



Ministry of Health

KENYA POLICY ON DONATION, TRANSFUSION AND TRANSPLANT OF HUMAN DERIVED MEDICAL PRODUCTS



Kenya Tissue And
Transplant Authority

Damu  KE
The Kenya Blood Banking Management System

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Ministry of Health

KENYA POLICY ON DONATION, TRANSFUSION AND TRANSPLANT OF HUMAN DERIVED MEDICAL PRODUCTS

Ensuring equitable access to safe blood, cells, tissues, organs, and other medical products of human origin; and safe transfusion and transplant services for all in Kenya



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ABBREVIATIONS

CBTC	County Blood Transfusion Coordinator
CDH	County Director of Health
CECM	County Executive Committee Member
CoG	Council of Governors
COVID	Coronavirus Disease
EQA	External Quality Assurance
FBO	Faith Based Organization
GoK	Government of Kenya
HDMPs	Human Derived Medical Products
HPTs	Health Product and Technologies
HSIGCF	Health Sector Inter-Governmental Consultative Forum
ICT	Information and Communication Technology
ISBT	International Society of Blood Transfusion
KBTTs	The Kenya Blood Transfusion and Transplant Service
MoH	Ministry of Health
MPHO	Medical Products of Human Origin
NACOSTI	National Commission for Science, Technology, and Innovation
NHIF	National Hospital Insurance Fund
NTSA	National Transport and Safety Authority
QA	Quality Assurance
QMS	Quality Management System
RBTC	Regional Blood Transfusion Centre
RTA	Road Traffic Accidents
TTI	Transfusion Transmitted Infection
UHC	Universal Health Coverage
VBM	Valuable Biological Material
WHA	World Health Assembly
WHO	World Health Organization

DEFINITION OF TERMS

Blood: A body fluid in the (human) circulatory system that is composed of cellular components suspended in plasma.

Blood product: Any therapeutic substance derived from human blood, including whole blood, blood components and plasma derived products.

Blood component: Any therapeutic constituent of blood that is separated by physical or mechanical means (e.g. red cells, platelets, plasma). It is not intended to capture plasma derived products.

Whole blood: Blood collected in an anticoagulant solution with or without additives.

Blood establishment: A facility that performs any of the following:

- Screening and selecting blood donors.
- Blood collection.
- Testing, and processing of blood units.
- Transportation, receiving, and storage of blood units.

- Pre-transfusion tests on patients' blood samples.
- Issue of blood or blood components for clinical transfusion.
- Compatibility testing.
- Issue of blood components for clinical use.

Cell: The smallest transplantable and functional unit of living organisms.

Death: Irreversible and permanent cessation of the critical functions of the human organisms, including the brain.

Brain death: Irreversible cessation of cerebral and brain stem function, characterized by absence of electrical activity in the brain, blood flow to the brain, and brain function as determined by clinical assessment of responses. A brain dead person is dead, although his or her cardiopulmonary functioning may be artificially maintained for some time.

Death by circulatory criteria: Death after five minutes of no detectable cardiac output or detectable respiratory effort.

Donation: Donating human cells, tissues or organs intended for human applications.

Health facility: The whole or part of a public or private institution, building or place, whether for profit or not, that is operated or designed to provide in-patient or out-patient treatment, diagnostic or therapeutic interventions, nursing, rehabilitative, palliative, convalescent, preventative or other health service.

Voluntary donor: A person willing to donate his or her cells, tissues, or organs without expecting any financial incentives.

Living donors: Donors who are alive and can be classified as follows:

- **Children and adult:** Children donors are those aged below 18 years while adult donors are aged above 18 years.
- **Related and unrelated:** Related donors are those who are related by blood or are spouses to the recipients while the unrelated donors are those who are not related by blood.
- **Directed and non-directed donors:** Directed donors are those who make donations to specific recipients while non-directed donors are those who do not make donations to a particular recipient.

Hemovigilance: A set of organized surveillance procedures relating to serious adverse, unexpected events, near misses or reactions in donors or

recipients, and the epidemiological follow-up of donors and blood recipients.

Organ: Differentiated and vital part of the human body, formed by different tissues, that maintains its structure, vascularization and capacity to develop physiological functions with an important level of autonomy.

Tissue: All constituent parts of the human body formed by cells.

Stem cell: Undifferentiated cell that can divide to produce offspring cells in a human being.

Transfusion: The process of infusing blood or blood components to a recipient.

Transplant: Replacement of stem cell, tissue, or organ or any of their parts with a healthy stem cell, tissue, organ or any of their parts.

Transplant centre: A health care facility where donation and transplant of organs, tissues and stem cells are performed.

Medical Products of Human Origin (MPHO): The MPHO encompass all biological materials, either anatomical components or secretions, that are derived wholly or in part from living or deceased persons for clinical intervention. They are also referred to as Medical Products of Human Origin or Human Derived Medical Products. This policy references Human Derived Medical Products.

FOREWORD



The Government of Kenya is investing in a well-coordinated and regulated system that ensures affordable, quality, and safe transfusion and transplant services to citizenry as part

of delivery on Universal Health Coverage (UHC). Blood, cells, tissues, and organs are lifesaving medical therapies that are donated by fellow human beings and have no medical substitute. A policy to provide protection to Kenyans and health care workers while ensuring safety of donors and patients, quality of products and efficacy of transfusion and transplant is imperative. It is based on the recognition that medical products of human origin are a national resource of strategic importance and must be provided whenever needed across the Republic of Kenya.

Kenya is a member of the World Health Organization and a signatory to World Health Organization resolutions that provide for governance and management of donation, transfusion and transplant of blood, tissues, and organs among member states. This policy aligns to these global expectations and will propel health care service delivery towards the highest

possible standards as set out in Article 43 of the Kenya Constitution and the Health Act No. 21 of 2017. It aligns to The Kenya Sessional Paper No. 7 of 2012 on the Universal Health Coverage (UHC), thus progressing aspirations of the Big Four Agenda.

The Ministry of Health (MOH) recognizes the importance of bio-medical products of human origin as a bio-security agenda. Thus, a governance framework in line with this policy envisions to provide the necessary autonomy in regulation and oversight and draws on various enabling sectors to promote robust industry, education, security and necessary finances. In line with devolved structure of governance, it provides for the creation of an inter-governmental framework for effective implementation.

I appreciate Kenyans who continue to selflessly donate blood, cells, tissues, and organs to save lives of their fellow citizens. I urge them to continue with this spirit.

A handwritten signature in black ink, consisting of a stylized 'M' followed by a long horizontal stroke that curves upwards at the end.

