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AN ETHICAL AND REGULATORY INQUIRY INTO ORGAN DONATION IN ZAMBIA

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Submitted to the Faculty of Health Sciences, University of Witwatersrand, Johannesburg, in partial fulfilment of the requirements for the degree of Masters of Science in Medicine in Bioethics and Health Law

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Qualifications:	MBChB, FCOG, LLM, PG Dip Int Res Ethics, PhD	LLB, LLM

February 2020

DECLARATION

I Noel Jacob Chulu declare that this Research Report is my own, unaided work. It is being submitted for the Degree of Master of Science in Medicine (Bioethics and Health Law) at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.

_____

(Signature)

_____day of_____20_____in_____.

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ETHICS WAIVER

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TO WHOM IT MAY CONCERN:

Waiver: This certifies that the following research does not require clearance from the Human Research Ethics Committee (Medical)

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Department: Clinical Medicine

Project title: An Ethical and Regulatory Inquiry into Organ Donation in Zambia

Reason: The study is purely normative. No human participants will be involved in the study.

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Chairperson: Human Research Ethics Committee (Medical)

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ABSTRACT

Zambia's organ transplant program is plagued with a multitude of health sector challenges and resource deficiencies. An ethically and legally robust organ donation system practically suited for Zambia is necessary. The Research Report begins with an analysis and discussion of pertinent aspects of Zambia's organ donation legislation and other international regulations influencing organ donation. Drawing on some key debates in the field, ethical perspectives of living and deceased donation are discussed. A critical evaluation of opt-in, opt-out and mandated choice systems of organ donation follows, with the successes and failures of the relevant systems discussed in countries that apply them. The influence of principlism is examined in each system and the question of what the best suited ethical and regulatory framework for organ donation in Zambia ought to be is addressed. An argument and recommendations are made for an opt-in system coupled with pertinent aspects of best practice models as being best suited for Zambia.

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LIST OF ABBREVIATIONS / NOMENCLATURE

DBD – Donation after Brain Death

DCD – Donation after Cardiac Death

DICG – Declaration of Istanbul Custodian Group

EDQM – European Directorate for the Quality of Medicines & Healthcare

GODT – Global Observatory on Donation and Transplantation

HCP – Healthcare Professional

HTA – Human Tissue Act

ICU – Intensive Care Unit

ICJ – International Court of Justice

ISN – International Society of Nephrology

NHA – National Health Act

NHCSZ – National Health Care Standards of Zambia

NHP – National Health Policy

ONT – National Transplant Organisation

SA – South Africa

SADC – Southern African Development Community

TTS – The Transplantation Society

UK – United Kingdom

UTH – University Teaching Hospital

USA – United States of America

WHA – World Health Assembly

WHO – World Health Organisation

1 CHAPTER 1 - INTRODUCTION

1.1 Background Literature Analysis and Critique

Organ transplantation is internationally recognised as a lifeline for patients suffering end-stage organ failure. It “is a surgical procedure to replace a failing, diseased organ with a healthier donor organ, such as a heart, liver, kidney, or lung” (*Organ Transplantation*, no date). It gives patients with irreversible organ failure “a new lease on life”. In order for transplants to take place, an appropriate ethical and legal system must be developed for organ donation. Most organs are acquired from deceased donors (cadavers) (World Health Organisation, 2010) but due to the increased need for organs, there is a global shift towards including living donors (Ghods and Savaj, 2006). This is an attempt to reduce the gap between demand and supply of organs (Shimazono, 2007).

Zambia is a multicultural and landlocked country in Southern Africa. With a population of 17.63 million people, the National Health Policy (NHP) in Zambia is modelled on the State’s commitment to providing “equity of access to cost-effective and affordable health services as close to the family as possible” (Government of the Republic of Zambia, 2012). The NHP lays out the State’s commitment to safeguarding the fundamental human rights of all men, women and children.

> “All key policies and strategies focus on ensuring equitable access to primary health care services and addressing the social determinants of health. The major challenges faced by the health system include inadequate funding; critical shortages of healthcare professionals (HCPs) and sub-optimal

distribution of available HCPs; inadequate infrastructures and equipment; and weaknesses in the supply of drugs and other medical items. These challenges largely affect health service delivery, particularly in rural communities and for disadvantaged vulnerable population groups, such as women, children, and those that are differently-abled" (World Health Organisation, 2018).

In a continuous effort to improve health services and their delivery to the people of Zambia, in 2018, the State, announced an initiative through the University Teaching Hospital (UTH), to start carrying out organ transplants with kidneys as the first organs to be transplanted. Zambia currently has approximately 8,000 to 12,000 patients (this figure may be higher) on dialysis (Mwale, 2018). Dialysis is "an artificial way of eliminating waste and unwanted water from the body due to failed or damaged kidneys" (Nordqvist, 2018). Until now, the State has transported and paid for the transplants of Zambians abroad, a practice that costs the State about 2 million United States dollars annually (Lusaka Times, 2018).

While heralded by some, the idea of organ transplantation has been met with scepticism from others regarding the transplant process (Kunda, 2018). In response to the public's concerns and fears, UTH Senior Medical Superintendent for Adults and Emergency Dr Clarence Chiluba, rightly pointed out that there is a need to educate the public and HCPs of the process and its importance. Education and awareness of the public and HCPs are vital especially in order to facilitate the development of an effective organ donation system.

As moral codes and legislative frameworks differ from one society to the other, it is vital to consider organ donation in terms of the practices employed among different countries. Of particular interest to this research report are South Africa (SA), Israel and Spain. Despite differences in donor age groups, population sizes and incidences of death, these countries have long-established organ donation systems. With the exception of SA which has been included because of its similarities with Zambia such as culture, ethnicity and membership of Southern African Development Community (SADC), the other countries have been selected because they reflect some of the best practices in organ donation globally.

Three systems are commonly discussed in organ donation literature. These are: Opt-in organ donation, opt-out organ donation and mandated choice organ donation. In all but one of these countries (Spain) the system adopted is opt-in organ donation. This is a system by which individuals are non-donors until they register their intention to donate their organs thereby giving consent for the use of their organs upon their demise. In SA regardless of the fact that you do "register" your family will still be consulted and will have the final say (Muller, Thomson and McCurdie, 2015).

Opt-out organ donation also referred to as 'presumed consent' (adopted in Spain) is where everyone (with the exception of the vulnerable such as children (Campbell *et al.*, 2013)) is considered to be a donor unless they formally declare (register) not to be one. This system is, however, considered morally controversial by some authors because it is viewed as infringing on an individual's autonomy (Consolo and Wigmore, 2017) i.e. their right to make a free and uncoerced decision to be a donor.

Lastly, in a mandated choice or ‘required response’ system individuals are required by the government to explicitly state their decision of whether to be a donor or not or whether to leave the decision to their next of kin upon their death. In the USA, for example, the government requires persons to make known their decision on drivers license application/renewal forms or when registering to vote (Laurance, 2009).

Organ donation is riddled with a multitude of ethical complexities such as: what constitutes death for purposes of organ donation i.e. brain death or circulatory/cardiac death; what age is appropriate for a person to donate; and how organs are to be procured i.e. retrieved for transplantation and the systems or authorities to do so. Other complexities include: organ donation by living donors with specific reference to their autonomy, consent and the health risk involved, as well as organ commercialisation and organ trafficking (Howard and Cornell, 2016).

It is subject to questions of who the appropriate organ donor will be, how the organ will be allocated, and who the appropriate organ recipient is (Consolo and Wigmore, 2017). This research report focuses on solid organs such as kidneys, liver, heart, lungs, pancreas and intestines. They are the most common organs discussed and transplanted globally. Of these organs, all of them can be acquired from deceased donors while only one of two kidneys, one of two lobes of the liver, one lung or part of it, part of the pancreas, or part of the intestines can be acquired from healthy living donors (Health Resources & Services Administration | U.S Department of Health & Human Services, no date).

Despite deceased organ donation rates generally being higher than living organ donation rates globally (Transplant Procurement Management - Donation and Transplantation Institute, 2017), organs from healthy living donors ideally provide the recipient more years in terms of functionality than the former. For example, a kidney (the most transplanted organ globally) when acquired from a living donor has an approximate 18 year survival period compared to a kidney acquired from a deceased donor which functions for approximately 13 years (National Kidney Foundation, 2017; Living Kidney Donors Network, 2018).

Organ donation is perceived as altruistic in nature i.e. it involves acts of selflessness, putting another's beneficial interests and well-being before one's own (Dalal, 2015). There are, however, situations, where altruism is deficient, such as where the donation is influenced by financial gain or donation is coerced and without consent from the donor, for example, the acquisition of organs from prisoners in China (Sharif *et al.*, 2014). The concept of altruism in organ donation is usually associated with living organ donation. Living organ donation tends to be by related donors (loved one or friend) and is known as 'directed donation'. The two other categories of living organ donation are 'nondirected donation', where the donor donates an organ to a waiting list program and the person highest on the list receives the organ; and 'directed donation to a stranger', where the donor will give an organ to a complete stranger with whom he/she shares no relationship (Truog, 2005).

Living organ donation has been criticised as being absent of "donor autonomy" as the donor cannot be said to have given his/her informed consent to donate their organ in

its strict sense (Reese *et al.*, 2006). Autonomy can be considered in two ways, the donor's free will (the 'autonomous agent's free will') or the donor's right to act without influence or interference from loved ones or physicians (Coggon and Miola, 2011).

According to Coggon and Miola (2011),

> "The two approaches can be distinguished by reference to the crux of concern that each has. Those interested in (Kantian) autonomy" (i.e. the school of moral philosophy grounded in the principles of Immanuel Kant) "are concerned with the essence of a decision and how it is reached. Those interested in (Millian) liberty" (i.e. school or moral philosophy grounded in the principles of John Stuart Mill) "are concerned that a decision is made by the person whose right it is to make it, be that an individual on her own behalf or a third party deciding for her, rather (directly) than the rationality underpinning it".

Donors such as parents to a child in need of an organ are emotionally driven and will not care what the health risks or potential social-economic burdens are on themselves (Kolata, 1991), (deSante *et al.*, 2014). This notwithstanding, there is a duty incumbent on physicians "..to prevent people from making potentially life-threatening sacrifices unless the chance of success is proportionately large" (Truog, 2005). Informed consent requires that there is full disclosure of the short and long-term benefits and health risks to the donor, that he/she is competent enough to understand the details of the procedure, that the donor is not coerced by the nature of the relationship, family or the physician involved, and that the decision to donate is given voluntarily.

Essentially, a donation by a parent to a child could be perceived to be unethical. Fortunately, the Nuffield Council of Bioethics (1995) has held that, “The ethically significant requirement is not that consent be complete, but that it be genuine”. This will be discussed below.

In terms of Zambian laws on organ donation, the Human Tissue Act (1962) (National Assembly, 1962) is the only piece of legislation that regulates the “use of, or of parts of, bodies of deceased persons for therapeutic purposes and purposes of medical education and research” (1962). It provides in section 2 for persons to voluntarily consent to donate their body or parts of the body after their demise by expressly stating so “either in writing at any time or orally in the presence of two or more witnesses during his last illness” (National Assembly, 1962) (a will). Despite the mention of the use of body parts for “therapeutic purposes” in the Act’s preamble, a close look at the 5 sections contained in this Act shows that the Act is inadequate and does not mention or address the relevant ethical and legal issues pertinent to organ donation as stated above. Zambia’s lack of directly correlating organ donation legislation is of grave concern.

A look at another African country - SA, shows that the country is still facing issues of organ shortage as a result of inadequate legislative frameworks (McQuoid-Mason, 2012a; Labuschagne and P. Carstens, 2014) and social inequalities despite having performed organ transplants for 52 years now since the first kidney transplant was performed in 1966 in Johannesburg. Worth noting about organ transplantation in SA is that 50 years ago, it was considered as successful as other developed countries. It

is in SA that the world's first heart transplant was performed in 1967 by a team led by Dr Christiaan Barnard in Cape Town (Etheredge and Fabian, 2016).

The Act regulating organ donation in SA is the National Health Act No. 61 of 2003 and its accompanying Regulations. Chapter 8 of the Act being the pertinent chapter covers the "control of use of blood, blood products, tissue and gametes in humans" (*National Health Act 61 of 2003*, 2004). It lays out parameters for the donation and removal of tissue of deceased and living donors (Section 62) and provides a safeguard by stipulating who may consent or authorize such use including next-of-kin of the deceased (Section 62(2) and (3)). It also strongly prohibits the sale or trade of human tissue, an offence which imposes a fine or imprisonment of up to 5 years or both (Section 60(5)) (*National Health Act 61 of 2003*, 2004). This strong position is in order to deter and combat organ trafficking. Organ trafficking is a problem not only in SA (Muller, Thomson and McCurdie, 2015) but the world over. The fight against organ trafficking is reinforced by international principles and guidelines enshrined in the Declaration of Istanbul on Organ Trafficking and Transplant Tourism (2008) (see appendix C).

A discussion of SA's legislation is relevant to this research report especially because of the similarities between SA and Zambia. It will provide guidance on the type of strict controls necessary for organ donation in Zambia as well as how the issue of consent is handled especially in a country where individuals are sceptical about donating organs, trust in medical institutions and personnel is low, and a society's behaviour and beliefs are influenced by tradition and the shortcomings of the legislation from

which Zambia can learn (Association of Chartered Certified Accountants, 2013; Kunda, 2018).

As is the case globally, statistics of people suffering irreversible organ failure and in need of an organ in SA are high. According to the Organ Donor Foundation (2018), there are at least 4,300 adults and children awaiting organ transplant with slightly more than 300 receiving solid organ transplants each year from 2009 to 2016 (these statistics are not accurate, figures may be higher). This illustrates the disparity between organs needed and those available for transplant. It illuminates the need for governments and organ donation organisations to implement strategies to increase organ donation to offset the numbers of people on waiting lists and those dying whilst on the waiting list.

A brief analysis of Spain shows that it has an opt-out organ donation system that began in 1979 (Mcdowell, 2012). “The Spanish model of organ donation is internationally recognised as the best model worldwide in terms of increasing donation rates over a sustained period of time”. The model has overcome barriers to organ donation such as undertrained HCPs, failure to identify donors and approaching the families to ask for consent to begin the organ donation process.” (Matesanz, 2003; Mcdowell, 2012) According to the Global Observatory on Organ Donation and Transplantation (GODT), the total number of organ transplants in Spain in 2018 was 114.68 pmp which is 5321 transplants with the majority being deceased donations.

Spain's organ donation and transplantation success are mainly attributed to the implementation of a transplant coordinator network at national, regional and hospital level (Organ and Tissue Authority, 2013). Other strategies implemented are, "medical training in the entire process of deceased organ donation, the establishment of the National Transplantation Organisation (ONT) as a supporting central office and particular attention to media and communication policies" (Organ and Tissue Authority, 2013) to mention a few. These will be discussed briefly below. The Spanish model illustrates that legislation alone or just having an opt-out system is not enough. An opt-out system may not be best suited for Zambia but it can certainly benefit from some of the strategies implemented, including those of reducing donor family refusal rates as seen in Spain.

Israel, a country with an opt-in organ donation system, recorded total transplant rates of 71.65 (509 transplants) in 2018 (Global Observatory on Donation and Transplantation, 2016). Transplants may indeed be successful in these countries, but the representative figures here reflect only a small fraction of people receiving organs in comparison to the respective populations and numbers of people on the waiting lists. Robinson et al. (2012) posit that organ donation rates are affected by factors such as "knowledge" and "trust" in the organ donation process but more importantly, "religious beliefs". These all play a vital part in influencing the attitudes of society towards organ donation. It would appear that some individuals in society may be misguided on what religion says regarding donation and saving human lives. Christianity, Hinduism, Buddhism and Islam to mention a few are all pro organ donation and put great value on saving human lives (National Kidney Foundation, 2018).

While the figures in the preceding pages may draw upon one to consider an opt-out system over an opt-in system of organ donation, Shepherd et al. (2014) highlight countries (France and Brazil) where opt-out systems have failed to increase the organ donation rates. They refer to the high number of intensive care (ICU) beds considered in the 'Spanish model' to be a contributing factor to the high rate of organ donation in contrast to that of the UK with fewer ICU beds but argue that Germany, for instance, has almost twice the number of ICU beds as Spain and this has not resulted in high organ donation rates there. What is clear here is that countries may be affected by similar or related factors influencing their organ donation rates but have implemented different strategies to deal with these factors, resulting in high organ donation rates in some of them.

The strategies implemented in the Spanish model and the ethical and legal issues of organ donation mentioned above will be discussed in assessing their application in the Zambian context. In this context, I will also discuss two sets of international responses to the ethical and legal issues apparent in organ donation: "an international governmental response created through the World Health Assembly and World Health Organization (WHO), and a professional response created through international societies spearheaded by The Transplantation Society and the International Society of Nephrology" (Rudge *et al.*, 2012), the WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation (2010) and the Declaration of Istanbul on Organ Trafficking and Transplant Tourism (2018a) respectively.

