

Has name of organisation

Committee of Blood Donation and Transfusion Stakeholders

POLICY BRIEF

Dated

31 May 2019

Title starts with positive outcome

Advancing health through safe and sustainable blood transfusion

Highlight box is good way to give quick summary

Highlights

Kenya needs to improve its supply of safe blood in order to save lives.

The World Health Assembly, in which Kenya is a participant, recommends the creation of national blood transfusion services.

The Ministry of Health is committed to developing a well-coordinated blood transfusion service.

A National Blood Transfusion Service was established in 2001 but has no statutory basis.

The Health Act 2017 requires further legislation to enshrine in statute the National Blood Transfusion Service.

The Committee of Blood Donation and Transfusion Stakeholders has prepared draft legislation. The Chair of the Parliamentary Committee for Health is keen to progress the adoption of this legislation promptly.

Introduction

Blood is a valuable resource and hence limited, exhaustible and costly. In clinical practice, blood transfusion is not a replaceable support; blood transfusion carries immense benefits, but also significant risks, including transfusion of transmissible infections. This is why blood needs careful management at national level to ensure its safety and availability.

In 2001, the Ministry of Health (MoH) committed itself to develop a comprehensive and well-coordinated blood transfusion service through the development of Policy Guidelines on Blood Transfusion.¹ The policy set out provisions to ensure adequate supply of blood based on a voluntary, non-remunerated blood donation system following a World Health Assembly resolution.² Key strategies in the policy guidelines include:

- ♦ The enactment of legislation providing a legal framework for the running of a national blood transfusion service;
- ♦ The phased removal of hospital-based

¹Ministry of Health (2001). Policy Guidelines on Blood Transfusion in Kenya, 2001.

²WHA.28.72 of 1975.

- blood bank systems; and
- ◆ the development of a National Blood Transfusion Service (NTBS) with regional and zonal blood transfusion centres.

The access to safe blood is predicated on the right to health, as stated in Articles 43 and 21(4) of the Constitution. Moreover, section 85 of the Health Act, 2017 provides for the enshrining in law of the Kenya National Blood Transfusion Service to:

- ◆ Develop comprehensive and coordinated national blood transfusion services;
- ◆ Guarantee the availability of adequate and safe blood in the country; and
- ◆ Establish settings and mechanisms that will enable the service to superintend and regulate the provision of blood services in the country.

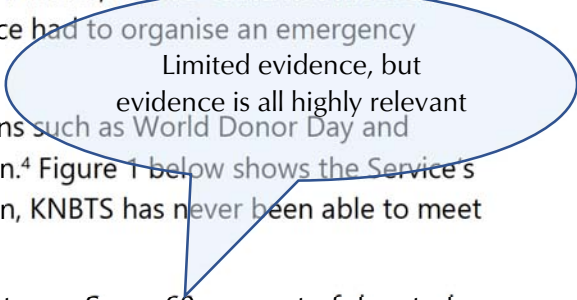
To date, however, no legislation has been enacted. However, following the adoption of the Health Act, a Committee of Blood Donation and Transfusion Stakeholders (CBDTS) developed a draft legislation which seeks to provide for the regulation of blood donation, blood and blood products safety and use. The chair of the Parliamentary Health Committee is now seeking to ensure that legislators support the passage of this legislation.

The demand for blood

The Kenya National Blood Transfusion service (KNBTS) was established in 2000 following the terrorist attack on the US Embassy. It operates as a division within the Department of Diagnostic and Forensic Service (DDFS) in the Ministry of Health. Its mandate is to provide access to adequate and safe blood, through the creation of a strong, efficient and self-sustaining national blood transfusion service. However, KNBTS has struggled to ensure the provision of safe and adequate blood in the country, due to lack of funding, systems and an organised way of collecting blood. For example, in the recent Dusit Complex attack, KNBTS could not meet the demand for blood for victims and survivors and the Service had to organise an emergency blood drive to meet the demand.