Sen. Mutahi Kagwe, EGH
Cabinet Secretary, Ministry of Health

ACKNOWLEDGEMENTS



The Ministry of Health recognizes the transfusion and transplant services as integral to the health of Kenyans. To cushion Kenyans from the out-of-pocket health expenditure on

transfusion and transplant services, the Ministry shall continue to provide support as guided by this Policy and other existing health financing arrangements, such as Universal Health Coverage (UHC) and National Health Insurance Fund (NHIF). Cognizant that Kenyans spent billions of shillings seeking advanced medical care and transplant services abroad, the implementation of this Policy will provide guidance to the necessary infrastructure, capacities and competencies to deliver these services within Kenya, thus promoting health and saving both lives and capital flight. The Ministry of Health shall continue funding the transfusion and transplant services and ensure self-sufficiency of these critical services in the country.

We appreciate the stakeholders and partners who were involved in the development of this Policy. The Technical Working Groups members, Faith Based Organizations (FBOs), Council of Governors (CoG) secretariat, County Executive Committee Members(CECM) of Health, County Directors of Health (CDH), and County Blood Transfusion Coordinators, (CBTC) provided input and guidance in the development of this Policy.

We thank the World Bank and Africa Resource Centre (ARC) for their technical and financial support during the development of this National Policy and the World Health Organization (WHO) for technical guidance.

A handwritten signature in black ink, appearing to read 'Susan N. Mochache'.

Susan N. Mochache, CBS

Principal Secretary, Ministry of Health

EXECUTIVE SUMMARY



In 2021, the Ministry of Health, through the Department of National Blood Transfusion, Tissue and Human Organ Service, initiated the process of development of

a National Policy on human derived products donation, transfusion, and transplant. This was informed by the need to provide a national framework for regulation, oversight and service delivery for blood transfusion, tissues and human organs transplant.

The goal of this Policy is to provide a framework to ensure safety, quality, efficaciousness, effectiveness, and efficiency in sourcing donations and delivering transfusion and transplant of medical products. The Policy aims to protect Kenyans from exploitation, while promoting equity in access to products of human origin. It guides on regulatory, legislative, financial, and technical matters related to the supply chain of blood, tissues and organs from donation to transfusion and transplant, including providers, facilities and processes.

The Policy is guided by the principles of the National Health Policy Framework that subscribes to the Constitution of Kenya and the laws thereof. It outlines ten key objectives and their aligned strategies that shall guide the transfusion and transplant services. The Policy also provides guidance for Kenya towards becoming a global centre of excellence in transfusion and transplant services while strengthening surveillance. A national track and trace system that leverages on technology through a Blood and Organs Management Information System (BMIS) is provided for. The Policy articulates a governance and regulation framework through semi-autonomous agencies, leveraging lessons from different jurisdictions and in line with the Health Act, 2017. With increased actors, this Policy guides on collaboration and coordination among various stakeholders and institutions in line with the National Health Policy Framework.

A handwritten signature in black ink, appearing to read 'Patrick Amoth', written in a cursive style.

Dr. Patrick Amoth, EBS
Director General for Health



01.

INTRODUCTION

1.1 Background and Context

Article 43 of the Constitution of Kenya 2010 on the Bill of Rights guarantees every Kenyan the right to the highest attainable standards of health. In the Vision 2030, Kenya aspires to become a globally competitive middle-income country by 2030. Therefore, an effective health care system that offers high quality services at different health care levels is a prerequisite for rapid national socio-economic development.

Tissues (including blood as a liquid tissue) and organs are categorized by the World Health Organization (WHO) as medical products of human origin (WHO: EB136/32, 136th session). These are described as human-derived medical products in this Policy. Tissues and organs are emergency medication usually prescribed for life-saving purposes. They have no pharmaceutical replacements and must be sourced from other human beings. The in-availability of tissues and organs results in avoidable deaths. These products form an essential part of any health system and a primary requirement for the attainment of Universal Health Coverage (UHC).

Blood, blood components and blood products are critical to any health care service. They are essential to all major surgeries since they require blood availability. Without them, waiting times for surgeries increase and health outcomes of Kenyans are

compromised. Blood un-availability leads to increased mortalities from maternal cases, accidents and injury and organ failure treatments that require transfusions. Blood availability reduces hospitalization periods.

Other tissues and organs are life-saving products. Transplants through surgical methods, organ preservation, and pharmaco-immunologic therapies are essential for management of severe organ failure. They are also complex and expensive. Major sources of organs are deceased persons and this often involves medical ethics, religion and society beliefs. Clear regulations and enforcement are necessary for safety and quality of processes, providers, establishments and products.

The World Health Organization expects member states to develop policies that promote access to life-saving medical products of human origin. With specific regard to blood, blood components and products, resolutions WHA 63.12 and 57.18, recommends member states '(2) to take all the necessary steps to establish, implement and support nationally-coordinated, efficiently-managed and sustainable blood and plasma programmes. This is expected to deliver effective organization and integrated blood supply networks and promote uniform implementation of standards and consistency in the quality and safety. With regard to organs and tissues, member states are expected to strengthen governance and

regulatory oversight of procurement, processing and transplant of human cells, tissues, and organs with compliance to standards in the context of Universal Health Coverage (UHC). The members are asked to establish accountability systems of traceability, surveillance, vigilance and rapid alert and data.

Kenya endeavors to conform to internationally agreed norms, principles, and standards for blood, organs, and tissue services. In this regard, the goals, objectives, and principles pursued in this Policy derive from specific international guidance instruments, in particular the World Health Organization guiding principles on the donation and management of blood, blood components and other medical products of human origin. The Policy is also informed by governance frameworks and institutional norms from International Society of Blood Transfusion (ISBT).

It is further informed by the Declaration of Istanbul on Organ Trafficking and Transplant Tourism (2018 Edition), which provides ethical guidance for professionals and policy makers who share the goal of maximizing the benefits of transplant equitably with those in need without reliance on unethical and exploitative practices that harm the poor and vulnerable persons globally. The Policy document borrows from UN Convention against Transnational Organized Crime (UNTOC);

which provides for the Protocol to prevent, suppress and punish trafficking in Persons, not only for sexual exploitation, but also for the forced removal of organs.

1.2 Rationale for this Policy

The current Kenya blood policy was developed in 2001 but has not been updated since then to align to the emerging epidemiological and clinical needs, technological advancements, medical practice and governance systems with devolution. A 1967 Human Tissue Act, Cap 252 (amended in 2012) provides limitations for organs removal and use of parts of bodies of deceased persons for therapeutic purposes and medical education. It did not envision the medical, legal and ethical complexities of tissue and organ transplants. It is against this background that the Health Act, 2017 provided for a legal framework requiring the regulation of matters related to tissue and human organs transplant (Section 84) and matters related to blood through establishment of the Kenya Blood Transfusion Service by an Act of Parliament (Section 85).

Kenya currently lacks a coherent policy direction to provide guidance on:

- Treatment of human-derived medical products that are a national resource and are to be ethically and equitably available to all Kenyans when they need them.

