Human Embryonic Stem Cell Research in Transplantation and Regenerative Medicine: A Principlist Assessment

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DECLARATION

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Signed – Dan K. Kidha (March 2020)

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Abstract

Bioethics and scientific literature present transplantation and regenerative medicine as the next frontier for medical practice. The status of global disease burden also indicates that traditional approaches to medical services may be outdated. Use of medicinal drugs that alter the metabolism of cells may not successfully tackle the insurgent noncommunicable disease that target and destroy human organs. Moreover, cadaveric organ transplantation is facing logistical and ethical challenges that has led to the limitation of its efficacy in fighting disease. Stem cell research, particularly, that which involves the use of human embryonic stem cells (hESC) has been hailed as the answer to debilitating medical conditions, including organ failure. Pluripotent stem cells derived from embryonic organisms can be used to regenerate failing tissues and organs. However, bioethical literature point to the opposition towards hESC research because of the process which involves the destruction of human embryos. Many consider embryonic destruction a morally undesirable behaviour. Traditional theories of morality, on the other hand, have only managed to heighten the debate on the embryonic personhood thereby stalling progress of hESC research. This thesis demonstrates that the stalemate created by the debates on the personhood and moral status of the embryo need not stifle the potentially beneficial research. It therefore offers Principlism as an ethical framework approach for assessing the moral suitability of hESC research. The study finds that hESC research, though morally contentious, has potential for saving lives and relieving human suffering. It therefore recommends rapid progress on the research while advocating for a research focus that gradually reduces reliance on human embryos as primary subjects of research. Finally, the research recommends that a multi-disciplinary approach to tackling the challenges of bioethics, particularly, those related to scientific advancement.

Opsomming

In bio-etiek en wetenskaplike literatuur word oorplantings- en regeneratiewe medisyne as die volgende grensverskuiwende stap vir mediese praktyke aangedien. Die status van die wêreldwye siektelas dui ook daarop dat tradisionele benaderings tot mediese dienste moontlik verouderd mag wees. Die gebruik van medisyne wat die metabolisme van selle verander, sal moontlik nie die agressiewe nie-oordraagbare siekte wat die menslike organe teiken en vernietig, suksesvol aanpak nie. Verder ervaar kadawer-orgaanoorplanting logistieke en etiese uitdagings wat gelei het tot die beperking van die effektiwiteit daarvan om siektes te beveg. Stamselnavorsing wat veral gebruik maak van menslike embrioniese stamselle (MES), word wyd beskou as die antwoord op ernstige siektes, insluitend orgaanversaking. Pluripotente stamselle wat van embrionale organismes afkomstig is, kan gebruik word vir die herstel van beskadigde weefsel en organe. Bio-etiese literatuur dui egter op die teenkanting teen MESnavorsing vanweë die vernietiging van menslike embrio's in die proses. Baie individue en instellings beskou die vernietiging vam embrios as immoreel. Tradisionele moraliteitsteorieë het aan die ander kand slegs daarin geslaag om die debat oor die embrionale lewe te intensifeer, en sodoende die vordering van MES-navorsing te stuit. Hierdie tesis demonstreer dat die dooiepunt wat ontstaan deur die debatte oor die menswees en morele status van die embrio nie die potensiële voordelige navorsing hoef te onderdruk nie. Dit doen "Principlism" as etiese raamwerk en benadering vir die beoordeling van die morele geskiktheid van MES-navorsing aan die hand. Die studie bevind dat MES-navorsing, alhoewel moreel omstrede, wel die potensiaal het om lewens te red en menslike lyding te verlig. Dit beveel dus aan om spoedige vordering in hierdie navorsing te bewerkstellig, asook om klem te plaas op 'n navorsingsfokus wat geleidelik die afhanklikheid van menslike embrio's as primêre navorsingsubjekte verminder. Laastens beveel die navorsing 'n multidissiplinêre benadering aan om die uitdagings van Bio-etiek aan te pak, veral die wat verband hou met wetenskaplike vooruitgang.

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Dedications

To my father, Gordon Omer Kidha. Your faith in what I can achieve has always inspired me. The words of a father to his son have eternal consequences.

Abbreviations

AAS African Academy of Sciences

ASCs Adult Stem Cells

B&C Beauchamp and Childress

CDC Center for Disease Control and Prevention

ESCs Embryonic Stem Cells

HESCs Human Embryonic Stem Cells

iPSCs Induced Pluripotent Stem Cells

MDGs Millennium Development Goals

MLINs Middle and Low Income Nations

NCDs Noncommunicable Diseases

RDE Rule of Double Effect

SCR Stem Cell Research

STIAS Stellenbosch Institute for Advanced Studies

SDGs Sustainable Development Goals

WHO World Health Organization

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<u>Chapter 1</u>: Introduction: Problem Statement, Global Status on Non-Communicable Disease Burden and the Rise of Transplantation Medicine

"Eneke the bird says that since man has learned to shoot without missing, he has learned to fly without perching"

Chinua Achebe

This chapter seeks to bring to light some background information about the global status of the non-communicable disease burden and in so doing demonstrates the need for organ and tissue transplantation therapy, as well as the moral challenges of organ donation and consequences of transplantation business.

In as much as communicable diseases remain a significant disease burden in the developing world, the occurrence and prevalence of non-communicable diseases (NCDs)1 has reached epic proportions in both the high-income nations, as well as the middle and low-income nations (MLINs). Deaths attributed to non-communicable disease are increasingly on the rise, and at a considerably alarming rate. This increase in the disease occurrence is now a global phenomenon as attested to by the copious amount of literature addressing the issue. The data obtained from the studies are similarly, alarming: The prevalence of chronic as well as non-communicable diseases (NCDs) has today exceeded that of communicable diseases as the major cause of mortality and morbidity (Abdesslam Boutayeb, 2005; World Health Organization (WHO), 2011; Omoleke, 2013). The Lancet 2018 status report on NCDs (derived from the World Health Organization)2 indicates that "in 2016, an estimated 40·5 million (71%) of the 56·9 million worldwide deaths were from NCDs"3 (Ezzati, 2018: 1072). "According to World Health Organization (WHO) estimates, deaths from cardiovascular disease, cancer, chronic respiratory disease and diabetes accounted for 63 per cent of global mortality in 2008"

¹ Just like Helen (Helen M. Robinson, 2012), this paper uses the same definition of NCDs as used by the WHO in recent reports and publications and by resolutions of the World Health Assembly. "Non-Communicable Diseases (NCDs) are non-infectious and non-transmissible diseases that may be caused by genetic or behavioural factors and generally have a slow progression and long duration. NCDs encompass four major health conditions: cancers, cardiovascular diseases, chronic respiratory diseases and diabetes."

² For an empirical data on this see World Health Organization. *Global Health Observatory Data: Deaths from NCDs.* This information is available online at: https://www.who.int/gho/ncd/mortality_morbidity/en/

³ The report further indicates that "of these, an estimated 1·7 million (4% of NCD deaths) occurred in people younger than 30 years of age, 15·2 million (38%) in people aged between 30 years and 70 years, and 23·6 million (58%) in people aged 70 years and older. An estimated 32·2 million NCD deaths (80%) were due to cancers, cardiovascular diseases, chronic respiratory diseases, and diabetes, and another 8·3 million (20%) were from other NCDs" (Ezzati, 2018).

(World Health Organization (WHO), 2011; Helen M. Robinson, 2012). The seriousness and urgency of this situation prompted the United Nations, in November 2011 to broaden the discourse around NCDs, from general consideration as a health problem to an issue that is global in nature and of concern to socioeconomic development (World Health Organization (WHO), 2011).

Apparently, "Non-communicable diseases (NCDs) are not a new problem, having long been of concern in developed countries; they are, however, of increasing concern in developing countries because of their transition from low-income to middle-income status, the influence of globalization on consumption patterns, and the aging of populations."45 The NCD situation has had major implications on national health systems, policies, and socioeconomic development (Sanghamitra Pati, 2019). Given the far-reaching ramifications to society,6 it is imperative that significant attention be directed towards the management of NCDs and its risk factors,78 as is already the case, and as manifested under the Sustainable Development Goals (SDGs). The management of the risk factors cannot be emphasized enough for it is the most logical starting point towards seeking a lasting solution to the NCD challenge.

In addition to dealing with the socio-economic, environmental, and behavioral risk factors that are attributed to the rise of NCDs, the specific imperative to treat those with the disease reigns supreme. This include the particular aspects of management of the disease as well as making concerted efforts on research aimed towards finding appropriate cures and efficient technologies

 $^{{\}tt 4~IHME}, \textit{The Global Burden of Disease: Generating Evidence, Guiding Policy}, 2013.$

⁵ The U.S. Government and Global Non-Communicable Disease Efforts. Published: Jan 29, 2019 - Source: https://www.kff.org/global-health-policy/fact-sheet/the-u-s-government-and-global-non-communicable-diseases/

⁶ The Kaiser Family Foundation Global Health Policy reports that "the impact of NCDs is growing rapidly, affecting people of all ages and income levels in all regions of the world. The problem is expanding most in developing countries, where more than three quarters (32 million) of all NCD deaths occur (see Table 2).9 Though NCDs are often associated with older people, 15 million deaths caused by NCDs each year occur before the age of 70 ("premature deaths"); nearly all (over 85%) of these premature deaths occur in developing countries.10 For all regions except Africa, NCDs are now the leading causes of death; it is projected that by 2030, this will also be the case in Africa.11 With the growing incidence of NCDs and the ongoing challenge of tackling infectious diseases, some regions like Africa are facing a "double burden" of disease" (Kaiser Family Foundation, 2019).

⁷The U.N. Political declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases reported that NCDs risk factors encompass "behavioural, environmental, economic, and other social determinants of health" (U.N., "Political declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases," A/66/L.1, Sept. 16, 2011). In addition, the Kaiser Family Foundation records that "behavioural risk factors are associated with higher health costs and reduced productivity; they include: tobacco use, unhealthy diets, physical inactivity, and harmful use of alcohol" (Kaiser Family Foundation, 2019).

⁸ There are other risk factors associated with the proliferation of NCDs, and these, according to KFF, include: growing *urbanization*, *poverty* and growing *inequalities in wealth*, and *indoor air pollution*. There is also the view that the risk for NCDs varies by age, sex, and genetics (Kaiser Family Foundation, 2019).

Mitigating NCDs Through Use of Transplantation Therapy

Approaches to the treatment of NCDs are numerous. Since most of them are associated with the debilitation of internal organs, one possible treatment option includes organ transplantation. Technological innovations in medicine continue to provide hope of good health and long life. Transplantation medicine, in particular – a masterpiece of medical technological innovation – through replacement of worn out organs with potentially live ones, has become a common practice, not only in the developed world, but also in those developing. Many people whose ailments have hitherto been considered a pronouncement of death sentence have benefited from these near-miraculous inventions. There has been a remarkable progress9 in transplantation therapy since Dr. Joseph Murray made his first successful organ transplant in 1954 (Cornell 2017: 123). Today medicine has progressed immensely. Take for instance, the Scribner Shunt – the first instance of renal dialysis – in 1960, and the "God committee" created in Seattle to make decisions about who will be allowed to go on the machines. Today, life supporting machines like the dialysis machine have become common place even in the developing countries. 10 These machines perform a great task in sustaining the lives of patients with kidney complications as they wait for kidney donations from viable donors. They also function as back up procedure for keeping patients alive in the event of a failed transplant. Another notable development that has contributed to the rapid growth of transplantation [and regenerative medicine]11 is the discovery and development of immunosuppressive drugs (Howard, 2017). This has ensured considerable survival of organs, thereby catalyzing the rapid development of transplantation. According to WHO12 as documented by AAS-STIAS13 "noncommunicable diseases are likely to surpass infectious diseases as the leading cause of mortality in Africa" (2016: 11). It avers that "cardiovascular disease alone is the largest/leading contributor to the disease burden, and by projection, would dominate mortality trends in future" (AAS-STIAS, 2016: 11). This has called for the "need to rethink strategies about fighting diseases in Africa and how stem cell therapy can be implemented" (AAS-STIAS, 2016: 11). Patients who have experienced organ failure, for example heart, kidney, liver, lung, pancreas, heart-lung etc, can now hope that a replacement from a matching donor would give them a new

⁹ Medical prerequisites for successful organ transplantation include perfected surgical techniques, adequate organ procurement and preservation systems, methods to prevent rejection of the transplanted organ, and understanding of the role of tissue matching (Kutner 1987: p. 24)

¹⁰ Kenya has invested a significant capital towards the purchase of dialysis machines for the treatment of the growing number of kidney patients. https://www.the-star.co.ke/news/2017/10/02/major-boost-as-dialysis-machines-increase-to-74-in-public-hospitals_c1644881

¹¹ Emphasis mine.

¹² WHO stands for World Health Organization

¹³ AAS is an acronym for the African Academy of Sciences, whereas STIAS is an acronym for Stellenbosch Institute for Advanced Studies

lease of life. Regenerative medicine has a distinct goal, which is, the replacement and restoration of normal function of cells, tissues, and organs that have suffered debilitation by disease. (Atala 20008). Organ transplantation is a treatment option for such patients with diseased organs. Unfortunately, there is a supply deficit, as there are more patients in need of new organs than can be supplied. Moreover, the organ supply deficit is set to increase as the aging population increases.

This promise of hope has, however, been fraught with encumbrances. Because of the inevitable benefit of a restored health and livelihood, society has been quick in according a solid embrace to the idea of organ transplantation. Paradoxically, organ donation has not found equivalent embrace. This has invited the challenge of need versus supply as there is evident disequilibrium in the supply chain. There are many more people in line waiting for organ transplantation than there are those donating organs for transplantation – whether dead or alive. This situation has brought with its multiple complex challenges that could dim the prospects of organ therapy going forward. Most notable are the ethical conversations on organ procurement and transplantation although another challenge is based on the argument that transplant technology is still in the "experimental" stage (Kutner: 1987).