The WHO Guiding Principles are concerned with living and deceased organ donation. They state, “The (following) Guiding Principles are intended to provide an orderly, ethical and acceptable framework for the acquisition and transplantation of human cells, tissues and organs for therapeutic purposes. Each jurisdiction will determine the means of implementing the Guiding Principles” (2010).

The Declaration of Istanbul refers to commercialisation and trafficking of organs, prohibiting the same. The two agreements are relevant to the discussion of this research report because they serve as guidance for professional conduct and development of government policy, and through their principles promote ethical practices of organ procurement and transplantation. The two international agreements will be discussed in detail below.

1.2 Research Question

What is the best suited ethical and regulatory framework for organ donation in Zambia?

1.3 The Rationale for the Study

Receiving an organ is truly ‘the gift of life’ for anyone suffering irreversible organ failure and staring death in the eyes. The scarcity of organs resulting in high demand and poor available supply is cause for the development of an efficient and effective organ donation system.

To the best of my knowledge, there has been no study carried out in Zambia to discuss and develop an appropriate ethical and regulatory framework for organ donation. As such, there exists a research gap. This research report will normatively evaluate the

application of the organ donation systems in the countries mentioned in the preceding pages respectively, discuss and answer questions concerning consent and how we can establish whether one's consent is genuine, and what the best-suited organ donation system for Zambia is. The research is important as it will potentially set a benchmark for matters relating to organ donation in Zambia based on elements of best practices in organ donation globally.

1.4 Thesis Statement

I argue that the best suited ethical and regulatory framework for organ donation in Zambia is one that observes a hybrid system of opt-in and 'soft' mandated choice and is consistent with the Declaration of Istanbul on Organ Trafficking and Transplant Tourism and the WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation.

1.5 Research Aim

To normatively assess the ethical and legal issues associated with organ donation with a particular interest in the Zambian context, taking into consideration the modern frameworks of organ donation practices.

1.6 Research Objectives

My main research objectives are:

- To normatively evaluate international regulatory instruments related to organ donation such as the Declaration of Istanbul on Organ Trafficking and

Transplant Tourism, and the WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation.

- To articulate and defend a normative position on the major ethical issues related to organ donation within the framework of living and deceased organ donation
- To critically evaluate organ donation systems and compare their application in South Africa, Israel and Spain.
- To argue in favour of an opt-in system of organ donation as being the best suited ethical organ donation system for Zambia.

1.7 Research Design

This study is an ethico-legal study and draws on normative philosophical theories. As a form of normative ethical inquiry as posited by Sugarman and Sulmasy (Sugarman and Sulmasy, 2001), the research report seeks to address what organ donation system Zambia ought to develop and whether everyone in society ought to be a donor. These questions are answered in a systematic, critical fashion and the answers offered will be justified.

1.8 Research Methods

This research is desktop and library-based. It, therefore, does not involve the collection or analysis of any new data or any study of human participants. The typical research methods and standards applicable to philosophical research are employed. I discuss findings from literature which are ethically analyzed. This primarily involves the interpretation and critical analysis of the most important texts, postings and relevant government legislation to answer the research question.

My analysis of the relevant texts includes the definition and clarification of concepts, the identification, and criticisms of assumptions, the analysis, and evaluation of theoretical frameworks, and the articulation of the most reasonable interpretation of significant concepts found in the sources. My sources of literature, therefore, includes but is not limited to research articles, books, Google Scholar, Scopus, Pubmed, Government legislation and other academic search engines for gathering data.

1.9 Argumentative Strategy

In the first part of the research report, I explain the domestic and international legislative and regulatory landscape of organ donation in Zambia and countries selected for their advances in organ donation as well as how they have reduced their organ shortage rates. I argue that the Human Tissue Act (1962) (National Assembly, 1962) is inadequate and outdated in that it fails to address organ donation with respect to organ donation systems and ethical issues related to living and deceased organ donors. I further argue that there is a need to reform this legislation and establish organ donation laws and regulations that are current and ethical observing recommendations of international regulatory instruments and guidelines on organ donation.

I then draw on the standard accounts of organ donation from both living and deceased donors by writers such as Robert Truog (2005) and Aiden McDowell (2012) among others, to explore the autonomous right of an individual to donate. I disagree with the argument posited by Reese et al (2006) that “donor autonomy can be respected only by strict adherence to informed consent” and argue that the need for voluntary

informed consent in living organ donation is not violated by the influence or moral self-interests at play in a donor-recipient relationship between loved ones or friends.

In order to give a holistic background and understanding of organ donation, I employ the philosophical theory of principlism to evaluate in turn the opt-in, opt-out and mandated choice systems. Espoused by Beauchamp and Childress (2013), principlism has been used for decades in medical practices globally in doctor-patient relationships and even to resolve conflicts of interest arising out of differences in the doctor's duty and advice and the patients choice and decision. I will use the pillars of this philosophical moral theory – respect for autonomy (individual's uncoerced autonomous choice), beneficence (individual's well-being and best interest observed), non-maleficence (do no harm-avoid harm to the individual), and justice (fairness), to establish the efficacy of the organ donation systems.

I argue that whereas there is a recent shift in Europe (British Medical Association, 2018) towards an opt-out system as this system could essentially increase organ donation rates as seen in the 'Spanish model' it is not without qualification as stated by the Royal College of Nursing (no date). I argue that a system encompassing principles of opt-in organ donation is best suited for Zambia. Considering that only a small percentage of the population is literate, the opt-in system has the advantage of avoiding injustices of coerced consent because people will have to be educated and informed (preferably in their native languages) about becoming organ donors before consenting. In this way, it protects the fundamental rights of the people by observing their right to freely consent to organ donation.

1.10 Ethics

The study does not involve research on any study participants.

1.11 Research Outcomes

Provide practical ethically justified recommendations for Zambian law on organ donation based on best practice.

1.12 Limitations

Organ donation is a topic that raises several areas of concern and an unlimited number of issues. This being the case, the allowed length of the study cannot cover all the areas. Zambia requires new legislation and guidelines to be drafted but unfortunately, this is something that is not achievable with this study.

1.13 Overview of Chapters

CHAPTER 1 – Introduction

CHAPTER 2 – Domestic and International Regulatory Frameworks

CHAPTER 3 – Ethical Perspectives of Deceased and Living Organ Donation

CHAPTER 4 – Critical Evaluation of the Organ Donation Systems and their Application

CHAPTER 5 – The Influence of Bioethics in Organ Donation Systems

CHAPTER 6 – Recommendations and Conclusion

1.14 Timing

Activity	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar
Protocol Development												

Protocol assessment and amendments												
Ethics application												
Data collection												
Data analysis												
Writing up research proposal												
Submit report for examination												

1.15 Funding

Item	**Costs**
Internet	Free
Printing	R 800.00
Binding	R 600.00
Transport	R 350.00
Total Cost	**R 1750.00**

2 CHAPTER 2 – DOMESTIC AND INTERNATIONAL REGULATORY FRAMEWORKS

2.1 Introduction

Suppose there were no laws governing professional conduct, health institutions and organ procurement, the result would be a scarcity of organs. The 'state of nature' would be such that there might be no trust in HCPs and health systems. As a greater social community living together, we adhere to rules and laws that guide our behaviour, afford rights and freedoms, and at the same time enforce certain limits, checks and balances to avoid one man infringing on another's rights. These rules and laws constitute what is termed a 'social contract' (Nuffield Council of Bioethics, 2007). A set of laws that adequately govern organ donation and transplantation in Zambia would be a form of a social contract. In this way, the government would recognise the collective will and rights of its people. Thus, responsibility is borne of government to its citizens.

The social contract theory is at the centre of what the Nuffield Council of Bioethics calls the 'stewardship model'. According to the Nuffield Council of Bioethics (2007),

> "the concept of stewardship means that liberal states have responsibilities to look after the important needs of people both individually and collectively. Therefore, they are stewards both to individual people, taking account of different needs arising from factors such as age, gender, ethnic background or socio-economic status, and to the population as a whole, including both citizens of the state, and those that do not have citizen status, but fall under its jurisdiction".

At an international level, organisations such as the WHO "mobilise the collective action of countries to generate global public goods such as research, while fostering a shared vision towards more equitable development across and within countries" (World Health Organisation, 2000). In its World Health Report of 2000 titled "Health Systems: Improving Performance", the WHO couched the responsibility of government (stewardship role) to its citizens as:

> "The ultimate responsibility for the overall performance of a country's health system lies with the government, which in turn should involve all sectors of society in its stewardship. The careful and responsible management of the well-being of the population is the very essence of good government. For every country, it means establishing the best and fairest health system possible with available resources. The health of the people is always a national priority: government responsibility for it is continuous and permanent. Ministries of health must, therefore, take on a large part of the stewardship of health systems. Stewardship encompasses the tasks of defining the vision and direction of health policy, exerting influence through regulation and advocacy, and collecting and using information."

The Zambian government ought to learn from the WHO's stewardship role with respect to organ donation in Zambia. This entails working to improve general public health, and in so doing reduce the demand for organs for transplantation. As one of the government's responsibilities, developing laws that define how organ donation can be carried out in a legally and ethically acceptable manner could assist in encouraging

people to donate more willingly. This may also have the effect of assisting in fostering steps to remove inequalities that affect disadvantaged and vulnerable persons.

The focus of this chapter is on the legislative framework on organ donation in Zambia particularly the Constitution of Zambia Act, Chapter 1 of the Laws of Zambia (as amended by Act No. 18 of 1996 and Act No. 2 of 2016) and the Human Tissue Act (1962) Chapter 306 of the Laws of Zambia in order to give a background of the legislative framework. Equally important to this chapter are international regulatory instruments related to organ donation such as the Declaration of Istanbul on Organ Trafficking and Transplant Tourism, and the WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation because they serve as guidance for professional conduct and development of government policy, and through their principles promote ethical practices of organ procurement and transplantation.

Lastly, relevant provisions of the South African National Health Act are discussed, thereby highlighting the kinds of strict controls necessary for organ donation in Zambia as well as how consent is handled in a country like Zambia where scepticism about donating organs, trust in medical institutions, low health personnel numbers, behaviour and beliefs influenced by tradition (Association of Chartered Certified Accountants, 2013; Kunda, 2018), and regulatory shortcomings are some of the major hindrances to organ procurement and consequently, organ transplantation. This chapter highlights the requirement to develop laws that define how organ donation can be carried out in a legally and ethically acceptable manner and is in alignment with objective 1, to normatively evaluate international regulatory instruments related to organ donation

such as the Declaration of Istanbul on Organ Trafficking and Transplant Tourism, and the WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation.

2.2 The Legislative Framework on Organ Donation in Zambia

2.2.1 The Constitution

In Zambia, the Constitution is the supreme law of the land. Any other written law conflicting with it is invalid to the extent of its contrariety (National Assembly, 2016). The provisions of the Constitution relevant to the discussion on organ donation are Article 52(1)(a) "right to healthcare services" and Article 58(1) the State's responsibility towards the people to "take reasonable measures for the progressive realisation of economic, social, cultural and environmental rights" (National Assembly, 2016).

It is recognised that through Article 52(1) every citizen has an undeniable right to expect at the very least that they will be able to access healthcare services. In turn, this translates to an obligation on the government to provide healthcare facilities that are accessible for all. The McGraw-Hill Concise Dictionary of Modern Medicine (2002) defines healthcare services as being:

1. "A business entity that provides inpatient or outpatient testing or treatment of human disease or dysfunction; dispensing of drugs or medical devices for treating human disease or dysfunction.
2. A procedure performed on a person for diagnosing or treating a disease."

Taking the second definition into consideration, organ transplantation can be said to be a healthcare service as it is a procedure performed on a patient in need of an organ to replace a failing organ and consequently treating a disease. In this regard, the government has an obligation to the people to provide organ transplant services to the people as a healthcare service to which they have a right.

However, providing healthcare services such as organ transplantation to the entire nation may be very expensive and especially burdensome on the government, a situation which the legal draftsmen guarded against through Article 58(1) which provides that government should take reasonable measures to progressively realise rights such as that under Article 52(1).

It is submitted that in the 21st century, a nation such as Zambia ought to be providing human organ transplant services to its people considering that several nations across the world are recognising it as a basic health service towards end-of-life care.

2.3 Deceased donation

2.3.1 The Human Tissue Act

The Human Tissue Act (HTA) (National Assembly, 1962) was promulgated in 1962. To date, it is the only Act directly regulating the donation of organs or the entire body of a deceased person in Zambia. As highlighted in the introduction, a discussion of the HTA is important here because it provides a background of the legislative framework

of organ donation in Zambia. The HTA is a short Act with only 5 sections all of which address deceased organ donation. However, the HTA does not provide for the donation of organs from living donors. To this end, a lacuna exists in the legislation. This is especially problematic because the focus for procuring organs in Zambia for transplant purposes will be living organ donation.

The examination and use of bodies for medical purposes are provided for under section 2 of the Act which stipulates that any person wishing to donate part of their body or their entire body may do so in one of two ways. Firstly, according to section 2(1), a person wishing to be a donor can expressly state their wishes to donate in a written document at any time. Secondly, the same section provides that they can express their wishes "orally in the presence of two or more witnesses during their last illness". In accordance with this section, the person in possession of the deceased's body has then the authority to direct the use of the specified organ or body to be used or examined as per written or oral instruction of the deceased person.

The section caters for written and oral instructions given by the deceased before his death to donate his organ(s) for "therapeutic purposes or be examined or purposes of medical education or research". However, in the case of an oral instruction, the section appears to suggest that where an individual orally instructs that his organ(s) be donated without the presence of two or more witnesses, such instruction may not be held to be executable. This position could be two-fold. On the one hand, it is a strong and worthy safeguard against malicious or wrongful procurement of organs from the "voiceless", the deceased. On the other hand, it limits donation of organs in that available viable organs may not be procured from donors simply because at the time

a donor wished to declare his instruction to donate, there may not have been at least two witnesses present, therefore, no consent to procure the organs could be granted. Consequently, possible viable organs are lost.

Section 2(2) of the Act goes further and provides that,

> "the person lawfully in possession of the body of a deceased person may, for the said purposes, authorise the examination or use of the body and the removal from the body of any part if, having made such reasonable inquiry as may be practicable, he has no reason to believe - (*a*) that the deceased had expressed an objection to his body being so dealt with after his death and had not withdrawn it; or (*b*) that the surviving spouse or any surviving relative of the deceased objects to the body being so dealt with".

After having obtained oral or written consent from the deceased before his death, for the use or examination of his body after his death, the person in possession of the body has then the authority to direct or withhold the authority to use or examine the body provided no alternate instruction was given or objection has been made by the deceased's family. In cases where the family of the deceased is opposed to their loved one being an organ donor, section 2(2) upholds their right to negate an instruction by the deceased whether written or oral. This section ensures that families of the deceased persons are consulted before organs are procured from their loved ones irrespective of the fact that written or oral consent to donate exists.

Section 3 of the Act prohibits such person from authorizing, in accordance with section 2, the use or examination of an organ or the body "where an inquest or postmortem of the body is to be held or the body or any part of the body may be required to be dealt with or disposed of in any other manner prescribed by or under any written law in force at the time". The Act further recognizes in section 3(3) instances where use or examination of an organ or the body may be delegated. It states that:

> "In the case of a body lying in a hospital, nursing home or other institution, any authority under section *two* may be given on behalf of the person having the control and management thereof by any officer or person designated for that purpose by the first-mentioned person".

This subsection, similar to a few other subsections and sections of the Act are not easy to read and could be better formulated. Section 3(3) seems to suggest that in a health institution, the authority to use or examine a specified organ or the body under section 2, may be exercised by any officer or person designated that authority by the manager or controlling officer of the institute. The Act fails to qualify what position or office the person delegated the authority and section 2 ought to have.

The authority granted under section 2 can only be exercised in accordance with section 4 of the Act which restricts the examination and removal of organs. Section 4(2) in particular provides that:

> "No removal of a part of a body in accordance with an authority given under section *two* shall be effected except by a medical practitioner, who must have satisfied himself by a personal examination of the body that life is extinct."

Two points are worthy of note from section 4(2). Firstly, it is clear that the removal of an organ can only be performed by a medical practitioner and the medical practitioner must also be satisfied that there is no sign of life present.

In 1991, the World Health Assembly, to which Zambia is a member, ('WHO | Alphabetical List of WHO Member States', 2014) endorsed the WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation. It was recommended by the Forty-fourth World Health Assembly that member states take into consideration the Guiding Principles in developing their internal policies on human organ transplantation (World Health Organisation, 1991). These guidelines have been endorsed by subsequent sittings of the World Health Assemblies, with the latest being in 2010. According to Guiding Principle 2:

> "Physicians determining that a potential donor has died should not be directly involved in cell, tissue or organ removal from the donor or subsequent transplantation procedures; nor should they be responsible for the care of an intended recipient of such cells, tissues and organs."