- Matters related to oversight and regulations for transfusion and transplant services, providers, facilities, and processing establishments.
- Legislation for protection of donors, recipients, and health care workers and necessary penalties for unlawful practices such as illegal organ harvesting.
- Management of a secure national supply chain of commodities and supplies for availability of safe products.
- Inter-governmental relations in the context of devolved and national health functions.
- Governance arrangements required to effectively implement safe, efficacious transfusion and transplant services.

This Policy integrates guidance on transfusion and transplant services, taking cognizance of the recommendations for a differentiated approach to governance and management as outlined in the Health Act, 2017. It demonstrates the commitment of the Government of Kenya to secure safe supply of blood and blood components, cells, tissues, and organs across Kenya on a daily basis and in the context of emergencies. The Policy also aligns with the guiding principles

for promotion of ethical practices in donation and management of medical products of human origin.

1.3 Principles

This Policy is in accordance with the National Health Policy Framework that subscribes to the Constitution of Kenya and the laws thereof. The implementation of the Policy will embrace the following principles:

Principle #1. Human derived medical products are national resources and will be equitably availed to and from where they are stored to those in need, wherever they are.

Principle #2. The national government is responsible for ensuring ethical, safe and effective donations, processing, distribution and use of medical products of human origin. This includes the obligation to develop and enforce regulations to ensure the maximum possible level of safety, quality, and efficacy, both within and across national borders.

Principle #3. Voluntary donation should be promoted and safeguarded through adherence to legislation, regulation and oversight. Policies and regulations governing donation of biological materials for use as medical products of human origin should seek to guard against the exploitation of vulnerable individuals or financially disadvantaged groups and promote equity in donation.

Principle #4. Medical products of human origin should be used only in situations of scientifically proven clinical utility in the absence of alternative and affordable therapies with a comparable or more favorable balance of risks and benefits.

Principle #5. Biological materials from living persons for use as medical product of human origin should be taken only with the donor's prior informed and voluntary consent. When biological material from a deceased person is to be used as medical product of human origin, it is imperative to verify that the individual had provided prior consent or had not expressed objections to be a donor, as mandated by national laws.

Principle #6. Prospective and actual donors of human biological materials for use in medical products should be fully protected against possible physical and psychosocial risks.

Principle #7. Medical products of human origin to prospective recipients should be disclosed without compromising the confidentiality of the donor's identity.

Principle #8. Medical products of human origin should be fully traceable and subject to effective quality-management systems, vigilance, and surveillance programmes.

Principle #9. The organization and delivery of activities related to medical products of human origin, as well as their clinical results, must be

transparent, while ensuring that the confidentiality of donors and recipients is protected.

1.4 Policy Development Methodology

The Ministry of Health initiated the development of the Kenya Blood Transfusion Service Policy in 2013, and the Blood Transfusion Management Bill 2014, which focused on blood and blood products donation and transfusion. Following the enactment of the Health Act in July 2017, the MOH constituted the Blood Transfusion and Organ Transplant Technical Working Group (TWG) in October 2017 that examined global guidance, resolutions of the World Health Assembly (WHA) and legal instruments from other jurisdictions and provided an initial roadmap for implementing part XI of the Act. In 2021, the Kenya Blood Transfusion and Transplant Service initiated the process of reviewing the blood transfusion policy that was integrated with tissue and human organ transplant. The integration was informed by the following two considerations:

- (i) The transfusion of blood and blood products; and the transplant of organs, cells and tissues, involve the transfer of therapeutic material derived from one human being to another. Both transfusion and transplant services in Kenya rely exclusively on altruistic non-remunerated donation by consenting



donors, hence it was found essential that their guidance is not duplicated.

- (ii) The management of donation services, including recruitment and care of donors and recipients, allocation of donated products to needy candidates, donor matching, and ethical considerations require regulation and oversight. Thus, to avoid duplication and potential role conflict, it was found essential to consider a harmonized approach to coordination and implementation.

The process of developing this policy was participatory, including stakeholder and public participation. There were inputs from national and county governments and relevant stakeholders who included development and implementing partners, academicians, civil society, practicing consultants and other practitioners from public, private, faith-based and health facilities.

Consultative meetings were held with County Directors of Health (CDH), County Executive Committee Members (CECM) of Health and Council of Governors (CoG). Insightful inputs to the policy were provided during the

meetings. The draft policy was then reviewed and approved by the Director General for Health and validated by stakeholders and partners.

Annex 1- Policy Development process

Annex 2 – Policy Validation process

1.5 Scope of the Policy

This Policy reviews the status of Kenya’s legislation, regulations and operational frameworks and service need coverage with regard to human derived medical products. Ten (10) objectives and deliberate strategies for each provide guidance for governance, oversight, organization, infrastructure, coordination and service delivery. Considerations related to ethics, quality, efficacy, and safety in processes and practice of donation, transfusion and transplant are addressed. Implementation of the policy is futuristic and multi-sectoral.

1.6 The Goal of the Policy

The goal of this Policy is to provide a framework to ensure safety, quality, efficaciousness, effectiveness, and

efficiency in sourcing donations and delivering transfusion and transplant of human derived medical products. It aims to protect Kenyans from exploitation, while promoting equity and ethical access to products of human origin and providing an operational framework for healthcare providers and institutions in the tissue and human organs value chain to operate in. The Policy aims to facilitate attainment of transfusion and transplant self-sufficiency in Kenya. Specific objectives for this Policy are outlined in part 3.

1.7 The Policy in Context of Devolution

Health is a devolved function. The county governments are responsible for health services delivery while the national government is responsible for health policy formulation, management of referral health facilities and capacity building of the counties. In this regard, various responsibilities of the two levels of government with regards to blood, organs, tissue, and stem cells are shared.

02.

SITUATIONAL ANALYSIS OF
BLOOD, CELL, TISSUE AND
HUMAN ORGANS IN KENYA

The evidence adduced in this situational analysis is mainly informed by reports on the assessment on Status of Donation and Transplant of Human Organs and Tissues in Kenya (2017) conducted by the Ministry of Health using World Health Organization standard assessment tools. Other sources are also referenced. The situational analysis provides status of the transfusion and transplant services, legislative and policy environment, institutional arrangements, welfare of donors and recipient.