The first concern is that of the prohibitive cost of the transplantation medical care (the requirement of sophisticated equipment and highly skilled medical personnel). It raises the utilitarian concern of investing heavily on personnel and equipment for the treatment of a few whereas the resources would be invested in more viable treatment options that would cater for many people. This question of fiscal prudence raises another question of human dignity and the value of human life. A deontological argument for non-maleficence is thus in view here. The second concern is that of limited supply of organs for transplantation against a swelling multitude of hopeful patients. As Nancy Kutner has asked, what criterion should be used to select organ transplant recipients? (1987: 23), and what kind of society would reflect that value? The question raised in this view is that of justice in the procedure of determining who the immediate recipients would be. It also raises the issue of organ donation and all its attendant challenges including the difficult question of consent as well as the criterion for determination of death in case of diseased donors. The case of living donors presents the challenge and concern of incentives (which may lead to the dangers of coercion, exploitation and commodification), donor well-being, and the rising vice of human trafficking for the purpose of organ harvesting and sale for profit. Underlying these concerns are the ethical questions of autonomy, dignity and the value of human life.

In view of these challenges, it would be imprudent to ignore the questions raised and wait to witness a potential setback posited by legal and moral challenges to the advancement of transplantation medicine. Since there is clear indication that transplantation medicine offers a potentially remarkable solution to the health challenges posed by most non-communicable ailments, wouldn't it be prudent to pursue an alternative therapeutic approach or strategy that explores the line of transplantation, but which is not imprisoned by the notion of organ donation and its pitfalls. Indeed, a solution that aids organ 'rebirth' without depending on donations from external entities would be a worthwhile endeavour of any decent human being.

Emerging studies continue to present a future of transplantation and regenerative medicine devoid of organ donation and harvesting, but which is instead, anchored on revitalization of the diseased organs. Stem cell research, and particularly embryonic stem cell research is a poignant indicator towards this future nirvana. Researchers and scientists have sustained a chorus of applause for the potentiality of the embryonic stem cell research, particularly in human enhancement and transplantation medicine. This development is not a preserve of the developed nations alone. Even the developing nations have begun to claim their stake. The *Stellenbosch Institute of Advanced Studies* has documented an ongoing effort to develop and promote stem cell technology in the African continent (STIAS workshop report on stem cell science and application on 27 June – 1 July 2016). The research is pioneered by African scholars under the mentorship of experienced researchers from all over the world. These are baby steps but they demonstrate a global phenomenon. Recently, doctors in Kenya announced their success in facilitating the first transplantation of stem cells in the eyes of a patient who was blind (Daily Nation 2019; The Star 2019). These, and other similar ventures indicate a general global inclination towards stem cell technology.

In this proposed study, the ethical viability of the use of human embryonic stem cell in transplantation medicine will be assessed, with a hope that it will give policy direction on the way forward with regards to the ongoing research and debates on transplantation medicine, and stem cell related research and therapies. This problem will be elucidated further with concrete details in the ensuing section on problem statement. The framework for ethical assessment that will be used here is the Principlist approach. The foreseen function of this approach will be expounded further in the section on methodology.

Problem Statement and Focus

The central problem that this thesis seeks to address, is that of whether the use of human embryonic stem cell in transplantation medicine ought to be pursued as an ideal therapeutic solution to organ and tissue failure. This problem statement in turn raises the question as to whether it is morally acceptable to indulge in mass production and destruction of embryos for the purpose of generating crucial pluripotent stem cells for the rejuvenation of diseased cells in the organs. It also entertains the question on the moral difference between using left over embryos from in vitro fertilization procedures and mass production of embryos particularly for stem cell research. It has already been stated that there are encouraging results from the preliminary studies on the use of embryonic stem cell research in transplantation medicine. 14 Indeed, such 'prospect of being able to repair damaged tissues to correct the results of disease by means of "cell implants" which may initiate the regeneration of lost, damaged or diseased cells and tissues" (Moodley, 2017: 387) is a major motivation for the proponents of stem cell therapy. Arguably, the triumph of stem cell therapy is that it causes the growth of new healthy cells to replace damaged once (Moodley, 2017: 387; Okarma 2001). Such prospects are exciting and desirable, and there should be no problem at all were it not for the procedure of extracting the stem cells, which inevitably leads to the destruction of the embryo. This is the source of concern.

The desirability for HES cells for research is found in the "unique characteristics of embryonic stem cells, [which] make them the preferred candidates for research and eventual therapeutic purposes: pluripotency, immortality and malleability... These properties may lead to proper tissue differentiation and organ development" (Moodley, 2017: 387). The same cannot be confirmed of the proposed alternatives to HES Cell research and therapy as available data do not showcase a demonstrable alternative to the use of embryos for the extraction of stem cells. This is what creates the tension among scientists, thinkers, policy developers, and the religious community who are at lose as to whether to embrace or reject HES Cell therapy.

Pursuing the use of HES cell in transplantation medicine and research raises a series of problems. The moral dilemmas posed by HES cell research forces one to make a choice between two ethical principles: The obligation to prevent or alleviate suffering (non-maleficence), and the obligation to respect the value of human life.

In the first instance, we are confronted with the utilitarian imperative to pursue the greatest good for the greatest number. This implies that the duty to alleviate suffering is a greater good than that of protecting the life of the embryo. This, in turn raises the question of

¹⁴ The *STIAS* reported that "stem cells are already in use for the repair of damaged corneas in India, and that clinicians (in India) have so far performed 1,500 operations since 2004" (JUNE/JULY 2016). One other widely reported case is that of the "production of the first synthetic trachea, based on biological 3D printing, which was developed at University College London and seeded with stem cells for implantation into a male patient.... this invention has greatly improved the chances for creation of artificial tissues and thus could lead to artificial transplants" (STIAS, JUNE/JULY 2016: 11). These and many other examples, continue to present an aura of hope for the use of embryonic stem cell in transplantation medicine.

the varied degrees of human significance. It asks the question: Is it morally desirable to take the life of one person in order to save the life of another? In what instances would there be justification for such an act, if any? This presumptive argument of embryonic personhood will be considered along with the contrasting views.

The second raises "the fear that research using human embryonic tissue could pull medicine down a slippery slope to a world where unborn human beings are harvested for the cells they could provide to another human being" (Wright: 1999: 352). This, not only raises the question of autonomy and value of human life, but is also a transgression of Kant's doctrine of the *Categorical Imperative*, particularly the second formulation, which states: "so act that you use humanity, in your own person as well as in the person of any other, always at the same time as an end, never merely as a means" (Kant: 2012:41).

This Kantian-utilitarian tension is of interest to this study, and it begs the question of the existence of a third alternative that can help diffuse the tension in the HES cell therapy dilemma.

Goals, Theoretical Points of Departure, Research Questions and/or Hypothesis/ Hypotheses

1. Research Goal: This research aims at developing a philosophical-ethical framework which addresses the objections raised against the use of HES Cells in transplantation medicine within the context of a Principlism. It proposes a model for ethical reasoning that would allow researchers, medical practitioners and policy makers involved in stem cell therapy debate to make decisions about human lives without fear of regret.

2. Assumptions:

- a. It is assumed that HES Cell Research though still in the developmental stages, has demonstrated remarkable potential for the alleviation of human suffering in transplantation medicine.
- b. It is assumed that other proposed therapeutic solutions have not met significant milestones that may warrant their consideration for transplantation medicine.
- c. It is assumed that good health is a basic human right which must be sought after and protected in all bioethics engagements.

Research Questions:

- d. Should transplantation medicine be encouraged as best possible alternative to the use of conventional medication in cases of organ and tissue deficiency?
- e. Is embryonic stem cell research the best possible solution for organ and tissue deficiency?
- f. What would be the drawbacks to the clinical implementation of HES Cell therapy if it were to find absolute scientific backing of its viability in transplantation therapy?
- g. What are the other clinically viable solutions to transplantation medicine that do not suffer the ethical dilemmas posed by the use of embryonic stem cell?
- h. What is the moral status of the embryo, and should this (status) affect the use of embryos in stem cell research?
- i. What are the promises and pitfalls of the classic approaches of morality to decision-making?
- j. What is the value of a Principlism approach to moral decision-making for this enterprise, and why is this approach to be preferred?
- k. Does the Principlism approach provide moral justification for the use of HES Cell in transplantation medicine?

Research Design and Methods

This research is based primarily on literature review that involves a careful study of all relevant literature, including ethical and philosophical works, available literature on ethical issues related to HES Cell research and therapy, as well as transplantation medicine. Additional literature review include those based on empirical scientific studies that focus on the possibilities and challenges of HES Cell therapy and transplantation medicine. Moreover, philosophical reflections on the use of Principlism as a framework for assessing the ethical implications of the use of HES Cells in transplantation medicine are also a significant component of this study.

In addition to the thorough review of relevant literature, this author ensured a thorough and consistent consultation, primarily with the supervisor, as well as with other available experts in the field.

Finally, being a student of philosophy broadly speaking, and of ethics to be precise, this study would be inconclusive if the author's independent thoughts and reflections are not demonstrated in the final work. This reflection will include a groundwork for careful

conceptual analyses and an assessment of the philosophical ideas and presuppositions that belie the construction of various thought patterns in this bioethical project. The distinguishing aspect of this approach to ethical reflection in this research is the way Principlism is employed as an approach to moral decision making in the dilemma posed.

It must be emphasized at the outset that the outcome of this study is supposed to benefit a diverse group of people since it takes a multidisciplinary approach. Most notably, the medical practitioners, scientists, ethicist and philosophers, the religious community, legislators and policy makers would be the primary beneficiaries of the conclusions and recommendations of this study. Thus, what benefits and whom the beneficiaries of a philosophical inquiry into the values of stem cell research in transplantation medicine are, is an unavoidable question in this research. The progresses of the Millennium Development Goals (MDGs) and, now the Social Development Goals (SDGs) have brought to fore the dwindling effects of the communicable diseases worldwide. This in turn has brought into sharp focus the devastating nature of the incommunicable diseases and their effects worldwide. In Kenya, for example, it was noted that cancer claims 60 per cent of its victims – 32,900 every year, with 47,887 new cases annually – about 130 cases daily (Nyaundi, 2018). Furthermore, "an estimated 18.1 million new cancer cases were predicted worldwide for 2018, with 9.6 million deaths, said a report of the International Agency for Research on Cancer (IARC). This is up from estimated 14.1 million new cancer cases and 8.2 million deaths reported in the agency's last assessment just six years ago" ((IARC), 2018). Cancer diagnosis, for example, has been equated with a pronouncement of a death sentence. The desperation caused by such diseases have led to increased scientific inquiry into a possible radical solution. That is why the announcement of the possibilities of regenerative therapies through transplantation of HES cell has been heralded as a novel idea. As things stand now, the most notable encumbrance to this noteworthy scientific possibility is the question of the moral justifiability of the therapy as it involves the destruction of embryos that are considered by many as potential humans. Is it morally appropriate to use one life to protect other lives? The big question this author must grapple with is whether this stalemate should remain. Utilitarians and deontologists are stuck in the debate as to which is important: the preservation of a life or the sanctity of another life? Presently, the options available in this dilemma are bound to either sanction the continued death of many patients whose only hope is in their tissue or organ rejuvenation through stem cell therapy, or give them a lease of life through destruction of another life. A choice must be made. As is presently conceived, it is a choice to alleviate suffering by sanctioning the death of others or a choice to allow the pain of others so as to preserve the sanctity of other lives. Could a different, even better definition of the problem help us raise new solutions? Even better break the stalemate?

When stuck between two opinions, it may sometimes be necessary to introduce a third opinion. A third opinion would serve as a necessary tool for: 1). Assessing the plausibility of the forgoing opinions, 2). Exposing the biases of the forgoing opinions, and 3). Exploring the possibility of a third way out of the competing opinions.

Principlism refers to an approach used by bioethicist that appeals to moral principles rather than a particular moral tradition or a philosophically articulated moral theory to justify their proposed moral solutions to dilemmas in medical care and health policy. The quintessential proponents of this view, Tom Beauchamp and James Childress, in their book, *Principles of Biomedical Ethics*, have proposed the four principles: respect for autonomy, nonmaleficence, beneficence, and justice, as a suitable and substantial framework for bioethics. This thinking is motivated by the philosophers' inability to agree on the best moral theory for the resolution of moral problems, particularly in bioethics. Beauchamp and Childress argue that regardless of the differences at the level of theory, philosophers are able to agree at the level of principles. In this regard, therefore, Principlism is understood as a practical commonsensical approach to the obstinate arguments found in moral philosophy.

According to Principlism, moral problems cannot be solved, rather they are "best approached by applying one or more of four basic "moral principles" to them" (Van Niekerk, 2011: 37). Principlism is a desirable way of approaching moral dilemmas because it understands that there is a difficulty of attaining consensus on the moral theory that is most appropriate and is universalistically applicable.

In this research, Principlism, which draws from the idea of *common-morality*, acknowledges the impossibility of a teleological and deontological convergence on the question of the use of HES cell in transplantation medicine. Whereas the former argues for the duty to preserve life (of the patient), the latter argues for the value and dignity of the human life (of the embryo). This conundrum places the thinker into the difficult situation of circular reasoning. In the process, nothing gets done while human beings continue to die whereas they would have benefitted from HES Cell therapeutic intervention. This is where Beauchamp and Childress come in. They argue, and agreeably so, that:

while it is impossible to consistently and coherently defend one single moral theory, it is remarkable that almost all the known theories yield insight into the general validity of the four principles. Therefore: while we can agree to disagree about the possibility

of consistently upholding one single moral theory, we can agree that the "common morality" compels us to embrace the four principles. (Beauchamp and Childress, 2001).

