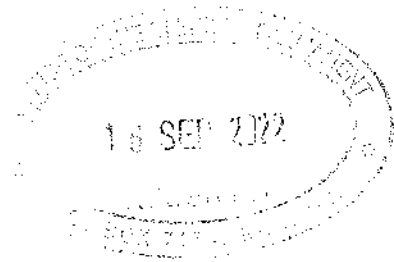


PARLIAMENT OF UGANDA



**REPORT OF THE COMMITTEE ON HEALTH ON THE
UGANDA HUMAN ORGAN DONATION AND
TRANSPLANT BILL, 2021**

SEPTEMBER, 2022

OFFICE OF THE CLERK TO PARLIAMENT

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1.0 INTRODUCTION

The Uganda Human Organ Donation and Transplant Bill, 2021 was read for the First Time on 05th July, 2022 and referred to the Committee on Health in accordance with Rule 129(1) of the Rules of Procedure of Parliament.

The Committee on Health scrutinised the Bill in accordance with rules 129 (2), 129 (3) and 129 (4) and now begs to report.

This report is being presented in compliance with Rule 130(2) which states that, "The Chairperson of the Committee to which the Bill is referred or a Member of the Committee designated by the Committee or the Speaker shall, after the Motion for the Second Reading has been moved under sub-rule (1) and seconded, present to the House the report of the Committee on the Bill."

2.0 BACKGROUND

Transplantation of human organs, tissues and cells has become a worldwide practice, which has extended and greatly enhanced the quality of hundreds of thousands of lives in patients affected by terminal organ failures. In 1954, the kidney was the first human organ to be transplanted successfully from one identical twin to another and then between siblings who were not twins. In 1967, the first successful liver and human-to-human heart transplant was carried out. In 1968, several important developments took place including the first successful pancreas transplant. In 1977, the first computer-assisted organ matching system was successfully done.

In 1991 at the World Health Assembly in Geneva, Switzerland, the World Health Organisation (WHO) through Resolution WHA 40.13 adopted guiding principles for human organ transplants which have had a great influence on professional codes and legislations. The principles emphasised voluntary donation, non-commercialisation and preference for deceased donors over living donors and for genetically related donors over non-related donors.

In 2004, the WHO's 57th World Health Assembly adopted another Resolution WHA 57.18 concerning human organ and tissue transplantation, recommending the use of living donors in addition to deceased donors and to take measures to protect the poorest and vulnerable groups from transplant tourism and the sale of tissues and organs, including attention to the wider problem of international trafficking in human tissues and organs.

Data on the unmet need of organ donation in Uganda and the African region is scanty. In 2016, a total number of 643 organ transplants were performed in Africa and this was lower compared to other WHO regions. In the United States of America, approximately 120,000 people (including children) need

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an organ transplant to live. In 2019, they were able to carry out more than 38,000 transplants.

The mismatch between the growing demand for organ transplants and the strict limits on available supply is the root cause of many of the legal, ethical and human rights issues that arise around organ transplantation.

In Uganda, medical tourism is equally a growing trend, with many patients regardless of social status considering treatment abroad as the only life-saving alternative. Medical tourism, especially to India, Turkey, South Africa and the United States of America is fast becoming a mainstay for Ugandans seeking organ, tissue and cell transplantation.

The Uganda Medical Board under the Ministry of Health, convenes at least once a month to approve 2 to 4 people to travel abroad for treatment. These medical procedures roughly cost about \$25,000 inclusive of travel and hotel fees abroad. However, it has been reported that a number of other facilities in India and Turkey both in urban and rural areas carry out these procedures for about \$18,000.

Travel for transplantation becomes transplant tourism and therefore unethical if it involves trafficking in persons for purposes of organ harvesting or trafficking in human organs or tissues.

However, Uganda does not have a law regulating organ, tissue and cell donation and transplantation, yet it is increasingly becoming an area of health care that requires urgent and constant attention.

Uganda is not a member of the World Marrow Donor Association (WMDA) which is a collective database of hematopoietic cell donor registries from 55 countries. About 37.9 million potential donors and over 802,600 cord blood units were available as of April 2021. When an individual joins a bone marrow donation registry, they are agreeing to donate using whichever method the healthcare professional deems appropriate.

The Uganda Human Rights Commission 2021 Annual report cites unlawful organ donation and transplantation in the country. The most affected are the poor and most vulnerable groups. This therefore creates the need for a law regulating and governing the transplanting and donating of organs in Uganda in order to prevent the above-mentioned challenges as well as promote health care in the country.