The Service relies heavily on school children³ and occasions such as World Donor Day and Valentine's Day to create awareness about blood donation.⁴ Figure 1 below shows the Service's blood collection compared to the demand. As can be seen, KNBTS has never been able to meet the demand for blood.

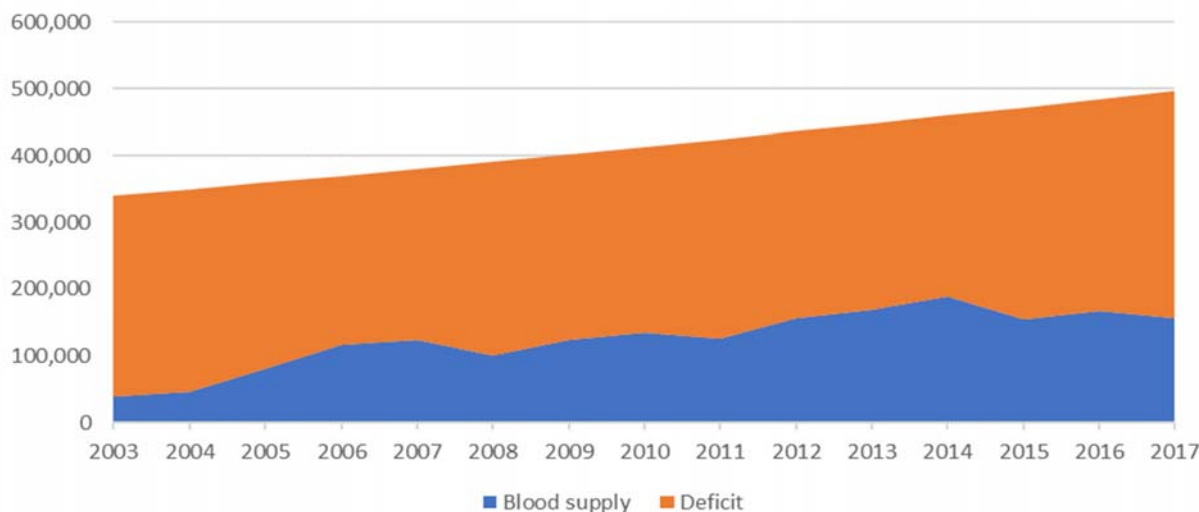
Women and children are the most affected by blood shortages. Some 60 per cent of donated blood is required by women and children for birth-related needs.⁵ Furthermore, MoH explains that 40 per cent of maternal deaths are due to obstetric haemorrhage.⁶ Other individuals



³ The standard (2019) Make blood donation and transfusion transparent and easy for Kenyans accessed at <https://bit.ly/2UKNwR8>
⁴ Daily Nation (2019). Let Us develop a culture of donating blood <https://bit.ly/2GaMxBT>
⁵ Daily Nation (2018). Running Low. The Story of Kenya's blood Bank. Accessed at <https://bit.ly/2JG3Sln>
⁶ Republic of Kenya (2017). Saving Mothers Lives 2017, First Confidential Report into Maternal Deaths in Kenya.

affected include those with non-communicable diseases such as cancer, anaemia, kidney or liver ailments, survivors of road accidents and those with medical emergencies.⁷

Figure 1: KNTBS blood demand & supply



Source: CBDTS computations with population data from World Bank Development Indicators and KNBTS data on blood supply

Challenges faced by KNBTS

Lack of legislation to guide the functions of KNBTS has resulted in:

- ◆ KNBTS operating in a limited way as a division within the Department of Diagnostic and Forensic Service (DDFS) despite having a nationwide responsibility;
- ◆ Limited funding from the government⁸ and thus an over-reliance on donor funding to meet the high cost of producing blood which averages at KShs 7,500 per unit.⁹
- ◆ Lack of clarity in the governance of the national blood transfusion. Some county governments such as Kakamega¹⁰ have established their own independent blood transfusion services contrary to the provisions of the Constitution and Executive Order No.1 of 2018 which puts the governance of blood under the national government. Running blood banks by county governments is likely to compromise the quality of blood as testing, processing and storage standards may not be assured.
- ◆ An inefficient national service and thus an inability to ensure the availability of safe blood and blood products to mitigate unforeseen events whenever they happen, and in whichever part of the country they occur.