The use of Principlism in this research is deemed desirable, not only because of its derivation from the *common-morality* idea, but also because of the quality of being able to draw from what Rawls has called "reflective equilibrium." Reflective equilibrium as a model would weigh the principles until an equilibrium is found in which the relevant weights of the principles in use come to rest (Beauchamp and Childress 2001: 398). This means that even though an absolute way out of a moral dilemma may not be found, a guideline for decision-making is availed that leaves the decision-maker without regrets. Principlism also acknowledge the dynamism resident in moral dilemmas and is open to continued interrogation and reflection. It leaves an open door for progressive investigation and revelation.

Principlism is desirable for this study because of its appeal to common morality and reflective equilibrium. It is also effective in diffusing conflict since it acknowledges that moral conflicts are seldom resolved. The advantage of Principlism is in the humble demeanour with which it approaches morally conflicting situations. Principlism does not suffer from triumphalistic and pompous tendencies common in the use of the classic theories of morality. It is rather deliberative and tentative, and does not purport to bring an absolute solution to a conflicting moral situation. The framework, however, allows the ethicist to decide on a moral situation (when a decision must be made) with justifiable confidence and live not to regret that decision. While other moral theories are engaged in endless debate without substantial directive or way forward in a morally conflicting environment, Principlism allows people to decide and move on. Other theories stock the fire, Principlism calms the fire.

This study will therefore interrogate the foregoing questions using the four principles of biomedical ethics. Where there is found a stalemate or contradiction, active resolve will be employed to weigh and seek equilibrium on the questions that are found daunting. It is argued that the use of the simple and available tools of Principlism would make decision-making a bearable task for those whom must decide on the use of HES Cell in transplantation medicine. Moreover, employment of Principlism would help diffuse the tension brought by the teleological-deontological warfare and provide middle ground for deliberation and decision making – considering the merits of all probabilities in the embryonic stem cell debate. The flexibility of the approach will allow for a peaceful resolution on a way forward on the HES Cell dilemma without the accompanying acrimony or regret that is oftentimes witnessed in the use of doctrinally rigid and obstinate classical theories of morality. This irenic nature of the approach is its trump card.

Although this study is not focused on the moral status of the embryo, it remains an inescapable question at the centre of this debate. Previously the question revolved around when life was thought to begin: does life begin at the time when the egg is fertilized, or after 14 days, which is thought to be the time of when cell differentiation begins? This has come with increased complexity given the successful cloning of Dolly, where scientists have demonstrated that fertilization is not required anymore, for the creation of an embryo. More pressing is the question as to whether the embryo is a kind of entity that is unethical to instrumentalize. This study tentatively adopts the argument of Ford who claims that "it makes no moral difference whether the embryo is naturally conceived, produced through in vitro fertilization, or is a cloned human embryo. Once formed, a human embryo is ethically inviolable" (Ford, 2000; Catherine Stanton, 2005: 222). This argument will be explored a little more later in the study.

Impact

This study, A Principlist Assessment of the use of HESCs research, with specific reference to Transplantation Medicine, seeks to establish the moral appropriateness of the use of HESCs in research and therapy. It hopes to equip the key stakeholders in the decision-making continuum – legislators, policy-makers, researchers and other major research and health sector implementors on the moral and ethical appropriateness and desirability of the therapy, and its benefit to the society. The dissertation will hopefully be published and brought to the attention of policy makers. A number of journal articles will also be written with reference to the thesis.

Summary of Research Design, Chapter Layout and Research Outcomes

This study shows that the aim of the analysis on the Principlism assessment of the argument against the use of embryos in scientific research has been to show that the problem of personhood and moral status of the embryo need not stall the progress on hESC research. In other words, the gravity of the global health status with regards to noncommunicable disease burden demands immediate concerted action by all stakeholders in the biomedical, health, religious, private, and governmental sectors. While recognising the place of private moral values and virtue, the study recognises that a continued liveability and sharing of space in a pluralistic world demand that moral human persons grant priority to the well-being of the human and community health.

Chapter 1 paints a picture of the grim status of human health across the globe. It provides the necessary background information concerning the global status of the noncommunicable disease burden, demonstrating the need for organ and tissue transplantation therapy, and the moral challenges of organ donation and consequences of transplantation business. Chapter 2 comprises of a comprehensive literature review on the status of hESC research and its potential for transplantation medicine. It also considers the medical alternatives to hESC research, including the use of ASCs as well as the iPSCs and finds that the moral arguments advanced in support of the alternative approaches do not outweigh the scientific, ethical and pragmatic arguments in favour of hESC research. What comes out, however, is not the supremacy of one research approach over the other, but rather a collaborative approach geared towards the search for medical and clinical solution to the prevailing global disease burden. Chapter 3a entails a presentation of a comprehensive motivation and justification for the choice of Principlism as an ethical approach in this research, with a thorough interrogation of the promises and pitfalls of the existing models of morality in assessing the subject in question. A detailed and thorough assessment of Principlism as articulated, primarily by Beauchamp and Childress, and other emerging thinkers in the field follows. The aim is to apply Principlism to bioethics, particularly in relation to the use of hESCs in research and transplantation medicine. Chapter 3b is an assessment of the classical theories of morality and their suitability for the determination of the morality of the hESC research. The study establishes that although the theories find no common ground for continued engagement, both the deontological and utilitarian theories have strengths relevant for the biomedical ethics engagements. In the same breath, their shortcomings also impede the bioethics agenda in general, and more particularly, the stem cell debate. The Principlism framework approach is therefore proposed as an arbitrator whose goal is to build consensus where possible.

Chapter 4 focuses on the arguments against pursuing hESC research in transplantation medicine. Based on bioethical reflections on Principlism, the study assesses the possible ethical reasons as to why HES Cell Research should not be pursued, and whether alternative remedies may be preferable. The scientific and moral suitability of these alternatives are explored. Chapter 5 is an analysis of the issues arising from the Principlism assessment on the arguments against hESC research. Using the Principlism framework, the study established the moral appropriateness of using HES Cells in Transplantation Medicine. It is determined that the benefits of the research would afford a revolutionary medical concept to society. The beneficent potential of the research, it is thought, outweighs the concerns of the moral permissibility of embryonic destruction. Moreover, by specifying and weighing the principles

against each other, it is established that use of embryos for research though fecund with potential for life transforming therapies, remain frowned upon by a section of society due to their rejection of "embryonic mistreatment." The study thus recommends that whereas hESC research provides the gold standard for scientific research on regenerative therapy, increased focus should be gradually directed towards research that does not need human embryos. It is advised that most information should be gleaned from the current stem cell sources and that moral conflict should be avoided by all means possible. Finally, these recommendations are suggested to form part of a wider policy proposal for governmental and other authorities concerned with policy and legislative development. Ultimately, the recommendations coming forth from the assessment should find relevance among stakeholders and decision-makers in the legislative, policy, healthcare research sectors.

<u>Chapter 2:</u> Human Embryonic Stem Cell Research: Promises for Transplantation Medicine and Regenerative Therapy

There is an acute shortage of organ donors for transplantation medicine. This shortage, notes Atala, has precipitated "research on stem cells as a potential resource for cell-based therapy" (2008). It is increasingly acknowledged that the future of biomedicine lies in stem cell research and therapy. Atala notes that for instance, "data from the Center for Disease Control and Prevention (CDC) estimated that approximately 3000 Americans die every day of diseases that could have been treated with embryonic stem cell–derived tissues" (2004: 1115). Furthermore, Gurdon and Colman as cited by Fischbach and Ruth and further by Nortje, noted that:

there seems to be a good prospect that the loss of somatic function induced by diseases such as diabetes, paralysis and myocardial infarction, to name but a few, may in future be ameliorated by injecting patients with cells which have differentiated into precursor cells, to cure or treat the symptoms of their degenerative diseases (Fischbach and Ruth 2004:1364-1370; Gurdon & Colman 1999:743; Nortje, 2007: 13).

Over time this chorus has been echoed again and again with most recent studies continuing to predict stem cell research as the future nirvana of medicine.

That stem cell research changes completely the way medicine is practiced, from changing the metabolism of cells to replacing worn out ones is in and of itself, significant promise, given the present global status of non-communicable diseases, which comes with massive organ failures. Whereas the diseased organs can be treated by organ transplantation, the challenge of demand and supply has created a situation of disequilibrium thereby raising the requirement for an alternative source of treatment. Regenerative medicine seeks to replace or restore normal functioning of cells, tissues and organs that are debilitated by disease.

Scientific projections indicate significant promise as it is hoped that stem cells will be the ultimate cure for a myriad condition. On these possibilities, Nortje cites Okarma (2001) who explains that in the foreseeable future, stem cells will:

...be used to help detect foetal genetic abnormalities; to reduce infertility, pregnancy loss, and birth defects; to aid the development of cardiomyocytes for therapy of congenital heart failure and myocardial infarctions; to find cures for insulin dependent diabetes mellitus; to assist in treatment of neurological diseases such as Parkinson's disease, strokes and Alzheimer's disease; to restore the haematopoietic systems of cancer patients; to treat arteriosclerosis; to aid in wound healing; to develop cartilage

forming cells which help those with osteoarthritis and rheumatoid arthritis; and so the list continues (Okarma 2001:6-10; Nortje, 2007: 14).

It is understood that the donor tissue source can be *allogenic*, which means they are donor derived. They may also be *autologous*, which means that they are derived from the host's cells. However, *autologous* cells are preferred for their compatibility with the immune system, thereby avoiding the need to use immunosuppressant drugs₁₅ (Atala, 2008). According to Atala:

Although the *autologous* cells are acknowledged as the ideal transplantation resource, some patients with end-stage organ disease do not produce enough cells for transplantation. In this case, allogenic cells may be advantageous. Furthermore, some primary cells, whether autologous or allogenic, cannot be expanded from particular organs, such as the pancreas. In these situations, pluripotent stem cells are envisioned as an alternative source of cells from which the desired tissue can be derived. Pluripotent stem cells represent an endless source of versatile cells that could lead to novel sources of replacement organs (Atala, 2008).

The desirability for HES cells for research is found in the "unique characteristics of embryonic stem cells [which] make them the preferred candidates for research and eventual therapeutic purposes: pluripotency, immortality and malleability... These properties may lead to proper tissue differentiation and organ development" (Moodley, 2017:387). However, the derivation of hES cells requires the destruction of embryos. This is what creates the tension among scientists, thinkers, policy makers, and the religious community who are at lose as to whether to embrace or reject hESC therapy.

What Are Stem Cells?

In 1981, scientists successfully isolated a mouse embryonic stem cell, and in 1998, scientists succeeded in the derivation of pluripotent human embryonic stem cells. This gave hope of a revolution in the practice of transplantation and regenerative therapy. Stem cells are immature cells that have not been differentiated. 16 Stem cells "have capacity for self-renewal and are also capable of forming at least one, and sometimes many, specialized stem cell types" (Gearhart, 2002: 92; Vicini, 2003). A stem cell is understood to divide into two cells: the first

¹⁵ However, inherent difficulty of ex vivo expansion is a major limiting factor for use of some autologous cells. Even though some organs have a very high regeneration rate in vivo (for example, the liver), cells from these organs can be difficult to expand in vitro, which hinders their clinical potential (Atala, 2008).

¹⁶ Differentiation means the cells have not yet decided what kind of cell they will be.

is a duplicate of itself, and the second cell develops into a more specialized cell type. Stem cells have the property of self-replacement each time they divide thus, giving them the capacity of a long-term self-renewal (Bioethics, 2005; AAS-STIAS, 2016; Brazier, 2018). In short, stem cells are said to exhibit two characteristics: They are undifferentiated and are capable of self-renewal. They "are also a potential source of new cells for the regeneration of diseased or damaged tissue and are thus central to normal human growth and development" (House of Lords 2002:15; Nortje, 2007). Vicini (2002) notes that stem cells could address the need for histocompatible cells in medicine, as well as provide therapeutic interventions for chronic and degenerative diseases, and human organ transplantation. Further, damaged tissues can be colonized and repaired by stem cells. The therapeutic potential of hESCs are numerous.

Stem Cell Sources and Potency

Stem cells are found in the tissue of the *born17* and the *unborn*. Those from the born are often called *adult stem cells*.18 Before birth, stem cells can be found in *amniotic fluid, in embryos19* and in *foetuses20*. Stem cells taken before birth should be called *prenatal stem cells* (Okarma, 2001; Brazier, 2018).

Accordingly, there are four categories that exists to describe the potency of cells: *Totipotent*, *Pluripotent*, *Multipotent*, and *Unipotent* cells. *Totipotent* cells have the ability to differentiate into a new organism²¹; *Pluripotent* can develop into specialized, multipotent stem cells. *Multipotent*²² cells can differentiate into specific types of cells (**terminally differentiated cells**) (Library of Congress, 2018);²³ and *Unipotent* cells can differentiate only into a cell of like type (Calva, 2015). Both the source of the stem cell and its potency are critical for determining the ethics of its use and its therapeutic value (Calva, 2015).

Prenatal Stem Cells

Because of their pluripotency, a coveted property of the prenatal stem cells, human embryonic stem cells (hESCs) have been brought into sharp focus. The hESCs are found only

¹⁷ e.g. in the umbilical cord, the placenta, bone marrow, fat tissue, nerve tissue, etc.

¹⁸ Okarma (2001) and Brazier (2018) advice that it would be more correct to refer to them as postnatal stem cells.

¹⁹ This is precisely the period from conception to the eighth week of gestation.

²⁰ This refers to the period from the ninth week of gestation all the way to birth.