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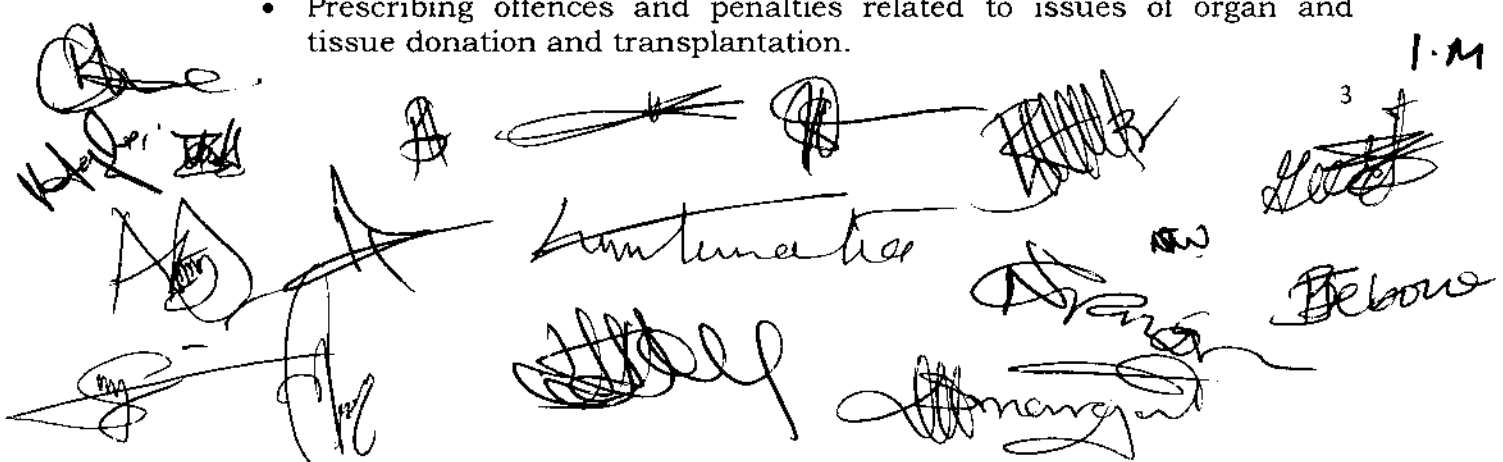
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3.0 OBJECT OF THE BILL

The object of the Bill is to establish a legal framework for the regulation of organ, cell and tissue donation and transplantation in Uganda by:

- Establishing the Uganda Organ Donation and Transplant Council to oversee and regulate organ, cell and tissue donation and transplantation in Uganda;
- Designating Mulago National Referral Hospital as the pioneering transplant centre;
- Prescribing a criteria to be followed when designating a hospital/institution as an organ, tissue or cell donation and transplant centre;
- Regulating the conduct of donation and transplant activities;
- Establishing policies and procedures for designated transplant centres and approved banks, including ethical standards and educational services to the public;
- Establishing a donation and transplant system which ensures equitable access to quality donation and transplantation services to donors and potential recipients;
- Establishing standards for storage of harvested organs, tissues and cells;
- Establishing a system of distribution of organs, tissues and cells;
- Providing for the transplant of organs, tissues and cells;
- Establishing and maintaining a national waiting list for potential organ, tissue and cell donors and recipients drawn from designated transplant centres and other hospitals and health facilities;
- Creating a database of information of donors and recipients to be retained by the transplant centres, hospitals and health facilities;
- Establishing procedures for the transplantation of organs and tissue from living donors including due diligence;
- Establishing procedures for the transplantation of organs and tissue harvested from cadavers;
- Prescribing appropriate consent to be given by donors;
- Prescribing requirements to be fulfilled before carrying out a post-mortem examination of a confirmed brain dead donor;
- Establishing a human organ and tissue database and reporting requirements;
- Prescribing offences and penalties related to issues of organ and tissue donation and transplantation.



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4.0 JUSTIFICATION FOR THE BILL

Worldwide, there is a sharp rise in trafficking of human organs with the poor and other vulnerable groups in society facing a high risk. Organs are unlawfully donated, transplanted and even stolen courtesy of a complex network of buyers, sellers and brokers at the international level. The forceful donations start with inhumane and illegal activities like human trafficking, kidnap and murder.

Uganda does not have a legal framework to regulate organ, tissue and cell donation and transplantation, yet it is increasingly becoming an area of health care used to cure infectious, genetic and non-communicable diseases.

There is need to protect the dignity and identity of every person and guarantee, without discrimination, respect for his or her integrity and other rights and fundamental freedoms with regard to donation and transplantation of organs, tissues and cells of human origin.

Annually, Ugandans spend a lot of money on medical tourism to countries like India, Turkey, UK and the USA through out of pocket expenditure. This upsets the country's balance of payments. Those who cannot afford have a poor quality of life which may result into death.

5.0 METHODOLOGY

While considering the Uganda Human Organ Donation and Transplant Bill, 2021; the Committee applied the following methods:

5.1 Meetings

Physical meetings

The Committee held meetings with the following entities:

- Ministry of Health (MoH)
- Uganda Medical Association (UMA)
- Uganda Human Rights Commission (UHRC)
- Uganda Law Society (ULS)
- Uganda Blood Transfusion Services (UBTS)
- Centre for Policy Analysis (CEPA)
- Association of Funeral Service Providers of Uganda (AFSPUL)
- Joint Clinical Research Centre (JCRC)

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- Lubaga Hospital
- Coalition of 43 civil society organisations specialising in health rights advocacy
- Pharmaceutical Society Uganda (PSU)
- Uganda Medical and Dental Practitioners Council (UMDPC)
- Plastic Surgeons (skin grafting specialists)