Guiding Principle 2, by inference, is couched in this manner to circumvent the instance of a possible conflict of interest arising where the medical practitioner/physician/health practitioner establishing the death of a possible donor is also involved in caring for an individual awaiting an organ. A comparison of section 4(2) and Guiding Principle 2 highlights the shortfalls of the former. It is evident that the HTA does not take into account the possibility of such conflict. It appears that under the HTA, a health practitioner who determines the death of the potential donor can also serve on the

transplant team. In Spain and other countries leading in human organ transplants, for example, policies and legislation have been developed to avoid such conflicts arising. Determination of death ought to be performed by health professionals who are independent of donation and transplant teams (Council of Europe: European Directorate for the Quality of Medicines & Healthcare, 2016).

2.4 International Regulatory Instruments

International regulatory instruments are important because they help maintain order and peace among member states. They seek to ensure the peaceful coexistence of human beings residing in different territories governed by differing laws and customs. With regard to healthcare, international regulatory instruments play a vital role in that they take into account the several geographic, economic and demographic inequalities present among states within the international community and seek to provide ethically justifiable regulations to safeguard the wellbeing and non-exploitation of humankind.

Furthermore, international regulatory instruments ensure that member states uphold uniform good practices, taking into account the economic and demographic state of the member states. This is realized by allowing member states to determine the means by which they implement principles and guidelines. Two such pieces of international regulatory instruments relevant to this research report are the WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation, and the Declaration of Istanbul on Organ Trafficking and Transplant Tourism.

2.4.1 Living donation

2.4.1.1 WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation

In May 2010, the Sixty-Third World Health Assembly led by the WHO resolved to endorse the WHO Guiding Principles which were updated to respond to "current trends in transplantation, particularly organ transplants from living donors and the increasing use of human cells and tissues. The Guiding Principles are intended to provide an orderly, ethical and acceptable framework for the procurement and transplantation of human cells, tissues and organs for therapeutic purposes. Each jurisdiction will determine the means of implementing these WHO Guiding Principles. They preserve the essential points of the 1991 version while incorporating new provisions in response to current trends in transplantation, particularly the protection of the living donor, and the increasing use of human cells and tissues" (World Health Organisation, 2010).

Pertinent to this research report are the following summarized Guiding Principles:

- Consent must always be obtained before cells, tissues and organs can be removed from persons for purposes of transplantation.
- HCPs providing care to a patient and who later determine death should not be part of or involved in transplant teams.
- It is encouraged that living donors are biologically, legally or emotionally related to persons receiving their organs.
- Payment or monetary reward for donation of cells, tissues and organs should be prohibited.

- The criteria for allocation of organs should be based on clinical and ethical values and not monetary considerations.
- Committees whose responsibility it is to allocate organs should do so transparently, equitably and in a justified manner.

In this regard, the WHO Guiding Principles emphasise the need for the Zambian government as well as organ donation and transplant authorities (when established) to develop clear policies or laws that define processes such as obtaining consent for organ procurement and transplantation; to increase staffing numbers of HCPs and train specialised personnel who will operate specifically on transplant teams in order to avoid conflicts of interest arising for attending HCPs; to prohibit exploitation of minors and payment for organs; and to support as well as ensure transparency throughout the organ donation and transplantation process.

As the country is only beginning transplantation of human organs, it is expected that donations of organs will generally be by individuals closely related or emotionally connected to patients requiring organs for transplantation.

2.4.1.2 Declaration of Istanbul on Organ Trafficking and Transplant Tourism

In 2004, the World Health Assembly (WHA) convened in Geneva, Switzerland and urged member states “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” (World Health

Organisation, 2004). A report in 2007 highlighted that up to 10% of organ transplant procedures globally involved the exploitation of poor and vulnerable groups in this manner (Shimazono, 2007).

Troubled by the escalating problems resulting from these unethical practices, The Transplantation Society (TTS) and the International Society of Nephrology (ISN) called a summit meeting in 2008, inviting representatives of scientific and medical bodies, government officials, social scientists, and ethicists. The result was the establishment of the Declaration of Istanbul on Organ Trafficking and Transplant Tourism, a document that has been widely accepted and endorsed worldwide (The Transplantation Society and International Society of Nephrology, 2018). Of a number of over 151 participants comprising national and international societies and governmental bodies, Zambia was not among the participants at the 2008 summit in Istanbul. The Declaration was updated in 2018 (see below). At present, Zambia has not endorsed the Declaration of Istanbul to date.

Set out in the Declaration are concise definitions of organ trafficking, transplant commercialism, and transplant tourism followed by a set of principles guiding professional conduct and state policy. It is summed by proposals consistent with the principles focusing on particular issues in transplantation (American Society of Nephrology, 2018).

In 2018, a decade from the establishment of the Declaration, a working group of professionals from different member states comprising the Declaration of Istanbul Custodian Group (DICG) convened and revised the Declaration (The Transplantation

Society, 2018). This was done in an attempt to ensure that the Declaration of Istanbul continues to be relevant in providing ethical guidance for HCPs and policymakers assisting them to combat the emanating global challenges in organ trafficking and transplant tourism (The Transplantation Society, 2018).

The 2018 revised Declaration like its predecessor consists firstly of revised definitions of organ trafficking, travel for transplantation, and transplant tourism. It goes a step further to include definitions of trafficking in persons for the purpose of organ removal, resident, non-resident, self-sufficiency in organ donation and transplantation, and financial neutrality in organ donation. Secondly, 11 concise principles are stipulated providing ethical guidance for professionals and state policymakers.

However, unlike the 2008 Declaration which contained brief proposals on the application of the principles, the 2018 Declaration refers to an accompanying commentary paper which is to be read with the principles. The “companion article explains concepts, offers justifications for normative positions, and provides examples of how the Declaration can be applied in practice” (Martin *et al.*, 2019). The principles and their accompanying commentary are presented in an article titled ” Strengthening Global Efforts to Combat Organ Trafficking and Transplant Tourism: Implications of the 2018 Edition of the Declaration of Istanbul” by Martin et al. (2019). This article is published on the Declaration of Istanbul website (Declaration of Istanbul Custodian Group, 2019).

The article provides practical recommendations reflecting best practices on issues such as ‘care of the living organ donor’, ‘consent for donation and transplantation’, and ‘financial neutrality in donation’.

In the wake of Zambia beginning to perform transplants, there is a need to establish laws that prohibit “trafficking in human organs in all its forms and trafficking in persons for the purpose of organ removal” (Martin *et al.*, 2019). This will allow for the nation not only to provide its people future safeguards but also confidence in the public that the vulnerable will not be exploited, victimised or treated as mere commodities but be respected as persons.

Principle 3 states that “Trafficking in human organs in all its forms and trafficking in persons for the purpose of organ removal should be prohibited and criminalized”. The companion article by Martin et al. (2019), with respect to this principle, illustrates the injustices realised by the commercialisation of organs or humans for purposes of harvesting organs. It states in part that,

> “..offering payments for organs undermines justice by reinforcing rather than reducing socioeconomic inequities; it targets the poor as a source of organs and stigmatizes donation. It also compromises the ethics of the medical profession and the public’s trust in healthcare systems. Ultimately, it weakens the solidarity needed for successful organ donation programs, thereby reducing the number of organs offered altruistically”.

This should be read with Principle 10 and 11 which respectively state that "Governments and HCPs should implement strategies to discourage and prevent the residents of their country from engaging in transplant tourism" (The Transplantation Society and International Society of Nephrology, 2018), and "countries should strive to achieve self-sufficiency in organ donation and transplantation" (The Transplantation Society and International Society of Nephrology, 2018).

Principle 5 of the 2018 revised Declaration encourages "each country or jurisdiction to develop and implement legislation and regulations to govern the recovery of organs from deceased and living donors and the practice of transplantation, consistent with international standards". Were Zambia to endorse the Declaration, a responsibility would arise on the government to its citizens to examine existing legislation in order to determine and address technical as well as ethical shortcomings. This process could allow for the development of organ donation and transplantation laws that outline an ethically and legally justifiable organ donation and procurement system in Zambia.

2.4.1.2.1 Deceased donation with respect to the Declaration of Istanbul

The accompanying article, also discusses some features of international standards, these being technical and ethical features. It refers to the criteria by which death is determined and the distinct separation of HCPs providing care and determining the death of a patient from those comprising the transplant team, respectively.

The aforementioned are two features that are vital to the process of procuring organs and transplantation. It is important that before organs can be procured, there is no

ethical impropriety. Determining death is an important step in ensuring ethical propriety in procuring of organs from deceased organ donors. Determination of death will be discussed in detail in Chapter 3. Laws assist HCPs in performing their duties in this regard because they instil confidence and clarity in the process of procuring organs for transplantation.

2.4.1.2.2 Living donation with respect to the Declaration of Istanbul

Donating an organ can be costly. Which costs are considered reasonable costs and who pays for these costs are necessary points that require establishing. Payment for organs as discussed above should not be confused with monetary reimbursement for donation. Principle 4 establishes that "organ donation should be a financially neutral act" i.e. to the same extent that donation should not become a money-making venture for living donors (or families of deceased donors), it should not become financially distressing either (Martin *et al.*, 2019). Noteworthy is the fact that these out of pocket costs that accrue to the living donor as a result of travel, loss of income, pre-screening and post-op care can be greatly burdensome on the donor. As a result, this could lead to potential donors being deterred from wanting to donate and in turn increase the shortage of organs.

Practical recommendations for the strategic implementation of Principle 4 are highlighted in the companion article. It provides that states may determine for themselves what kind of reimbursement or coverage implements they may put in place depending on their respective socioeconomic factors (Martin *et al.*, 2019).

As such, Zambia ought to “develop clear guidance for healthcare providers, donation and transplantation programs and the public concerning reimbursement or coverage of donation-related costs, and policies or guidelines should be regularly reviewed”. This will show the state’s support and commitment to providing access to health services for everyone as well as encourage the public to come forward and be donors. Consequently, there could be more organs available for transplantation.

Endorsement of the Declaration of Istanbul would show Zambia’s acknowledgement and support of the development of ethical programs for organ donation and transplantation, and the prevention of organ trafficking, trafficking in persons for the purpose of organ removal, as well as of individuals purchasing organs from impoverished and vulnerable people.

2.5 Comparative Law – The Case of South Africa

2.5.1 South Africa’s National Health Act

In South Africa, organ donation is regulated by the National Health Act No. 61 of 2003, Chapter 8 in particular as well as by the Act’s accompanying regulations. As stated above, in section 1.1, a discussion of SA’s legislation is relevant to this research report especially because of the similarities between SA and Zambia. It will provide guidance for Zambia on the type of controls necessary for organ donation in Zambia as well as how consent is handled especially in a country where individuals are sceptical about donating organs, trust in medical institutions and personnel is low, and a society’s

behaviour and beliefs are influenced by tradition (Association of Chartered Certified Accountants, 2013; Kunda, 2018), and regulatory shortcomings are some of the major hindrances to organ procurement and consequently, organ transplantation.

2.5.1.1 Deceased donations

The donation of human bodies and tissue of deceased persons is regulated by Chapter 8 of the National Health Act (NHA) which was promulgated on 1 March 2012 having repealed the Human Tissue Act No. 65 of 1983. The specific sections are:, section 61 - allocation of organs only under prescribed conditions; section 62 - donation of human bodies and tissue can be expressed in a will; section 64 - the purpose for donation; section 65 - revocation of donation; and section 68 - authorisation of the Minister to make regulations regarding the chapter.

Section 62 is concerned with granting consent for the donation of one's body or tissue after one's death by way of a will. A will is a testamentary document that is usually written in one's confines to express one's wishes after their demise. As such, it may not see the light of day only until the testator (owner of the will) has died. Two issues of concern arise here. Firstly, several years could have passed between the time the will was written and the death of the testator. During this time the testator may have changed his mind but neglected to update his will. Even in the event that he or she did not change their mind, their next-of-kin may not be aware of their wishes expressed in the will and oppose the donation at the present day (Venter, 2012). Secondly, a will must go through certain legal procedures of probate before it can be presented as a

valid and legally binding document expressing the testator's wishes which are to be followed (South African Medical Association, 2012).

This is problematic because Section 8(1) of the regulations (see below), provides that tissue must be removed from a body within 24 hours of the death of the person. It is most unlikely that the deceased person's will would be read within this time period. This may only be possible where the deceased made an oral statement before his death.

The regulation relevant to this research report is Regulation 35099 - Regulations Regarding the General Control of Human Bodies, Tissue, Blood, Blood Products and Gametes. Of particular relevance are: section 8(1) - the requirement that tissue must be removed within 24 hours from donated bodies ; section 8(3) - the removal of eye tissue ; section 9 - the parties responsible for determining death of a person whose organs are to be removed for transplantation purposes; section 24 - confidentiality and publicity regarding tissue and organ transplants; and section 26 - the exclusivity of rights in respect of tissue donations (McQuoid-Mason, 2012b).

It is clear from these provisions that SA unlike Zambia has taken on board and implemented the principles laid out in international documents such as the WHO Guiding Principles and Declaration of Istanbul shown above. Zambia could follow the example set by South Africa in developing organ donation and transplantation laws that emulate international best practices and safeguard against donation, transplant and organ trafficking injustices.

2.5.1.2 Living donation

The sections to Chapter 8 of the NHA relating to living donors and relevant to transplantation cover the need for written consent to be obtained in accordance with prescribed conditions for removal of tissue (Section 55); use of tissue removed or withdrawn from living persons (Section 56); requirement for removal and transplantation to be performed in a hospital (Section 58); requirement that only a medical practitioner may perform removal (Section 59); reimbursement for organ donation (Section 60);

Irrespective of these largely inclusive provisions, SA's legislation on organ donation and transplantation is not without its shortcomings. According to Labuschagne and Carstens (2014) the NHA "does not meet the standard of a reasonable legislative measure with regards to organ transplantation law". Section 55 of the NHA, for example, stipulates that removal of tissue from a living person can only be done having obtained written consent from the person donating the tissue and in accordance with prescribed conditions. Section 56 stipulates in part that "tissue which is not replaceable by natural processes may not be removed by any person from a person younger than 18 years".

The problems that this provision was couched to avoid are clear. The conflict arises when it is read with Section 2(1)(b) of the amended Regulation 35099, i.e., Regulation 39982 which provides that "where written consent has been obtained from the parents or guardians of a person younger than 18 years, the tissue may be removed from such person". Whether the tissue referred to in the regulation includes that which is not

replaceable by natural processes is unclear. The same is the case when read with the Children's Act No. 38 of 2005 section 129 (3) which provides for a child of age 12 and above to give consent for a surgical procedure on themselves or their child provided they are of sufficient maturity and a parent or guardian assists the said child. These provisions are evidently problematic and could result in some absurdity.

Sections 60, 61, and 62 equally highlight the ethical and legal lapses of SA law and regulations. According to Section 60(4), it is an offence for a person who has donated tissue to be remunerated for the donation but they can be reimbursed for "reasonable costs incurred by him or her to provide such donation". "Reasonable costs" may cover travel, loss of income for the period in hospital and recovery; the cost of an ICU bed space; and post-op care. It is submitted that these costs could be argued to be reasonable costs incurred by the donor.

In this regard, section 60 appears to align with the Declaration of Istanbul's principle of financial neutrality (The Transplantation Society and International Society of Nephrology, 2018). The reimbursement to the donor is not a form of enrichment but a way to alleviate the financial distress on the donor and/or their family.

Held et al. posit that the costs incurred by living donors could "… be paid in a delayed non-cash form—such as tax credits, health insurance, tuition assistance, retirement funds, etc.—so people who are desperate for cash would not be tempted to sell a kidney" (2018). It is not enough to state what may or may not be reasonable costs, an

important issue to take into consideration is who would bear the responsibility to reimburse donors (Venter, 2012).

Reimbursement of donors for costs incurred is an issue that ought to be seriously considered especially because it has the added direct benefit of resulting in more organs being donated (Held *et al.*, 2018). According to Held et al. (2018), opponents of fair compensation for organ donation argue that the underprivileged are at risk of being exploited by the wealthy as they are more likely to accept compensation. De Castro (2003)on the other hand, argues that “the concerns are weighty and valid, but not insurmountable”. He submits that “the possible disadvantages of compensated organ giving are not greater than the possible benefits, and these can be minimised through the implementation of safeguards” (de Castro, 2003).

Organ donors are the cornerstone of any organ donation and indeed organ transplant program. It is almost impossible to envisage human organ transplantation without human organ donors. Despite their involvement in the organ transplantation process, donors are the only individuals that do not realise a tangible benefit (Shaikh and Bruce, 2016) from living donor transplants (Friedman, 2006). Knowing that they would be fairly compensated for their altruistic act would certainly be an added incentive.

Currently, no legislative provisions exist in Zambia that provide for reimbursement of costs incurred by donors. There is clearly a need for the Ministry of Health and other relevant organisations to take this into account before proceeding with organ transplants.

Finally, section 61 refers to prescribed procedures being used in allocating organs. However, the section fails to state what these procedures are or where they can be found.