²¹ The zygote repeats the process of mitosis for about 5 or 6 days creating a small ball of a few hundred cells called a **blastocyst**. 22 The difference between totipotent and pluripotent cells is only that totipotent cells can give rise to both the placenta and the

²³ For example a blood stem cell (multipotent) can develop into a red blood cell, white blood cell or platelets (all specialized cells). There are multipotent stem cells for all of the different types of tissue in the body.

in the human embryos, in their earliest days, and their extraction inevitably necessitates destruction of the embryo. It would be helpful to illustrate the general situation here. A three to five-day old embryo is known as a *blastocyst*. The blastocyst is made up of the *trophoectoderm24* and the *Inner Mass Cell* (IMC) (Jeoung Eun Lee, 2011). The Inner Cell Mass "contains the pluripotent stem cells which will differentiate into the types of cells needed to form tissue, organs and systems. To obtain the hESCs, the IMC must be extracted, [destroying] the embryo (Calva, 2015).

Postnatal Stem Cells

These are undifferentiated cells found in diverse tissues or organ that can renew itself, and are differentiated after birth, to yield some or all of the major specialized cell types of the tissue or organ (The National Institutes of Health (NIH), 2015). They are procured directly from the patient with very minimal discomfort, and no death. "As they are used to treat grave illness, the therapeutic principle is fulfilled, i.e. a greater good is expected than the inconvenience caused" (Calva, 2015). Moreover, the extraction of the Postnatal Stem Cell warrants no ethical objection.

Distinctions of the Stem Cells: Adult Stem Cells and Embryonic Stem Cells

Stem cells may be divided broadly into two classes: adult and embryonic. David Prentice25 defines stem cells as "...cells that can proliferate with almost unlimited potential, maintaining a pool of growing and dividing cells, with the added ability that some of the daughter cells can differentiate into specific cell types." (Prentice, 2000).26 Accordingly, "Adult Stem Cells tend to be tissue specific, self-renewing populations of cells which can differentiate into cell types associated with the organ system in which they reside" (Spradling, 2001; Presnell, 2002; Atala, 2008). Literature reveals that "Adult Stem Cells are quite rare, on the order of 1 in 10,000 cells within the tissue of interest" (Marshak, 2001; National Institutes of Health, n.d.; Atala, 2008), and as Atala et al adds, "currently it is known that niches of stem cells exist in many tissues, such as bone marrow, brain, liver, skin, skeletal muscle, the

²⁴ The trophoectoderm, which is a cavity filled with fluid, is also known as a trophoblast. It is this trophoectoderm which eventually makes up the child's placenta, umbilical cord, and amniotic membranes.

²⁵ This author is indebted to Dr. David Prentice who introduced him to the ethics of stem cells research while serving as a Whitherspoon Fellow of the Family Research Council in the Fall of 2008.

²⁶ Okarma explains that "among organs with self-renewal capability, resident stem cells are capable of periodically (or continuously) providing new population of functional, differentiated cells that can replace those lost by normal physiologic turnover or even some types of catastrophic losses due to injury or disease" (Okarma, 2002).

gastrointestinal tract, the pancreas, the eye, blood, and dental pulp" (Presnell, 2002; Spradling, 2001; Al-Rubeai, 1999; Jiang, 2002). According to Atala,

research on adult stem cells has been slow, largely because great difficulty has been encountered in maintaining adult non-mesenchymal stem cells in culture. There are challenges involved in maintaining and expanding long term cultures of adult stem cells in large numbers. Isolation has also proven to be quite problematic as these cells are present in extremely low numbers in the adult tissue (Atala, 2008).

In 2007, Douglas reported that AS cells cannot distinctly transdifferentiate into multiple unrelated tissue types, and that they (ASCs) are often inaccessible or difficult to obtain in large numbers. This means that even if they were able to transdifferentiate, there is an inevitable limitation of their cell replacement therapy potential, which leaves ES cells as the best therapeutic alternative (Douglas C Wu, 2007). However, this report has since been repudiated by Atala who reasons that "while current use of adult stem cells is quite limited, there is great potential in future utilization of such cells for the use of tissue specific regenerative therapies" (Atala, 2008). This is agreeably the mood on scientific research in general. Most of the perceived benefits border on potentiality, which is a futuristic notion. Moreover, Atala argues that the advantage of adult stem cells is that the use of stem cells from the same individual for therapy helps to avoid immune rejection complications (Atala, 2008). This research potential is still in progress as prevailing statistics gives a picture of a lack of consensus among the scientists on the status and efficacy of the AS cell use in transplantation and regenerative medicine. More studies reveal that hESCs, however, appears to exhibit a more demonstrated potential than the ASCs.

Conversely, Human Embryonic Stem cells are versatile and full of demonstrated potential. Okarma defines the human embryonic stem (hES) cell as "a self-renewing cell line that gives rise to *all* cells and tissues of the body" (2002: 3). Douglas et al instructs that "embryonic stem (ES) cells possess the potential to generate *all* the tissues of the body (Douglas C Wu, 2007: 4525). Moreover, they are capable of 'self-renewal', a property that allows them "to be passaged indefinitely in vitro under non-differentiating culture conditions" (2007: 4525). It should be noted that other than the Embryonic Stem (ES) cell which has the capacity for producing all types of body cells and tissues, most stem cells are characterized with a restriction of differential potential.

On the one hand, "Adult Stem (AS) cells are responsible for maintaining cell turnover homeostasis and organ-specific regeneration, whereas ES cells play a central role in embryogenesis and the formation of fetal tissues" (Douglas C Wu, 2007). It is notable that

despite some similar characteristics, these two cell types exhibit important differences which have significant implications for their potential use as a cell replacement therapy (Atala, 2004). Three distinct qualities are attributed to the ES cells: *pluripotency*, *immortality* and *malleability*. They said to be *pluripotent* because they are able to develop into many types of cells and tissues. The quality of *immortality* is attributed to the ES cell because they exhibit the property of eternal self-renewal and are therefore able to continue dividing indefinitely without losing their genetic structure. The third known distinctive property of the ES cell is the *malleability*, and this is because of the ES cell's capacity for manipulation without losing their function.27

There is more advantage in use of the hESCs over the ASCs for scientific research, as the latter is fraught with limitations. Atala attests to this: "One of the limitations of applying cell-based regenerative medicine techniques toward organ replacement has been the inherent difficulty of growing specific cell types in large quantities" (Atala, 2004: 1113). This makes the ASC an unlikely candidate for transplantation and regenerative material. Thus, "for many patients with extensive end-stage organ failure, a tissue biopsy may not yield enough normal cells for expansion and transplantation" (Atala, 2004: 1114). "In these situations, pluripotent hESCs are envisioned as a viable source of cells because they can serve as an alternative source of cells from which the desired tissue can be derived" (Atala, 2004: 1114). The suitable property of the hESCs is that they "are derived from the inner cell mass of the trophoblast, and have the ability to differentiate into all the tissues of the fetus. As such, their potential in cell replacement therapy and regenerative medicine has been widely acknowledged" (Douglas C Wu, 2007). Investigators claim that hESC research hold promise for the treatment of various diseases such as Alzheimer's, sickle cell anemia, prostate cancer, stroke, diabetes, Parkinson's disease, and spinal cord injuries (Green, 2008).

To underscore the peculiarity of the ES cells, Atala, quoting multiple authors, writes that "Human embryonic stem cells have been shown 'to differentiate into cells from all three embryonic germ layers in vitro. Skin and neurons have been formed, indicating ectodermal differentiation' (Zhang SC, 2001; Schuldiner M, 2001; Schuldiner M, 2000; Zhang SC, 2001). 'Blood, cardiac cells, cartilage, endothelial cells, and muscle have been formed, indicating mesodermal differentiation' (Kaufman DS, 2001; Kehat I, 2001; Levenberg S, 2002). And 'pancreatic cells have been formed, indicating endodermal differentiation' (Assady S, 2001). In addition, as 'further evidence of their pluripotency, embryonic stem cells can form embryoid bodies, which are cell aggregations that contain all three embryonic germ layers, while in culture, and can form embryoid bodies, which are cell aggregations that contain all three embryonic germ layers, while in culture, and can form teratomas in vivo (Itskovitz-Eldor J, 2000; Atala, 2004: 1114 – 1115).

There is, however, a cry that hESC "research could create false hope in patients because there are no guarantees that embryonic stem cells can cure diseases" (Green, 2008). It is further argued that "if cures are found during the next decade or two, medical treatment costs could be astronomical" (Green, 2008). Such fears are allayed by hESC researchers who argue that the promise is greater and the potential is demonstrable, at least as shown by the experiments with animal subjects. Whether or not this will translate into clinical practice is a matter of time. The promise is too great to just dispel just by mere repugnance or general aversion to research using embryonic organisms. An interesting concept is the way this technology will shift how medicine is practiced – from the use of drugs to alter the cell metabolism to actually growing new healthy cells for replacement of the damaged ones. There is significant hope in regenerative medicine, through the injection of healthy cells, have the potential to revitalize the debilitated organs. Indeed, commentators have predicted that this approach could widen the scope of medical practice from the focus on managing progress of debilitating disease to incorporate revitalization of lost organ function. In this regard, hESC research holds enormous promise for the future of transplantation and regenerative medicine.

Arguments Against Human Embryonic Stem Cells (hESC) Research

In spite of the promises carried by the research, there are those who are opposed to hESCs research and who therefore advance scientific as well as ethical arguments against hESCs research. Some of the arguments relate to the methodology of HES cells extraction, the alleged occurrence of ESCs tumorigenesis, immunological factors, and the doubt regarding the inconclusiveness of the research. hESCs are the primary sources of the *pluripotent* stem cells which are derived from the inner cell mass of the 5 to 7-day old blastocyst. hESC research is, however, controversial because it involves the destruction of human embryos. There are those who hold that an embryo is a person with distinct moral status like an adult, while other groups hold diverse views on the exact period in the development when the embryo acquires moral status, still some contest the whole idea of an embryonic moral status *in toto*. These views have implications on the ethics of the use of the embryonic organisms in research. The morality of hESC research is the subject of this thesis, and therefore not much will be discussed about it here. Later chapters will treat the concerns of hESC research in detail.

Those who oppose hESC research propose other approaches. One of the solutions proposed is the use of Adult Stem Cells (ASCs), which we have compared with hESCs above, and found to be limiting in terms of therapeutic potential. The other important alternative that

is proposed in the place of hESCs is the induced Pluripotent Stem Cells (iPSCs). We will look briefly into the nature and viability of this proposed alternative.

Induced Pluripotent Stem Cells (iPSCs): The Alternative to hESCs?

The term, pluripotent, was coined by Takahashi and Yamanaka (2006) in reference to direct reprogramming of mammalian somatic cells, which they achieved by inducing differentiated cells back to pluripotent state by transfecting the cells. Induced Pluripotent Stem Cells (iPSCs) appear very similar to hESCs but do not require destruction of embryos (Meyer, 2008). As opposed to the hESCs, they are not derived from embryonic organisms, therefore not necessitating the destructions of embryos. This fact allows them to hold an apparent ethical advantage over the use of hESCs. The destruction of embryos for scientific research is a major clog in the wheel of hESC research, and the opposition to the research is buttressed by the puritanical claims of iPSCs. Moreover, there are alleged scientific superiority over hESC research. This is attributed to their virtue of being patient specific, which allows them to circumvent concerns over immuno-rejection with stem cell therapy (Vitale et al. 2011).

Those morally opposed to using embryos in research, as well as those wishing to bypass the stalemate on the status of the embryo and proceed with stem cell research alike, have advocated in favour of iPSC research. And so, we have to ask whether iPSC technology might provide a historic opportunity to move away from embryo destruction and proceed with morally uncontentious research (Bridge, 2013).

Scientific Considerations: iPSCs are not Identical to ESCs29 and thus cannot replace ESCs

Induced Pluripotent Stem Cell research is not necessarily the trump card in stem cell research and the consequent use in transplantation and regenerative medicine. Despite iPSCs being deemed "ethically unproblematic and acceptable for use in humans" by the President's Council on Bioethics (Bioethics, 2005), there exists a series of other practical and ethical considerations. Bridge (2013) agrees with Lysaght and Campbell (2011) that "ethical considerations that need to be made should go beyond the moral status of the embryo. How, for instance, will research translate to practice? The ethical analysis needs to encompass the

²⁸ Transfecting is the process of deliberately introducing genetic material into cells (Bridge, 2013: 26).

²⁹ I am largely indebted to Sophie Bridges for the most part of the analysis on iPSC as they compare with hESCs research.

whole process from procurement and manipulation of iPSCs and ESCs to the culmination of their actual efficacy and use in treating targeted conditions" (Bridge, 2013).

In addition, Bridge presents two key questions for consideration: which is the more practical option for stem cell research? And which cell type can be used to develop therapies that will best translate from research to actual treatment? She argues that without these considerations, attempts at ethical analyses are incomplete (Bridge, 2013).

Bridge's questions are best answered by studying the trend in the scientific field. It is notable that in spite of the various noises in favour of iPSC research as a replacement to hESCs research, there are reports that most stem cell scientists believe ESCs are irreplaceable, whether by iPSCs, or any other alternative (Hug, 2011).

Overall, it is observed that whereas iPSCs have considerable promise and potential for regenerative therapy, they cannot in any way serve as the ultimate replacement of the hESCs due to the moral issues associated with the research. If anything, research on iPSCs, by association with hESCs research has succeeded in offering more insights in stem cell research and embryology, particularly with regards to the biology of cell differentiation. This may not be good news to those opposed to hESC research, especially those who oppose the research because of their revulsion to the alleged immorality of embryonic destructions, as hESCs appear to remain the gold standard for SCR and regenerative medicine. In any case, the assumption that the use of iPSCs obviates the need for stem cells extracted from the embryonic organism is ill informed, as evidence confirm that hESCs research is essential and indistinguishably tied to iPSC research; as one researcher said, "It is out of the question to even suggest phasing them out...we will be lost without them" (Bridge, 2013; Belmonte, 2010: 882). There is still much to learn about the mechanisms of ESCs pluripotency and self-renewal, and this would directly inform the development of more efficient iPSCs (Plath and Lowry, 2011). Sophie Bridge has provided this useful analysis on the clinical use of the iPSCs vis-à-vis the hESCs. Quoting Brynes (2008) she says that "advocates for iPSCs research as a way of bypassing the moral hurdles associated with hESCs research 'assume that existing ESC lines are sufficient to carry out the necessary comparative pluripotency studies."