Zoom meetings

- Dr Guarav Kharay, a bone marrow specialist from Apollo Hospitals in India
- Officials from the University of Derby, United Kingdom

5.2 Written memoranda

The Committee received written memoranda from the following:

- Uganda Law Reform Commission
- Laboratory technology students from Clarke International University, Institute of Allied Health Sciences and Makerere University College of Health Sciences

5.3 Document review

The Committee reviewed and made reference to the following documents:

- The Declaration of Istanbul on Organ Trafficking and Transplant Tourism (2018 edition)
- Status of Human Organ and Tissue Donation and Transplantation in the WHO African Region
- Applicable laws

5.4 Workshop

The Committee held a workshop with medical specialists in various fields of organ, tissue and cell therapy like kidney, heart, lung, liver, cornea, stem cells, plastic surgery (skin) and a post-operative care nurse.

6.0 COMPLIANCE WITH GENDER AND EQUITY, HUMAN RIGHTS AND SUSTAINABLE DEVELOPMENT GOALS

HUMAN RIGHTS

Prohibition of children as potential donors

Clause 72 explicitly prohibits any donation from a living child. Children are vulnerable and are never in position to consent to such procedures. This is important in protecting children from exploitation and abuse. However, this provision only applies to living children.

Protection of poor and vulnerable persons

The risk of exploitation of vulnerable and poor persons is high. Guiding principle 5 of WHO Guiding Principles on Human Cells, Tissue and Organ Transplantation states that, "The human body and its parts cannot be the subject of commercial transactions." In order to protect persons from exploitation, the bill under Clause 86 prohibits commercial dealings in human material for transplantation. This means that monetary or any other form of compensation for organs, tissues or cells other than reimbursement of donation related expenses is prohibited. The sale of one pair of organs such as eyes or kidney by a living donor for financial or other form of compensation is also prohibited.

The success of transplantation as a lifesaving treatment should not require nor justify victimising of the poor or vulnerable people as the source of organs for the rich.

Requirement for registered practitioners to obtain authority and consent before harvesting any organ, tissue or cell

Clauses 61 and 67 require all registered medical practitioners in transplant centres to obtain consent before harvesting of any tissue, cell or organ from a donor. Clause 71 also provides for authority for removal of human organs, tissue and cells. The process of obtaining the consent shall be written or spoken in a language that is understandable to the donor or the recipient

next of kin under sub clause 61(6). Obtaining consent from any donor before harvesting is necessary to ensure that the right to health is respected and protected.

GENDER AND EQUITY

Fair and equitable system

Clause 53 describes organ, tissue and cell donation and transplant as a fair and equitable system. Subsection (5) that access to organs, cells and tissues shall be provided without regard to recipient sex, age, religion, race, colour or financial standing. In other words, access to transplant of organs, cells or tissues is based on the principle of non-discrimination. This is further galvanised by Clause 52 which provides for a national waiting list for potential recipients that promotes equity and national solidarity.

Informed Consent

Any intervention in the health field can only be carried out after the person concerned has given free and informed consent to the procedure. Clause 67 (4) (b) and (c) includes the responsibility of the Council to inform the donor of the long-term benefits and risks related to the procedure. This will enable donors to make informed decisions about the donation. In accordance with the WHO guiding principles on human cell, tissue and organ transplantation, there needs to be an adequate balance of interests of recipients and donors. Benefits to both parties should outweigh the risks associated with the donation and transplantation.

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SUSTAINABLE DEVELOPMENT GOALS (SDGs)

SDG – 3 Good health and well being

The Bill is in line with SDG number 3- Good health and well being which aims at ensuring healthy lives and promoting well-being at all ages.

Transplantation of an organ, tissue or cell is a life-saving procedure which gives patients with mal or non-functioning organs to have a better quality of life and live longer. The patients can be children or adults.

7.0 COMMITTEE OBSERVATIONS AND RECOMMENDATIONS

PART I – PRELIMINARY

PURPOSE OF THE ACT

Clause 2(c)

Clause 2 of the Bill lists the purpose of the Bill. Clause 2 (c) designates Mulago National Referral Hospital as a pioneer transplant centre.

The Committee observed that:

Designating Mulago as a pioneer transplant centre may prevent other facilities that are ready for organ, tissue and cell harvesting and transplantation from commencing. Different types of organs can be harvested and this clause presumes that Mulago will have to pioneer in transplantation of all the different organs, tissues and cells.

The provision also presumes that Mulago meets all the standards and is ready for transplant activities.

The Committee recommends that Clause 2(c) be deleted.

Clause 2(d)

Clause 2(d) provides for designation of hospitals as organ, tissue and cell transplant centres.

The Committee observed that a hospital should be accredited before designation.

The Committee recommends that the word accreditation be inserted in Clause 2(d).

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The Committee further observed that the amount of data generated from organ, cell and tissue harvesting and transplantation is a repository for knowledge and research for teaching purposes and development of medicines, new transplant techniques, prevention and policy development.

The Committee recommends that a new paragraph (j) be inserted to provide for a framework for scientific research and development in organ, cell and tissue donation and transplantation.

