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Memorandum on the Proposed Bill for an Act to Establish National Blood Service Commission to Coordinate, Regulate and Ensure the Provision of Quality Blood and Blood Products and Related Matters (HB. 181) in Nigeria.

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Preamble

One of the greatest challenges associated with blood transfusion service delivery in Nigeria is accessing safe and adequate supply of blood and blood products. Effective blood transfusion is the right blood, transfused in the right quantity, quality, right condition, at the right time for the right clinical indication. The collection, manufacturing and distribution of blood products and its products are facilitated by Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP) with responsibilities of a qualified trained Medical Laboratory Scientists, competent nurses and medical staffs for effective co-ordination of the Transfusion establishment.

Blood transfusion is an essential component of effective healthcare delivery and has life saving potential. Timely access to the right quantity and quality of blood and blood products is a life saving measure in most clinical conditions. Every second somebody in Nigeria desperately need blood and blood products for surgery, trauma, nutritional anaemia, anaemia of chronic disease, haematological malignancies, haemoglobinopathies, malaria as well as complications associated with pregnancy. Access to safe and adequate blood and blood products remains a mirage in Nigeria more than 44 years after the first WHO resolution (WHA28.72) (WHA, 1975) to address the issue of universal and equitable access to safe blood as well as effective and rational use of blood and blood products. Every year more than a 100 million people sustain life threatening injuries and more than 5 million die from trauma and

injuries sustained from road traffic accidents, insurgencies, inter communal clashes and intra and post-operative bleed (Kauvar and Wade, 2005). Haemorrhage is the major cause of preventable death in Nigeria. A significant number of Nigerian women die every year from pregnancy- related complications (malaria-related anaemia, ante partum and post-partum haemorrhage) (Erhabor *et al.*, 2015).

Blood transfusion adequacy and safety remains an issue of major concern in transfusion practice in Nigeria because the National Blood Transfusion Service is functioning sub-optimally due to lack of appropriate infrastructure including trained personnel and inadequate financial resources to support the running of a voluntary non-remunerated donor transfusion service. This is further complicated by the predominance of unsafe and unsustainable family replacement and commercially remunerated blood donors, rather than regular benevolent, non-remunerated donors who give blood as a result of altruism.

Provision of safe and effective blood transfusion services in Nigeria is plagued by a number of challenges; high incidence of transfusion-transmissible infections, absence of a functional national blood transfusion service, reliance on commercial remunerated and family-replacement donors, education, cultural and awareness – related challenges associated with blood donation, transfusion of whole blood rather than component therapy, lack of effective stewardship in the management of allogenic blood by stakeholders, absence of red cell

alloimmunization testing services, sub optimal usage of non-pharmacologic and pharmacologic alternatives to allogenic blood, absence of specially selected products to meet the special transfusion requirements of certain patients, absence of indication coding tool to facilitate effective clinical use of blood products, absence of evidenced- based approaches to the management of major haemorrhages, absence of uninterrupted power supply and challenge of cold chain management of blood and blood products, absence of universal access to anti-D prophylaxis under the Routine Antenatal Anti-D Prophylaxis Programme (RAADP) for Rhesus D negative pregnant women and absence of regular stock of emergency group O Negative blood for emergency use (Erhabor and Adias, 2015). Addressing these challenges should be a central priority of the Nigerian government to ensure the uninterrupted supply of safe blood and blood products (Erhabor *et al.*, 2013).

The regional Blood Transfusion Faculty of the West African Postgraduate College of Medical Laboratory Science sincerely believes that this proposed Bill for an Act to Establish a National Blood Transfusion Commission to Coordinate, Regulate and Ensure the Provision of Quality Blood and Blood Products and Related Matters (HB. 181) sponsored by Hon. Abass Tajudeen is very relevant and timely. The need to set up a Blood Service Commission to provide a safe, adequate, quality and efficient blood and blood products cannot be over emphasized. However, there is the urgent need for the proposed National Blood Service Commission to be inclusive of key stakeholders involved in blood transfusion service delivery in Nigeria and that suggestions be solicited from these relevant stakeholders to make the proposed bill and by extension the National Blood Service Commission better and result- oriented.

In the light of the above we submit the following request for amendment of pertinent sections of the bill.

1. Section 3(2). Constitution of the board

We request that the board of the commission should include a representative of the following relevant stakeholders:

- a. A representative of the Faculty of Blood Transfusion Science of the West African Postgraduate College of Medical Laboratory Science.
- b. A representative of the Haematology and Blood Transfusion Scientists Society of Nigeria (HBTSSN). Membership of this society currently stands at about 500 members and includes Medical Laboratory Scientists working in hospital-based blood transfusion laboratories across the nation screening and collecting blood from donors as well as carrying out alloantibody testing and crossmatching of blood for patients that require blood transfusion across the nation.