Bridge (quoting multiple sources) continues to argue:

there are questions as to the adequacy of the existing ESC lines to carry out comprehensive comparisons. A wide array of ESC lines is needed for three reasons. First, the current ESC lines have significantly restricted ethnic diversity (Laurent, 2010; Bridge, 2013). It is important to have stem cells from a variety of ethnic (and therefore genetic) backgrounds to ensure the generalisability of results. Furthermore, if ESCs are

ever to be used for regenerative medicine, recipients of cell transplants will more likely be immunologically matched to donors who share their ethnic background. Second, it is important that ESC lines are able to differentiate into the tissues of interest. Some research has shown that different ESC lines can differ in their differentiation properties. For stem cells to be used for regenerative medicine, it is necessary for them to follow a desired lineage of differentiation. Finally, to study human disease, ESCs need to be created that are disease-specific. Animal model systems (typically mice) may fail to represent human pathology. To date, ESCs representing 33 heritable diseases have been created, but this is only a small fraction of hereditary disorders that could be modelled (Loser, 2009). Successful modelling and development of treatments for genetic disorders would require the derivation of more ESC lines representative of specific human genetic diseases. Moreover, it has been suggested that since most of the existing ESC lines do not meet good manufacturing practice standards that eliminate all sources of contamination (human or animal derived), it would be safer to start over and establish new lines if ESCs are to be used in human stem cell therapy (Martin, 2005). The scientific and clinical need for continuing ESC research reveals a fallacy in the assumption that iPSC research is ethically superior to ESC research. Instead of circumventing the moral problems associated with ESC research, it is becoming increasingly clear that iPSC research requires ongoing destruction of embryos (Bridge, 2013).

As has been argued above, lots of literature have been written that demonstrate a favour for the continued experimentation with embryos, and which argue that iPSC is not necessarily a possible, let alone, ideal replacement for ESC research.

iPSCs are Complicit in Embryo Destruction

Opponents of hESCs research would be disappointed when they discover that iPSC research inevitably confers it the status of co-accused together with hESC researchers. Certainly, iPSC research cannot claim to be untouched by the moral dilemmas facing hESC research since iPSC research cannot happen without hESC research. As a technique, iPSC research offers no tangible scientifically satisfactory alternative to hESCs. In any case, use of iPSC depends on and encourages continued research on embryos, thereby furthering the destruction of embryos. From this, it follows that iPSC research is complicit in the very act it

was designed to circumvent. The two technologies are inextricably tied together — in the past, the present, and most likely into the future as well (Bridge, 2013).

This argument by Bridge confirms that inevitability of the theory of moral complicity who by way of illustration shows that an example of permissible material complicity is the case of vaccines derived from the tissues of aborted foetuses, which is an instance of moral complicity somewhat parallel to the case in stem cell research (Prieur, 2006). Vaccines for German measles and chickenpox were developed from foetal cells obtained from elective abortions in 1961. As is the case with ESC research, the source of the treatment is morally contentious, but since then vaccination has prevented many cases of death and mental retardation (Maher, 2002: 52). Inevitably, iPSC research has its origin in an ongoing research program and any successes in iPSC research will contribute to ongoing interest in ESCs (Bridge, 2013; Brown 2009). Consequently, there are two main ways in which iPSC research is complicit in ESC research: first, by increasing demand for ESCs research, and second, by implicitly condoning the destruction of embryos (Devolder, 2010).

In summary, current iPSC research will necessitate the need for embryo destruction. This is because iPSC research is heavily dependent on initiation of new ESC lines. Furthermore, because of their genomic instability and subsequent risk of causing cancer, doubts have been raised about the usefulness of iPSCs for therapy. For this reason, any research with iPSCs, will have to be accompanied by ESC research to determine if the latter will more safely achieve the desired outcome. In this way, iPSC research will indirectly create demand for ESC research, an incentive created by iPSC research (Bridge, 2013).

The Future of Stem Cell Research

Induced pluripotent stem cell research, the pioneering work of Yamanaka and Molten, may hold promise to the reduction, and perhaps ultimate termination of research using human embryos. This is plausible – but only in the distant future. Although iPSCs have demonstrated a considerable potential for therapy (Mauritz, 2011), they are still bound to face a myriad hurdle in the quest for their regulatory approval (Laflamme, 2011). Meanwhile, hESC "are already being tested in humans for retinal diseases and spinal cord injury" (Schwartz, 2012; Bretzner, 2011). As for now, it is impractical to call for the termination of hESC research with the hope that iPSC research will smoothly replace it in the search for the ultimate answer to transplantation and regenerative medicine.

For now, hESC research must soldier on as it offers the best promise for regenerative medicine. It is the anchor upon all the stem cell researches are tied as it provides not only the

best possible promise for future treatments, but is also the learning guide upon which emerging regenerative technologies will depend. It follows, as Bridge has noted "that if we do not ask we will never know: in order to learn more, stem cell research will need to continue" (Bridge, 2013). This process of inquiry should be done with a focus on balancing the concerns of persons averse to embryonic research and those in support. Fueling the conflict that is already hampering research progress is of no gain to society – not in the immediate or distant future. Therefore, an ethical framework that thaws the moral battle heat is invited, not those that fuel it.

Conclusion

The scientific progress in stem cells research, particularly the human embryonic stem cell is phenomenal. It is however, fraught with ethical, regulatory and scientific encumbrances. The most prominent challenge is that regarding the use of embryonic organisms in research. The morality is questioned because of the inevitable destruction it metes on the embryos during the extraction of pluripotent stem cells. This has created a heated debate, particularly on the moral acceptability of destruction of embryos. The debate is shrouded in controversy, and some thinkers argue that "this is not the sort of debate that is susceptible of a final answer" (Anthony Dyson, 1990: 1). To mitigate the ethical challenge associated with the destruction of embryos to facilitate research, iPSCs have been promoted as the best possible alternative to hESC research. However, iPSCs research is still inconclusive, has not yet found way in clinic trials and use, and it has been found to be intricately dependent on hESCs both for research continuation. This makes iPSCs research morally complicit to embryonic destruction, both by increasing demand for hESC research, and by implicitly condoning the destruction of embryos. Touted as the gold standard for SCR, hESC research will therefore remain the most promising, and indispensable approach in the scientific investigations regarding transplantation and regenerative therapies. Other research approaches may be regarded as just footnotes that find their grounding in hESC research.

Chapter 3A: The Case for Principlism as a Preferable Assessment Tool on the Morality of hESC Research in Transplantation and Regenerative Medicine

This chapter argues for a comprehensive motivation and justification for the choice of Principlism as an ethical approach in this research, with a thorough interrogation of the potentials and limitations of the existing approaches to morality – specifically, the deontological and the utilitarian arguments as used in the stem cell debate – in assessing the subject in question. A detailed and thorough assessment of Principlism as articulated, primarily by Beauchamp and Childress (hereafter B&C), and other emerging thinkers in the field will follow. The arguments advanced for and against the use of hESCs in transplantation and regenerative medicine, and an ensuing interrogation of the same within the ambit of Principlism. The counterarguments to these positions will be equally considered before proceeding to assess other alternative remedies advanced, taking cognisance of their merits and demerits as well as the counterarguments in response to these positions. Finally, a pitch will be made for the preference of Principlism over other theories in making assessments against the use of hESC research and its relevance to transplantation and regenerative medicine.

Introduction and Overview

This chapter begins with a thorough explication of Principlism as a suitable framework for assessment of the morality of hESC research in transplantation and regenerative medicine. The explication includes a thorough exposition, assessment and evaluation of the nature, necessity, possibility, and efficacy of Principlism as a credible and commendable tool for use in biomedical ethical inquiries. This includes the arguments for the grounding, usability and claims of Principlism.

Principlism refers to the approach used by bioethicists that appeals to moral principles rather than a particular moral tradition or a philosophically articulated moral theory to justify their proposed moral solutions to dilemmas in medical care and health policy. The quintessential proponents of this view, Tom Beauchamp and James Childress, in their book, *Principles of Biomedical Ethics*, have proposed the four principles: respect for autonomy, nonmaleficence, beneficence, and justice, as a suitable and substantial framework for bioethics. This thinking is motivated by the philosophers' inability to agree on the best moral theory for the resolution of moral problems, particularly in bioethics. Beauchamp and Childress argue that regardless of the differences at the level of theory, philosophers are able to agree at the

level of principles (B&C, 2001). In this regard, therefore, Principlism is understood as a practical commonsensical approach to the obstinate arguments that reside in moral philosophy.

According to Principlism, moral problems cannot be solved, rather they are best approached "by applying one or more of four basic 'moral principles' to them" (Van Niekerk, 2017). Principlism is a desirable way of approaching moral dilemmas because it understands that there is a difficulty of finding consensus on the moral theory that is most suitable and may be applied universally.

In this research, Principlism, which draws from the idea of *common-morality*, acknowledges the impossibility of a teleological and deontological convergence on the question of the use of HES cell in transplantation medicine. Whereas the former argues for the duty to preserve life (of the patient), the latter argues for the value and dignity of the human life (of the embryo). This conundrum places the thinker into a position of unending fallacy of circular logic where nothing gets done while human beings continue to die whereas they would have benefitted from HES Cell therapeutic intervention. Beauchamp and Childress, however, argue, and agreeably so, that although it may not possible logically and consistently uphold one single theory of morality, it is notably significant "that almost all the known theories yield insight into the general validity of the four principles" (B&C, 2001). This means that, wherefore we may not be synonymous on the prospects and dependability of defending a single theory of morality, it is possible to have consensus on the idea that the "common morality" obligates the embrace of the four principles (B&C, 2001). Common Morality shows why it is impossible to approach moral reasoning from only one principle, and biomedical ethics requires all the four principles.

The use of Principlism in this research is deemed desirable, not only because of its derivation from the *common-morality* idea, but also because of the quality of being able to draw from what Rawl has called "reflective equilibrium." Reflective equilibrium as a model would weigh the principles until an equilibrium is found in which the relevant weights of the principles in use come to rest (Beauchamp and Childress 2001: 398). This means that even though an absolute way out of a moral dilemma may not be found, a guideline for decision-making is presented that leaves the decision-maker without regrets. Principlism also acknowledge the dynamism present in moral dilemmas and is open to continued interrogation and reflection. It leaves an open door for progressive investigation and revelation.

Principlism is desirable for this study because of its appeal to common morality and reflective equilibrium. It is also effective in diffusing conflict since it acknowledges that moral conflicts are seldom resolved. The triumph of Principlism is in the humble demeanour with

which it approaches morally conflicting situations. It is not triumphalistic and pompous, but rather deliberative and tentative, and does not purport to bring an absolute solution to a conflicting moral situation. It, however, allows the ethicist to decide on a moral situation (when a decision must be made) with justifiable confidence and live not to regret that decision. While other moral theories are engaged in endless debate without substantial directive or way forward in a morally conflicting environment, Principlism allows people to decide and move on. Other theories stock the fire, Principlism calms the fire.

This study will therefore interrogate the foregoing questions using the four principles of biomedical ethics. Where a stalemate or a contradiction is found, active resolve will be employed to weigh and seek equilibrium on the questions that are found daunting. It is argued that the use of the simple and available tools of Principlism would make decision-making a bearable task for those whom must decide on the use of HES Cell in transplantation medicine. Moreover, employment of Principlism would help diffuse the tension brought by the teleological-deontological warfare and provide middle ground for deliberation and decision making – considering the merits of all probabilities in the embryonic stem cell debate. The flexibility of the approach will allow for a peaceful resolution on a way forward on the HES Cell dilemma without the accompanying acrimony or regret that is oftentimes witnessed in the use of doctrinally rigid and obstinate classical theories of morality. This irenic nature of the approach is its trump card.

Explication of Principlism: Nature, Necessity, Possibility, and Efficacy of Principlism

Principlism is the doctrine which prescribes that moral agents should make decisions, whether right or wrong, by following certain moral rules. These moral rules are summarised into four principles that have since been known as Principlism. Beauchamp and Childress postulate that these principles form a moral framework in biomedical ethics which, could be used by the physician and patient to analyse a difficult ethical situation. This is contrary to the nature of the other competing frameworks, like the classical theories of ethics, which make moral decision-making in a biomedical environment difficult given their [the classical theories] perpetual state of contest and contradictions. The deontological and utilitarian approaches, by their contradicting positions, have merely intensified the debate on hESC research, instead of giving guidelines for decision making.

Principlism has grown over time into a notable framework in the bioethics enterprise. It has attracted friends and foes alike since it was first introduced thirty-four years ago, leading to a presently vibrant debate on methodology in bioethics.₃₀

Nature of Principlism

Beauchamp and Childress (2013) advocate for a position that is opposed to Mill's doctrine of categorical happiness – the view that we should optimize good consequences at all times and at all costs, irrespective of the prevailing rules. In this sense, Principlism is a rule ethics as opposed to acts ethics, and is therefore deontological rather than teleological. This is evidenced by the fact that the "principles are prima facie binding meaning that they must be fulfilled in every situation if they do not conflict with other principles. If the principles conflict they ought to be specified and balanced" (Mette Ebbeseb, 2012; Childress, 2013). It should, however, be recognised that Principlism is not entirely deontological as it allows a degree of flexibility in its pursuit for decision-making in situations of moral dilemma. This is backed by the authors' insistence on prima facie duty. Fletcher explains that "prima facie duty to follow a rule means 'unless something better' may be gained by departing from the rule. For rule ethics the something better would be a "higher" rule, while for consequential ethics it would be something that resulted in more-good than following the rule would" (Fletcher, 1980: 596). This is further elucidated by the B&C's preference of a prima facie duty rather than the moral rule in the case of self-elected death where they argue that under normal circumstances people should not commit suicide, however, there are some situations where suicide is not only permissible but are in fact commendable (1979: 82). This argument is equally applicable to the debate on the hESC research, particularly with regards to its moral desirability vis-à-vis necessity.