CLAUSE 3 - APPLICATION

Clause 3 lists organs, tissues and cells which can be donated and transplanted.

Clause 3(c)

The Committee observed that blood is among the list of organs, tissues and cells yet facilities like hospitals and health centres where blood transfusion is ongoing, will fall short of the criteria for accreditation for organ, tissue and cell transplant centres. This means that hospitals and health centre IVs where blood transfusion is taking place will have to shut down blood transfusion services.

The Committee recommends that paragraph (c) of Clause 3 be deleted.

Clause 3(n)

The Committee observed that cells constitute organs and therefore, there is no need to make a separate mention of them in (n).

The Committee recommends that the word cells is deleted from the list.

The Committee observed that hair has not been listed yet it is a tissue for transplant.

The Committee recommends that the word cells is replaced with hair in paragraph (n).

Clause 3(s)

The Committee observed that paragraph (s) is restrictive and does not envisage emerging developments in the field of organ, tissue and cell donation and transplantation.

The Committee recommends that paragraph (s) be amended to delete the words, "related to those in paragraphs (a) to (r)"

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PART II – THE MINISTER AND THE HUMAN ORGAN TRANSPLANT COUNCIL

ASSISTANCE AND SUPPORT

According to Clause 6, the Minister can provide assistance and support to any person providing or proposing to provide a service relating to human organ, cell or tissue donation or transplantation.

The Committee observed that the assistance and support referred to is ambiguous and can be exploited.

The Committee recommends that Clause 6 be deleted.

UGANDA HUMAN ORGAN DONATION AND TRANSPLANT COUNCIL

Clause 7(5) states that, “The Council shall be independent but shall work in collaboration with the Uganda Medical and Dental Practitioners Council, especially in relation to disciplinary cases against registered medical practitioners certified by the Council under this Act to undertake organ, tissue and cell donation and transplant activities.”

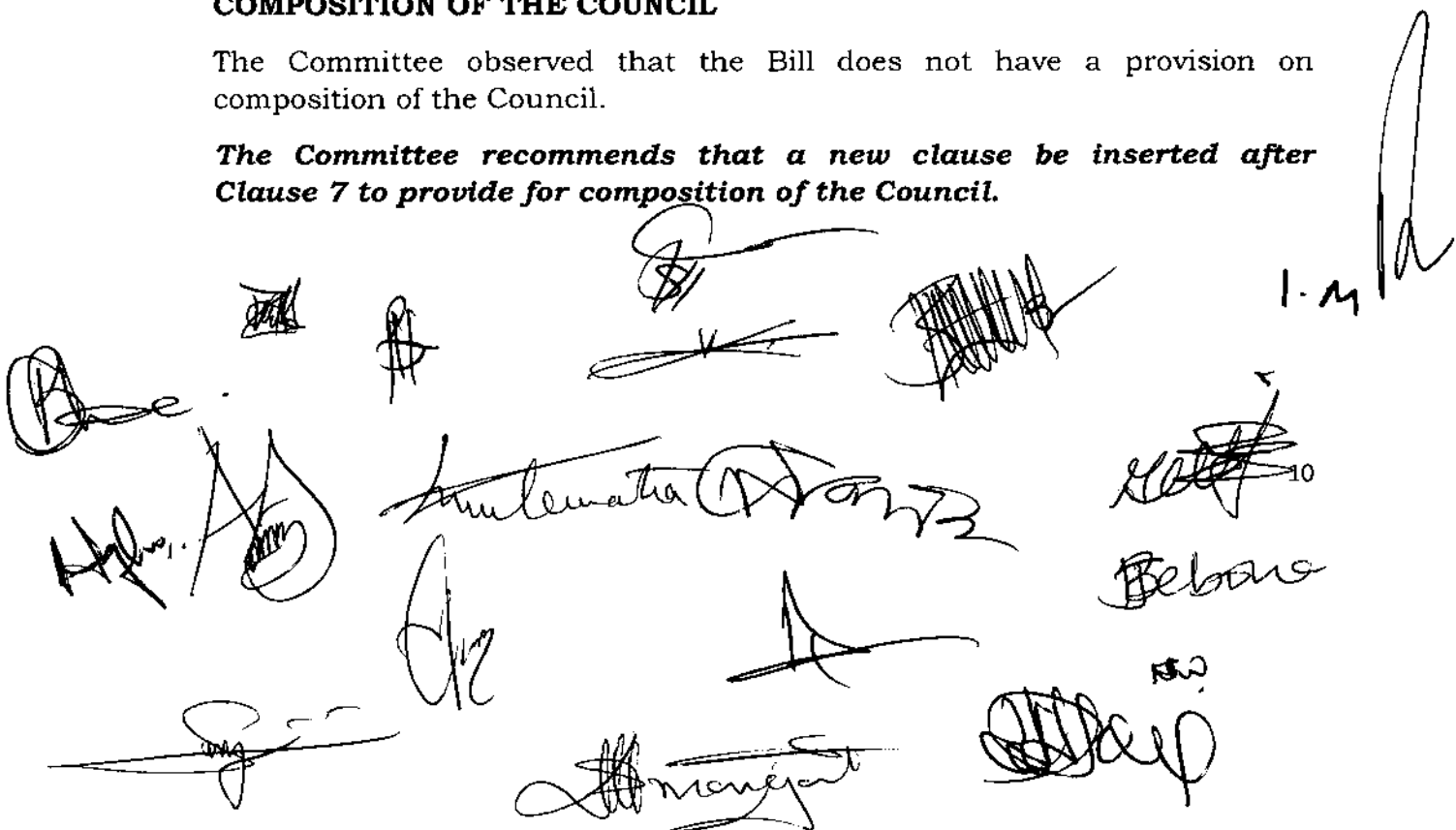
The Committee observed that Uganda Medical and Dental Practitioners Council is one of the four professional bodies of health workers. The others are Uganda Nurses and Midwives Council, Allied Health Professionals Council and the Pharmacy Board.