2.1 The Legislative and Policy Environment

World Health Assembly (WHA) resolution on availability safety and quality of blood products (WHA 63.12) urges members states to take the necessary steps to ensure operation of regulatory authorities. In addition, WHA resolution on human organ and tissue transplant (WHA 57.18) urges member states to implement effective national oversight of procurement, processing and transplant of human cells, tissues, and organs. Over the past years, the Government of Kenya (GoK) has developed constitutional, legal and policy frameworks for enhanced health care of her citizens and for the management of health products that are both manufactured and those derived from humans. These include:

- The Constitution of Kenya: Article 43 of the Constitution of Kenya 2010 on the Bill of Rights guarantees every Kenyan the right to the highest attainable health standards, as a fundamental economic and social right. This includes the right to health care services, such as reproductive health care and emergency medical treatment.
- The Health Act, 2017; Part XI on Human Organs, Human Blood, Blood Products, other Tissues and Gametes requires regulation on matters related to Tissue and Human Organs Transplant (section 84). It further provides for enactment, through Parliament, of the Kenya National Blood Transfusion Service (part 85).
- The Human Tissue Act, Cap 252, 1967 was amended in 2012 and provides limitations for organs removal and use of parts of bodies of deceased persons for therapeutic purposes and medical education.
- The Data Protection Act No. 24 of 2019; Part V, sets grounds for the processing of sensitive information for personal data relating to health, and conditions for transferring data out of Kenya.
- The Kenya Universal Health Coverage Policy 2020 - 2030 provides direction towards protecting the poor and vulnerable, investing in human capital and making progress towards inclusive human development.

- The Kenya Health Policy_2014–2030 aims to harmonize the national regulatory framework for health products and technologies. This framework seeks to advance quality, safety, and efficacy/ effectiveness based on sound science and evidence. The Health Policy highlights the provision of safe and adequate blood, tissue, and organ components as an essential healthcare objective.

2.1.1 An analysis of the implications of the legislative and policy environment

The World Health Organization recommends for member states to strengthen governance and regulatory oversight of standards and products have been adopted variedly. Different jurisdictions have adopted an integrated approach to have a single independent oversight agency or two oversight agencies distinct for transfusion and transplant services. The Health Act 2017 provides for a differentiated approach of governance and thus the need for a coherent approach for regulation of transfusion and transplant services.

The Human Tissue Act 1967 did not envision the medical, legal and ethical complexities of tissue and organ transplants. It does not address the advancements in medicine, society, and technology for the last 50 years and thus, is redundant. It also has no explicit prohibitions, protections or provisions

relating to organ trafficking, import or export of organs for transplant purposes. There are no options for recourse in cases of illegal organ harvesting, or legal consequences for involvement in organ trafficking practices.

The scarcity of certain organs or tissues for donation, and the prohibitive costs associated with transplant service, has the potential to contribute to the exploitation, coercion, or abuse of individuals for the purpose of obtaining an organ or tissue from them. The Kenya Patient Charter 2013 guides clients and patients on their rights and responsibilities thus encouraging demand for quality services. However, without a regulatory system, transplant services are largely accessible only to Kenyans who can afford insurance outside the country. For transplant services done in Kenya, there is no national allocation criteria/scheme to optimize benefits for those most in need. Organ banking in Kenya operates without regulatory and operational framework. There is also no guidance on the coverage of donation costs for living donors.

The existing blood policy developed in 2001 focused on national government as the primary provider of blood, blood components and products. It does not take cognizance of the constitutional delineation of power and roles, which transferred direct patient health care to counties, outside of national referral hospitals. 54% of health care services are provided in the private sector, which also

undertakes blood transfusion services such as collection, facility banking, transfusion and quality control. The Blood Transfusion Service Bill considered these factors, and anticipates that the Service will regulate and superintend blood transfusion services in Kenya.

2.2 Service Need

Blood, blood components and products are critical to health care services. Surgeries in the country require blood availability, which reduces waiting times for surgeries. Chronically ill Kenyans suffering cancers, kidney and other organ failures require regular transfusions during chemotherapy, dialysis or surgery. Access reduces hospitalization periods. Kenya has experienced increased need for blood and blood products due to increased cancer cases, shift in epidemiological patterns, population growth and Road Traffic Accidents (RTAs). The World Health Organization indicates that in 2020, cancer was the third leading of cause of deaths in Kenya. Further, WHO reported that there were 42,000 new cases of cancer in 2020. Cases of blood cancers are on the rise in Kenya, causing an increase in the number patients who need transfusion. Leukemia and Non-Hodgkin's lymphoma are the top two most common blood cancers for children below 18 years (Kenya Cancer Policy ,2020). According to the National Transport and Safety Authority (NTSA) data, 6,938 serious injuries and 5,186 slight injuries were

recorded in 2019. The serious injuries contribute to increased transfusion need and hence increase in demand for blood and blood products. Hemorrhage causes 35% of maternal deaths, thus clawing back the gains being made in reducing maternal deaths through investments in UHC, such as the Linda Mama initiative.

By the end of June 2021, there were 36 blood establishments in the public health sector in Kenya, six (6) of them were testing centers and 30 satellite centers. The centers have traditionally collected less than the annual minimum need of at least 500,000 units¹. To make up for the deficit in the national supply of blood, some health facilities undertake family replacement donations to supplement the supply from the KBTTS. Such blood, if collected under well-regulated conditions, can potentially be factored into the national estimates, as part of planning for the country needs. Blood collection in health facilities is a potential avenue for expanding the national capacity towards transfusion self-sufficiency, but must be organized within standards to protect and promote the health of donors and recipients.

Other tissues and organs are life-saving products without which the intended recipients are likely to die or suffer long-term incapacity. Kidney, heart, liver, lung, pancreas, small bowel, skin, ligaments, bones, and cornea are common vital organs used in transplant.

1 WHO blood need estimates

Transplants through surgical methods, organ preservation, and pharmac-immunologic therapies are essential for management of severe organ failure. Major sources of organs are deceased persons and this often involves medical ethics, religion, society behavior and beliefs for which each country requires clear regulations with enforcement. In particular, matters related to organ trafficking, payments for organs, and the delicate balance in live donations between the benefit to the recipient and the possible harm to the donor and others. Organ transplant is complex and expensive dealing with matching donors, defining death and global shortage of donors.

The need and availability of tissues and organs in Kenya is largely unquantified and unregulated, thus not much information exists. Various data suggest that up to 10,000 Kenyans travel abroad annually in pursuit of medical treatment, spending at least KES10 billion². Those approved through the Ministry of Health for NHIF funding in 2019 were 400 patients, spending up to KES2 Billion according to the Kenya Medical Practitioners and Dentists Council³. The most common reasons for referrals are cancers, heart disease and organ transplants.

In the Global Observatory on Donation and Transplant data repository, Kenya has been reporting only on kidney transplant from related living donors. The highest reported was 77 transplants in 2018. According to the review of policies and programmes for human organ and tissue donations and transplants, WHO African Region (WHO, 2020), financial resources for organ and tissue donations and transplants did not come from public resources, recipients were responsible for paying for post-transplant care and drugs and living donors had to pay for follow-up care.

2.2.1 Institutional arrangements, governance and infrastructure capacities for donation, transfusion, and transplant services in Kenya

The Kenya Blood Transfusion Service (KBTTs) was established in 2000 as a Department in the Ministry of Health. Its mandate is to collect, test, process and distribute blood and blood products to all transfusing hospitals in Kenya. KBTTs operates a national coordinating office and a national testing laboratory in Nairobi, six regional blood transfusion centres (RBTCs)⁴ and 30 satellites in different counties. The service has experienced human resource capital that is the backbone to its success.