According to B&C, the four principles form a comprehensive and coherent framework upon which a moral agent can use to analyse a difficult moral situation. The principles are not necessarily peculiar to bioethics, but rather are a core part of a universal common morality

30 For vibrant conversations on the methodology of bioethics, with a focus on Principlism, see: "R.M. Veatch & C.M. Spicer (eds). 1995. Theories and Methods in Bioethics: Principlism and Its Critics (Special Issue). *Kennedy Institute of Ethics Journal* 5: 181 – 286; Matti Häyry. 2003. European Values in Bioethics: Why, What, and How to be Used? *Theoretical Medicine* 24: 199 – 214; T.L. Beauchamp. 2003. Methods and Principles in Biomedical Ethics. *Journal of Medical Ethics* 29: 269 – 274; Mette Ebbeseb, S. A. a. B. D. P., 2012. Further Development of Beauchamp and Childress' Theory Based on Empirical Ethics. *Journal of Clinical Research and Bioethics*, 56:e001. Doi:10.4172/2155-9627.S6-e001; Beauchamp, T. L., 2003. A Defense of the Common Morality. *Kennedy Institute of Ethics J*, Volume 13, pp. 259-274; Page, K., 2012. The Four Principles: Can they be measured and do they predict ethical decision making?. *BMC Medical Ethics*, 13(10), pp. 1-8."

which are recognised, upheld and practiced by morally serious persons. These four principles are respect for autonomy, nonmaleficence, beneficence, and justice.

The principle of respect for autonomy is derived from the concept of autonomy by which it is presumed that the moral agent is free to choose. It entails the obligation to respect the decision-making capacity of autonomous persons, and does not in any way imply that ethics is independent of authority.

Beauchamp and Childress (2013) acknowledge the difficulty with settling this principle's precise demands and thus leaves it open to legitimate interpretation and specification. This is quite telling given the insistence that the principles are universal (drawing from the quality of common morality) and are thus useable in multicultural contexts. This principle may provide ground for contesting the use of human embryos in research. It is also the principle that embryo donors latch on to defend their right to informed consent before their donated biological parts are put into use for scientific research. These arguments are expounded on further in chapter four. It is hereby noted this particular principle may still find a rough ride in the African context given the communal nature of the traditional African lifestyle. Applying this principle wholesomely in a predominantly African context would be a tall order. Beauchamp and Childress are however, witty, as they leave room for further "legitimate interpretation and specification" according to context.

The other principle that B&C have discussed almost exhaustively is that of nonmaleficence – the obligation to avoid causing harm. This principle comes out as a doubleedged sword. On the one hand it obligates the moral agent to do no harm, on the other hand it seems that what it obligates may sometimes be impossible to implement. In the context of biomedical practice, the nature of medicine is often such that it routinely involves performance of acts that may be considered by many people as harmful. Not doing the first (doing no harm) might mean not doing the second, which is tantamount to not doing anything at all. It may be asked whether the principle holds any water? Critical readers may be left questioning the incoherence or inconsistency in the idea that persons may be morally obligated to refrain from injuring others, but not obligated to help them. B&C have attempted to provide some helpful nuance with the suggestion that the principle of nonmaleficence means avoiding anything which is unnecessarily or unjustifiably harmful. But even this explanation can only go so far. If anything, doing no harm is infinitely impossible to execute given that the ultimate harm is in the concept of dying which is also an ultimate inevitability. Somewhere somehow the living being has to die someday – and that death will have been caused anyway. So, even the guideline of asking the right questions still remain paralysed in the place of inevitable death situation.

This principle is problematic in the hESC debate. It may be contested that destruction of human embryos is equal to causing harm. Debate abounds on what constitutes harm. This thought is elaborated further in chapter four where the principle is used to assess the arguments against use of human embryos in research.

The third principle is beneficence, which is understood as the obligation to provide benefits and to balance benefits against risk. Although it has been suggested that nonmaleficence and beneficence are two sides of the same coin, B&C insists on their distinctiveness. Accordingly, beneficent persons go beyond the call of duty. A beneficent physician will not only treat his patient but will also treat them well. The obligation for beneficence, in a sense is a call to virtuousness in being. It is not merely an action-demanded theory but a question of being. It is about a cultivation of virtues that shape the moral agent's heart and which in turn compels him towards expressing behaviour patterns that correspond with the virtue in him. This is the principle that beneficiaries of hESC research would rely on to plead their case for continuation of the research. Researchers, scientists and bioethicists who support hESC research may also argue that they have a moral obligation supported by the principle of beneficence, to give hESC therapy to patients in need.

The fourth principle, justice entails the obligations of fairness in the distribution of benefits and risks. B&C have undertaken a brief, yet considerably comprehensive look at social ethics with the view of justice in mind. They conceive justice as a distributive and/or allocative principle, as opposed to commutative. Distributive justice continues to find application especially in government, in a utilitarian manner. Yet, B&C do not just provide their own theory. They guide the readers towards various philosophers and theorists of justice that are available for their consumption. It is observed that "how resources are distributed will depend on which theory of justice is in utilization. One of the weaknesses of Principlism is B&C's refusal to provide direction to the reader on the specific actions moral agents ought to take in situations of moral dilemmas. Principlism, it appears, isn't precise enough to help people decide what to do. The questions in hESC research, include: whether it is morally justifiable to use the living (human) organism to support the livelihood of others.31 The question of those who qualify for hESC therapy is also raised. How can just distribution of hESC therapeutic services be ensured in a situation of limited resources and innumerable wants? In addition, the question of potential commodification of human biological substance, and the justification of

^{31 (}This is the same question raised by some people who support abortion. They question whether it is morally right for the foetus to claim right of dependence on the mother. The inference is that distinct individuals must be self-reliant, and that any altruistic action must be voluntary, not obligatory)

that possibility is advanced. In other words, should profit be made from human biological parts?

Notably, these four principles are drawn from different theories: the principle of autonomy is distinctively Kantian; the principle of beneficence is a utilitarian position espoused by John Stuart Mill; the principle of nonmaleficence is largely drawn from the common morality theory of Clouser and Gert; whereas the justice principle is extracted from John Rawls theory of justice. In this sense, therefore, Principlism is a framework comprising of a cocktail of theories.

Moreover, the Principlism approach does not claim moral absoluteness or finality, rather, the principles are understood as universally valid norms that provides the necessary grounds for making ethical judgements irrespective of the contexts. Thus, the bioethical principles are proposed as a framework approach designed to be helpful guides for facilitating consultations and dialogue regarding options for treatment.

Although B&C deny any preference or hierarchy of the principles (2013: 101), it appears as if autonomy is the primary principle upon which other principles weigh their decisions. This apparent emphasis on autonomy way above/beyond the other principles betrays the epicurean worldview which seems to pervade the larger part of Americanism. One gets the sense that what matters most is the "self" and not much else, or rather, when everything else is considered, the self still towers above all other considerations. This informs the justification for the robust debate that involves paternalism and autonomy. Whether or not the principles are fully adaptable in all cultural contexts is still a subject of ongoing conversation. The next question we ask of Principlism is of whether it is necessary as an approach to bioethics. Can bioethics decisions be made even without the guidance of the four principles? What makes the four principles necessary tools for decision making in bioethics, if any?

The Necessity of Principlism

Biomedical ethics interacts with human pain – both physical and emotional and our responses to the pains. It seeks to give justifications of our prescribed or performed responses. According to Beauchamp, morality aims at preventing or limiting challenges related to "indifference, conflict, hostility, scarce resources, limited information" among others (Beauchamp, 2003; Mette Ebbeseb, 2012: 2). It seeks to address moral conflicts, not necessarily by giving the right answer, "but merely providing a well-justified moral solution" (Leticia Erig Osório de Azambuja, 2015). In this sense, therefore, Principlism answers affirmatively to the question of necessity particularly in the biomedical ethics context where

the urgency for decision-making in a morally problematic situation is desirable. Unlike the other theories of morality, the suitability of Principlism lies in its flexibility and readiness of individual principles to surrender roles for another principle that is deemed to be most suitable in a given context. The use of deliberated judgement, as well as the arrival of reflective equilibrium in the decision-making process enables moral agents to reach their goal of finding solutions to morally disturbing circumstances. The biomedical context is one that does not benefit from the luxury of time. Decisions regarding life and death have to be made in split seconds, and the consequences of those decisions remain with the moral agents involved for the rest of their lives. It is this flexibility of the principles and the capacity to cede position in a given moral context that makes Principlism not only a necessary but also an essential framework approach for bioethics engagement. Given the pervading contests of other theories, as shall be witnessed in part B of this chapter, it has been deemed both necessary and desirable that a way out – even if only temporal – be found that moves the conversation towards practical solutions, rather than stay put on the raging debate on the morality of hESC research. In this sense, principlism is deemed desirable for making decisions in the context of hESC research.

The Possibility of Principlism

Is principlism possible? Possibility conveys the idea of likelihood to happen. It connotes capacity. So the question at hand is that of whether within the framework of principlism there is an inbuilt capacity for delivering solutions to moral dilemmas. It can be argued that necessity anticipates possibility. In other words, since a moral framework that is handy in delivering quick decisions in a biomedical ethics situation is necessary, it is also required that such a framework be possible. However, the fact that something is necessary or required does not necessary imply that such a thing is also possible. It may or may not be. Looking at the four principles, undergirded by the idea of common morality, one may ask, how possible is this framework? One may argue that the Principlism's dependence on common morality for justification is its insurance. This is so far as its tentative positioning is concerned. It is possible because the four principles can be weighed against another and whichever of the four that is found to be the best solution for the situation carries the day. There is not one principle that is considered superior than the other. Besides being flexible and tentative, Principlism may also be deemed possible because the four principles derive their origins in the antagonistic theories of morality. Rather than emphasize the antagonistic aspects of these theories, Principlism borrows the positive aspects. For example, the respect for autonomy

principle seeks to emphasize the positive values of Kantian ethics. It is however, flexible and does not demand normative absoluteness as the categorical imperative would do. This shared background is also possibly the downside of Principlism. Each principle is somehow correspondingly tied to the difficulties associated with the theories. For example the tension between utilitarianism and deontology may easily transfer itself to a case where beneficence and respect for autonomy are in play. The reprieve in Principlism, however, is its reluctance to wage a spirited war of conquest. Using deliberative judgement and reflective equilibrium, a tentative decision can be made that allows the moral agents involved to progress with acts that at the time of decision-making they consider as the best they could have made – all factors being constant. This is further supported by the use of "additional specification and balancing as methods for solving conflicts between principles and specified norms in concrete situations" (Oliver Rauprich, 2011: 582). So, yes, in this regard, Principlism is a possibility. It is a possibility because it is tentative and not absolute. It is redeemed by the understanding that it seeks not correct solutions but rather justified decisions as responses to moral dilemmas. Principlism is possible because its use in bioethics has been demonstrated in other contexts. It is deemed possible for hESC research as well. This will be determined in chapter four as the moral assessment of their use is considered.

The Efficacy of Principlism

Now we ask the question: is Principlism efficacious? On this, Katie Page (2012) admits that "there is no denying the impact and importance of the medical ethical principles in medical ethics, or the high esteem in which they are held" (Gillon, 2003; Page, 2012: 1). This is testament to the efficacy of the use of the four principles of biomedical ethics championed by B&C. Gillon avers:

But I think the four principles should also be thought of as the four moral nucleotides that constitute moral DNA—capable, alone or in combination, of explaining and justifying all the substantive and universalisable moral norms of health care ethics (Gillon, 2003: 308).

The alleged criticism on their limitation of practicability as well as in academic literature notwithstanding, the four principles are not only well fleshed out in the *Principles of Biomedical Ethics*, but are also widely used as evidenced by the number of literatures that is increasingly referring to their use. This is a fairly reasonable pointer to their efficacy. However, the fact that little work on their empirical importance and merit has been done, legitimately

questions their efficacy. As Page has explained, this may be attributed to "the difficulty associated with the quantification of the principles and/or the focus on more practical and case specific goals" (Page, 2012: 1). The fact that this matter of empirical study is being raised by some authors is a fair point of commencement of for legitimate evaluation of the efficacy of the principles. More data on this will help give clear, concrete and possibly final assessment that could put the debate to rest. Till then, the efficacy of the Principlism cannot be assessed accurately and with finality even though the series of editions written by B&C are remote pointers to the success, conceptually speaking. Empirical verification will be the ultimate answer. In the hESC research, the efficacy is found in how the assessment will help provide guidelines for decision making in a way that clear moral implications of the continuation or discontinuation of the research are seen. In other words, efficacy may be affirmed or denied depending on whether it is affirmed that hESC research should continue or be discontinued. A definite finding, by way of thorough Principlism assessment will define the efficacy. Also, the policy proposals and recommendations made by this study will consequently answer the question of efficacy.

One Last Word on Principlism

Although the authors deny that Principlism is not in and of itself, a theory in the normal sense, the series of production of this literature comes out as a systematic presentation of a specific doctrine intended for consumption by those in the business of bioethics. Thus, Clouser and Gert's criticism, as recorded by Rauprich "that the principles are not derived from one unified moral theory but are free standing, eclectically picked from diverse types of traditional moral philosophies, lacking systematic relationship to each other," is not far-fetched (Rauprich 2011). On this, the idea of Principlism may be misleading and even fall short of philosophical requirements. However, as Rauprich (2011) argues, Principlism may not meet philosophical requirements, but it is still "better than lacking any framework of norms that can structure ethical discussion in practice" (Rauprich, 2011: 582).