2. Objectives of the Commission number 2 (d): Accredite blood transfusion service facilities throughout the country.

This above proposed objective *is in conflict with the already existing function of the Medical Laboratory Science Council of Nigeria (MLSCN)* (a Federal Government Statutory Regulatory Agency established by an Act of the National Assembly number 11 of 2003). One of the functions of the Council under Act 11 of 2003 is *to inspect, regulate and accredit Medical Laboratories (Public and Private) including blood transfusion laboratories in Nigeria.*

We pray for reframing to this section to say: *The National Blood Service Commission shall work collaboratively with the Medical Laboratory Science Council of Nigeria to ensure joint accreditation of blood transfusion laboratories.* For example, the Medicines and Healthcare products Regulatory Agency (MHRA) (an executive agency of the Department of Health and Social Care in the United Kingdom is responsible for ensuring that medicines, medical devices and blood transfusion service are acceptably safe) organizes joint accreditation with the United Kingdom Accreditation Service (UKAS) (sole national accreditation body recognised by the British government to assess the competence of organisations that provide certification,

testing, inspection and calibration services). This kind of mutual relationship can exist between the proposed National Blood Service Commission and the MLSCN.

3. **Part V Offences and Penalties**

Number 27- (1) the phrase “Any person who without the supervision of a registered Medical Practitioner” should be expunged from the bill and replaced by “*Any person who without the supervision of a registered Blood Transfusion Science Specialist*”. Blood Transfusion Science practice is a multi-professional responsibility. Nevertheless, the Medical Laboratory Scientist has broader roles in it than any other health professionals. Medical Practitioners are not the only professionals that can supervise the collection of blood from donors. This function is part and parcel of the curriculum for the training of Medical Laboratory Scientists in Nigeria both at the university level and at the post-university Fellowship training of the Medical Laboratory Science Council of Nigeria and the West African Postgraduate College of Medical Laboratory Science, This role is currently played by Medical Laboratory Scientists who are specialists in Blood Transfusion Science across the nation. This function can potentially be played by a qualified nurse with the requisite training and qualification in blood transfusion science. These professionals with the relevant qualification in blood transfusion science can clinically be responsible for the donation session to ensure the care of the donors and the safety of the blood. This prayer is to allow for professional harmony and team work among the key stakeholders responsible for blood transfusion service delivery in Nigeria.

Our General Suggestions and Prayers

The major challenge the Nigerian national blood transfusion service has had over the years is poor funding. This has prevented them from rendering a fit for purpose transfusion service that Nigerians deserve. There is need to put measures in place to prevent the proposed Blood Transfusion Commission from suffering the same fate. Currently in Nigeria, 1% of the

Consolidated Revenue Funds goes to the funding of Universal Health Coverage and this amount is shared between the Primary Health Care Development Agency, National Health Insurance Scheme, Nigerian Center for Disease Control and Emergency Services. There is nothing left for the National Blood Transfusion Commission as this was not anticipated. This sharing formula is as enshrined in the National Health Act, 2014. We need to look at other funding sources like direct allocation from the Federation Account or Private Sector Funding. Our prayer is that 0.5% of the Consolidated Revenue Funds be allocated to the funding of the proposed National Blood Service Commission to prevent the current funding gap that is preventing the national blood transfusion service from performing optimally.

1. The Bill needs to state categorically the Standards of Blood Transfusion Service (BTS) practice the Commission must uphold for Donor selection/blood and apheresis collections, components (specify entire spectrum with clear definitions for clarity) processing, disease markers testing (markers of the infective agent to be tested for and the technology to be employed for such testing) and pretransfusion compatibility testing: storage and distribution; administration and monitoring; transfusion programs for certain patient categories (preterm/term neonate, paediatric, obstetric emergency, critically bleeding trauma patients, patients with cardiovascular disease risk factors, chronic anaemia, haemoglobinopathies, etc) (National Blood Service, 2013).
2. There is need for the proposed Commission to be periodically assessed and accredited by appropriate reputable national and/or international accrediting agencies to allow for credibility and validity of facilities.
3. The bill needs to state categorically that there should be a 100% traceability and retrievability of information vein-vein from the donor to the recipient. There is also the need for haemovigilance (reporting scheme to manage all adverse reactions and events including near misses associated with blood donation and transfusion to facilitate the provision of continually improving blood transfusion service delivery) to be given

utmost priority in this bill (Bolton-Maggs *et al.*, 2018).

- The following blood transfusion service laboratories should be headed by qualified Medical Laboratory Scientists who are specialists in blood transfusion science (transfusion-transmissible infection markers testing laboratories, component manufacturing and storage laboratory; receipt and distribution laboratory; Human Leukocyte Antigen (HLA) typing and molecular testing laboratory; haematology and bacteriology laboratories.

We in the Blood Transfusion Science Faculty of the West African Postgraduate College of Medical Laboratory Science are solidly in support of this bill, subject to membership of the Board being inclusive of all major stakeholders and the above highlighted grey areas being amended. Members of our Faculty at the regional and national levels are willing to collaborate with your Committee to offer specialist advice as well partner with the Commission once implemented in a bid to ensuring the delivery of evidenced-based best practices and a continuous quality improving blood transfusion service delivery across the West African subregion (Erhabor *et al.*, 2018).

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