The Committee recommends that Clause 7(5) of the Bill is amended to replace Uganda Medical and Dental Practitioners Council with the relevant professional bodies.

COMPOSITION OF THE COUNCIL

The Committee observed that the Bill does not have a provision on composition of the Council.

The Committee recommends that a new clause be inserted after Clause 7 to provide for composition of the Council.



DISQUALIFICATION FOR APPOINTMENT TO THE COUNCIL

Clause 9 of the Bill lists the grounds for disqualification for appointment to the Uganda Organ Donation and Transplant Council. Clause 9(d) states that a person shall not be appointed to the Council if he or she is serving on any other Council or Board.

The Committee observed that Clause 9(d) is too general and may prevent qualified persons from serving on the Uganda Human Donation and Transplant Council on account that they are serving on other councils or boards.

The Committee recommends that the councils or boards for which a member is disqualified be limited to statutory bodies and councils in the health sector.

PART IV- DESIGNATION OF TRANSPLANT CENTRES AND APPROVAL OF BANKS

DESIGNATION OF TRANSPLANT CENTRES

Clause 28(1) designates Mulago National Referral Hospital as a pioneer transplant centre.

Clause 28 (2) states that, "Notwithstanding sub-section (1), the Minister may, on recommendation of the Council, by statutory instrument, designate a hospital as an organ, tissue or cell donation and transplant centre."

The Committee observed that designating Mulago as a pioneer transplant centre may prevent other facilities that are ready for organ, tissue and cell harvesting and transplantation from commencing. Different types of organs can be harvested and this clause presumes that Mulago will have to pioneer in transplantation of all the different organs, tissues and cells.

The provision also presumes that Mulago meets all the standards and is ready for transplant activities.

The Committee recommends that Mulago Hospital should be subjected to accreditation by the Council and designation by the Minister like other health facilities. Therefore, Clause 28 (1) should be deleted.

APPLICATION FOR DESIGNATION AS A TRANSPLANT CENTRE

Clause 29(1) states that, "A hospital that wishes to be designated as a transplant centre under section 28 shall apply to the Council in a manner prescribed by the Minister by regulations."

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Clause 29 (3) states that, "Where, after the due diligence carried out under subsection (2) and after giving an opportunity to the applicant to be heard, the Council is satisfied that the applicant does not meet the requirements of this Act and the regulations made under this Act, the Council shall, reject the application giving reasons for the refusal in writing.

The Committee observed that a hospital should be accredited before designation to ensure compliance with approved standards.

The Committee recommends that Clause 29(1) be amended to include the word accredited.

The Committee observed that the timeframe within which to communicate the Council's decision is not stated.

The Committee recommends that Clause 29(3) be amended to include 30 days as the timeframe within which to communicate the Council's decision to the applicant.

The Committee further observed that quality assurance and control is a continuous process and as such, transplant hospitals need annual accreditation and designation so as to ensure that they continuously adhere to standards.

The Committee recommends that a new paragraph (5) be added to provide for a hospital designated as a transplant center to be accredited annually for suitability to offer services and issued an accreditation certificate which expires by the 31st of December of every calendar year.

QUALIFICATION FOR DESIGNATION AS A TRANSPLANT CENTRE

Clause 30 lists qualifications for designation as a transplant centre.

Clause 30(a) states that a designated transplant centre shall have, "Intensive Care Unit and High Dependent Unit beds dedicated to the transplant programme connected to the theatre by a sterile corridor or interconnectivity with dialysis capability;

Clause 30(b) states, "specialised medical professionals, including a transplant surgeon, physician, anaesthesiologist, intensivist and transplant nurse qualified and experienced in the type of organ, tissue or cells to be harvested and the transplant activities to be carried out;"

Clause 30 (c) states that a transplant centre should have two adjacent theatres; one for the donor and another for the recipient.

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Clause 30(g) states that, "any other requirement that the Minister may prescribe by regulations or standards issued by the Minister."