Common Morality as Grounding [Foundation] for Principlism

As already mentioned above, Rauprich cites Clouser and Gert for having attacked Principlism on the basis that it is not "derived from one unified moral theory... lacking

systematic relationship to each other"₃₂ (Gert, 1990; Rauprich, 2011). This argument does not necessarily and accurately represent the views of Beauchamp and Childress (2013) for they argue that Principlism is grounded on the foundation of what they call *common morality*.

The "principles form the core part of a universal common morality" (B&C, 2009). Although the understanding of this concept has morphed with successive revisions of their book, the authors define Common Morality in the 7th edition of *Principles of Biomedical Ethics* as "a set of universal norms shared by all persons committed to morality" (2013: 3).33 Kukla, citing Beauchamp and Childress argues that "Common morality theories 'rely on ordinary, shared moral beliefs for their starting content; and they make no appeal to pure reason, rationality, natural law, a special moral sense, or the like" (B&C, 2009: 387; Kukla, 2014: 75). They add that "common morality is applicable to all persons in all places, and we rightly judge all human conduct by this standard" (B&C, 2013: 3; Ebbesen M, 2015). "It is the universal morality" adds Rauprich, "that contains only a small set of general moral norms... [and] ... it is distinguished from particular morality that spring from cultural, religious and institutional sources of particular communities and societies, which are not shared universally" (B&C, 2013; Oliver Rauprich, 2011). B&C further elucidates that whereas Common Morality "contains moral norms that are abstract, universal and content-thin, particular morality present concrete, non-universal, and content-rich norms" (B&C, 2013). In other words, particular morality is specific to defined groups or communities and are distinguished by the specificity of their norms which are not justified if they violate norms in common morality (2013:5). In this sense, professional morality is also understood as a form of particular morality (B&C, 2013).

B&C also hold "that morally serious persons do share some moral rules, principles, rights, and virtues in common" (2013). Although the norms are cross cultural, they are not implemented uniformly across all cultures – thus, their use call for some form of contextual intelligence or awareness. Although "Common Morality is based on human nature," and should be the same for everyone," according to Leticia, it does not follow that "a single global standard of morality should exist, nor that such a standard should resolve all moral questions, or be rationally endorsed by all" (Leticia Erig Osório de Azambuja, 2015: 633).

The question they pose is that of whether Common Morality is normative, nonnormative, or both, and they respond that it is both – in a sense. How so? They argue that

³² Dan Clouser and Bernard Gert who coined the term 'Principlism' are the most notorious critiques who made the argument that the four principles lack any conceptual foundation and systematic relationship to each other.

³³ Kukla explains further that morality is not grounded in some underlying abstract moral theory; these norms are socially and historically constituted.

"there is a transparent correlation between moral rules and principles of the common morality" (2013). In other words, "the Common Morality has normative force, i.e. it sets moral standards for everyone, and all human conduct can be judged by its standards" (B&C, 2013). Therefore, "anyone violating the rules of common morality is acting unethically" (B&C, 2013). On the other hand, and as noted by Ebbesen, "the authors appeal to common morality nonnormatively by claiming that 'we can study empirically whether the norms of common morality are actually present in our cultures" (Ebbesen, 2012: 1; Childress, 2013). Thus, they hold onto both "normative force of common morality and objective of studying it empirically" arguing "that all persons committed to morality accept the standards found in Common Morality" (2013: 5).

If the idea of Common Morality mitigates the concerns of critiques regarding the lack of a unified moral theory for the foundation and grounding of Principlism, then the answer births more problems than the tensions it purports to resolve. Various critics have raised diverse questions ranging from the claims of moral normativity, empirical verifiability, definitions and scope of common morality.34

D Micah Hester asks, "what, if anything, is truly common about Common Morality?" (Hester 2014: 73). He questions further whether its claimed centrality for morality can hold up to philosophical scrutiny?" (D. Micah Hester, 2014). Kukla (2014) agrees with B&C "on the importance of common morality", particularly the notion that morality is the "starting point for moral reasoning." They however, part ways on the understanding of what constitutes common morality and "the source of its normative force" (D. Micah Hester, 2014). According to Kukla, "we are bound by our common morality by virtue of our lived experience.... and that common morality derives its normative force in the virtue of our inability to opt out of it" (Kukla, 2014; Hester, 2014: 74). In other words, common morality provides just but a moral lens through which moral agents can "view the world and make sense of" their "normative interactions with others" and even their own actions (Hester, 2014: 74). Kukla's views are obviously in contradiction with B&C who she claims to perceive Common Morality as centrally including "a set of thin general principles that although partially justify our particular, concrete moral judgements, need to be balanced and specified in each concrete context before they are useful (Kukla, 2014: 75).

³⁴ Oliver Rauprich has written several objections to B&C's idea of common morality, including objections to the idea of common morality as shared moral beliefs of a society. His list of objections includes: objections of non-existence; objections of indeterminacy; objections of inconsistency; objection of ethical relativism; and finally, objection of lack of critical potential. For further treatment of this, see Oliver Rauprich et al (2011). Another critic of Common Morality include Rebecca Kukla (2014).

Another critic, Oliver Rauprich (2011) claims that he "defends the existence and empirical significance of common morality as delineated by Beauchamp and Childress" although he criticizes its normative role (Rauprich, 2011). His argument is that B&C's explanation of common morality is neither convincing as a moral foundation nor well compatible with a standard coherentist justification (Rauprich, 2011: 45). Rauprich even suggests to Beauchamp and Childress to "give up on the foundational account for a more modest account of common morality as a resource of well-established moral insights and experiences, which have proved generally valid but neither sufficient nor infallible" (Rauprich, 2011: 45-46). Markus Christen et al have tested the empirical argument and have concluded that their results are negative – "in conflict with the common morality hypothesis of Beauchamp and Childress" (Christen, 2014: 10). They write that "our findings support the suggestions by other scholars that the principles of biomedical ethics serve primarily as instruments in deliberated justifications, but lack grounding in a universal 'Common Morality'" (Markus Christen, 2014).

Other commentators like Carson Strong have responded to the arguments on empirical verifiability, and the no general common morality objections against common morality, concluding consistently with B&C that Common Morality is "neither an ethical theory nor a procedure for resolving controversial cases and issues" (Strong, 2009: 4).

In summary, the idea of common morality is one that has drawn so much interest in the bioethics community. One, there is no unified agreement on the exact meaning and specification of common morality. Two, there is also no agreement on its potency – whether normative or empirical. These further call into question "its justification and usefulness, as well as it (sic) relation to other moral concepts" (Strong, 2009: 9). Given the interest it draws, and given its argued grounding for the principles of bioethics, this author recognizes the inconclusiveness of the conversations regarding Common Morality and therefore proposes a continued, thorough and robust dialogue with a clear focus on the questions of justification, viability and usefulness. The principles of biomedical ethics are grounded on the feasibility, meaningfulness and usability of common morality so much so that if it can be strongly refuted that common morality is a façade, then the implications to the use of the four principles might also somewhat be jeopardized.

Conclusion

Ultimately, a Principlism assessment should help determine the morality and consequently, recommendation on the continuity or termination of the research on human

embryos. As to whether Principlism is the best possible approach for determination of the morality of hESC research, we turn to part B of this chapter where two classical theories of morality are considered. The question asked is whether utilitarianism and deontology can sufficiently resolve the moral conundrum that hESC research brings.

Chapter 3B: Assessment of the Classical Theories of Morality and Their Applicability in the hESC Research

The ensuing section will review the nature of two traditional theories of ethics: the deontological, and the utilitarian ethics – citing their meanings, strengths and weaknesses particularly as construed within the context of biomedical ethics in general, and hESC research in particular. The paper draws from the meanings, functions, and parallels of these theories and then proposes Principlism as a framework that transcends Kant's deontology and Bentham-Mills utilitarianism. It concludes that although the two theories find no common ground for continued engagement, both the deontological and utilitarian theories have strengths relevant for the biomedical ethics engagements. In the same breadth, their shortcomings also impede the bioethics agenda in general, and more particularly, the stem cell debate. The Principlism framework approach comes in as an arbitrator whose goal is to build consensus where possible.

Deontological Ethics

Timmermann (2014) argues that deontology was first coined by Jeremy Bentham as attested to in his 1834, posthumous publication titled *Deontology*, in which he discussed "the virtues and vices of the good utilitarian agent" (Timmermann 2014: 76). In most simple terms, deontology "is a composite of the Greek word for what is 'proper' or 'ought' to be done' (*to deon*) and the usual suffix denoting the doctrine, science or study of a thing" (Timmerman, 2014: 76). Basically, deontology is construed as "the science of duty' or 'that branch of knowledge that deals with moral obligations', in one word: 'ethics'" (Timmermann, 2014: 76). To Bentham, deontology was used to reference any ethical system, in the broad and literal sense, "that contains concrete action prescriptions" (Timmermann, 2014: 77). Today, this definition is unknown beyond the lexicographical circles.35 Thus today's modern philosophers' reference to deontology bears a completely different meaning or connotation: "a style of ethical theory that is not teleological or consequentialist" (Timmermann, 2014: 77). It is this modern conception of deontology that this paper seeks to evaluate.

Kant's Moral Doctrine: The Categorical Imperative

The quintessential protagonist of the deontological ethic is Immanuel Kant (1724 – 1804). He argued that moral rules are absolute and should be obeyed without exceptions.

³⁵ Jens Timmermann notes that the Oxford English Dictionary quotes Bentham in its definition of deontology to this present day.

Kant's deontology is a rational ethic, and thus the understanding of the "ought" command, or rather the imperative, is pertinent to the comprehension of this rational ethic. To explain this, Kant distinguished the *categorical imperative* from the *hypothetical imperative*. The latter holds no moral obligation as it is merely dependent on the moral agent's possession of the requisite desires. It is anchored by the if clause and is merely conditional. It has a simple exit clause – which is determinable by just one question: Do I desire XYZ? If so then I must do ABC. If I however possess no desire for XYZ, then I am under no obligation to pursue ABC. It could also be called a conditional imperative, or a conditional command.

The *categorical imperative*, on the other hand, is not straightforward as it has moral requirements that are strictly obligatory and are not malleable at all. The *categorical imperative* is a command which is an end in and of itself and does not need a specific reasoning to rely upon except an *unbiased* reason "inherently" good in itself. As mentioned earlier, Kant attributes the possibility of the *categorical imperative* to the principle of human rationality. He argues that the reason the principle is binding is because humans are rational. So just as the sole requirement for the *hypothetical imperative* is desire, the requirement for the *categorical imperative* is reason.

Underlying Kant's ethic is the assumption "that humans must make moral decisions in everyday life; therefore, the reasons and ways to make moral decisions must be obvious, comprehensible, and accessible to all" (Reuschling, 2008: 33). It follows therefore that for Kant, "the aim of moral philosophy is not to provide a theoretical or speculative foundation for moral claims but to provide the practical means by which we, ordinary human beings who live in a moral world, understand and enact moral duties based on the use of pure reason as a guide for the will" (Kant 1964: 4/404; Reuschling, 2008: 33-34). In a sense, therefore, the appeal of this methodology is that it, *prima facie*, appears to pave the way for evaluating moral actions and thus be able to make decisions in any situation. It, however, must be understood clearly from the outset that Kant's task is to "define and defend the human's ability and obligation to act morally – not to understand or explain that power" (Sullivan, *Immanuel Kant's Moral Theory*, 94).

Kant desired a common morality, a universal ethic that would be applicable to all humans in all contexts all the time. He therefore understood pure practical reason as the source of morality, "since this is what humans have in common, unlike religious faith, experience, personal interests, and desires" (Reuschling, 2008, p. 34). He argued that "everything in nature works according to laws [and therefore] only a rational being has the capacity to act *according*

to the representation of laws, i.e. according to principles, or a will. Since reason is required for deriving actions from laws, the will is nothing other than practical reason" (Kant 1964: 4/412).

So how does the use of pure practical reason give moral guidance to humanity? Given that morality and the human will are intricately bound together, and seeing that reason is what ultimately provides moral guidance to the will, the *categorical imperative* is therefore, according to Kant, that which provides moral guidance to our reason governing our will. Van Niekerk summarises:

For Kant, we act morally when we act on the right motive, and that motive must always be to do one's duty... to do one's duty means doing the right thing for the right reason....reason commands the human will by means of what he [Kant] calls the 'categorical imperative', i.e., an unconditional demand, the validity of which we have to see if we are rational human beings (Niekerk 2017: 26).

The most popular versions of the *Categorical Imperative* say that we should act on the basis of a maxim that we would be willing to see everyone else act on, and that we should treat human beings always as an end, never as a means.₃₆ Rachels (2013) explains that the first principle – the maxim of act – summarizes the procedure for determining whether an act is morally permissible. Thus, when a person contemplates doing a particular action, they have to inquire what rule they would need to follow if they were to execute that action. This means the contemplator is to question whether they would will for the rule to be obeyed by everyone all the time. This would in effect make it a universal law. If found agreeable then the rule would be obeyed, making the act acceptable. If the contemplator finds that he may not desire that for everyone to obey the rule, then they may not obey it, and that renders the act morally unacceptable.

Bioethics draws from various principles within the Kantian thought system. For instance, the principle of autonomy is derived from Kant's understanding that "people act autonomously if they are able to make their own decisions." This informs the patient autonomy and the requirement that they are given sufficient information to enable them decide on the matters of their health and treatment.