2.6 Conclusion

This chapter set out to discuss the requirement to develop laws that define how organ donation can be carried out in a legally and ethically acceptable manner. It is submitted that Zambia's legislation on organ donation requires reform to allow HCPs to be able to confidently perform their duties such as determination of death and removal of organs. At the same time, this will build public confidence and trust in the health system and the organ donation and transplantation process.

As Zambia is an existing member of the WHO, adopting the WHO Guiding Principles should be a welcomed move. The Zambian government should have a 'stewardship' role in organ donation and ensure the continuous review of relevant policies and guidelines.

Zambia cannot set itself apart from the rest of the world in the hope that organ trafficking, trafficking in humans for parts and transplant tourism will not mushroom in the country if it has not started already. Furthermore, Zambia's ratification and endorsement of the Declaration of Istanbul will be greatly advantageous and will aid in developing laws specifically to address these atrocious evils by stipulating explicit offences to deter such activities from the outset.

Finally, as is evident from the brief review of SA legislation, there is the need for clear guidance for HCPs, development of donation and transplantation programs, and clear guidance for the public concerning reimbursement or coverage of donation-related costs.

3 CHAPTER 3 – ETHICAL PERSPECTIVES OF DECEASED AND LIVING ORGAN DONATION

3.1 Introduction

Organ donation rates vary greatly across the globe. The need to increase the supply of organs has led to more and more countries adopting living donor organ procurement to supplement the number of organs procured from deceased donors. The practice of procuring organs raises a multitude of ethical dilemmas that HCPs are faced with each time an organ is to be procured. This chapter focusses on these issues, discussing deceased organ donation in the context of donation after the determination of death and acquiring consent for donation of the deceased's organs from their family or next-of-kin after death; and living organ donation in the context of donor autonomy and informed consent. This chapter is aligned with objective 2, to articulate and defend a normative position on the major ethical issues related to organ donation within the framework of living and deceased organ donation

3.2 Deceased (Cadaveric) Organ Donation

A vital requirement in the process of procuring of organs from deceased donors is determining that the donor is dead. The standard used to ascertain death is called the 'dead donor rule' - "organs should only be recovered from donors who have died and nothing should be done by transplant or organ recovery programs that would hasten the death of a donor" (Howard and Cornell, 2016). The purpose of this rule is to safeguard against lives being ended for the mere purpose of organ procurement and protect the donor before his/her death (Girlanda, 2016). According to Girlanda (2016), the importance of this rule lies in its effect to foster public trust in the donation and

transplantation process and safeguard against the possibly preconceived notion that patients deaths are hastened in order for organs to be procured.

The determination of death follows two forms: brain death (neurologic determination of death) and circulatory death (circulatory determination of death) which will be discussed here.

3.2.1 Donation after Brain Death (DBD)

Donation after brain death (DBD) or neurologic determination of death "occurs when the entire brain including the brain stem has no detectable function" (Howard and Cornell, 2016). This criterion despite being the standard commonly relied upon is not without criticism. According to Sade and Boan (2014) and admittedly so, "a brain-dead donor's beating heart, rhythmic respiration, warm skin, and urine flow from a Foley catheter simply do not appear to be 'real death' to most families and health professionals".

Truog and Miller (2008) posit that trust in the transplantation as a whole is at risk of being eroded with continued dependence on the dead donor rule. According to the two authors, the definition of brain death is confusing at the very least because it requires the "complete absence of all functions of the entire brain" yet in reality, several patients declared brain dead still show signs of neurologic functions. These patients are for all intents and purposes legally dead but cannot be said to be biologically dead (Sade and Boan, 2014).

They further hold that it is, therefore, possible that HCPs manipulate this concept in a way to aid them better acquire organs for transplantation. Truog and Miller suggest that “whether death occurs as the result of ventilator withdrawal or organ procurement, the ethically relevant precondition is valid consent by the patient or surrogate”. This supposition is problematic because it suggests that so long as valid consent is acquired from the patient or their next-of-kin, even where the patient has not yet been determined and declared dead, organs can be recovered from the patient irrespective of the fact that this will result in their death.

It is probable that in the African context, Zambia to be specific, this would most likely result in mistrust in the health system and HCPs as the belief would be that patients are being murdered by HCPs for the purpose of procuring organs the use of which would most likely be seen as witchcraft. This will inevitably result in a reduction in the number of consents given for donation.

On the other hand, organ donation ought to be integrated into the end of life care. According to Girlanda, “the integration allows for the donation process to begin well before the death of the donor” (2016). The process makes it possible to identify and manage would-be donors through careful coordination of end of life care and organ donation. The end result is an opportunity for more organs to be donated.

3.2.2 Donation after Cardiac Death (DCD)

Donation after cardiac death or circulatory determination of death is the occurrence of no detectable “cardio-circulatory activity” detectable in a patient. Depending on the

protocols used within hospitals (as these may vary) an observation time of 2–5 min is adhered to ensure that there is a complete cessation of blood flow (Truog and Miller, 2008; Girlanda, 2016; Howard and Cornell, 2016). Historically, since the first organ transplant in the 1960s, DCD was the only way by which organs could be procured until after 1968 when brain death was conceptualised and defined by members of a committee of Harvard Medical School (Girlanda, 2016).

TABLE 1 DONATION AFTER CIRCULATORY DEATH: CATEGORIES OF DONOR

Maastricht category and type of donation after circulatory death (DCD)	**Observations**
I: Found dead (uncontrolled) I.A: out of the hospital I.B: in hospital	Sudden unexpected cardiac arrest, with no attempt at resuscitation by a medical team
II: Witnessed cardiac arrest (uncontrolled) II.A: out of the hospital II.B: in hospital	Sudden unexpected irreversible cardiac arrest, with unsuccessful resuscitation by a medical team
III: Withdrawal of life-sustaining therapy* (controlled DCD)	Planned, expected cardiac arrest, following the withdrawal of life-sustaining therapy
IV: Cardiac arrest while brain dead (uncontrolled or controlled)	Sudden or planned cardiac arrest after brain death diagnosis process, but before organ recovery

Modified Maastricht classification, Paris 2013.

* This category mainly refers to the decision to withdraw life-sustaining therapies. Legislation in some countries allows euthanasia (medically-assisted cardiac arrest) and subsequent organ donation is described as an additional category.

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As with DBD, some authors such as Sade and Boan (2014) posit that patients declared dead by circulatory determination are not biologically dead despite being termed legally dead in accordance with accepted medical practices. Their reasoning is that death is declared 2 – 5 minutes following a heart attack but the attack can be reversed

– it is common for circulation to be restored even after prolonged periods in individuals who have suffered a sudden cardiac episode.

Furthermore, they argue that DCD results in wastage of organs because of the time-lapse between cessation of circulation after the withdrawal of life support and circulatory arrest of which only then can death be declared. This period could take up to an estimated 65 minutes (up to 60 minutes for complete "cessation of circulatory-cardiac activity and 2 – 5 minutes before pronouncement of death) by which time the falling mean arterial pressure reaches 50 mm Hg or less, organ perfusion becomes inadequate and organ damage ensues due to warm ischemia" (Sade and Boan, 2014).

Sade and Boan support Truog's argument that the dead donor rule should be done away within a bid to increase the number of usable organs. Nonetheless, there is inadequate evidence provided in the literature to support this argument and as such it will not be discussed further in this report.

Worth noting is the Council of Europe's Guide to the Quality and Safety of Organs and Transplantation 6th edition (Council of Europe: European Directorate for the Quality of Medicines & Healthcare, 2016) which highlights the WHO's critical pathway for deceased donation. It emphasises the need to uphold and respect the dead donor rule. "Conceived as a useful clinical tool applicable to every country (region or hospital) for assessing the potential of deceased organ donation, evaluating performance in the deceased donation process and identifying areas for improvement, the particular value of this tool is that it creates uniformity in the description and assessment of the

deceased donation process. The Critical Pathway for Deceased Donation builds upon both DBD and DCD and defines types of donors based on the different phases of the donation process: possible, potential, eligible, actual and utilised organ, donors" (Council of Europe: European Directorate for the Quality of Medicines & Healthcare, 2016).

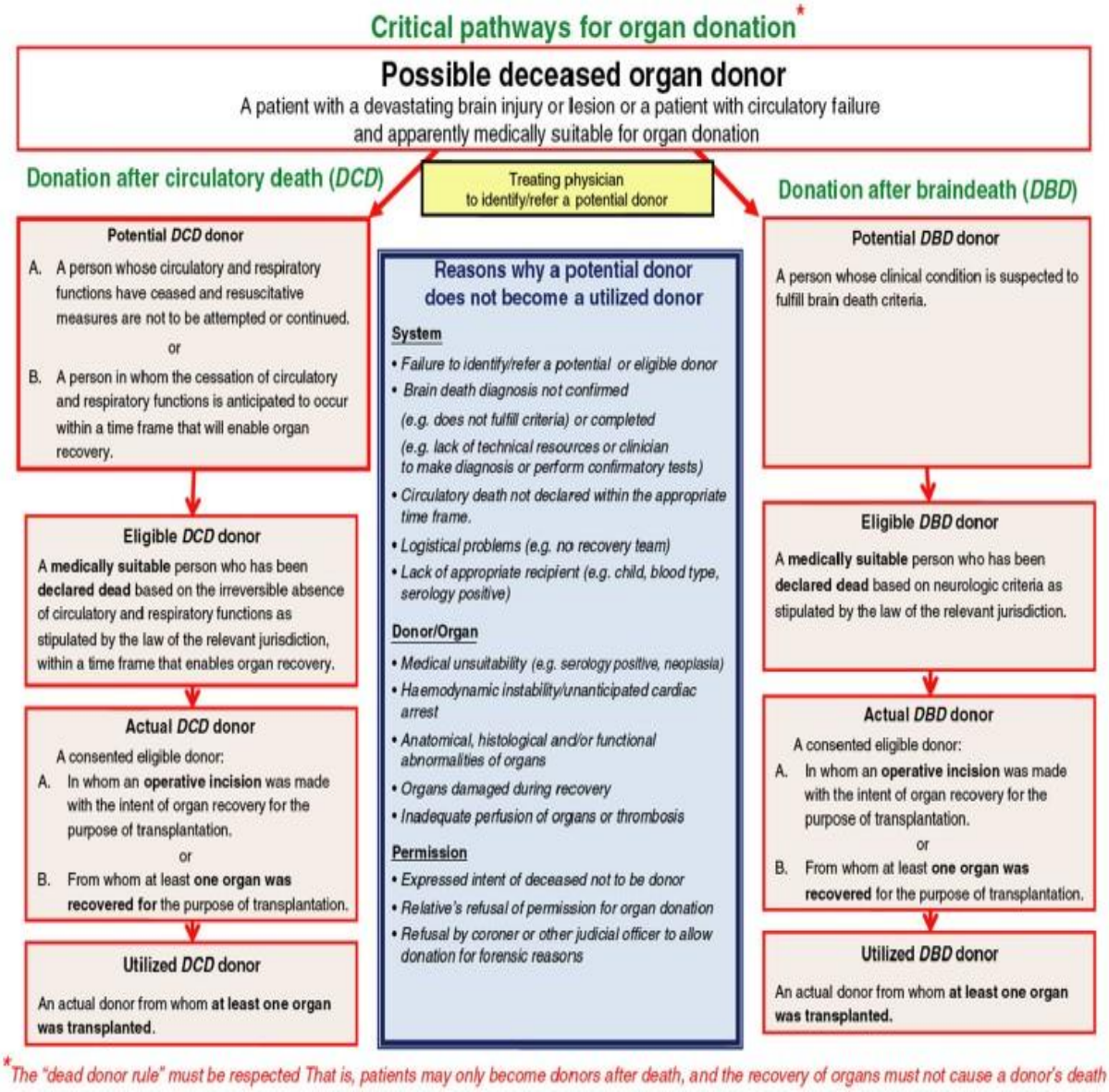

FIGURE 1 THE CRITICAL PATHWAY FOR DECEASED ORGAN DONATION

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3.2.3 Deceased Organ Donation and Family Consent

One of the major barriers to procuring organs for transplantation worldwide is family refusal to donate organs of their deceased loved one. Refusal rates are highest in Turkey – 72.9%, Brazil – 42.3%, Australia – 41.3%, the United Kingdom – 35.2%, and Argentina – 34.3% (Council of Europe, 2018). On the other hand, Countries with highly developed organ donation systems and well-organised procurement mechanisms such as Spain and Italy represent amongst the lowest refusal rates at 13% and 28.7% (Council of Europe, 2018) respectively. Of great importance is understanding the reason for the disparity in consent rates. Vincent and Logan citing several other studies posit the following reasons for families refusal of consent to organ donation:

> "Relatives do not wish surgery on the body/concerns regarding disfigurement; feelings that the patient had suffered enough; uncertainty regarding the patient's wishes; disagreements among the family group; religious/cultural beliefs; dissatisfaction with healthcare staff and process; concerns over delay of funeral/burial process; unable to accept death/lack of understanding of brain death; concerns regarding the integrity of the process, e.g. unfair organ allocation and organ selling; relatives had decided on their own that organs would not be suitable; longstanding negative views on organ donation; and relatives being emotionally exhausted." (Vincent and Logan, 2012)

Noteworthy is the fact that in some circumstances, some of these views held by donor families cannot be changed (Vincent and Logan, 2012). A cross-sectional study conducted in South Africa in 2014 on the "attitudes to organ donation among some urban South African populations" between 1993 and 2013 revealed that "a decrease

in willingness to donate heart, liver and corneas was expressed by the black African population" (Etheredge, Turner and Kahn, 2014). According to Etheredge et al. "this is consistent with cultural beliefs that emphasise the role of the ancestors after death, and the notion that the body should remain intact for spiritual reasons" (2014). Similar beliefs were recorded in an earlier study in which indigenous Zulus expressed that "… the deceased join the family of ancestors, therefore, before donating organs or accepting a transplant, the ancestors must indicate ap-proval otherwise the family will be haunted or lose ances-tral protection" (Bhengu and Uys, 2004).

It is submitted that traditional beliefs of ancestral disapproval of organ donation and life after death are not unique to South Africa. As a people connected through the ideology of ubuntu as well as the migration and intermarriages of bantu speaking tribes across Africa, africans share several cultural beliefs. It is, therefore, possible that the beliefs expressed in South Africa could be shared in Zambia.

On the other hand, ubuntu can also be said to encourage organ donation based on interrelatedness, interdependence and the importance of community relations.

It is on this basis that a well-developed organ donation system must establish protocols or interventions that facilitate effective organ procurement. Communicating with the family or chosen family representative(s) of the imminent death or death of their loved one and the importance of organ donation is necessary. Conducted in a sensitive and informative manner by a trained doctor, nurse or coordinator, it has the potential to increase the rate of consent from the family members or chosen family representative(s).

Best practice guidelines for approaching families have been developed and successfully implemented in Canada (Shemie *et al.*, 2017), Europe (Consent/Authorisation Best Practice Development Group, 2013; Council of Europe: European Directorate for the Quality of Medicines & Healthcare, 2016), and Australia (Australian Government Organ and Tissue Authority, 2017) to mention a few. "Professional guidance advocates that as a standard of care, specialist nurses – organ donation should be involved in planning the family approach and the initial discussions that raise the possibility of organ donation as a part of end-of-life care" (Consent/Authorisation Best Practice Development Group, 2013). The Spanish model's "Good Practice Guidelines in the Process of Organ Donation" (National Transplant Organisation, 2011) provides recommendations as follows:

THE INTERVIEW WITH THE FAMILY MEMBERS OF THE POSSIBLE DONOR SHOULD FOLLOW A SPECIFIC METHODOLOGY AND SHOULD BE PLANNED AS MUCH AS POSSIBLE
The interview should always be prepared. It is important to obtain information on the family, plan the site where the interview will be conducted and how the death will be communicated, notify the family in good time and organize the necessary human and material resources
It is not appropriate to limit the number of persons who participate in the interview. All those persons who are important for the decision should be present and contact should be maintained with them
It is recommended that prejudging the result of the interview should be avoided and an attempt should always be made (except in those cases in which it is known with certainty that the transplant will not be performed). Furthermore, no maximum time for the interview should be pre-established
It is very important to establish a professional helping relationship that facilitates the necessary trust so that the relatives accept the option for donation. To do so, it is essential to know and to use the communication tools
The interview is structured into a series of successive and independent phases: initiation, communication of death, request for consent to donation, and completion. These phases of the interview should not be mixed and it is important to make sure that the family has understood the fact of death before requesting the consent
The communication of death should be made by the patient's physician, who will answer any questions the family may have. There is no clear recommendation on how to communicate the death, that is simply stating that the patient has died or that the patient is brain dead

The request for consent for donation should be made clearly, directly and plainly by the coordinator, as an option, a right, a privilege, or a way of helping others. This should always occur after verifying that the family has understood the fact of death
In the case of a negative response, rejection reversal techniques are recommended. The family shows signs of when the interview is over
Regardless of the outcome of the interview, it should end with signs of condolence and affection, maintaining the helping relationship until the final moment
It is recommended that some days later the family should be thanked for the donation through a letter or telephone call
The interviews should be documented and then analyzed, especially the refusals to donate

FIGURE 2 RECOMMENDATIONS OF THE SPANISH MODEL'S "GOOD PRACTICE GUIDELINES IN THE PROCESS OF ORGAN DONATION"

3.3 Living Organ Donation

Today, organs from living donors cater for approximately half of the total number of organs successfully transplanted worldwide (Transplant Procurement Management - Donation and Transplantation Institute, 2017). Living donors are healthy individuals who are able to give an organ or part of an organ to another individual suffering end-stage organ failure. It is for the very fact that they are healthy that they are selected or approved (by ethics committees) to be donors.

