTCs and Satellites. The finding remains as reported.
Paragraph 4.47 – 4.49 ***Quality and Safety of Blood and Blood Products*** **4.49** Document review and interviews with the KNBTS management, staff in 15 sampled Centres, and Laboratory staff in 27 hospitals revealed inadequacies which may compromise quality and safety of blood transfused to patients. These include lack of a centralized system for blood collection and processing, inadequate regular donors, lapses in blood cold chain, inadequate donor recruitment practices, equipment gap, lack of preventive maintenance for equipment, inadequate staff, lack of adequate	**The management agreed with the finding** Management response indicated that since 2020, the management has: i. Invested in quality audits and quality improvement, resulting in accreditation of 3 regional laboratories. ii. Invested in review of guidelines and standards for all blood transfusion services. iii. Invested in a Blood Management Information System that will centralize blood collection and processing. iv. Strengthened the cold chain through investments in cold chain transport and	• The action being taken by MOH and KNBTS to ensure quality and safety of blood is commendable. • Since 2020, three regional Centres have been accredited, that is the National Testing Laboratory, Eldoret and Nakuru Regional Blood Centres and these are working towards maintaining the required standards. The other three Centres, Embu, Mombasa and Kisumu are still under mentorship and audit processes.

Audit Finding	KNBTS Response	Auditors' Comments
haemovigilance activities in hospitals, outdated policies and guidelines and lack of accreditation of KNBTS.	storage as per distribution list in **Appendix 18.** v. Printed and distributed hospital registers to capture transfusion data, **Appendix 22** – Laboratory accreditation certificates. **Appendix 23** – Hemovigilance registers distribution list **Appendix 24** – Approval for the review of guidelines and standards and current draft copies **Appendix 25** – Distribution list approval for data	• Blood policy and guidelines have been reviewed and are undergoing validation. The Standard Operating Procedures have been submitted for legal review and other additional guidelines have been finalized and validated by stakeholders and experts. • However, there is need for MOH and KNBTS to fast track accreditation of the remaining Centres. • During a future follow up audit, the Office shall establish whether the measures are working towards improvement in ensuring the safety and quality of blood. The finding remains as reported.
Paragraph 4.50 – 4.51 ***Failure to meet blood component targets*** **4.50** Analysis of requests of the various blood components for the period 2018 to 2019 (January to September) shows that not all requests made by hospitals for the various types of blood components are met.	**The management agreed with the finding** Management response indicated that: i. Since 2020, additional equipment for blood component preparation and processing	• The action being taken by MOH and KNBTS to improve on component preparation is commendable. • Machakos, Thika, Nyeri, Meru, Voi, Kisii, Siaya, Kericho, Naivasha,

Audit Finding	KNBTS Response	Auditors' Comments
4.51 Failure to meet the requested units of blood components was attributed to KNBTS inability to met its targeted percentage of component preparation for the period.	has been procured and placed in different Satellites **(Appendix 18).** ii. Component preparation champions were identified from all regions and training has been carried out. Participants were drawn from different facilities in the country. This was done with the aim of disseminating the specialized skills achieved to all facilities that can prepare blood components. **Appendix 26** – Training approval	West Pokot and Kitale each received an automated Plasma Extractor. • Thika, Meru, Voi, Homabay, Naivasha and West Pokot each received a Refrigerated Centrifuge. • Thika, Nyeri, Meru, Marsabit, Voi, Kisii, Naivasha and West Pokot each received a Platelet Agitator. • During a future follow up audit, the Office shall establish whether the measures taken have ensured that transfusing hospitals' blood components needs are met. However, the finding remains as reported.
Paragraph 4.52 – 4.56 ***Appropriate Use of Blood and Blood Products for Efficient Blood Transfusion Services***	**The management agreed with the finding** The management response indicated that: i. Since 2020, the management has initiated review of the Hemovigilance manual as	• Action being taken by the management in addressing the issue of Hemovigilance activities is commendable.

Audit Finding	KNBTS Response	Auditors' Comments
4.53 Hospital Transfusing Committees (HTCs) are the link between the transfusing hospitals and KNBTS which should be established in each hospital to implement the national policy and guidelines. HTCs should have authority within the hospital structure to determine hospital policy in relation to transfusion, ensure availability of the required blood and blood products at all times. The Committee monitors usage of blood and ensure appropriate clinical use of blood as well as training all hospital staff involved in transfusion. HTCs should also monitor investigation of severe adverse effects or errors associated with transfusion, take any corrective and preventative action required and carry out reporting through the haemovigilance system to the national committee on the clinical use of blood. **4.54** The audit revealed that the HTCs which were formed in the hospitals are not functional. The Committees would enable KNBTS know the needs of blood and blood products at specific hospitals, help with issues pertaining to adverse reactions of patients, address the issue of appropriate	part of all manuals under review, that will guide formation of Hospital Transfusion committees. ii. The management requested the Director General to issue a circular to all transfusion facilities registration for strengthened hemovigilance activities. **Appendix 28** – DG Circular **Appendix 29** –Draft Hemovigilance Manual	• KNBTS is in the process of setting up a National Hemovigilance Technical Working Group which will develop a national hemovigilance framework and also advise on its implementation. • However, the management needs to fast track these measures to ensure they have been actualized and are serving the purpose intended. Effectiveness of these measures will then be confirmed during a follow- up audit. Therefore, the finding remains the same.