2 Kenya sets sights on rising medical tourism sub-sector (pd.co.ke) Thursday, December 26th, 2019; accessed on 20th January 2022

3 <https://kmpdc.go.ke/2021/04/01/forget-the-sparkle-going-abroad-for-treatment-comes-with-many-hidden-costs/>; accessed on 20th January 2022

4 Leukemia and Non-Hodgkin's lymphoma are the top two most common blood cancers for children below 18 years in Kenya (Kenya Cancer Policy, 2020.)

In 2019, the Ministry of Health expanded the mandate of the Department of Blood Transfusion Service to include tissue and human organ transplant. In 2020, the Ministry initiated reforms in the Department to align it with the Health Act, 2017 and the constitutional delineation of health functions. In unbundling health functions, the Transition Authority retained Blood Transfusion Services as a function of National Government in line with the World Health Assembly (WHA) Resolution 63/12, requiring a Coordinated National Blood Service. Kenya is a signatory to this resolution. Blood transfusion to patients is done mostly in hospitals that are under the management of county governments and hence they are the primary consumers of human derived medical products. Thus, a successful blood sufficient ecosystem for Kenya requires the national and county governments to have a common approach for effective and seamless donation, processing, banking, distribution, inventory, transfusion and transplant services.

To build infrastructure capacities for the blood ecosystem, exchequer resources were deployed towards renovations, repairs and serving of blood transfusion satellites and regional centres; procurement of blood processing and banking equipment; and securing the commodities and supply chain system. Service delivery systems including sample referral mechanisms, quality assurance and control, forecasting

and quantification were strengthened. A track and trace national blood management system was developed.

The service delivery results of these investments began bearing fruits in 2021/22. In 2021, 297,796 units of blood were collected, impacting over 280,000 Kenyans. Blood banking capacity was increased by 100% from 24,000 units to 50,000 units. Satellites in 16 of 47 counties have capacity to prepare blood components, including packed red cells, cryoprecipitate, plasma and platelets for cancer, dialysis and burns patients. Four apheresis machines in the public sector increased access to fresh platelets at no cost in comparison to KES30,000-40,000 spent on donation of platelets in the private sector.

While the Health Act 2017 provides for regulation of the human derived medical products, the Department of Blood Transfusion Service does not have the mandate for oversight and enforcement of standards. This makes private and public providers to undertake blood collections, testing and transfusion services without an operational framework and oversight, potentially risking patient's safety.

Tissue and human organ transplant and regenerative medicines are coordinated through the Ministry of Health, Directorate of Health Care Services, and Specialized Clinical Services Unit. There are six operational kidney transplant centres and cornea transplant facilities.

However, there is no centre for liver, heart, lung, pancreas and small bowel transplant. The lack of a legislative and policy framework, regulatory standards with necessary protections for donors, facilities and health care providers contributes to the increased number of Kenyans seeking medical treatment abroad. Mandate to enforce compliance with regulations could safeguard against this capital flight.

The coordination of transplant services in health facilities is not linked to a coordination donation approach, banking and allocation system. Illegal organ harvesting and trafficking of persons for organ has been raised by the United Nations as a matter of global concern and has been highlighted in local media. Kenya has no institution with powers of entry, inspection and search of premises or facilities believed to be used in conducting unlawful human bio-medical research or tissue harvesting and banking activities.

2.2.2 Socio-cultural enablers and barriers to donation, transfusion, and transplant services

The culture of donating blood and organs in Kenya has been associated with catastrophic events. After national disasters such as terror attacks, fire and traffic accidents, needy families, friends and colleagues of victims often appeal for individual donations. Some communities in Kenya have positive

organ donation practices, leading to establishment of private organ banks such as cornea banks. Conversely, varied cultural and religious beliefs hamper blood donations, and especially organ donations from living persons or deceased bodies. Acceptability of transfusion, and transplant services in some communities is also influenced by cultural and religious beliefs regarding medical interventions. The creation of long-term pools of regular donors among citizens is a requirement for sufficiency in blood, tissues and organs. Such efforts require an institution with mandate for standardized communication, development of targeted, culture and age specific health communication package and non-remunerated incentive systems for donors.

2.2.3 Quality standards for blood, tissues, and organs

The Kenya Blood Transfusion and Transplant Service (KBTTTS) has instituted internal arrangements to ensure that the blood collected in KBTTTS centres, and the blood components processed by KBTTTS from such blood, are safe and of assured quality. However, there is no documentation system, regulatory mechanism or mandated institution to ensure that blood collected in health facilities is tested in a quality assured manner for all potential Transfusion Transmitted Infections (TTIs), and that it meets all the requirements for quality and safety.

The quality of blood is assured through various quality control requirements. Blood component preparation and testing laboratories are regulated by the Kenya Medical Laboratory Technologists and Technicians Board and are required to gain accreditation status. Service providers, including nurses and medical officers, are regulated by the Nursing Council and Kenya Medical Practitioners and Dentists Council. National standards for blood processing, cold chain management, banking, transport and hemovigilance are intended to provide regulations for the blood ecosystem. However, these require review and updating. The national medicines regulatory body, the Pharmacy and Poisons Board, has a legal mandate for regulation of blood products in line with good manufacturing practice requirements. There is External Quality Assurance (EQA) schemes for blood but there is none for tissues and organs. Kenya does not have registries for accountability and quality of private and public transfusion and transplant facilities and transplant services providers. Current gaps exist in a comprehensive Quality Management System for tissues and organs services.

A national scheme for organ matching and allocation based on a well-defined criterion is essential for fair, ethical and equitable allocation

2.2.4 Ethical and equitable allocation of blood, tissues, and organs

Kenya does not have an accountability system with unique identification and traceability of each organ donor or recipient.

A national scheme for organ matching and allocation based on a well-defined criterion is essential for fair, ethical and equitable allocation. It must link registries of donors, recipients, providers, transplant facilities and banks. The registries must also ensure the unique identification of post-transplant traceability of living donors of solid organs (kidney, liver, heart, lung, and pancreas). There is no mandate or mechanism in Kenya to manage such a scheme.

While blood is more readily available, an effective blood ecosystem must be based on availability of blood by type, component and matched to need. Currently, systems and data to granulate blood needs as per epidemiological patterns, such as to counties with high prevalence of maternal mortality rates, trauma due to road accidents or high rates of anemia are not in place. Bio-data and tissue samples collected from Kenyans are of national security interest. This is because bio-data and bio-samples are the foundation of pharmaceutical technologies and also bio-weapons. The development of a blood and organs Management Information System as part

of the Digital Health Platform is essential to ensure security of these data in line with the Data Protection Act through an institution with the relevant mandate.

2.2.5 Costs related to organ and tissue transplant services

The costs for transfusion and transplant services are not regulated and hence there is variability of costs to patients.