According to some commentators, the non-maleficence principle could be infringed when a healthy individual donated an organ. According to Howard and Cornell, a perfectly healthy person is cut into, a perfectly working organ or part of it is harvested and this person's body is patched up. This person is no longer perfectly healthy, they will suffer pain for a prolonged period and may eventually need an organ transplant themselves (Howard and Cornell, 2016) at a later stage in their life. In other words,

living organ donation would appear to be unethical - violating the principle of non-maleficence. Professionally and ethically, HCPs are duty-bound by the Latin maxim "*primer non nocere*" meaning first do no harm.

Wright et al state that (Wright *et al.*, 2004), the risk of dying during kidney donation surgery (nephrectomy) is 0.03% and that of dying while donating a lobe of the liver (partial hepatectomy) is 0.28%. Howard and Cornell (2016), however, state that "some reports from the United States have reported no adverse effects on longevity, hypertension renal function, or quality of life with follow-up as long as 40 years after donation". This notwithstanding, there have been transplanting complications recorded by the Scientific Registry of Transplant Recipients (Hennepin Healthcare Research Institute, no date).

On the other hand, living organ donors do benefit psychologically and emotionally from being able to help or save the life of a loved one or as is the case with donating to someone on a waiting list, a stranger in hopeless need. As for recipients, benefits include longer functioning organs than those from deceased donors, little to no time (directed donation) spent waiting for an organ, reduced loss of functionality, and reduced financial burden as a result of reduced time on a cadaveric organ waiting list (Wright *et al.*, 2004).

3.3.1 Autonomy and Decision making

It follows that a decision to donate ought to be autonomous and uncoerced. Medical law expects that HCPs will not question a patient's decision making or its "rationality"

no matter the individual's values or motives, but instead consider a patient's "exercise of autonomy" based on how sound their reasoning is (Coggon and Miola, 2011). Beauchamp and Childress (Beauchamp and Childress, 2013) put forward a three-condition theory to establish agent autonomy. They posit that autonomy requires that moral agents of sufficient competence act "intentionally", with "understanding" and free of "controlling influences" motivating their actions.

According to Coggon and Miola (2011) "information, understanding, and the use of reason all contribute to the exercise of autonomy". It is their view that "we can assess the coherence of a decision without having to judge the values underpinning it". Respecting a patient's autonomy means accepting their medical decision even where the HCP does not agree with it. This may be so, but HCPs have an obligation to prevent patients from making life-threatening decisions where it is clear that such a decision may not entirely be the patient's own or is ill-conceived due to a lack of understanding or the patient's mental capacity is underdeveloped, resulting in poor decision making.

The exercise of autonomy is a vital ethical component in deciding to be or being considered as an organ donor. In organ donation, the promotion of autonomous decision making is championed in various transplant centres. According to the Council of Europe "to ensure donor autonomy, it is important: to provide extensive specific information; to allow a reflection period; to involve an independent 'living donor advocate', and to exclude minors and non-competent persons from being LDs. The 'living donor advocate' is defined as an independent medical, psychosocial and legal

counsellor, with neither time constraints nor interests shared with any party, someone who ensures the protection and safety of the living donor" (Council of Europe: European Directorate for the Quality of Medicines & Healthcare, 2016). Equally important is the need for surgical teams caring for the donor be completely independent of the HCP or HCP teams caring for the recipient to avoid conflict of interest and medical bias (Howard and Cornell, 2016).

Organisations such as The Transplant Society and the World Health Organisation strongly advocate against the sale and trade of human organs and body parts and obtaining organs from prisoners for transplant purposes. This abhorrent practice violates the principle of autonomy as it is normally against the wishes of the donors (in most cases poor people or prisoners) with organs being obtained under severe coercion and unethical practices. The sale and trade of kidneys, for example, is prominent in largely poor nations where these kidneys are harvested from poor vulnerable people willing to do anything or accept any amount irrespective of the risk to themselves just so that they and their families can survive. The kidneys are then sold off to wealthy individuals who are able and willing to pay a premium for the kidneys (Etheredge, 2015). Autonomy is clearly violated in such situations.

3.3.2 Informed Consent

"volenti non fit iniuria" - no wrong is done to one who is willing.

In bioethics as well as medical law, a discussion on living donation is incomplete without considering both autonomy and informed consent. The two are closely linked (Etheredge, 2015) with informed consent being a norm or standard derived from

autonomy. In Zambia, informed consent is mandated within the National Health Care Standards for Zambia (NHCS) (Health Professions Council of Zambia, 2011). It is recognised as a requirement in the provision of healthcare by all HCPs as well as in clinical trials and other research involving human participants or tissue under the provisions of the National Health Research Act No.2 of 2013 (National Assembly, 2013).

As stated above in chapter 1, section 1.1, informed consent requires full disclosure of the benefits and risks, competency, understanding, freedom from coercion in deciding, and voluntariness on the donor's part. Truog (2005) in emphasizing the ethical concerns raised by each of the three types of living donation puts forward a consideration of when the tenets of informed consent may not align as ethically and legally envisaged. Such is the case where donors completely disregard or do not care for the risk of surgery or the harm that could befall them in an attempt to save the life of a loved one. In 1991, the New York Times (Kolata, 1991) reported a case of a 9-year-old girl, Alyssa Plum who suffered lung failure. Both Alyssa's parents and other relatives offered to donate a lobe of their lung.

Despite Doctors' advice against the donation, Alyssa's father insisted and was the first to donate. Two weeks later, despite successful transplant surgery, the girl's conditioned worsened and doctors performed another transplant, this time with a lobe from her mother's lung. However, this proved futile and Alyssa Plum died on the operating table. Truog holds that "simply obtaining the informed consent of the relative

is insufficient — physicians are obligated to prevent people from making potentially life-threatening sacrifices unless the chance of success is proportionately large".

Reese et al (2006) go further and posit that decisions of such a nature ought to be rejected because "donor autonomy can be respected only by strict adherence to informed consent." If we applied the presumption put forward by Reese et al to the case above, it would appear that Reese et al suggest that seeing as the Plums were motivated to donate by their daughter's condition and the need to save her life (arguable coercion), they cannot be said to have made their decision to do so free of any coercion and thus autonomously.

It is submitted that this cannot be morally tenable. Medical decisions made by patients are often psychosocial (Spital and Taylor, 2007). It is not realistic to expect that a patient faced with making a decision to save the life of a loved one following disclosure of a life-threatening impairment/disease would make such a decision free of all emotion, values, or motivation or without haste, thereby adhering strictly to informed consent in its strictest construct. Moreover, studies (FELLNER and MARSHALL, 1970; Stothers, Gourlay and Liu, 2005) have shown that most donors made their decision to donate immediately despite full disclosure of the procedure and risks – which were inconsequential to their decision making.

The Nuffield Council on Bioethics (1995) has held that "the ethically significant requirement is not that consent be complete, but that it be genuine". According to the Nuffield Council, "ensuring that consent is genuine is mainly a matter of care in detecting and eliminating lack of consent". Furthermore, there are numerous factors

that can result in a finding of incomplete consent, a list of which is inconceivable simply because of human nature. “Obtaining genuine consent requires medical practitioners to do their best to communicate accurately as much as patients, volunteers or relatives can understand about procedures and risks, and to respect the limits of their understanding, and of their capacities to deal with difficult information. If all reasonable care is exercised, adequate and genuine consent may be established, although it will necessarily fall short of fully informed consent” (*NUFFIELD COUNCIL ON BIOETHICS Human Tissue Ethical and Legal Issues*, 1995).

Tying together with this position, Spital and Taylor (2007) citing Sauder and Parker (Sauder and Parker, 2001), conclude that there is a risk in failing to realise a prospective donor’s decision to donate an organ on the basis that it was made in haste and as a result of being overwhelmed by emotions. Notably, a healthcare professional may consider the decision irrational and poorly arrived at, lacking foresight of how the risks and benefits stack against one another. It could be their view that informed consent is much greater than strict adherence to its requirements. To consider such a decision unworthy or ill-conceived, would be to undermine the importance of the relationship between the prospective donor and recipient (Spital and Taylor, 2007).

From a local standpoint, this is the true depiction of Ubuntu Ethics. Desmond Tutu cited by Metz (2007) expressed that “Ubuntu speaks to the very essence of being human…It…means my humanity is caught up, is inextricably bound up, in theirs. We belong in a bundle of life… Harmony, friendliness, community are great goods. Social harmony is for us the *summum bonum*—the greatest good. Anything that subverts or

undermines this sought-after good is to be avoided like the plague….". Tutu expressed the key facets of Ubuntu – an individual identifies with the community or family to which he/she belongs; as Zambians, we are all connected through relationships with one another and infinitely, the community. To make a decision to donate an organ and more so in circumstances such as those discussed above whether to a loved one or a member of one's community without hesitation or putting another's health and well-being above oneself is to live in the true spirit of Ubuntu as it is altruistic.

3.4 Conclusion

It is accepted that deceased organ donation is indeed ethically less controversial to have as opposed to living organ donation. Living organ donation poses real ethical and legal challenges that deceased organ donation does not such as the risk of harm to the donor, the fundamental ethically and legally vexing decision borne by a physician whether to assist such a patient or not, whether a patient can truly be said to have understood the risks of organ donation to which they have agreed, whether the consent is genuine and so on.

Elliott addressed the question of what "the 'fundamental ethical problem' for HCPs who evaluate potential living organ donors is." According to him, "The most worrying part of living organ donation is not freedom of choice…. The worrying part is the chance of harm to a healthy donor." He illustrated this by stating that, "If a patient undergoes a harmful procedure, the moral responsibility for that action does not belong to the patient alone; it is shared by the doctor who performs it. Thus a doctor is in the position of deciding not simply whether a subject's choice is reasonable or morally justifiable,

but whether he [the doctor] is morally justified in helping the subject accomplish it. (Elliott, 1995)".

In addition to this, evidence shows that organs acquired from living donors as opposed to deceased donors have longer functionality.Like in South Africa, as a result of traditional, cultural, and religious values and beliefs, Zambians may not be ready to accept a system where loved ones' bodies are "violated" and buried without some organs which in some circumstances may be viewed as preventing one from entering the spiritual realm or may upset the ancestors.

4 CHAPTER 4 - CRITICAL EVALUATION OF THE ORGAN DONATION SYSTEMS AND THEIR APPLICATION

4.1 Introduction

In the previous chapters, the ethical issues that arise from the donation and procurement of organs have been highlighted and discussed. Legally, the law must be implemented to regulate the donation, procurement and use of the organs in order to safeguard especially vulnerable individuals from harms such as socio-economic injustices and exploitation. Therefore, there is a need to have an organ donation system that is ethically and legally justified, and upholds the precepts of medical ethics.

In order to establish what could be an ethically and legally justified system, a critical evaluation of the three common organ donation systems must be developed. In this chapter, the opt-in, opt-out, and mandated choice organ donation systems are critically evaluated, thereby highlighting the salient points of each system. In order to demonstrate their application, the systems in South Africa, Israel and Spain are discussed. These three countries have been selected for their challenges with organ donation and similarities (South Africa) to Zambia, as well as their advances, practices and continued success (Israel and Spain) in increasing organ donation rates. This chapter aligns with objective 3 of this research, to critically evaluate organ donation systems and consequently compare their application in South Africa, Israel and Spain.

4.2 Critical Evaluation of Opt-in Organ Donation System

Opt-in organ donation is based on acquiring informed consent from the potential donor. It is the system currently in use in Zambia, having been adopted in the National Assembly in 1962 (National Assembly, 1962). The method of granting legally recognised consent in Zambia is either orally in the presence of at least two witnesses or documented in the form of a written will by the potential donor (chapter 2, section 2.4). However, current legislation (National Assembly, 1962) guiding opt-in organ donation only recognises cadaveric donations and not living donations.

This opt-in system of donation requires individuals to expressly state their desire to be a donor (Etheredge, Penn and Watermeyer, 2017), having understood and appreciated the risks involved. Despite its realisation of the principle of respect for autonomy, it is viewed as being an ineffective system of donation (Labuschagne, 2013) as evidenced, for example, in South Africa, where the system adopted is opt-in organ donation and the organ donation rates remain low (Labuschagne, 2013; Etheredge, Penn and Watermeyer, 2017; Hawkins, 2017).

4.2.1 Opt-in Organ Donation in South Africa

Legally mandated by the NHA 61 of 2003, explicit consent must be granted by the donor in both living and deceased organ donation procedures. The NHA provides for living donation in sections 55 and 56, and for deceased donations in section 62 (*National Health Act 61 of 2003*, 2004), (chapter 2, section 2.7.2, and section 2.7.1 respectively). In contrast to Zambia, potential donors in South Africa are not legally limited to expressing their desire to donate only as outlined in the NHA. They can

register their intent to be an organ donor by registering their names with the Organ Donor Foundation of South Africa.

South Africa is a culturally diverse nation (South African History Online, 2017). The opt-in system takes into account the wishes of the family of the deceased. Certain rights over the body of the deceased are afforded by common law to his/her family. In addition, healthcare professionals are reluctant to procure organs without obtaining consent from families as a result of their emotional state (Labuschagne, 2013). According to a survey carried out at Groote Schuur Hospital, a state-funded hospital in Cape Town, 82% of families refuse to consent to donate their relatives' organs (Thomson, 2017). High family refusal rates are not common only to South Africa but several countries worldwide.

4.2.2 Opt-in Organ Donation in Israel

A multicultural and traditionalist nation, Israel experienced low organ donation rates prior to the enactment of the Organ Transplant Act in 2008, a consequence of high volume transplant tourism from the nation (Berzon, 2018). However, there was an increase in live organ donations post-2008. According to Berzon (2018), the increase is greatly attributed not only to legislative change but to the altruistic nature of the orthodox Jews in Israel. She posits that *Matnat Chayim* ('Gift of Life'), a charitable organisation in Israel, has contributed to an approximated 40% of live kidney donations since 2009. This appears to suggest that, the opt-in organ donation system may actually be effective where altruism is maximised.

4.3 Critical Evaluation of Opt-out Organ Donation System

Also known as presumed consent, the opt-out system is associated with higher organ donation rates compared to the opt-in system (Arshad, Anderson and Sharif, 2019). Countries that have implemented the opt-out system either have a 'hard opt-out' approach where families are not consulted for consent or 'soft opt-out' approach where consent is sought from the families as in the opt-in system (Bramhall, 2011).

Presumed consent presupposes that everyone has consented to donate their organs until or unless one expressly opts out of donating. This means that if an individual, during his/her lifetime, forgets or fails to make known his/her decision not to be a donor, it will be assumed that they wished to donate their organs and their organs may be procured upon their demise. This could be problematic and may result in a number of ethical transgressions. Such an assumption could be argued to be a disregard for the individual's autonomy and right of conscience. However, Maxwell Mehlman (1991) arguing in favour of presumed consent states that:

> "… People are in favour of donation in the abstract, but that psychological factors involved in contemplating their own deaths, or those of their loved ones, make them unable to articulate their true wishes. By eliminating the need to confront donation actively in order to donate, presumed consent might overcome these psychological impediments and allow individuals to give effect to their true beliefs."

Generally, African culture does not encourage the discussion or contemplation of one's death or that of a loved one (Ekore and Lanre-Abass, 2016). The untimely death of a loved one or the contemplation of one's own death could cause an individual to have a mental block. According to Natalie Lamy (2015), "having a presumed consent system would eliminate this blocker if they really wish to be organ donors because they are already registered".

Worthy of note, is that it is generally recognised that presumed consent would be costly for the state to implement (Bramhall, 2011; Labuschagne, 2013). It requires expansive education campaigns for both medical professionals and the public for it to be effective. Unlike the opt-in system discussed above, presumed consent would require widespread dissemination of information. Bramhall (2011) suggests that this system would require a robust and up to date digital registry system listing everyone that has opted out of being an organ donor. From a financial and resource-based perspective, this system would most likely be impossible to implement in a developing nation. However, it is possible in a developed nation such as Spain.