Audit Finding	KNBTS Response	Auditors' Comments
clinical use of blood in hospitals as well as monitor blood consumption and reduce wastage of blood and blood products.		
Paragraph 4.57 – 4.61 ***Surveillance and Hemovigilance Activities in the Hospitals*** **4.57** Surveillance procedures and hemovigilance systems are needed to monitor adverse events and known threats to blood safety and availability and to enable informed decisions to be taken in response to new challenges or threats. Effective hemovigilance enhances traceability of donated blood, that is from donor to recipient and vice versa in a timely manner. This is essential to ensure the ability to recall at-risk products, to identify recipients of non-conforming products that may require additional follow-up, and to fully investigate adverse events. There is therefore need for an efficient system for tracking throughout the transfusion pathway that captures the details at each stage and maintains necessary linkages.	**The management agreed with the finding** i. Reference to the Blood Management Information System (BMIS). It has the capability for vein to vein visibility of donated blood from the donor to patient using unique donation numbers. The donor number uniquely identifies the donor and donation number the donation and keeps changing at every donation. The BMIS will link Satellites to hospitals. ii. Internet connectivity is available at all regions and Satellites and the management requested NOFBI support.	• The measures taken in installing a Blood Management Information System noting its capability and the fact that it will link KNBTS Centres to hospitals is commended. • However, it is important for KNBTS to fast track actualization of the vein to vein concept in the blood service delivery in the country. • Confirmation of the systems operation and its efficiency and effectiveness, as well as internet connectivity will be done in a follow- up audit. However, the audit findings remain as reported.

Audit Finding	KNBTS Response	Auditors' Comments
4.58 Interviews with KNBTS management revealed that currently the system for tracking blood is manual through the unique identification numbers where each blood bag has an identification number which can be traced from the person who donated blood to the person who was transfused the blood. This is however not effective since it will take time to trace the path of a unit of blood from the source to the recipient unlike when done electronically where real time information sharing is possible.		
Paragraph 4.62 – 4.65 ***Lack of Appropriate Legal and Supervisory Framework by KNBTS*** **4.63** KNBTS lacked an appropriate legal and supervisory framework to monitor assurance controls for blood collection, testing, processing, storage and distribution in private transfusing hospitals at the time of the audit. KNBTS in collaboration with the MOH developed a Bill in 2014, "The Kenya National Blood Transfusion and Transplant Bill, 2018" which seeks amongst other things to enable KNBTS provide technical support to private as well as national referral hospitals on best blood transfusion	**The management agreed with the finding** The management response indicated that: i. Since 2020, the management has undertaken a process of development of a Kenya policy for donations, transfusion and transplant services that has been submitted for approval. ii. The Kenya National Blood Transfusion and Transplant Bill 2020 has passed the National Assembly and is now in Senate. iii. Two standards namely; the National Standards of Blood Transfusion Services in Kenya and Standards for Setting up Blood Establishment have been developed and	• KNBTS management is encouraging blood collection and component preparation at the county level but retaining the responsibility for testing. In such cases, KNBTS still have the responsibility of ensuring the right standards for equipment used at county facilities by undertaking installation, validation, calibration and inspection. • For the case of Kakamega Blood Transfusion Centre, it has since reverted to a KNBTS regional Centre for its blood testing. This