The goal of Universal Health Coverage is to provide financial cushion when seeking health care for all Kenyans and mitigate catastrophic expenditures. Currently, the costs for patients for tissue and organ transplant services are prohibitive to those without medical insurance. State insurance through the National Health Insurance Fund (NHIF) has been enhanced to cover transplants both locally and abroad. The NHIF covers up to KES700,000.00 for kidney transplant locally and up to KES 1 million abroad, according to 2021 rates. Post-transplant care is at the cost of the donor and recipient. The living organ donors pay for all interventions (diagnostic, drugs and surgery) derived from the transplant and follow-up care.

At policy level, cooperation frameworks have been used by countries or hospitals to make transplant arrangements more accessible. Currently, Kenyans without insurance pay for their own costs, the costs of organ donors, and their follow-up medical costs upon return.

There is no costing framework of donations, transfusion and transplant services in Kenya. This leads to exploitation and exorbitant costs to the patients.

2.2.6 Vigilance for adverse events following donation, transfusion, or transplant

The vigilance system for reporting of adverse events in donation, transfusion and transplant is not well structured. Haemovigilance reporting in the country is low and uncoordinated hence need for more sensitization to health care providers. There is no well-defined system for reporting of adverse incidents following transplant. The practice of transplant continues and thus the safety of donors and efficaciousness of organs transplanted is unmonitored without organo vigilance mechanisms to report and act on adverse events.

2.2.7 National contingency planning mechanism

The lack of dedicated institutional responsibility and mechanism for command leads to inefficiencies in deployment of daily emergency response mechanisms and response in the context of national emergencies. COVID-19 has adversely affected blood system activities in many countries. Following the pandemic, Kenya developed an Interim Guidance for Blood Management IntraCOVID-19 in January 2021 that has been applied. However, Kenya has not had

an emergency preparedness plan with a coordinated deployment system for blood or organ emergencies. This has been experienced in previous terror attacks.

2.2.8 Supply chain systems and information management

The supply chain system in the blood ecosystem varied health products and technologies (HPTs) required for input supply, including commodities and supplies for collection, processing, testing, grouping, storage and transportation. Output supply chain includes distribution, stocking and use to safe products for transfusion and transplant. These supply chains in Kenya remain largely ill-defined, unquantified and unlinked. Both generic and granulated estimations are lacking and the commodity information flow, logistics parameters and national quantification systems are not in place,

therefore causing stock outs. Granulated clinical and inventory blood needs by facility, age, sex and geographic location are unknown, thus product stocking and management is constrained. An information management system that can provide real-time data on availability of MPH is urgently required.

2.2.9 Coordination between two levels of government and private sector

There is no well-defined and coordinated engagement between the central government through KBTTS and county governments in management of blood and blood products. Some of the private sector players conduct transfusion and transplant services in inadequate operational and regulatory framework. There is need to have a regulatory framework which assures quality and corrective actions enforcement.



03.

POLICY OBJECTIVES AND
STRATEGIES

This Policy recognizes blood, tissue and human organs as national resources that should be allocated equitably and safely delivered to all Kenyans when and where they need them. This necessitates an enabling operating environment, a functional regulatory and quality oversight framework. The Policy covers the following objective areas and strategies:

3.1 Policy Objective 1: Establish a coherent legislative, governance, regulatory and management framework for accountability and equitable access to blood, stem cells, tissue, and organs

Strategies

- (i) There shall be legislation to mandate semi-autonomous governance and management of blood, tissues and organs, transfusion and transplant services.
- (ii) There shall be mechanisms to ensure equitable access of blood, cells, tissues, and organs to all in need.
- (iii) In line with the Health Act 2017, the mandate of the Department of Kenya Blood Transfusion and Transplant Service shall be expanded to include regulation and oversight of human-derived medical products.
- (iv) There shall be a national tissue and organs allocation scheme that shall be reviewed regularly.
- (v) There shall be regulations and standards for safety, processes and practice for blood, tissues and organs services, service providers, facilities and establishments.
- (vi) There shall be national guidelines to guide different transplant services.
- (vii) There shall be criteria for the approval of organ transplant activities in compliance with the Health Act 2017.
- (viii) There shall be systems for registration, licensure and accreditation of transfusion and transplant services, establishments, facilities and providers as appropriate.
- (ix) There shall be up-to-date national registries of transfusion donors and establishments.
- (x) There shall be up-to-date national registries of transplant service providers, facilities and establishments and donors.
- (xi) Transfusion and transplant facilities and establishments in the Republic of Kenya shall register with the prescribed national information management system.

- (xii) There shall be implemented, by the mandated agency, a track and trace system for accountability of blood, tissue and organs for Kenya.
- (xiii) Infrastructure to ensure bio-security protection, control, and accountability for Valuable Biological Materials (VBM) shall be maintained.
- (xiv) There shall be an agency with the power to enter, search and inspect places suspected of unauthorized removal, procurement or transplant activities.
- (xv) There shall be application of systems that adopt international best practices in donation, transfusion, and transplant services.
- (xvi) A legislative action shall be undertaken to address the gaps in Human Tissues Act, 1966.

3.2 Policy Objective 2: To ensure safety of donors and recipients of human-derived medical products

Strategies

- (i) There shall be regulations on donation processes and practices in transfusion and transplant services.
- (ii) There shall be guidelines for donor safety and management in transfusion and transplant services.
- (iii) There shall be assessments and promotion of adherence to the regulations and national guidelines in all transfusion and transplant establishments and services.
- (iv) There shall be regulations on donations of human derived medical products in conformity with the Health Act 2017.



- (v) There shall be formation of hospital transfusion and transplant committees to coordinate the appropriate use of blood, cells, organs, and tissues and undertake hemo and organ vigilance reporting.
- (vi) There shall be oversight on implementation of guidelines on selection, compatibility and matching for donor organ eligibility.
- (vii) There shall be legislation and regulations to protect vulnerable groups and individuals from coerced and involuntary donation of blood, tissue, and organs.
- (viii) There shall be a transfusion and transplant appeals tribunal to offer recourse on unlawful or coerced donation practices.
- (ix) There shall be code of practice and ethics for donations, transfusion, and transplant services.
- (x) There shall be oversight and compliance mechanisms for the implementation of appropriate counselling, notification, and referral procedures nationally.
- (xi) There shall be donor registries for blood, cells, tissues, and organs.

3.3 Policy Objective 3: Ensure safety and efficacy of donations, transfusion, and transplant services

Strategies

- (i) There shall be registration, licensure and certification of transfusion and transplant services and establishments as appropriate.
- (ii) There shall be guidelines for hemovigilance, cell and tissue vigilance and organ vigilance implementation and reporting.
- (iii) There shall be oversight and compliance requirements and mechanism for hemovigilance and organovigilance requirements in transfusion and transplant services and facilities.
- (iv) Quality Assurance (QA) scheme for donations, testing, processing, banking, distribution of human derived medical products shall be developed, implemented and sustained in transfusion, and transplant establishments and services.
- (v) There shall be standards for quality management systems for donations, transfusion, and transplant services.