The Committee observed that:

- *Clinical pharmacists and counsellors are missing from the list of key professionals needed. Clinical pharmacists trained in organ transplant understand the medicine requirements and in the event of adverse reactions, they are capable of responding. Professional counselling is needed before the procedure to avoid cases of depression.*
- *The requirements for an intensive care unit and adjacent theatre apply to donation and transplant of solid organs;*
- *The need for therapeutic drug monitoring facilities is not indicated among the requirements.*
- *The need for a well-stocked pharmacy is missing from the list of requirements.*
- *The provision caters for solid organ transplants and ignores cells and tissues.*

The Committee recommends that:

- **Clause 30(a) and 30(c) be amended to state that the provisions qualify for solid organ transplants.**
- **A new sub-clause be inserted after (f) to provide for a requirement for therapeutic drug monitoring facilities.**
- **A new sub-clause be inserted after (g) to provide for a requirement for a pharmacy stocked with relevant medicines and supplies.**
- **A new sub-clause be inserted after (h) to cater for cell and cornea transplant centres whose requirements will be prescribed by the Minister.**

DESIGNATION BY A MINISTER

Clause 31 (1) states that, "The Council shall, after being satisfied that a hospital meets all the requirements of this Act, regulations made under this Act, standards issued by the Minister and any other applicable law, recommend the hospital to the Minister for designation as a transplant centre."

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The Committee observed that different institutions are qualified in different in different areas of transplantation.

The Committee recommends that the sub-clause be amended by inserting the requirement by an institution to offer specific transplant services for which the facility is qualified to do so.

REGULATION OF CONDUCT OF DONATION AND TRANSPLANT ACTIVITIES

Clause 33(4) states that, "The Council shall, in a manner prescribed by regulations, approve local and expatriate transplant surgeons before they can undertake transplantation activities under this Act."

Clause 33(5) states that, "A transplant surgeon shall not be approved under subsection (4) unless he or she is registered by the respective professional Councils."

The Committee observed that the mandate mentioned in 33(4) and 33(5) is for Uganda Medical and Dental Practitioners' Council.

The Committee recommends that Clause 33(4) and 33(5) be deleted.

APPROVAL OF BANKS

Clause 34(7) states that, "the national blood bank shall be accredited by the Council, but shall in its day to day activities report to the Minister."

The Committee observed that Uganda Blood Transfusion Services has a system in place for the collecting, processing, storage and distribution of blood countrywide. The Committee was informed by the Minister that a separate law will be developed to regulate blood and its products.

The Committee recommends that Clause 34(7) be deleted.

POLICIES AND PROCEDURES FOR DESIGNATED TRANSPLANT CENTRES AND APPROVED BANKS

Clause 35 (1) of the Bill states that, "Designated transplant centres and approved banks shall maintain policies and procedures which shall detail all aspects of retrieval, processing, testing and storage and practices for organs, tissues and cells."

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Clause 35(3) states that, "Modifications of standard procedures and development of new procedures shall be approved by the registered medical practitioner."

The Committee observed that there will be no consistency and standardisation if each designated transplant centre develops their own policies and procedures.

The Committee further observed that there will be no independent review of these policies and regulations developed by the designated transplant centre.

The Committee recommends that Clause 33(1) be amended to provide that all policies developed by the designated transplant centres shall be approved by the Council and should conform to the regulations.

EDUCATIONAL STANDARDS TO THE PUBLIC

Clause 37(1) states that, "Each designated transplant centre shall assist hospitals and health centres in establishing and implementing protocols for making routine inquiries regarding organ, cell and tissue donations by potential donors."

Clause 37(4) states that, "Every designated transplant centre shall produce or have available literature and media items that provide education and awareness creation for donation of organs, tissues or cells."

Clause 37 (5) states that, "A designated transplant centre shall be responsible for establishing and assisting in the dissemination of the materials referred to in subsection

The Committee observed that:

- *The word "protocols" is not consistent with other laws.*
- *There will be no consistency and standardisation if each designated transplant centre develops their own education and awareness literature and media items.*
- *There will be no independent review of education and awareness literature and media items developed by the designated transplant centre.*

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The Committee recommends that the word protocols in Clause 37(1) be replaced with guidelines.

The Committee further recommends that Clause 37(4) and 37(5) be amended to provide that all education and awareness literature and media items developed by the designated transplant centres shall be approved by the Council.

PART VII-STORAGE OF ORGANS, TISSUES AND CELLS OUTSIDE THE BODY

FRAUDULENT ACTIVITY

Clause 51 (1) states that, "Where a designated transplant centre or approved Bank discovers that a fraudulent activity has occurred in the distribution, shipping or labelling of any organ, tissue or cell imported or exported by the designated transplant centre or Bank, an investigation shall be conducted to identify the root cause of the fraudulent activity.

The Committee observed that scope of fraudulent activities in organ, tissue and cell donation and transplant goes beyond distribution, shipping or labelling.

The Committee recommends that Clause 51(1) be amended by expanding the scope for fraudulent activity to harvesting, transplanting, returning or recall.

NATIONAL WAITING LIST

Clause 52 states that, "The Council shall establish and maintain a national waiting list for potential organ, tissue and cell donors and recipients drawn from designated transplant centres; hospitals and health centres."

The Committee observed that the procedure for people who donate is done real time, hence no need for waiting.