4.3.1 Opt-out Organ Donation in Spain

Spain's model of presumed consent is internationally recognised as the best practice model of organ donation (Organ and Tissue Authority, 2013; Sadler and Sadler, 2018). Despite having a presumed consent system the unrivalled success of Spain's transplant system is more accurately attributed to other factors such as the introduction of transplant donor coordinators (TDCs), extensive training of specialised medical staff at every level of the organ donation process, and establishing a central

authority as an overwatch body for organ donation and transplantation (Matesanz *et al.*, 2011), to mention a few. Spain may indeed have higher organ donation rates than other countries (Transplant Procurement Management - Donation and Transplantation Institute, 2019) but the measures adopted to achieve those rates indicate that reducing the organ shortage gap may require more than just an organ donation system (The Lancet Gastroenterology & Hepatology, 2017).

While the opt-out system may lead to more potential donors being readily available this alone may not be enough to reduce a country's organ shortage. This is especially true where relevant medical infrastructure and specialised healthcare staff training is lacking.

4.4 Critical Evaluation of Mandated Choice Organ Donation System

Mandated choice or required response is similar in several ways to hard opt-out. It must be legally implemented and requires that individuals formerly document their consent or refusal (Cotter, 2012). Mandated choice is a utilitarian approach to organ donation. It is argued that it undermines the principle of respect for autonomy in that it seeks to maximise the number of available organs for transplantation by forcing individuals to make a choice whether to donate or not without taking into consideration that some may not wish to confront the thought of their death. (Childress, 2001). Chouhan and Draper (2003) submit that it does not undermine the principle. It, in fact, champions respect for autonomy by ensuring that every individual makes a choice.

The form of implementation, as stated above in chapter 1, section 1.1, is by the state and achieved through state documents such as driver license application forms or tax returns (Cotter, 2012). This approach is used in some states in the USA (Laurance, 2009). There is a dearth of literature on this system and very few countries have implemented it (Etheredge, Penn and Watermeyer, 2017). Like presumed consent, mandated choice requires that everyone is able to receive and understand the information about organ donation and the requirement to elect their choice. More importantly, it requires that everyone is literate to the level required to appreciate the information. Zambia has several undeveloped and underdeveloped localities with a low national literacy rate (World Health Organisation, 2018). As such, mandated choice would not be feasible to implement in Zambia.

4.5 Conclusion

The various organ donation systems discussed above present with differing positive and negative aspects. No one system of organ donation can be said to be completely acceptable nor unacceptable. The discussion above shows that while the opt-in system may be uncontroversial (Labuschagne, 2013) and clearly respects the donor's autonomy, it fails to increase organs for transplantation purposes. The opposite is true of the opt-out system. Literature shows that it fails to satisfy the principle of respect for autonomy because individuals are not given the opportunity to express their preference for organ donation from the beginning. The opportunity arises at a time when it may be too late to choose to opt-out because one is already dead. However, where it has been implemented alongside other measures, it has shown promise in increasing organ donation rates (The Lancet Gastroenterology & Hepatology, 2017). With regard to the mandated choice system, Hayley Cotter argues that despite the

view held by some authors that it does not respect autonomy, it actually does in that the mandated choice system encourages individuals to make a decision. This ensures that the individual actually makes a conscious decision whether or not to be a donor and it consequently could result in increased numbers of organs being available. The brief discussion on the mandated choice system suggests that just as with the opt-in system, when pertinent factors are taken into consideration and implementation is correctly approached this system could be implemented in an ideal environment.

It is submitted that the ethical and legal acceptability of an organ donation system could be a matter of where it is implemented and a country's socio-economic status.

5 CHAPTER 5 – THE INFLUENCE OF BIOETHICS IN ORGAN DONATION SYSTEMS

5.1 Introduction

Medical ethics is commonly linked with the Hippocratic Oath (Jotterand, 2005). It is a sub-branch of bioethics, the crux of which is the question "what ought one do?" (Sugarman and Sulmasy, 2001). In this regard, the Hippocratic Oath sets the backdrop constantly considering the actions of HCPs and the relationship between HCPs and patients. This relationship is at the core of medical ethics.

Trust drives the nature and continuing existence of the doctor-patient relationship. It follows that for there to be trust, paternalism i.e. the dominant influence of a doctors expertise and knowhow superseding his/her patients choice or decision making, (Arneson, 2005) must be overridden by the application of the principle of autonomy a concept that *inter alia* exemplifies respect for the person and respect for his/her bodily and psychological integrity.

The principle of autonomy is one of four principles that have been espoused by Beauchamp and Childress (Beauchamp and Childress, 2013). As stated above in chapter 1, section 1.9, principlism has been used for decades in medical practices globally to resolve conflicts of interest arising out of differences in the doctor's duty and advice and the patient's choice and decision (Fu-Chang, 1999; Lindridge, 2017). It reflects the four prima facie principles of philosophical moral theory in bioethics – respect for autonomy, beneficence, non-maleficence, and justice. In this chapter, these principles are discussed in order to set the basis for the discussion on the ethical

defensibility of the various organ donation systems in order to answer the question: what system of organ donation is best suited to Zambia?. This chapter aligns with objective 4 of this research, to argue in favour of an opt-in system of organ donation as being the best suited ethical organ donation system for Zambia.

5.2 The Four Principles of Bioethics

5.2.1 Respect for Autonomy

A vital aspect of becoming an organ donor is one's autonomy. As stated in chapter 3, section 3.3.1, autonomy requires that moral agents of sufficient competence act "intentionally", with "understanding" and free of "controlling influences" motivating their actions (Beauchamp and Childress, 2013). According to Beauchamp and Childress (2013), essential to the concept of autonomy are the elements of liberty "independence from controlling influences" and agency "capacity for intentional action". They state that there may be different theories of autonomy but all the theories agree on the two essential elements, liberty and agency.

One such theory is posited by Coggon and Miola (2011) who state that autonomy can be considered in two ways; the autonomous agent's free will or the right to act without influence or interference from third parties such as loved ones or persons with authority such as a physician, as highlighted in chapter 1, section 1.1. They further state that "conflation of, or disregard for the difference between, autonomy and liberty cause conceptual flaws in analysis" and it is, therefore, appropriate to consider both together, although this is not usually done (Coggon and Miola, 2011).

However, a different school of thought rebuts this argument and posit three reasons why the general analysis of respect for autonomy or in this case, respect for autonomy without considering liberty, is problematic in the context of living organ donation.

Ross and Thistlethwaite (Ross and Thistlethwaite, 2018) argue that “First, living donation is only undertaken because of the lack of a readily available, comparably effective alternative treatment for end-stage renal disease”. While it is accepted that living donation poses risk to the donor in order to save the life of the recipient, currently, no alternative treatment exists. An alternative treatment could negate the need for living donation. Second, focus on the liberty exercised by an individual “employs an exclusively negative conception of autonomy”. Autonomy in the context of organ donation is largely concerned with respect for persons which is the positive aspect of autonomy. In living donation, the positive aspect of autonomy is illustrated by the role healthcare professionals play in ensuring that donors not only have all the relevant facts but the risks and benefits are explained in a way that is understood and appreciated by the donor in order for them to make a truly informed decision. This is the agency element of autonomy. Third, for an individual, the decision to be a donor is usually made within the context of their social relationships and interactions.

However, both Coggon and Miola (2011), and Ross and Thistlethwaite (2018) appear to agree that autonomy without considering liberty falls short of the full scope that respect for autonomy ought to address in analysing dilemmas in the healthcare setting. While their formulations of what autonomy is may vary, these authors agree with

Beauchamp and Childress' (2013) theory of autonomy and the principle of respect for the autonomy.

An illustration of the application of respect for autonomy is the case of Madrigal v Quilligan (Manian, 2018). Decided in the United States of America (USA), the case highlights the need to obtain informed consent and not merely consent from patients. Ten women of Hispanic origin in the USA underwent hysterectomies without their informed consent. The women who spoke Spanish were given consent forms in English which they were required to sign. The consent obtained by the doctors cannot be said to have been adequate because the women lacked understanding. It can also be argued that the women lacked the mental capacity to consent to the emergency cesareans performed on them because of their state of mind at the time consent was sought. Therefore, the women lacked agency and hence autonomy in consenting to the surgical operations.

Positively, autonomy requires physicians to fully disclose relevant information to allow patients to make an informed and reasoned decision (The Ethics Centre, 2017). Analysing Madrigal v Quilligan, the physicians attending to the Hispanic women appear to have taken advantage of their authority as physicians and neglected both the positive and negative autonomous duties required of them and as such disregarded the women's autonomy.

Respecting the person's autonomous decision making is important. In Zambia, organ transplantation has not been heralded by all. Scepticism is high among the few literate

individuals that have heard of the new medical initiative being implemented while a large portion of the public may have no knowledge of what organ transplantation is (Kunda, 2018). In light of this, allowing individuals to come forward and donate out of their own volition, free of any controlling influences or coercion would express the state's respect of their autonomy.

5.2.2 Non-maleficence

In line with the Hippocratic Oath, non-maleficence imposes a professional and ethical duty on HCPs to ensure that they avoid causing harm to their patients. In the context of organ donation, this harm may arise as a direct consequence of transplantation for both donor and recipient. It is sometimes "permissible to cause a harm as a side effect (or "double effect") of bringing about a good result even though it would not be permissible to cause such a harm as a means to bringing about the same good end" (McIntyre, 2019). Known as the principle of double effect, it is relied on to explain how permissible a particular action is in medical ethics. It is, therefore, "ethically permissible to perform an act that has both a good and a bad effect if all the following conditions are met" (Marker, 2011):

1. The act is good in itself or at least ethically neutral.
2. The good effect is not obtained by means of the bad effect.
3. The bad effect, although foreseen, is not intended for itself, but only
4. Permitted there is a proportionately grave reason for permitting the bad effect.

Considering the double effect principle in the context of living organ donation helps illustrate its application. Taking each condition in turn, it is submitted that:

1. Donating an organ in itself is a good act.
2. With organ donation, there are two resulting effects. On the one hand, the good effect is that the donor will save the life of the recipient. On the other hand, the bad effect is that the donor will suffer harm and possibly loss of income for the period when he is donating his organ and recovering from surgery. The donor does not save the recipient by means of his/her dying. Should the donor's organ be successfully donated and transplanted into the recipient, the recipient's life will be saved.
3. Although harm to the donor and possibly death is foreseen as an outcome of his/her donation, that is not the intended purpose of donating the organ. However, it is permissible as it may occur and the donor has given their informed consent in order to save a life.
4. Saving a life can be ethically justified as being a proportionately grave reason for risking one's well-being as the donor does by donating an organ. In this sense, the bad effect is justified.

However, writers such as Jacob M. Appel and Peter Singer belong to a different school of thought and have dismissed the principle. Arguing in favour of child euthanasia and child organ donation, they submit that there is a need for "'aid-in-dying' to be available to children at the request of their parents" (Marker, 2011) and "it must be justifiable, in some cases at least, to end the child's life swiftly and painlessly" (*Dangerous Words:*

Professor of Bioethics Peter Singer and His Views on Life and Death Have Challenged the University and the World at Large, 2000).

Singer is a utilitarian and as such he advocates for the maximisation of the greatest good. He appears to champion alleviating children of pain and suffering. However, according to Sakali (2014), his view is problematic in that the killing of one child who is brain dead but has a beating heart and is warm to the touch in order to procure his heart to save another child with a defective heart is morally difficult to palate.

It is submitted that physicians applying Singer's principles would be intentionally causing harm on one child by murdering that child in order to save the life of another. It would be a violation of the Hippocratic oath - their ethical obligation not to cause harm in the performance of their profession. A possible resulting effect of this disregard of the principle of double effect and the principle of non-maleficence would be a breakdown in the doctor-patient relationship as well as a reduction in potential organ donors. Potential organ donors may feel that their lives may be ended as a means to procure organs for other patients.

With regard to organ donation, opt-in organ donation is defensible in that organ donors' rights are not violated. Ethically, no harm can be said to be done to organ donors in this regard as they voluntarily consent to donate their organs.

5.2.3 Beneficence

The principle of beneficence is generally understood to involve doing good to and promoting what benefits others. It encompasses prevention of harms to others, “protecting and defending the rights of others” (Labuschagne, 2013), assisting disabled people, and positively acting in ways to benefit the patient. The doctor-patient relationship heavily depends on this principle. HCPs have a duty to their patients to act and treat their patients with the best possible care ensuring that the treatment is beneficial to the patient notwithstanding that it may conflict with the HCP’s interests. Vital to fostering trust between physicians and patients is the autonomy that patients expect to be able to exercise over medical treatments and procedures involving their bodies.

The need to help others and do good goes beyond physicians. Actors such as the state have an obligation to ensure that physicians are equipped with the necessary tools to fulfil the principle of beneficence in their interaction with patients. Labuschagne (2013) submits that such tools include “enactment of legislation, policies and guidelines”.

The principle of beneficence requires an account of the benefits and risks in assessing the efficacy of organ donation systems (Labuschagne, 2013). This is aimed at achieving a net balance of good. The system of opt-in organ donation fails to achieve the required number of organs for transplantation (Hawkins, 2017). However, according to Labushagne (2013), it partially satisfies the principle of beneficence to the extent that it respects and promotes the donor’s autonomy and therefore, does

good. Moreover, in this regard, it upholds people's constitutional rights (Labuschagne, 2013).

5.2.4 Justice

Healthcare, especially in most developing countries, is confronted with constant shortages of resources such as healthcare personnel, equipment, facilities and medicines. Transplantable organs, being such a scarce resource are no exception. There is a need to ensure that the limited resources available are fairly allocated. The principle of justice is described as "fair, equitable, and appropriate treatment in light of what is due or owed to persons" (Beauchamp and Childress, 2001). When considered within the health setting, three categories of justice are discussed: "fair distribution of scarce resources (distributive justice), respect for people's rights (rights-based justice) and respect for morally acceptable laws (legal justice)" (Gillon, 1994).

The three categories of justice are related and may overlap considering that what a person is due is a consequence of his rights to it while such rights are more than likely enshrined or codified under specific laws such as the Constitution (National Assembly, 2016). For the purpose of the Research Report, this discussion will focus primarily on justice in the context of the distribution of scarce resources.

Distribution or allocation of scarce resources can be complex. Two principles espoused by Beauchamp and Childress could assist in decision-making for allocating resources fairly. These principles are the formal principle of justice and the material principles of justice (Beauchamp and Childress, 2001). Attributed to Aristotle, the

formal principle guides that equals be treated equally and unequals be treated unequally (Gillon, 1994). The material principle of justice, on the other hand, is more helpful in applying distributive justice because it “specifies the relevant characteristics for equal treatment” (Beauchamp and Childress, 2001). Beauchamp and Childress (2001) submit six principles by which the principle of material principles can be used to address equal treatment: to each person an equal share, according to need, effort, contribution, merit, and free-market exchanges.

Justice is a difficult principle to implement because, on the one hand, it seeks to do good by prioritising the need to allocate scarce resources and on the other hand, a consequence of the balance of fairness is that not everyone will benefit from the way in which it is applied. As such, an unavoidable consequence of distributive justice is that some individuals will be dissatisfied because not everyone's needs can be met (Gillon, 1994).

5.3 The Best Suited System Of Organ Donation For Zambia

In the chapters above, both legal and ethical perspectives of organ donation have been discussed. Chapter 4 highlighted the four principles of bioethics and the salient points of the three organ donation systems. These discussions have set the basis upon which the current chapter is structured, analysing the ethical defensibility of each organ donation system. This chapter aligns with objective 4, to argue in favour of an opt-in system of organ donation as being the best suited ethical organ donation system for Zambia.

5.4 Opt-in organ donation

5.4.1 Respect for Autonomy

The opt-in system of organ donation is built on the doctrine of informed consent (Labuschagne, 2013). It respects the donor's right to decide what will happen to his/her body. It respects the donor's autonomy. Like with soft opt-out and soft mandated choice systems, family consent is always sought for procurement of organs from the deceased relative irrespective of the deceased's wishes (Hawkins, 2017). Because it is voluntary and mostly altruistic, it generally does not require information to be disseminated. However, because organ transplantation is new to Zambia, the state would be expected to carry out widespread education and awareness campaigns to enlighten the public and HCPs respectively.

Notwithstanding its positive aspects, this system does have significant shortfalls. Low rates of organ donation are a prominent issue among even the leading explicit consent organ transplant countries (Transplant Procurement Management - Donation and Transplantation Institute, 2017). With the exception of Israel, the explicit consent system of organ donation does nothing to encourage or incentivise individuals to donate or at the very least register their wishes to be donors. In Zambia, this would be worsened by the fact that the current legislative framework (National Assembly, 1962) does not cater for living organ donation and like South Africa, the legislation does not provide for an organ donor registry (Labuschagne, 2013) where those wishing to donate can register their particulars.

5.4.2 Non-maleficence

It has been established above in the analysis of respect for autonomy that the opt-in system is voluntary and requires an individual to express his or her desire to donate. On this basis, it is submitted that the opt-in system does not ethically violate the principle of non-maleficence that requires that no harm be done to the donor considering that the choice is entirely his/hers.

5.4.3 Beneficence

Beneficence imposes a moral obligation on individuals in society to do good. The term *beneficence* connotes acts or personal qualities of mercy, kindness, generosity, and charity. It is suggestive of altruism, love, humanity, and promoting the good of others. In ordinary language, the notion is broad, but it is understood even more broadly in ethical theory to include effectively all norms, dispositions, and actions with the goal of benefiting or promoting the good of other persons (Beauchamp, 2019).