- (vi) There shall be a mechanism to enforce implementation of quality management standards.
 - (vii) There shall be standards and regulations for services, processes, and products related to transfusion and transplant, and a mechanism to enforce compliance in the Republic of Kenya.
 - (viii) Blood, cell, tissue, and organ establishments and services shall enroll to global and regional recognized certification and accreditation.
 - (ix) There shall be guidelines for management of blood, cells, tissue, and organs.
- (iii) There shall be implemented, national communications and culture adoption campaigns to promote routine and regular donations of blood, cells, tissues and organs.
 - (iv) There shall be central mechanisms and networks for coordination and distribution of available blood, cells, tissues and organs across Kenya.
 - (v) A national forecasting and quantification statement of clinical and inventory needs for blood, cells tissues, and organs across all levels shall be maintained.
 - (vi) Capacity of testing laboratories and blood banks to include cells, tissues and organ compatibility matching, storage, and handling shall be enhanced.

**3.4 Policy Objective 4:
Promote and educate, on a nationalistic and humanistic approach that enhances donation and access of blood, cells, tissues, and organs**

Strategies

- (i) Access to blood, cells, tissues, and organs as a national resource for all Kenyans shall be maintained.
- (ii) There shall be development of a national communication plan and dissemination of targeted information, education, and
- (iii) There shall be a national tissue and organ allocation criteria/ scheme that shall be regularly reviewed.
- (iv) A regularly updated blood, cells, tissues, and organs emergency preparedness and response plan that provides contingency measures shall be maintained.

- (ix) Implementation of donor mobilization and recruitment strategies for blood, cells, tissues, and organs donors shall be ensured.

3.5 Policy Objective 5: To provide a financial framework for donation, transfusion, and transplant services for all Kenyans

Strategies:

- (i) There shall be provision of budgetary allocation from exchequer to finance the functions related to regulation, oversight and service delivery for transfusion and transplant.
- (ii) There shall be regular published and gazetted costing framework that provides reference for costing of blood, cells, tissues and organs services.
- (iii) There shall be a financing framework between the mandated institution providing support services and private health care providers.
- (iv) Private public partnerships that strengthen self-sufficiency in human derived medical products and services shall be promoted.
- (v) There shall be multi-pronged financing strategies of blood, cells, tissues, and organs services beyond the exchequer.

3.6 Policy Objective 6: Establish a framework for an efficient and stable supply chain that ensures security for laboratory and medical commodities for collection, manufacturing, processing, testing, banking, transportation and distribution of blood, cells, tissues, and organs

Strategies:

- (i) Annual national forecasts and quantification for sufficient commodities for transfusion and transplant services shall be maintained.
- (ii) There shall be guidelines for quality assurance for laboratory and medical commodities required for collection, processing, testing, transfusion, and transplant services.
- (iii) There shall be guidelines on inventory management for laboratory and medical commodities required for collection, processing, testing, transfusion, and transplant services.
- (iv) There shall be guidelines for safe disposal of expired and damaged laboratory and medical commodities as well as blood, tissues and organs.

- (v) There shall be routine review and inclusion of laboratory and medical commodities and supplies required for collection, processing, testing, transfusion, and transplant services in the national essential medicines and medical supplies list.
- (vi) Procurement, availability, accountability, proper storage of laboratory and medical commodities required for collection, processing, testing, transfusion, and transplant services shall be ensured for the public sector.
- (vii) There shall be accurate and timely collection and reporting of logistic data by all service points.
- (viii) Manufacture of reagents and consumables required for processing and screening of blood, cells, tissues and organs shall be promoted.



3.7 Policy Objective 7: To establish and build capacity of human resource for blood, cells, tissues, and organs transplant regulation, management, and service delivery

guidelines for donation, processing, testing, banking, transportation, transfusion, and transplant.

3.8 Policy Objective 8: To define and clarify the role and linkages of national and county government, private sector, and faith-based organizations

Strategies:

- (i) There shall be guidelines for human resources for blood, cells, tissues, and organs establishments.
- (ii) Collaboration framework with the relevant professional associations, boards and organizations shall be adopted to continuously improve pre- and in-service transfusion and transplant knowledge and training.
- (iii) Collaboration framework with higher education institutions and medical colleges shall be advanced to standardize and update transfusion and transplant medicine and science as subjects in existing health courses.
- (iv) A capacity building framework shall be maintained and continuously implemented to strengthen transfusion and transplant services.
- (v) There shall be partnerships with relevant stakeholders in oversight of human resource, to ensure adherence to the national code of practice and ethics, and clinical

Strategies:

- (i) There shall be guidance to define and facilitate the role of non-state actors including the private, faith-based, and non-government stakeholders in transfusion and transplant services, aligned with the Health Sector Coordination Framework 2019.
- (ii) There shall be a mechanism to maintain formal engagements with counties for coordination of transfusion and transplant services as may be relevant to ensure equitable access, uninterrupted supply chain, and countrywide access to safe and quality blood, tissues, and organs.
- (iii) Counties shall appoint the County Blood Transfusion Coordinators (CBTC) to coordinate transfusion services.
- (iv) Coordination mechanisms in line with the Health Sector Partnership Framework with regulators,

specialist associations, patient groups, and stakeholder groups will be promoted.

- (v) A multi-sectoral collaboration and mechanisms of engagement with private, civil society and faith-based players to create a viable ecosystem for blood, cells, tissues and organs services will be promoted.
- (vi) There shall be joint committee between the national and county governments to oversee the implementation of this policy as per the Health Sector Intergovernmental Consultative Forum (HSICF).

3.9 Policy Objective 9: Contribute and apply scientific evidence from surveillance, monitoring and evaluation and research to inform policy, practice, and technical advances in blood transfusion, cells, tissues, and organs transplant

Strategies:

- (i) There shall be national data management information systems for transfusion and transplant services that shall comply with the Data Protection Act 2019.

- (ii) National Strategic Plans for transfusion and transplant services shall be developed, and implementation monitored.

- (iii) There shall be national blood transfusion monitoring and evaluation systems with regular tracking of progress.

- (iv) There shall be national organ transplant monitoring and evaluation systems with regular tracking of progress.

- (v) Reporting requirements for blood, tissue and organs donation, transfusion, and transplant services in Kenya shall be defined and disseminated by relevant bodies as required.

- (vi) All facilities and establishments undertaking transfusion or transplant services shall adhere to established national requirements on monitoring and evaluation guidance.

- (vii) Mechanisms to utilize monitoring and surveillance data for decision making shall be established and shared with stakeholders.