Audit Finding	KNBTS Response	Auditors' Comments
practices. Subsequently, post audit, the Kenya Tissue and Transplant Authority came into existence on 1 August 2022 vide Legislative Supplement No. 61 and Legal Notice No.142. **4.65** Further, due to increasing shortage of blood for transfusions in hospitals County Governments are seeking for alternative ways of ensuring sufficiency of blood in the hospitals as evident by the **case study** for Kakamega County. This goes against the objective of centralising blood service through KNBTS that was meant to ensure provision of quality and safe blood to patients throughout the country.	validated by the key stakeholders and submitted to MOH legal department for review. iv. Kakamega County runs the blood Satellite and the lessons have been borrowed and applied with other counties through the Inter-Governmental Coordination Framework, while aligning to the constitution and global standards.	was necessitated by the high costs of testing which was not sustainable. • All these issues will be revisited and confirmed during a follow-up audit. The finding remains as reported.
Paragraph 4.66 – 4.69 ***Outdated Blood Policies and Guidelines*** **4.67** KNBTS is the body in-charge of the national blood transfusion programme and has over the years developed guidelines, policies and procedures that govern activities in the blood sector. According the management, these Guidelines /Polices should be reviewed and updated after 3 years (ideally every after 2 years) but this has not been done and therefore most of the	**The management agreed with the finding** The management response indicated that: i. Three guidelines and manuals (Hemovigilance Manual, National Standards and Appropriate Use) have been reviewed and are under-going validation and peer review. ii. Three other guidelines and manuals (Cold chain manual, supervision manual and guideline on establishing blood facilities in	• The audit notes the action and progress made by the Management, but there is need to fast track approval of these standards, guidelines and manuals since they have been outdated for quite a long period of time. • The finding remains as reported to be confirmed in the follow- up audit.

Audit Finding	KNBTS Response	Auditors' Comments
critical polices and guidelines are outdated with some of the policies dating as far back to 2001.	Kenya) that did not exist have been developed. iii. These standards, guideline and manuals have been developed, reviewed and validated by experts and stakeholders. They are currently undergoing content peer review by the counties within the region before approval by the MOH. **Appendix 30** – Peer review request of the documents **Appendix 31** – National Standards for Blood Transfusion Services **Appendix 32** – Guidelines on Appropriate Use **Appendix 33** – The Cold Chain Manual **Appendix 34** – The Supervision Manual	
Paragraph 4.70 – 4.75 ***Delayed Accreditation of KNBTS Laboratories*** **4.72** In September 2019, KNBTS through partner support was able to pay assessment fee for its four out of the six regional facilities namely Kisumu, Nakuru, Eldoret and the National Testing Laboratory. Embu was omitted due to the lean number of human resource while Mombasa was left out due to lack of funds to pay for the	**The management agreed with the finding** The management response indicated that: i. Three laboratories are accredited towards ISO 15189. ii. EQA service provider procured and currently KNBTS is in an EQA program. Teams have been trained on implementation of ISO 15189.	• The effort being made by KNBTS management towards ensuring accreditation of all its laboratories is appreciated. • Three laboratories have so far been accredited, that is the National Testing Laboratory, Eldoret and Nakuru Regional Blood Centres and these are working towards maintaining the required standards. The other

Audit Finding	KNBTS Response	Auditors' Comments
assessment fee. The external assessment based on ISO 15189:2012 was conducted by the national accreditation body, Kenya Accreditation Service (KENAS) in October and November 2019. **4.73** Several non-conformities were raised and KNBTS was given a timeline to close and submit evidences of closure. According to KNBTS management most of the non-conformities had been closed at time of the audit except those requiring financial input and KNBTS was waiting the verdict from KENAS. **4.74** KNBTS participated in an External Quality Assurance Scheme sponsored by donor partners since the year 2009 that was aiding in quality monitoring. However, this ceased in April 2020 when funding came to an end and therefore as at the time of the audit KNBTS had not participated in any EQA since then.	iii. Audits for other regional labs have been initiated to prepare for additional accreditation.	three Centres, Embu, Mombasa and Kisumu are still under mentorship and audit processes. The finding remains as reported for the issue to be confirmed in a follow-up audit.
Paragraph 4.76 – 4.84 ***Storage and Transportation of Blood and Blood Products*** **4.77** Interviews with KNBTS management revealed lack of sufficient storage facilities	**The management agreed with the finding** The management response indicated that: i. Since 2020, the management has increased its storage capacity across regions and	• The measures taken by the management are commendable but there is need to confirm the equipment in the respective regions and how well they have addressed the gaps that were

Audit Finding	KNBTS Response	Auditors' Comments
for blood in the cold chain management process. The management noted that if they were to collect the ideal amount of blood units, there would be no sufficient space for storage since most of the cold rooms are broken. Further interviews with KNBTS staff in the 15 Centres visited showed equipment gaps in the blood cold chain as well as inadequacies in routine preventive maintenance of the available equipment.	Satellites by up to 100% from 24,000 to 50,000 through procurement and distribution of storage equipment, repair of cold rooms and procurement of cold rooms **(Annex 18).** All 9 (six old and 3 new) cold rooms are functional. ii. As part of the monthly monitoring of equipment performance, a schedule of preventive maintenance is available.	existing at the time of the audit. This will be done in a follow-up audit. The audit finding remain as reported.