The opt-in system satisfies the principle of beneficence in so far as altruism is concerned in that individuals are able to voluntarily make a choice to donate an organ. However, on a larger scale, as a health measure implemented to provide organs for transplantation, it fails to meet the need to supply an adequate number of organs. In this regard, the opt-in system does not adequately benefit individuals on the waiting list for organs and the waiting does, in fact, result in harm. It is, therefore, submitted that it would fail to ensure the supply of organs well enough to alleviate the Zambian government of the burdensome high cost of transporting transplant patients abroad

for the service. Moreover, the costs involved in seeking treatment outside the country does not benefit the country's economic situation in any way.

5.4.4 Justice

In medical ethics, justice is more commonly associated with the distribution of benefits, resources, risks and burdens in a fair and just manner (Labuschagne, 2013). One such resource is the availability of donor organs for transplantation purposes. The worldwide shortage of this resource constantly calls into debate and analysis issues "such as urgency of need, the probability of success, societal contribution, or ability to pay" (Childress, Domnitz and Liverman, 2017). For example, South Africa (Labuschagne, 2013; Etheredge, Penn and Watermeyer, 2017; Hawkins, 2017) , among other countries, has questioned and debated the adequacy of the opt-in system in light of alternative organ donation systems due to its failure to reduce the organ shortage gap and achieve a sustainable number of organs for transplantation.

Providing organ transplantation to the public will impose a duty on the Zambian government or organ transplant authority (should one be established) to distribute available organs in a fair and just manner. Additionally, the state or relevant authority would have an obligation to the people of Zambia to ensure that the highest number of organs is procured for transplantation. This could be difficult to achieve with the opt-in system alone and may require additional measures to be implemented to comply with the principle of justice.

5.5 Opt-out organ donation

5.5.1 Respect for Autonomy

The ethical defensibility of the opt-out system of organ donation hinges mostly on its interrelation with the principle of autonomy. According to Marquardt (2017), “the most common objection against presumed consent is that it does not give an individual default rights over her body, but instead makes her take an action if she is opposed to donating her organs after death”. This means that where a person did not explicitly state their objection to donating, his/her family may not be consulted for consent on the decedent’s behalf (hard opt-out) as it would be presumed that his/her wish was to donate when in actual fact it may not have been so. Evidently, the presumed consent organ donation system disregards the rights of the person.

Pivotal to the concept of principlism is the assertion that one should “Act so that you treat humanity, whether in your own person or in that of another, always as an end and never merely as a means only” (Rachels and Rachels, 2015). Known as the humanity formulation of Immanuel Kant’s categorical imperative, its application amplifies the fact that assuming that the donor has consented to donate his organs without actually obtaining his/her informed consent all in the name of saving the recipient’s life is, in fact, using the donor as a means to an end and not as an end in himself or herself. Here, the benefit accrues only to the recipient as an end.

In Zambia, as previously stated, literacy is an issue of concern. In addition, organ transplantation is a new initiative that the general public is not knowledgeable about.

It is submitted that expecting the ordinary man (being a rural dweller) to explicitly express his/her objection to donating when they are uninformed about organ transplantation, would result in a repugnant absurdity. As several Zambian's may not be able to do so, assuming their consent would be a violation of their autonomous right and ultimately constitutional rights. As such, the opt-out system cannot be said to be ethically justifiable in this regard.

5.5.2 Non-maleficence

Paramount to the practice of medicine is the moral rule 'first do no harm'. Organ donation is no exception to this presumption. Organs procured from donors must be procured with the donor's explicit informed consent. However, the opt-out system disregards this moral and legal requirement and in doing so results in harm being caused to the donor. In this sense, harm arises out of a failure by the system to recognise and respect his autonomous right and right to bodily integrity expressed through the donor's wishes in the case of deceased donation.

In Zambia, distrust in healthcare professionals in public hospitals is high. This is possibly a result of the poor attitudes of some healthcare professionals towards patients and patient care (Musika, 2016). It is submitted that the perception of the public towards healthcare may already be negative and, therefore, trusting that healthcare professionals will respect an individual's wishes not to donate may be difficult especially where the fear may be that their loved ones' bodies will be violated. This may also be against some cultural and religious beliefs held by some Zambians.

5.5.3 Beneficence

The principle of beneficence requires that doctors act in a way that is beneficial to their patients thus complying with the principle to do good. The doctor-patient relationship requires the existence of trust without which the relationship will not exist. As established earlier, presumed consent disregards donor autonomy and as such cannot be said to comply with the principle of doing good. As with non-maleficence, it does more harm than good despite the fact that it is recognized as increasing the number of available organs for transplantation (Mcdowell, 2012; Labuschagne, 2013).

Marquardt submits that where the wishes of a deceased person are not known or were not to donate, “a conflict arises between beneficence to the donor and to the recipient, and no decision can be made based solely on beneficence”. He goes further to state that,

> “In theory, if a presumed consent system were enacted, a subtle shift in the attitudes of medical personnel could take place. Since the working assumption would shift to the notion that every patient is a donor unless evidence says otherwise, doctors could be tempted more frequently to refrain from using every effort to save a patient who they do not expect to return to a high quality of life … All in all, there are too many unknowns and competing interests involving beneficence to use it alone for a judgment of presumed consent. Thus, one must default to the input of another moral principle”. (Marquardt, 2017).

5.5.4 Justice

Several applications of justice to presumed consent exist (Labuschagne, 2013; Hawkins, 2017). Marquardt (2017) posits that “any policy that discriminates against a particular class or group of people would be unjust”. Justice promotes fairness and non-discrimination of individuals irrespective of their class, colour, culture or beliefs. Marquardt suggests that “members of society who choose to opt-out of donating could be viewed with contempt” (Marquardt, 2017) and shunned by the community in which they live. Israel’s priority points system (despite being an opt-in system) is an example of where individuals could be looked at negatively for choosing not to donate despite willing to receive an organ should they need one.

It is submitted that social harm of this nature is one that can be foreseen in Zambia because trust in the medical system is low and as a result, people are sceptical of organ transplantation. This would directly translate into an unwillingness to donate thereby leading to people opting out of donation and possibly being discriminated against by the few who may be keen to be donors.

In sum, it is clear that an opt-out organ donation system is rife with several ethical and legal issues. As such it would not be an ethically justifiable system of organ donation in Zambia.

5.6 Mandated Choice organ donation

5.6.1 Respect for Autonomy

Patient autonomy requires that the patient gives informed consent. In order for informed consent to be given, the relevant information must be explained to the patient in a manner that the patient is able to understand and appreciate the information and procedure. Mandated choice respects patient autonomy and the requirement for informed consent as it does not impose the presumption of being a donor on individuals. Instead, it requires that every person formerly answer a question asked on official documents whether they wish to donate their organs or not and which organ(s) they wish to donate in the case that they do wish to.

However, implementing mandated choice (similarly opt-in and opt-out) in Zambia would require that Zambians from all over the country are able to receive the information on organ donation and are able to understand and appreciate this information in order to be able to state their donation preference. Etheredge et al. in their paper titled “Opt-in or opt-out to increase organ donation in South Africa? Appraising proposed strategies using an empirical ethics analysis” present two reasons as to why disseminating information to all individuals may be difficult. Their research highlights issues that could be of value to Zambia as concerns organ donation.

They posit that “Firstly, communicative challenges posed by language and literacy barriers, as well as limited access to information, mean there is no guarantee that all

will be adequately informed….Secondly, public awareness campaigns need to be cost-effective" (Etheredge, Penn and Watermeyer, 2017). Just as is the case in SA, it is submitted that the awareness and education campaign required would be expensive and burdensome on the state to the extent that it could result in a shortage of resources for other areas within the health sector.

5.6.2 Non-maleficence

Mandated choice puts the power of decision making in the potential donor's hands. While the mandated choice system may allow for rational decision making; result in increased organ donation rates; and it alleviates the anxiety in HCPs when having to consult a family for consent (Hawkins, 2017), in a hard mandated choice system, it causes harm on the decedent's family because their wishes are not sought. Only the donor's wishes matter. This could be problematic in the Zambian context as a result of cultural beliefs and local customs.

Furthermore, literacy levels vary greatly. In circumstances where the question to donate is on a driver's licence application form, an applicant may be literate enough to obtain a driver's licence but may not have the necessary level of literacy to understand well enough and appreciate organ donation or the related questions. This may result in people agree to be donors whereas had they understood the information they would not have given informed consent to be a donor. It is submitted that in the Zambian context, the mandated choice system is negated as the reality of informed consent cannot be assured.

5.6.3 Beneficence

Mandated choice satisfies the principle of beneficence as it respects the donor's autonomy and leads to the availability of more organs for transplantation. This in itself is beneficial to all individuals in need of life-saving organs. However, it is unlikely that this type of beneficence could apply in Zambia in light of the low literacy levels and hence poor understanding as to the need to donate.

5.6.4 Justice

Labuschagne (2013) stresses that in order for mandated choice to comply with justice, resources must be allocated properly and correctly. To fail to do so may result in other areas of the health system lacking well-needed resources. There is a real danger for this to occur especially because, as stated above, mandated choice in Zambia would require widespread dissemination of information and comprehensive education campaigns for both the public and HCPs. The human resource and financial drain of such an exercise would be difficult to justify.

5.7 Conclusion

It is evident from the discussion above that no one organ donation system is perfect and without shortcomings. With that in mind, recognition must be given to the fact that Zambia is a culturally, linguistically and religiously diverse country. These values also present as challenges when considered in light of organ donation. Two of the organ donation systems (opt-out and mandated choice) have been identified as having some success in increasing organ donation numbers despite other factors also being attributed to the increase, for example, in Spain (Matesanz *et al.*, 2011) and Illinois,

USA (Cotter, 2012). However, the two systems are synonymous with assertions of violations of rights, coercion and disregard for the donor's autonomy (presumed consent), disregard for the families wishes (especially with hard opt-out) and are resource intense. Justifying opt-out or mandated choice as ethically defensible may prove challenging.

However, a soft opt-out system may appear feasible in Zambia because the donor is required to make an informed choice to donate or not and the family's wishes are also recognized and upheld. A soft opt-out system is arguably ethically justifiable on the basis that the families of the deceased are still consulted for consent (Mcdowell, 2012). Families are less likely to refuse consent because they can be approached before the potential donor dies. This would allow for them to be given the relevant information in order to make an informed decision (Etheredge, Penn and Watermeyer, 2017). Soft opt-out is also less controversial (Labuschagne, 2013) and "is seen as not being legally problematic" (Etheredge, Penn and Watermeyer, 2017).

This notwithstanding, presumed consent would be difficult to implement in Zambia especially because it requires widespread awareness and education campaigns which are expensive (Etheredge, Penn and Watermeyer, 2017) and resource-heavy. Moreover, with 72 languages in which to translate organ donation information, dissemination of information would be exceptionally challenging, an issue not only unique to a soft opt-out system.

As stated in chapter 2, section 2.4 above, Zambia's preference for organ donation is living organ donation and not deceased donation. Living organ donation depends especially on the donor's altruistic will to donate his/her organ(s) directed to an unrelated recipient, or non-directed to a complete stranger on the organ waiting list. Familial living organ donations are also not uncommon within the context of living organ donation. The donor exercises their autonomy freely deciding when and to whom to donate an organ.

This is synonymous with the opt-in organ donation system. Despite failing to comply with the principle of beneficence and justice, this system of organ donation recognizes and upholds the need for informed consent in organ donation. Zambians' trust in the health system and HCPs is low and requires building (Musika, 2016). A system that respects the autonomous decision making of the donor and requires that informed consent is obtained before any organs can be procured would certainly go a long way in building public trust in the health system, healthcare professionals and in organ transplantation as a medical option in Zambia.

In this vein, it is submitted that the current opt-in organ donation system is arguably the most practical system for organ donation in Zambia. However, as established previously in chapter 2, substantive legislative reform is required for this system to be applied optimally. Legislative reforms can be applied alongside organ donation measures borrowed from well-structured and highly organised healthcare systems such as Spanish and Israeli organ donation systems (Ashkenazi, Lavee and Moradi,

2015). The well-structured and highly organised healthcare systems in the two countries are undoubtedly a contributing factor to their high organ donation rates.

The Spanish model has shown that presumed consent alone cannot guarantee increased organ donation numbers. On that premise, provided Zambia reforms its legislative framework to include living donation (while maintaining the opt-in system), it is submitted that the Israeli priority points system or the Spanish model also present varying options of which Zambia could study and emulate according to its capability in order to have a chance at a sustainable supply of organs for transplantation. South Africa has for some time debated the most appropriate organ donation system towards the possibility of changing the current system (opt-in) (Labuschagne, 2013; Etheredge, Penn and Watermeyer, 2017; Hawkins, 2017). Ultimately, the opt-in system is the most ethically and legally appropriate system (Etheredge, Penn and Watermeyer, 2017).

The chapter that follows will make recommendations on the way forward for Zambia with respect to organ donation and in so doing, propose a system for the country drawing from the positive aspects of the Israeli and Spanish systems that could be incorporated into a legislative framework.

6 CHAPTER 6 – RECOMMENDATIONS AND CONCLUSION

6.1 Introduction

Three systems of organ donation have been discussed in order to ascertain the best and most practically suited system to Zambia. This system must be cost-effective, non-labour and resource-intensive, non-burdensome on the health system and the State, and be fairly implementable in a multicultural, multilingual, and multireligious country such as Zambia.

6.2 Summary of Findings

6.2.1 Chapter 1 – Introduction

The aim of this research report was to normatively assess the ethical and legal issues associated with organ donation with a particular interest in the Zambian context, taking into consideration the modern frameworks of organ donation practices. The need for an ethical and legal framework for organ donation in order to satisfy a fast-growing demand for organs could not be overstated. Highlighted, were the ethical complexities affecting organ donation such as: what constitutes death for purposes of organ donation i.e. brain death or circulatory/cardiac death; what age is the appropriate for a person to donate; how organs are to be procured i.e. retrieved for transplantation and the systems or authorities to do so; donation by living donors with specific reference to their autonomy; consent and the health risk involved; and organ commercialisation and organ trafficking, to mention a few.

As an introductory chapter, it highlights the focus of the research report and the rationale for carrying out this study in Zambia where no such study has been done.

6.2.2 Chapter 2 – Domestic and International Regulatory Instruments

This chapter set out to discuss the requirement to develop laws that define how organ donation can be carried out in a legally and ethically acceptable manner. It considered the provisions of the current Human Tissue Act and its application to organ donation within the Zambian context. The Act's shortcomings were glaring and indicative of its failure to address organ donation. Consequently highlighting the immediate need for relevant regulation with respect to organ donation.

In order to provide a holistic picture of the country's lack of relevant organ donation regulations, comparative laws and regulatory instruments such as South Africa's National Health Act and its accompanying regulations with respect to organ donation, the World Health Organisation Guiding Principles on Human Cell, Tissue and Organ Transplantation, and the Declaration of Istanbul on Organ Trafficking and Transplant Tourism were normatively assessed. This further highlighted the need for robust organ donation regulations. The importance for Zambia to adopt and implement internationally recognised guiding principles and join other countries performing organ procurement and transplantation in a legally and ethically justified manner could not be understated.

6.2.3 Chapter 3 – Ethical Perspectives Of Deceased And Living Organ Donation

The aim of this chapter was to articulate and defend a normative position on the major ethical issues related to organ donation within the framework of deceased and living organ donation. A discussion of deceased organ donation in the context of donation after the determination of death; acquiring consent for donation of the deceased's organs from next-of-kin; and living organ donation in the context of donor autonomy and informed consent brought into focus the role of autonomy and informed consent as precepts of ethical organ procurement and donation. Despite living organ donation having significantly more complex ethical dilemmas, it is established as being a necessary form of organ procurement in the effort to reduce the overwhelming demand for transplantable organs.

6.2.4 Chapter 4 – Critical Evaluation Of The Organ Donation Systems And Their Application

The various organ donation systems discussed present with differing positive and negative aspects. It was indicated how no one system of organ donation can be said to be completely acceptable or unacceptable. When considered based on their application in a few select countries performing organ transplantation, the three main systems of organ donation illustrated shortcomings in their ability to increase organ donation rates. The evaluation of these systems in South Africa, Israel and Spain highlighted the additional implementation of other organ donation practices such as the priority points system and the introduction of transplant donor coordinators (TDCs), extensive training of specialised medical staff at every level of the organ donation process, and establishing a central authority as a watchdog body for organ donation

and transplantation (Matesanz *et al.*, 2011) in order to increase organ donation. Thus, the implementation of an organ donation system on its own is not enough.

6.2.5 Chapter 5 – The Influence Of Bioethics In Organ Donation Systems

The aim of this chapter was to answer the question: what system of organ donation is best suited to Zambia?. Having set the backdrop in chapter 4, this chapter began with normative analysis of the four principles of bioethics – respect for autonomy, beneficence, non-maleficence, and justice which then culminated into a discussion on the ethical defensibility of the various organ donation systems.