- (viii) A research agenda shall be developed by the transfusion and transplant agency in conformity with national research regulations.

- (ix) The national reporting mechanism and system for donations, transfusion, and transplant services shall be linked to national health data repositories and platforms and comply with the requirements of the Data Protection Act 2019.
- (iv) There shall be a robust framework for collaboration with other countries for exchange of technology, medical products of human origin, tissues, and organs.

**3.10 Policy Objective 10:
Transform Kenya into a self-sufficient centre of excellence in blood, cells, tissue and organ services and products**

- (i) There shall be established a funded national blood risk management and emergency contingency and deployment plan.
- (ii) There shall be established a strategic reserves bank for blood components and products.
- (iii) Reference laboratories that meet global standards on blood, cells, tissues, and organs shall be established.
- (v) There shall be established agreed reciprocal arrangements with other established organ exchange organizations globally for the exchange of human derived medical products where appropriate.
- (vi) There shall be established capacity for production of medical products and byproducts of human origin for use in advanced life saving interventions, research and teaching purposes accessible to Kenya and the African region.
- (vii) There shall be established secure and safe banking for tissues, cells and organs and valuable biological material of human origin.

04.

GOVERNANCE AND
IMPLEMENTATION
FRAMEWORK

4.1 Shared functions and assigned roles of National and County Governments

National Government Agency on Transfusion & Transplant	County Government	Transfusing and Transplant Facilities
<p>Policy and Regulations</p> <ul style="list-style-type: none"> • Develop policy, standards and guidelines. • Regulations. • Quantification. • Emergency preparedness & response. • Oversight, licensure, registration, certification. • Monitor and enforce compliance within regulations. <p>Technical Support and Capacity Building</p> <ul style="list-style-type: none"> • Blood: Blood testing, re-distribution, and banking. • Organs: National Organs allocation scheme; banking & transportation. • National Information Management System. • Hemovigilance and organovigilance. • National Quality Management Systems (QMS). • Capacity building system 	<p>Manage donations, transfusion, and transplant services</p> <ul style="list-style-type: none"> • Guide implementation of services for blood donation drives. • Maintain the structures and standards of blood (and where applicable) cell, tissue, and organ establishments. • Guide in local mobilization for blood donations. • Oversee the transfusion services and where applicable transplant services within the county. • Undertake Blood testing as per national standards. <p>National Standards</p> <ul style="list-style-type: none"> • Enforce compliance of national standards in public, private and FBOs transfusing and facilities within the county. • Sign onto the national Blood (and organs) management information system. • Share blood, tissue, and organs as a national resource. 	<p>Manage donations, transfusion, and transplant services</p> <ul style="list-style-type: none"> • Implement services for blood donation drives. • Maintain the structures and standards of blood, cell, tissue, and organ establishments. • Undertake local mobilization for blood, (and where applicable, for cell, tissues, and organs collection within standards. <p>National Standards</p> <ul style="list-style-type: none"> • Comply with National standards and regulations. • Sign onto the national Blood (and organs) management information system. • Share blood, tissue, and organs as a national resource.

National Government Agency on Transfusion & Transplant	County Government	Transfusing and Transplant Facilities
<ul style="list-style-type: none"> • Key supplies: Supply of blood bags and reagents. • Support to equipment (on agreed plans). <p>Collaborate and support National Government Hospitals in Transfusion and Transplant Services.</p>	<p>Human Resource</p> <ul style="list-style-type: none"> • Provide the adequate human resource in donation, transfusion, and transplant centers. <p>Requests and Reports</p> <ul style="list-style-type: none"> • Submit requests and reports to relevant national agency. 	<p>Human Resource</p> <ul style="list-style-type: none"> • Provide the adequate human resource in donation, transfusion, and transplant centers. <p>Requests and Reports</p> <ul style="list-style-type: none"> • Submit requests and reports to relevant national agency and counties.

4.2 Establishment of Regulatory and Oversight Body

The national government shall comply with the Health Act 2017 and establish, by legislation, semi-autonomous government-owned entity or entities to regulate, oversight and enforce compliance on matters relating to transfusion and transplant services. This entity/entities shall be within the national Ministry of Health, for the purposes of performing the Ministry’s strategic function relating to promoting and securing the effective coordination, oversight, and regulation of ethical and lawful sourcing, equitable supply and use of safe and quality human-derived medical products in the Republic of Kenya.

4.3 Transition Mechanism into the Policy Regime

Existing guidelines and regulations relating to blood, cells, tissues, organs, and other medical products of human origin will remain in force and shall be revised to conform to this policy. New guidelines shall be issued by implementing institutions as and when need arises to operationalize this policy. Such guidelines shall take into consideration the principles of this policy.

4.4 Policy Review

This policy will be reviewed every five years, or any other period as shall be determined by MOH in collaboration with county governments and other relevant stakeholders.

05.

ANNEXES

5.1 Schedule of Meetings for Development of Kenya Policy on Donation, Transfusion and Transplant of Human Derived Medical Products

Date	Name of the Meeting
October 2017	Blood, transfusion, and organ transplantation Technical Working Group (TWG).
October 2020	Review of draft Blood policy.
8 th December 2020	Blood donation Intra COVID-19.
17 th December 2020	Consultative meeting with County Executive Committee (CEC)Members of Health.
22 nd December 2020	Blood policy inaugural meeting.
13 th May 2021	Internal review meeting with KBTTS managers.
19 th May 2021	1 st Stakeholders review meeting.
19 th May 2021	1 st Partners review meeting.
26 th May 2021	2 nd Partners review meeting.
26 th May 2021	2 nd Stakeholders review meeting.
9 th June 2021	Consultative meeting with County Directors of Health (CDH), County Blood Transfusion Coordinators (CBTC) and Council of Governors (CoG).
26 th June 2021	Consultative meeting with County Executive Committee Members of Health(CECM) and Council of Governors (CoG).
14 th September 2021	Presentation of the policy document to the Ministry of Health (MoH) departmental meeting.

5.2 Schedule of Meetings for Validation of Kenya Policy on Donation, Transfusion and Transplant of Human Derived Medical Products

Date	Name of the Meeting
29 th September 2021	Consultative validation meeting with stakeholders and partners.
7 th October 2021	Consultative validation meeting on policy with Faith Based Communities (Christian Health Association of Kenya (CHAK), Supreme Council of Kenya Muslims (SUPKEM) and Kenya Conference of Catholic Bishops (KCCB).
25 th and 26 th October 2021	Consultative validation meeting on policy with County Blood Transfusion Coordinators (CBTC).
4 th and 5 th November 2021	Consultative validation meeting on policy with County Directors of Health (CDH).
11-12 th November 2021	Validation meeting on policy with County Executive Committee Members (CECM) of Health and Council of Governors (CoG).
18 th November 2021	Final validation meeting of the policy with County Executive Committee Members (CECM) of Health Caucus and Council of Governors (CoG).

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