The Committee recommends that Clause 52 is amended by removing the word donors.

FAIR AND EQUITABLE SYSTEM

Clause 53(3) states that, "The Council may also authorise the importation of organs, tissues and cells from an international transplant organisation referred to in subsection (2)."

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The Committee observed that use of the word importation may be misinterpreted to mean commercialisation of organs, tissues and cells yet the Bill prohibits the sale of organs, tissues and cells.

The Committee recommends that Clause 53 is amended by replacing the word, "importation" with "sharing" where sharing means medically sanctioned transboundary movement of organs, tissues or cells from one organ bank to another in cases where there are agreements approved by the Minister.

TRANSPLANTATION ACTIVITY

Clause 54 (1) states that, "The retrieval and preservation of human organs, tissues and cells for transplantation shall only be performed by a registered health professionals approved by the Council and in accordance with this Act, regulations made under this Act, any other applicable law and standards issued by the Minister.

The Committee observed that the retrieval team includes various health professionals who are not only licensed by their respective professional bodies. Subjecting them to approval by the Council may constitute double licensing.

The Committee recommend that relevant professional bodies should replace the Council appearing in Clause 54(1).

Clause 54(4) states that, "All transplant activity shall be performed to the highest professional and ethical standards."

The Committee observed that ethical standards are set by the professional bodies.

The Committee recommends that Clause 54(4) should be amended by putting a provision for all transplant activities to be prescribed by the relevant professional bodies.

Clause 54(5)

Clause 54(5) states that, "When a person has been confirmed brain dead by the team in care, the Council shall immediately be notified to send an independent neurological team to confirm the death for purposes of donation."

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The Committee observed that the team which confirms brain death includes other professionals like neuro surgeon, neuro physician, anaesthesiologist and intensivist.

The Committee recommends that the word neurological be deleted.

Clause 54(8) states that, "The independent team in (5) shall consist of a neuro surgeon, neuro physician, and an anaesthesiologist or intensivist."

Clause 54(9) states that, "The independent team and organ retrieval team shall be self-sufficient and shall not require anesthetic, theatre or surgical staff from the donor hospital and shall be available 24 hours a day without other elective commitments during their time on call and able to respond appropriately if there is more than one donor on the same day."

The Committee recommends that the two clauses be merged.

Insertion of a new sub-clause (9)

The Committee observed that no provision has not been made for a brain dead potential donor who is in an intensive care unit in a hospital that does not provide organ, tissue and cell transplant services.

The Committee recommends that a new sub-clause (9) be inserted to cater for brain death in an intensive care unit of a hospital.

DONATION AND TRANSPLANT OF ORGANS, TISSUES AND CELLS REMOVED FROM LIVING DONORS

Clause 67 (4) states that, "The Council shall ensure that the donation is legal and justified by ensuring that the proposed donor—

- (d) understands that it is illegal to accept any financial or other inducement for the donation but that he or she may have any expenses or loss of earnings reimbursed.
- (e) understands that he or she may be compensated for any unanticipated harm resulting from the donation."

The Committee observed that the organs, tissues and cells are donated free of charge. Reimbursement for loss of earnings and compensation for any unanticipated harm resulting from donation may be construed to mean a payment for the organ, tissue or cell.

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The Committee recommends that:

Clause 67(4) (d) be amended to remove a provision for any expenses or loss of earnings reimbursed.

Clause 67(4) (e) should be changed to put a provision to the effect that a living donor understands that he or she may be compensated for justifiable expenses which should be approved by the Council.

AUTHORITY FOR REMOVAL OF HUMAN ORGANS, TISSUES AND CELLS

Clause 71 (4) states that, "The authority given under subsection (1) or subsection (2) or, as the case may be, subsection (3) shall be sufficient warrant for the removal, for therapeutic purposes, of the human organ, tissue or cell but no such removal shall be made by any person other than a registered medical practitioner from a designated transplant centre".

The Committee recommends that, if a potential donor dies without giving his/her consent, and the next of kin cannot be contacted, that body should not be used for donation purposes.

PROHIBITION OF DONATION FROM LIVING CHILD

Clause 72 prohibits donation of an organ, tissue or cell from a living child.

The Committee noted that medically, stem cells are drawn from bone marrow and peripheral blood, which regenerate and they do not cause any harm.

The Committee recommends that the clause be redrafted to cater for the following:

Prohibition of donation from a living child save for exceptional circumstances approved by the Council with the consent of parent/guardian.

Put provisions under which a living child may donate. The provisions include: stem cell therapy for minors who are twins or close siblings after approval by the Council

Prescribe a penalty of life imprisonment for a person who contravenes the provision .

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APPROPRIATE CONSENT FOR DONATION FROM A BRAIN DEAD OR DEAD CHILD

Clause 73 (a) states that, "Where a child is brain dead or has died, appropriate consent means- (a) the express consent of the child in force immediately before the child died witnessed by at least one close relative or an authorised officer."

The Committee observed that a minor cannot give consent since children do not have the capacity to enter into any binding agreement except for exceptional circumstances.

The Committee recommends that Clause 73(a) be deleted.