⁷ Daily Nation (2018). How lack of blood for transfusion is killing women as they give birth <https://bit.ly/2BcjMEo>
⁸ Republic of Kenya (2018). Health Sector Working Group Report.
⁹ Empty blood Banks: Hospital, patients resort to black market and donors. Accessed at: <https://bit.ly/2V0QLnF>
¹⁰ Republic of Kenya (2018). Kakamega County integrated development plan (2018-2022). <https://bit.ly/2ZCp04g>

These challenges have hindered KNBTS from meeting the clinical demand for blood and blood products.^{11,12} Consequently, some medical facilities have been forced to rely on family or family replacement donors¹³ contrary to WHO recommendations that all blood donors should be voluntary and non-remunerated.

The use of family replacement donors constitutes a safety risk since such donors have been shown to have a higher rate of transfusion transmissible infections.¹⁴ Additionally, blood collected in health facilities may not undergo stringent quality testing as required by ISO 15189¹⁵ further compromising safety.¹⁶

Legislating with organs and tissue

The Ministry of Health is working on a Bill which proposes to merge the regulation of organ and tissue donation with the regulation of blood transfusion services. Whilst the World Health Assembly (WHA) requires member states to take national level responsibility to ensure self-sufficiency in blood and blood products,¹⁷ and in organ and tissue transplants,¹⁸ it does not insist on a joint administration of blood and organs.

Good reasoning

While blood transfusion and organ donation services are similar in terms of dependence on professional expertise, medical suitability of donors and recipients and the willingness of donors to donate, they differ in various ways. For example, in blood transfusion, blood is donated by living donors while organs can be given by both living and deceased donors. Blood can be refrigerated and stored for up to six weeks, but organs can only be preserved for a much shorter period. A heart or lung, for example, can be kept viable for only six hours, a pancreas or liver for 12 hours and kidneys for less than 36 hours.¹⁹ Moreover, in Kenya, the only organs that are currently transplanted are corneas and kidneys. The transplant of corneas is quite common but is already covered by the Tissue Act. There is barely one kidney transplant every three months.

The difference in viability of blood and organs reinforces the need for different regulations. Furthermore, given that both require different processing procedures, there is a need for

Well referenced

¹¹ The national annual blood need is estimated at 400,000 units. In 2016, KNBTS collected 167,100 units from voluntary non-remunerated blood donors meeting 42% of the country's blood need

¹² How Kenya's largest network of blood donors (Kenya National Blood Transfusion Service) built the capability to hit consistent donor targets year after year. Accessed via <https://bit.ly/2BcjMEo>

¹³ A donor who gives blood because a family member or friend needs blood

¹⁴ Kimani et al. (2011). Blood donors in Kenya: a comparison of voluntary and family replacement donors based on a population-based survey. *VoxSanguinis*. DOI: 10.1111/j.1423-0410.2010.01376.

¹⁵ ISO 15189 is the major standard for accreditation of blood transfusion institutions globally.

¹⁶ Allain, J. P. (2011). Moving on from voluntary non-remunerated donors: who is the best blood donor? *British Journal of Haematology*, 154 (6), 763-769.

¹⁷ World Health Assembly Resolution 28.72

¹⁸ World Health Assembly Resolution 63.22

¹⁹ Solheim, J. (2016). *Emergency Nursing: The Profession, The Pathway, The Practice*. Sigma Theta Tau.

Compares approach in other countries

Uses existing legislation to make case

different legislative frameworks to ensure adequate funding, increased donation, ethical procedures and practices, safety and optimal patient care as provided for in the Health Act.