Audit Recommendation	KNBTS Response	Auditor's Comment
6.1 Provision of safe and adequate supplies of blood is dependent on a well-organised blood transfusion service, with dedicated, well-trained manpower and resources for the service. This would require the MOH to ensure adequate sustainable financing, including specific budget for KNBTS.	MOH has increased investments in the National Blood Transfusion Services and Counties.	Post-audit review indicates reforms on various aspects of the blood service delivery have been initiated by the MOH. The Office of the Auditor - General intends to establish at a later date, whether over time, these reforms have impacted on the blood service delivery and whether sufficient, secure supplies of blood and blood products and safe transfusion services have been realised.
6.2 KNBTS should prioritise the blood donor recruitment function. This is by developing an all-inclusive nation-wide communication strategy for sensitizing potential donors in order to ensure increased voluntary blood donor recruitment and retention. KNBTS should fully implement the post-audit strategies on improving public awareness,	The management prioritized through developing a strategic plan and is executing the proposed strategies.	

Audit Recommendation	KNBTS Response	Auditor's Comment
information and education; increased media coverage on matters relating to blood; and increased public responsibility towards blood donations.		
6.3 KNBTS should leverage on ICT in enhancing haemovigilance activities. This includes ensuring that the national track and trace Blood Management Information System developed post-audit is put into optimal use. This will enhance traceability of blood, receiving timely feedback from HTCs, as well as training and mentorship of transfusing clinicians. This will contribute in improving appropriate utilization of blood and blood components in hospitals.	The management has leveraged ICT with the development and on-going deployment of the BMIS	
6.4 To ensure that blood is only used for deserving cases, thus reducing on demand for blood, it is important that KNBTS ensures that clinicians are continuously trained and advised on the importance of prevention and early management of anaemia and the use of blood alternatives where possible. It is imperative for KNBTS to fast-track the development and implementation of the National Haemovigilance Framework in order to strengthen haemovigilance activities in hospitals.	The management has initiated investments in training clinicians, such as through the COVID Training webinar platform that reach more than 1,500 clinicians across the country.	

Audit Recommendation	KNBTS Response	Auditor's Comment
6.5 KNBTS needs to improve on donor notification and referral of Transfusion Transmissible Infection positive cases to care and treatment services. Further, KNBTS should ensure that linkages are established with facilities to ensure that the deferred donors seek care and treatment as advised.	The BMIS will improve donor notification and referral of TTI positive cases.	
6.6 The MOH and KNBTS should consider developing a human resource policy for KNBTS staff that addresses recruitment, retention, training and motivation of staff so as to ensure effective service delivery. Post-audit review indicates that KNBTS requested the MOH for recruitment of 50 staff and also developed a capacity building framework for guiding training of health care workers on blood transfusion management. Therefore, the MOH should fast-track the staff recruitment and KNBTS ensure adequate training for all staff in the blood service.	The management will consider developing a human resource policy for KNBTS.	
6.7 KNBTS should ensure that there are sufficient quantities of the required consumables for blood transfusion service. This is by making sure that new stock is ordered well before the existing stock runs out in order to enhance efficiency in the blood service delivery. In addition, KNBTS should ensure that the Forecasting and	The management is regularly reviewing the forecast and quantification for consumables and supplies and using this to plan for procurement, pipeline and make additional requests for resources if need be.	

Audit Recommendation	KNBTS Response	Auditor's Comment
Quantification Committee set up post-audit ensures stock and pipeline security for reagents and other consumables.		
6.8 KNBTS should improve on quality of blood products through modernisation of blood processing and component preparation. This will also ensure optimal use of the scarce blood resource. Post-audit, KNBTS through MOH has acquired four apheresis machines and other equipment for blood component preparation. Therefore, KNBTS should ensure optimal utilisation of the equipment for efficient service delivery.	The management has significantly strengthened modernization of blood processing and component preparation.	
6.9 The MOH and KNBTS should ensure prompt maintenance and replacement of motor vehicles and laboratory equipment. Major laboratory equipment needs to be placed under service contract and users trained on basic preventive maintenance.	The management has developed a system to ensure faulty machines are promptly repaired, and placed major laboratory equipment under service contract.	
6.10 The MOH and KNBTS should fast track updating of outdated policies, guidelines, manuals and other documents that guide blood service delivery in the country in order to ensure efficiency in the blood service delivery. Post-audit review indicates that three guidelines and manuals have been reviewed and new ones developed. However, there is still need for KNBTS to	The management has already reviewed, updated and developed new policies as appropriate.	

Audit Recommendation	KNBTS Response	Auditor's Comment
fast-track the content review and approval of the policies, manuals and guidelines.		
6.11 KNBTS should review and revive programmes geared towards attaining and maintaining international quality standards for accreditation of blood transfusion services. Post-audit review indicates that three out of the six KNBTS regional Centres have so far being accredited. There is need for KNBTS to fast-track accreditation of the remaining three regional Centres and also ensure that the accredited ones maintain the required standards.	The management has revived programmes towards attaining international standards.	

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