APPROPRIATE CONSENT BY LIVING ADULT

Clause 74 (2) states that an adult between the age of 18 and 21 years requires two witnesses while giving consent. One of the witnesses should be a person with parental rights over them.

The Committee noted that clause 74(1) takes care of the interest of sub-clause (2).

The Committee recommends that Clause 74(2) be deleted.

APPROPRIATE CONSENT FROM BRAIN DEAD OR DEAD ADULT

Clause 75(4) states that, "The Council may apply to court for consent where a person dies without express consent and does not have any close relations."

The Committee observed that securing a court order to harvest organs or tissues from cadaver takes time and by the time it is granted the organ may be spoiled. The requirement to get consent from court can create a window which can be abused. Furthermore the Committee observed that the timeframe within which to make the application is not stated.

The Committee recommends that the sub-clause 74 (4) be deleted.

REQUIREMENTS FOR CARRYING OUT POST-MORTEM EXAMINATION

Clause 78 lists the requirements for carrying out a post-mortem on cadaveric donor.

[Handwritten signatures and initials including 'Haha', 'Mentematis', 'D.G.', 'Beboas', '20', 'Paha' are present at the bottom of the page.]

Clause 79 is about authority for removal of human organ, cell or tissue from a body sent for post-mortem examination for certain purposes.

The Committee noted that Clause 78(1) requires that a post-mortem shall be carried out on all cadaveric donors and shall be conducted at the same time as the harvesting of the organs to determine the cause of death and the suitability of the donor.

The Committee observed that harvesting organs, tissues and cells sent for post mortem could be abused and in cases of medico-legal nature, it may destroy evidence that might be needed at a later date. For instance, in cases of exhumation.

The Committee further observed that there is no requirement for certification of death by the Council before a post mortem is carried out. This could create a possibility of a person alleging that the organs are harvested from donors who are still alive. In addition, Clause 75 already takes care of how organs are harvested from the dead.

The Committee recommends that Clause 78 and Clause 79 be deleted.

PART XI-OFFENCES AND PENALTIES

PREVENTION OF ORGAN, TISSUE OR CELL TRAFFICKING

Clause 88 (2) (a) states that, "The prohibition under subsection (1) shall not prevent payments which do not constitute a financial gain or comparable advantage, in particular—

- (a) compensation for living donors of loss of earnings and any other justifiable expenses caused by the removal or by related medical examinations;

The Committee observed that the provision is silent on who approves the justifiable expenses. Compensation for loss of earnings can be abused and commercialised. It may be construed as payment for the organs, tissues or cells provided by the donor.

The Committee recommends that Clause 88(2) (a) should be amended to allow only justifiable expenses which should be approved by the Council.

The bottom of the page contains numerous handwritten signatures and initials in black ink. Some legible names include 'Lunternato', 'Belone', and 'I-M'. There are also several scribbled-out signatures and initials, including one that appears to be 'A.D.' and another that looks like 'P.S.'. The signatures are scattered across the bottom half of the page, with some overlapping the page number '21'.

Clause 88 (2) (b) states that, "payment of a justifiable fee for legitimate medical or other related technical services rendered in connection with the transplantation; and (c) states that, "compensation in case of undue damage resulting from the removal of an organ, tissue or cell from a living person.

The Committee observed that the fee for legitimate medical and other technical services rendered in connection with transplantation may vary from time to time; hence it should be catered for in the regulations.

The Committee further observed that consent is sought before going for any surgical procedure and before consent is given, the donor must have received all the relevant information and explanations including any eventualities that may arise.

The Committee recommends that clauses 88(2) (b) and (c) be deleted.

OFFENCES BY BODY CORPORATE

Clause 91 provides for offences by body corporate.

The Committee observed that the clause does not prescribe penalties for body corporate.

The Committee recommends that a new sub-clause be inserted after 91(4) to prescribe a penalty not exceeding five hundred thousand currency points.

GENERAL PENALTY

According to Clause 92, "A person contravenes a provision of this Act or any regulations made under this Act, or any condition of the designation granted under this Act for which no punishment is separately provided in this Act is liable, on conviction, to a fine not exceeding ten thousand currency points or imprisonment not exceeding three years or both."

The Committee observed that the penalty and the prison sentence are not deterrent enough.

The Committee recommends the penalty to be increased to one hundred thousand currency points and the prison sentence to 12 years.

A collection of handwritten signatures and initials in black ink, including names like 'H. H.', 'A.', 'S. M.', 'B. B.', 'M. M.', 'P. P.', 'R. R.', 'S. S.', 'T. T.', 'U. U.', 'V. V.', 'W. W.', 'X. X.', 'Y. Y.', 'Z. Z.', 'A. A.', 'B. B.', 'C. C.', 'D. D.', 'E. E.', 'F. F.', 'G. G.', 'H. H.', 'I. I.', 'J. J.', 'K. K.', 'L. L.', 'M. M.', 'N. N.', 'O. O.', 'P. P.', 'Q. Q.', 'R. R.', 'S. S.', 'T. T.', 'U. U.', 'V. V.', 'W. W.', 'X. X.', 'Y. Y.', 'Z. Z.'