While the four principles were considered individually, in the context of organ donation, they are interrelated and no one principle can be dispensed with. Their importance was highlighted through their application to each organ donation system.

Of the organ donation systems, opt-out and mandated choice systems were identified as having some success in increasing organ donation numbers despite other factors also being attributed to the increase, for example, in Spain (Matesanz *et al.*, 2011) and Illinois, USA (Cotter, 2012) respectively. However, the two systems are synonymous with assertions of violations of rights, coercion and disregard for the donor's autonomy (presumed consent), disregard for the families wishes (especially with hard opt-out) and are resource intense.

On the other hand, a soft opt-out system was indicated as being arguably ethically justifiable on the basis that the families of the deceased would still be consulted for consent (Mcdowell, 2012). Families would be less likely to refuse consent because they can be approached before the potential donor dies. This notwithstanding, the opt-out system would not be feasible in Zambia.

With regard to the opt-in system, despite failing to comply with the principle of beneficence and justice, this system of organ donation recognizes and upholds the need for informed consent in organ donation. While the current opt-in organ donation system is arguably the most practical system for organ donation in Zambia, it requires substantive legislative reform in order for the system to be applied optimally.

6.3 Recommendations

A practical and well-established organ donation system will require legislative reform reflecting the system and its application to both living and deceased organ donation. It is recommended that legislation must clearly:

- Prohibit and criminalise trafficking of human organs in all its forms and trafficking of persons for the purpose of organ removal.
- Prohibit donation by minors and persons who cannot provide informed consent.
- Provide guidelines and regulation for the general public and HCPs on living and deceased donation.
- Define a reimbursement program to cover donors' and their families' related costs arising out of organ donation.

- Provide for criminalisation of commercialisation of organ donation
- Develop a national waiting list. As a database holding information of individuals in need of an organ, it would be referred to in order to match transplantable organs to prospective recipients.
- Develop a national donor registry. The function of the registry is to allow potential donors to formally make their wishes to donate known during their lifetime. This is important because it alleviates the need for uncomfortable discussions about donation at the bedside when the family is emotional and most likely to refuse to donate their loved ones' organs.

The development and implementation of such regulations coupled with the endorsement of the Declaration of Istanbul on Organ Trafficking and Transplant Tourism would show Zambia’s acknowledgement of the need to procure organs in a legally and ethically justified manner.

Furthermore, as seen in the Israeli and Spanish models, among several other nations, the establishment of an independent national transplant authority is vital for the proper management of organ donation and transplant activities. Among other tasks, the authority would oversee the living donor process ensuring that information, evaluation and approval of donors, recipients and transplantation are in line with national policies and regulations.

There is also a need for a mandatory training exercise to be rolled out providing training to HCPs and support staff in the organ donation process. It is submitted that it may not be practical for Zambia to focus solely on living organ donation especially with a system of opt-in organ donation. Zambia should consider running both living and deceased organ donation parallel. It could emulate nations such as South Africa, Israel and Spain to mention a few by training and establishing transplant coordinators within private and public hospitals.

A direct consequence of having specialised healthcare personnel is that obtaining informed consent from families through transplant coordinators encourages family discussion, reduces family refusal rates, and equally reduces the number of viable organs wasted as a result of conflicts in donation decision making between the donors and their families.

In the same vein as specialised training, widespread organ donation education and awareness campaigns would be needed. Albeit expensive and resource-heavy, according to Kirstin (2017), “for the introduction of any new nationwide medical system which impacts the entire population, there needs to be extensive awareness campaigns and educational programs”. Evidently, education and awareness campaigns would be undoubtedly necessary for the Zambia context. They would serve to educate the people on the topic of organ donation, the system of donation, how to register to be a donor, how important and effective organ donation is, the benefits of being a donor (such as in Israel) (Ashkenazi, Lavee and Moradi, 2015), and who can donate to mention a few. Additionally, these campaigns would encourage individuals

who are already aware of organ transplantation to become donors. The result would be awareness and public trust in the organ donation system and organ transplantation (considering public scepticism) which translates into an increasing availability of organs.

6.4 Conclusion

The aim of this research report was to normatively assess the ethical and legal issues associated with organ donation with a particular interest in the Zambian context, taking into consideration the modern frameworks of organ donation practices. In order to achieve this, Zambia's current legislation regulating the donation of organs was initially discussed, pertinent ethical issues arising out of living and deceased donation analysed, different organ donation systems evaluated, and the influence of ethics in each organ donation system and in particular that in Zambia assessed. This culminated into pertinent recommendations that could be implemented reforming the current opt-in system.

As seen from this ethico-legal study, reform of legislation in itself is not sufficient. For Zambia to have a real chance at having a sustainable and successful organ donation system and consequently a transplant practice, there is need for enablers to assist the opt-in system such as education and awareness campaigns, HCP and specialist personnel training, establishment of a regulating body, and procedures for reimbursement and incentives such as Israel's priority points system. This is likely to create an environment where adequate organs are available for transplantation.

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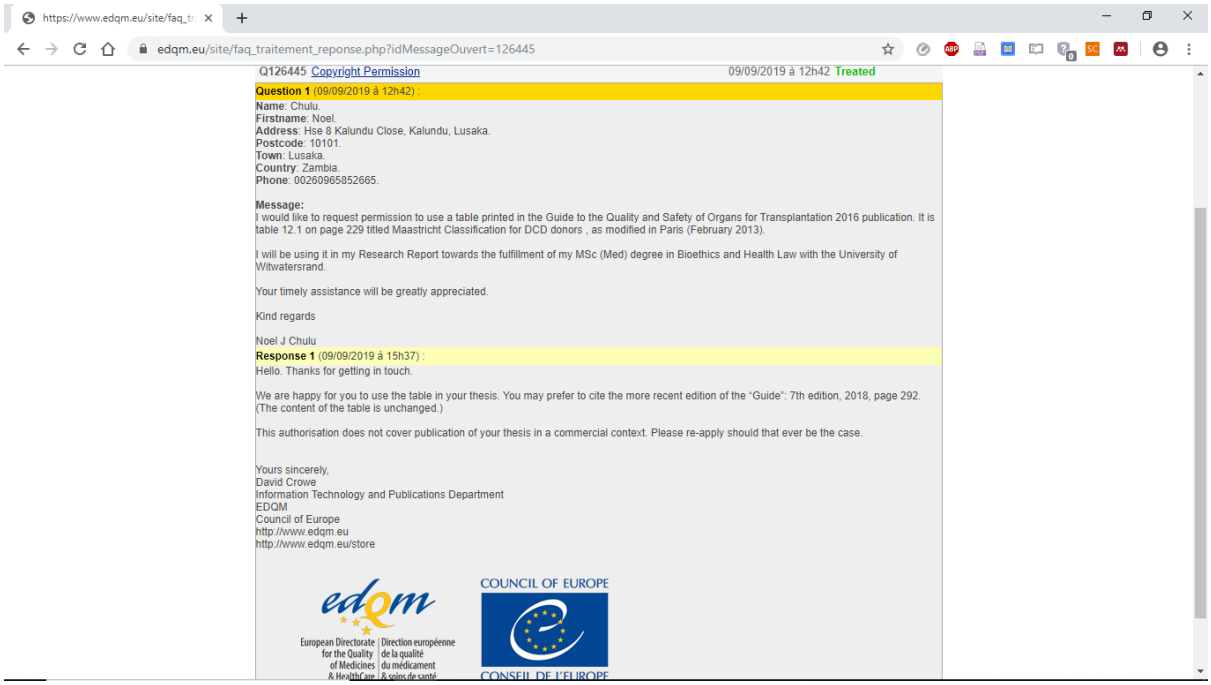
APPENDICES

Appendix A

Permission received for use of table 1, Modified Maastricht classification of Donation after circulatory death: categories of donor.



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Address: Hse 8 Kalundu Close, Kalundu, Lusaka.
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Message:
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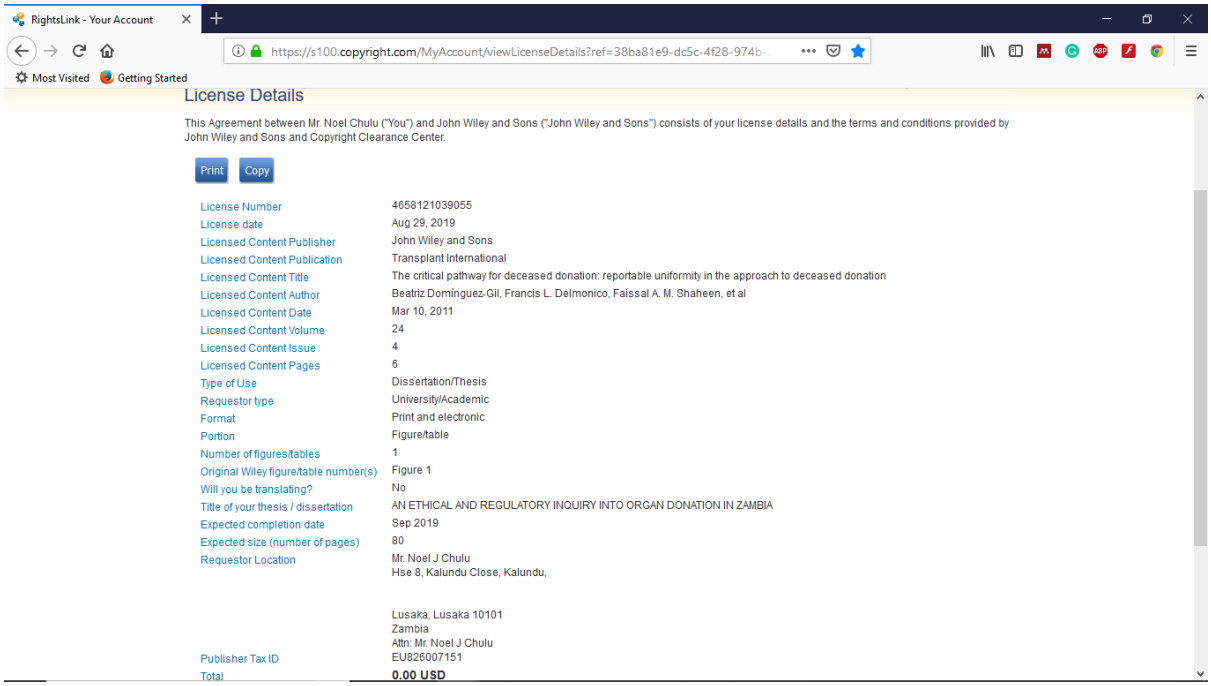
Appendix B

Permission received for the use of figure 1, the critical pathways for deceased donation.



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Appendix C

The Declaration of Istanbul on Organ Trafficking and Transplant Tourism 2018.






THE DECLARATION OF ISTANBUL ON ORGAN TRAFFICKING AND TRANSPLANT TOURISM (2018 Edition)

Preamble

Organ transplantation, one of the greatest medical success stories of the twentieth century, has prolonged and improved the lives of hundreds of thousands of patients worldwide. Countless acts of generosity by organ donors and their families, as well as the many important scientific and clinical advances achieved by dedicated health professionals, have made transplantation not only a life-saving therapy but a symbol of human solidarity. Yet these accomplishments have been tarnished by numerous instances of organ trafficking, of trafficking in persons for the purpose of organ removal, and of patients who travel abroad to purchase organs from poor and vulnerable people. In 2007 it was estimated that up to 10% of transplants worldwide involved such practices [1].

To address the urgent and growing problems posed by these unethical activities, the Transplantation Society (TTS) and the International Society of Nephrology (ISN) convened a Summit Meeting in Istanbul in April 2008. 151 participants—representatives of scientific and medical bodies, government officials, social scientists, and ethicists—reached consensus on the Declaration of Istanbul [2], which has been subsequently endorsed by more than 135 national and international medical societies and governmental bodies involved in organ transplantation.

The Declaration of Istanbul expresses the determination of donation and transplant professionals and their colleagues in related fields that the benefits of transplantation be maximized and shared equitably with those in need, without reliance on unethical and exploitative practices that have harmed poor and powerless persons around the world. It aims to provide ethical guidance for professionals and policymakers who share this goal. The Declaration thus complements efforts by professional societies, national health authorities, and inter-governmental organizations such as the World Health Organisation [3], the United Nations [4,5], and the Council of Europe [6-8] to support the development of ethical programs for organ donation and transplantation, and to prevent organ trafficking and transplant tourism. These efforts have contributed to the considerable progress made in countries around the world since 2008.

In 2010 TTS and ISN created the Declaration of Istanbul Custodian Group (DICG) to disseminate the Declaration and to respond to new challenges in organ trafficking and transplant tourism. Between February 2018 and May 2018, the DICG carried out a wide-ranging consultation, open to all interested parties, to update the Declaration in response to clinical, legal and social developments in the field. The results of the consultation process were presented, reviewed, and adopted as set forth in this document in Madrid in July 2018 during the International Congress of TTS.

The Declaration should be read as a whole and each principle should be applied in light of all the other principles which are equally important. The accompanying Commentary Paper explains and elaborates the text of the Declaration and suggests strategies for implementation.

Definitions

The following terms have specified meanings in the context of this document.

Organ trafficking consists of any of the following activities:

(a) removing organs from living or deceased donors without valid consent or authorisation or in exchange for financial gain or comparable advantage to the donor and/or a third person;
(b) any transportation, manipulation, transplantation or other use of such organs;
(c) offering any undue advantage to, or requesting the same by, a healthcare professional, public official, or employee of a private sector entity to facilitate or perform such removal or use;
(d) soliciting or recruiting donors or recipients, where carried out for financial gain or comparable advantage; or
(e) attempting to commit, or aiding or abetting the commission of, any of these acts.[1]

Trafficking in persons for the purpose of organ removal is the recruitment, transportation, transfer, harbouring, or receipt of persons, by means of the threat or use of force or other forms of coercion, of abduction, of fraud, of deception, of the abuse of power or of a position of vulnerability, or of the giving or receiving of payments or benefits to achieve the consent of a person having control over another person, for the purpose of the removal of organs.[2]

In the context of this Declaration, the term **resident** denotes a person who makes their life within a country, whether or not as a citizen; the term **non-resident** denotes all persons who are not residents, including those who travel to, and then reside temporarily within, a country for the purpose of obtaining a transplant.

Travel for transplantation is the movement of persons across jurisdictional[3] borders for transplantation purposes. Travel for transplantation becomes **transplant tourism,** and thus unethical, if it involves trafficking in persons for the purpose of organ removal or trafficking in human organs, or if the resources (organs, professionals and

[1] This definition is derived from the Council of Europe *Convention against Trafficking in Human Organs* (2015). [8]

[2] This definition is derived from the *Protocol to Prevent, Suppress and Punish Trafficking in Persons, Especially Women and Children, Supplementing the United Nations Convention against Transnational Organized Crime* (2000).[4] The Protocol provides that 'consent' of a victim of trafficking in persons shall be irrelevant where any of the means set forth in the definition have been used.

[3] In the context of this Declaration, the term jurisdiction encompasses not only nations but also states, provinces, other formally defined areas within countries, and regional or other supra-national legal entities with the authority to regulate organ donation and transplantation.

transplant centres) devoted to providing transplants to non-resident patients undermine the country's ability to provide transplant services for its own population.

Self-sufficiency in organ donation and transplantation means meeting the transplant needs of a country by use of donation and transplant services provided within the country and organs donated by its residents, or by equitably sharing resources with other countries or jurisdictions.

Financial neutrality in organ donation means that donors and their families neither lose nor gain financially as a result of donation.

Principles

1. Governments should develop and implement ethically and clinically sound programs for the prevention and treatment of organ failure, consistent with meeting the overall healthcare needs of their populations.

2. The optimal care of organ donors and transplant recipients should be a primary goal of transplant policies and programs.

3. Trafficking in human organs and trafficking in persons for the purpose of organ removal should be prohibited and criminalized.

4. Organ donation should be a financially neutral act.

5. Each country or jurisdiction should develop and implement legislation and regulations to govern the recovery of organs from deceased and living donors and the practice of transplantation, consistent with international standards.

6. Designated authorities in each jurisdiction should oversee and be accountable for organ donation, allocation and transplantation practices to ensure standardization, traceability, transparency, quality, safety, fairness and public trust.

7. All residents of a country should have equitable access to donation and transplant services and to organs procured from deceased donors.

8. Organs for transplantation should be equitably allocated within countries or jurisdictions, in conformity with objective, non-discriminatory, externally justified and transparent rules, guided by clinical criteria and ethical norms.

9. Health professionals and healthcare institutions should assist in preventing and addressing organ trafficking, trafficking in persons for the purpose of organ removal, and transplant tourism.

10. Governments and health professionals should implement strategies to discourage and prevent the residents of their country from engaging in transplant tourism.

11. Countries should strive to achieve self-sufficiency in organ donation and transplantation.

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