This separation was in fact recognised in the Health Act: sections 80 to 84 of the Act which makes specific provisions relating to human organs and tissues. Section 80(3) specifically gives the Cabinet Secretary the mandate to make regulations (but does not call for further legislation) providing for organ transplant. Section 85, however, calls for an Act of Parliament to establish the Kenya National Blood Transfusion Service and gives it specific mandate regarding blood.

International best practice supports the separation of oversight and regulation of blood transfusion services from organ and tissue donation. In South Africa, for example, the National Health Act makes general provisions for control and use of both blood, blood products, tissue and gametes in humans and the transplantation of tissues and organs from one person to another. Notably, the Act provides for the establishment of a distinct institution to regulate blood donation and transfusion services only. Moreover, the regulation of tissue and organ donation and transplantation is regulated by the Health Act and other health related law without the establishment of a distinct institution.²⁰

While the United Kingdom has a national body that is responsible for providing blood, organs and associated services to the National Health Service,²¹ the regulation of blood and organs is conducted separately. Blood is regulated under Blood Safety and Quality Regulations 2005 and organs are regulated under the Human Tissue Act, 2004.

Conclusion

The provision of timely, affordable access to screened blood depends greatly on three key aspects: adequate volume of blood supply, safe protocols for blood donation and transfusion, and appropriate regulation to ensure safe, equitable and sustainable distribution.

The draft Kenya National Blood Transfusion Service (KNBTS) Bill proposes strengthened coordination, a specific mandate, structure and governance mechanisms for blood transfusion in addition to strengthening links to County health care systems. It strives to ensure adequate funding and sustainability of blood services in the country while safeguarding the quality and adequacy of blood, blood components and related products.

The proposed Bill ensures the establishment of KNBTS as a state entity with the sole responsibility to regulate and co-ordinate blood transfusion services in Kenya. The set-up is important since national government has direct responsibility for collecting, screening, testing and distributing blood and thus there is a need for a service institution. The set-up also ensures

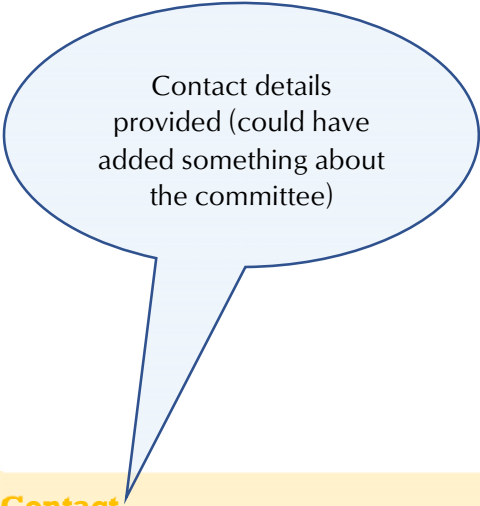
²⁰ Pepper, M. S., & Slabbert, M. N. (2015). Human tissue legislation in South Africa: Focus on stem cell research and therapy. *South African Journal of Bioethics and Law*, 8(2), 4-11.

²¹ NHS Blood and Transplant (Gwaed a Thrawsblaniadau'r GIG) (Wales) Directions 2005

that the blood transfusion service is regulated as a public good in accordance with global standards.

The separation of organs and blood donation is important because the mandate of government differs in the two issues. Organ donation, screening, harvesting and transplantation is carried out by individual hospitals. Therefore, the Ministry of Health only needs to provide for regulations for organ and tissue transplantation as provided for in Section 80(3) of the Health Act which can be anchored under the Human Tissue Act, 2004.

This briefing note – and the fact that blood and blood products are listed as essential medicine in the Kenya Essential Medicine List (KEML), 2016 – demonstrate the need to promote its availability and accessibility. The Committee of Blood Donation and Transfusion Stakeholders therefore encourages legislators to support the draft legislation. Access to adequate and safe blood is a core component of the right to health and necessary to attain universal health coverage.



Contact details
provided (could have
added something about
the committee)

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