In sum, the categorical imperative, as explained by Beauchamp and Childress, "is a canon of the acceptability of moral rule, a criterion for judging the acceptability of the maxims that direct actions, and it adds nothing to the maxim's content, but rather determines which maxims are objective and valid" (2013: 363). This determination of the objectivity and validity

³⁶ Kant, Foundations of Metaphysics of Morals, trans. Lewis White Beck (Indianapolis: IN: Bobbs-Merril, 1959). P58; Ak. 439 – 40.

of a maxim is made through the consideration of the consistency of these maxims, which is in turn affirmed through the considerations of the universalizability of the same maxim. It remains to be seen whether the normative approach of kantian theory can be good guide to decision making with regards to the morality and acceptability of hESC research.

Strengths of Kantianism

Kantian deontology does not seek to justify acts that are *prima facie* immoral (Moodley, 2017). By advocating for consistency in character, the Categorical Imperative seeks to obliterate every possible excuse that may be advanced for the justification of immoral action and character. In arguing for the imperative to speak the truth at all times, for example, he writes: "To be truthful (honest) in all deliberations, therefore, is a sacred and absolutely commanding decree of reason, limited by no expediency" (Kant, 1964). To rely on the outcome of an act as the basis of decision-making is a hopeless gamble since we can never be certain what the outcome (consequences) of our actions will be. Indeed, the results may either be desirable or undesirable. However, that outcome cannot be known apriori. Therefore, in the case where it may be seen that truth-telling in certain circumstances may be detrimental and that holding the truth may be beneficial, the Kantian response would be that it is impossible to tell whether the proposition is true or could hold since there is no way of knowing the consequences of an action that is yet to be performed, and that the results could go either way -i.e., desirable or undesirable. Therefore, the moral agent is admonished to stick to the already established moral norm – that of truth-telling. Truth-telling is consistent and safe since it keeps the moral agent from the tyranny of committing an obviously known evil of lying. Rachels advises that "the best policy is to avoid the known evil, lying, and let the consequences come as they will. Even if the consequences are bad, they will not be our fault, for we will have done our duty" (Rachel, 2003: 125). This thinking is found in, and advanced by those who object to hESC research. They claim that the act of destroying lives in general – irrespective of the recipient of the benefit – is morally unacceptable. Objectionists argue that those who advocate for hESC research must be willing to have their lives terminated at any time, if it is deemed that killing them would support other lives or lead to a better cause.

Secondly, Kantianism appeals to those who espouse that morality, by its very nature, must be universal and binding for everyone. It provides a response to post-modern relativism and the subjection of ethics to personal wishes and desires. In so doing, it offers a morality that is universal and obligatory for all, with clearly desired delineations between right and wrong.

Thirdly, based on Kant's second formulation of the Categorical Imperative, 37 there is value in the notion that the fundamental nature of humanity is essentially rational, essentially individual, and essentially autonomous. This rational, autonomous person, as opposed to nonhumans, has desires, has passions and has values; and, that is why he treats human beings as an end and not merely as a means. Moreover, humans have "an intrinsic worth, i.e., dignity." Given the worth and dignity, it follows, as Rachels would argue, that "on the most superficial level, we have a strict duty of beneficence toward other persons: we must strive to promote their welfare; we must respect their rights, avoid harming them, and generally 'endeavour, so far as we can, to further the ends of others" (Rachels 2003: 132). The acknowledgement of human rationality, autonomy, dignity, and worth compels us to respect their rationality and therefore we do not manipulate or use them to achieve our purposes, thereby merely using them as a means to an end.38 Objectionists to hESC research find this aspect of kantianism quite appealing. Those who hold, particularly, to the personhood and moral status of the embryo demand that demonstration of respect to the embryo (given its humanity) prohibit their destruction and use in research. They argue that the embryonic life, like any other human life, is precious on its own way and must therefore be allowed to thrive or die naturally – but not by other human causes, for egoistic purposes.

Lastly, Kant's concept of duty provides a clear, direct and easy understanding of ethics and fits with an understanding of ethics as "decision making, following rules, and acting on objective, "given" principles about the moral life". In this regard, Kantianism's attempt to highlight moral versus immoral human actions makes it easier to make choices that particularly involve evil against good.

Weakness of Kantianism

First, the Kantian argument against consequentialism is anchored on an overly pessimistic conception of the possibility, depth, and extent of human knowledge. Some consequences can be known with certainty before the act. As Rachels (2003) argues, there are certain circumstances that warrant considerable confidence on the outcome of a possible action. In such circumstances, it is meaningless to hesitate citing uncertainty. For instance, shooting another human being using a gun could cause their death, and on the bare minimum, serious injury. There is no room for meaningful debate as to the consequences of shooting another

³⁷ The second formulation of the Categorical Imperative, "so act that you use humanity, whether in your own person or in the person of any other, always at the same time as an end, never merely as a means but always at the same time as an end (Kant 1964)," is closely tied to Kant's anthropology which is shaped by enlightenment assumptions of what it means to be human.

38 This is clearly demonstrated in Kant's example of the individual who contemplates borrowing with the promise to pay back the money owed knowing very well his immediate incapability to repay the loan.

human being because that is not in doubt. The fact that shooting would instil severe bodily harm and even possibly cause death, is something we know *apriori*. The question to ask therefore is not whether shooting is fatal, but whether that prior known consequence of fatality – be it death or injury, and for whatever reason – is a good thing.

Secondly, although Kantianism attempts to distinguish moral from immoral actions, it does not give guidance on decision-making when faced with an exclusive choice of two evils where a decision has to be made for either of the two. In any case, this theory suffers the tragedy of inconsistency and incoherence, as it is self-contradicting in certain instances. Rachels argues, for example, "that Kant seems to assume that although we would be morally responsible for any bad consequence of lying, we would not be similarly responsible for any bad consequences of telling the truth" (2003: 125). So, for whatever consequences telling the truth brings, even if it causes death, Kant seems to hold that the moral agent is not morally responsible. This, unfortunately, is an argument that is difficult to sustain given that the very act of truth telling led to one's loss of life. In one way or the other the truth-telling moral agent takes responsibility. The question is thus not whether he is responsible but rather whether he accepts responsibility.

Thirdly, the deontological postulation of moral absolutes is implausible. A casual encounter with deontology indicates a 'divine command' moral system which makes it appealing to the theistic religious proponents, particularly for those of the Judaeo-Christian persuasions. Yet, a closer look draws a completely antithetical conclusion since even the divine moral command theory cannot sustain an absolute moral position. This clearly demonstrates how inconsistent and unsustainable deontological ethics is, especially where duties are found to be in conflict. It cannot be willed that you tell the truth while at the same time cause no death, like in Kant's analogy of the Inquiring Murderer where the moral agent is faced with a dilemma. On the one hand he has the duty to tell the truth at all times, on the other hand he has the obligation to respect the dignity, and consequent sanctity of human life, and must thus prevent death by all means. Such conflicting cases are documented by the Hebrew Bible, also known by the Christians as the Old Testament. It is recorded that Yahweh has willed that humans must not bear false witness, that humans must not commit adultery and that they must not murder (Exodus 20). However, in separate stories, it is documented that Tamar tricked her father-in-law, Judah, into committing adultery (Genesis) and this is recognised in the Christian New Testament as an act of faith (Hebrews). Moreover, Rahab, a practicing prostitute tells a lie in order to protect Hebrew spies (Numbers/Judges) and it is credited to her as an act of righteousness (Hebrew). Finally, David's claim to fame attributed to his murder of Goliath,

with the help of Yahweh himself – the very one who has prohibited murder (1 Samuel). Also, Phinehas kills and the act of murder is not charged against him, if anything, it is his attitude and motivation – "Jealousy for the Lord" that is credited as right and desirable. These peculiar situations where Yahweh the law giver acknowledges and appreciates the actions of the moral agents who have gone against his moral decrees demonstrates that the principle of moral absolutes is inconsistent and unsustainable as it cannot transcend the law of non-contradiction. If even the divine moral law cannot be absolutely maintained by the formulator, who is man to insist on the absolutes?³⁹

Finally, Kant's dependence on duty makes the theory overly transactional and therefore impractical. Humans are relational beings who possess a cocktail of emotions at varying degrees, times, and proportions. These emotions are what make a human being complete, for just as much as humans are rational, and with a distinct capacity for reason, so they are also endowed with a capacity to feel and express those feelings. These emotional situations determine human decisions and consequent actions as emotions are part of the whole – the whole human being. We tend to act positively towards those whom we feel positive towards, and we would express negativity towards those whom we harbour negative feelings. These are emotional contributions to human lifestyle and decisions. The chances that a person would intentionally and willingly harm people whom they are excited about are close to zero, whereas the chances of acting harmfully towards people whom they are distasteful of are significantly higher. To neglect or trivialize the place and contribution of such emotions in the moral decisions of humans is to be insincere, even cruel to the very humans. Each action has a distinct moral worth irrespective of the emotion that propelled it – whether joy, anger, jealousy, greet, etc. All these emotions contribute to the sum total of our being, whether they be virtuous or not. In the long run, our interpretation of their contributions in our decision-making and in everyday interactions will determine whether we live relationally or transactionally with fellow humans. We cannot therefore downplay the significance or moral worth of human emotions in given ethical situations. The fundamental problem with Kantian deontology is that the theory is mostly abstract, thus making the Categorical Imperative difficult to translate into practice. We will see the implications of deontological ethics to the debate on the morality of hESC

³⁹ It should be noted that these biblical examples are exceptions to the divine rules for whatever reason. They are not acts prescribed for emulation, but rather the black sheep in those cluster of rules, demonstrating somewhat or perhaps an acknowledgement of norms but not as absolutes without exceptions. This is not to undermine or rather to make a peccadillo of divine decrees but rather to demonstrate the illogical consistency on the claims of moral absolutes such as those postulated by the *Categorical Imperative*.

research in chapter four. For now, we turn to the other ethical theory: utilitarianism, its meaning, use, and relevance to bioethical engagements.

Utilitarian Ethics

Utilitarianism is an ethical theory that derives its name from the term utility, which has to do with the uses or benefits that one gets by performing some action. Utilitarianism is a consequentialist theory in that it explains a human action by considering their consequences. According to this theory, whether an action is right or wrong is dependent on the consequences. When properly articulated, utilitarianism is the theory that advocates for the greatest good for the greatest number of people. 40This theory does not just consider the highest number of people but also the maximum benefit that can be reaped from an action. It thus has both a quantitative and a qualitative tone to it.

Contrasted to ethical egoism, utilitarianism advocates for the benefit of the majority. In this sense, utilitarianism has also been labelled ethical universalism. Moreover, utilitarianism measures the benefits in terms of the weight of good as opposed to the evil consequences of the action. In other words, it is a balance of the good over the evil, and views the consequences which benefit the interest of the people as good whereas those which work against the interest of the people as evil. Odera Oruka (1990:49) defines utilitarianism as the view that an action is right if it will, is intended or likely to, bring about a greater balance of good over evil than, or as, any available alternative. Van Niekerk defines utilitarianism as the "specific consequentialist theory that argues that the *relative amount of happiness* or *pain* brought about by our actions is the most important indicator of moral worth" (Niekerk, 2017: 21).

Historically, utilitarianism is credited to two thinkers though it has found many followers over time.⁴¹ The first was Jeremy Bentham (1748-1832), an English thinker who advocated for what is now known as standard utilitarianism or hedonistic utilitarianism. This view promotes the understanding that good is synonymous with pleasure whereas evil is synonymous with pain. The second thinker was James Stuart Mill (1806-1874), also an English philosopher and politician who built on the work of Bentham. By Mill's understanding, the principle of happiness holds that "actions are right in proportion as they tend to promote happiness, wrong as they tend to produce the reverse of happiness" (Mill, 1957: 10; Mill, 2002:

⁴⁰ However, Reuschling (2008) warns that it should be understood clearly that Mill's utilitarianism is not about the satisfaction of one's personal desires. It is distinct from hedonism. It transcends the egoistic perspectives and broadly encompasses the comprehension of the greater society, upon which their well-being is complexly connected to the happiness of others.

41 James Rachels (2012) contends that utilitarianism as a theory was initially proposed by David Hume (1711 -1776) but given definitive formulation by Jeremy Bentham and John Stuart Mill.

239; Islam, 2008: 22). This puts moral emphasis on the consequences of decisions and actions as consequences are needed in achieving a desired end. In his book *Utilitarianism* (1861), Mill writes that "according to the greatest happiness principle ... the ultimate end, with reference to and for the sake of which all other things are desirable ... is an existence exempt as free as possible from pain, and as rich as possible in enjoyments" (Mill, 1861; Schneewind, 1965).42

In utilitarianism, the consequences of a moral act are viewed as the balance between the greatest benefit – and the just and equal distribution. In deciding what to do therefore, Rachels writes, "we should... ask what course of conduct would promote the greatest amount of happiness for all those who will be affected. Morality requires that we do what is best from that point of view" (Rachels, 2003:93). In contrast to Kant's second formulation of the categorical imperative, utilitarianism appears to hold that the end does indeed justify the means, even if that means is a human being.

Utilitarianism is quite often misunderstood as a hedonistic theory, particularly because of its emphasis on the pursuit of pleasure and avoidance of pain. However, Reuschling (2008) warns that it should be understood clearly that Mill's "utilitarianism is not about the satisfaction of one's personal desires" (Reuschling, 2008: 46). It is distinct from hedonism. It transcends the egoistic perspectives and broadly encompasses the comprehension of the greater society, upon which their well-being is complexly connected to the happiness of others. Accordingly, therefore, there is an ontological relatedness between the individual, the good of society and the nature of happiness.

In whichever form it appears, utilitarianism has been "probably the most influential ethical approach in English-speaking philosophy during the twentieth century" (Holmes, 1984). Holmes argues that this theory is attractive because of its appeal to self-interest as most people would benefit in case of maximization of the good consequences for the society at large (1984:41), and that it provides a bedrock for building on socio-economic policies and legislations that are popular with the majority.

Utilitarianism has found itself in the contemporary bioethical conversation through the works of John Rawls (1999) and Peter Singer (1993). Singer is seen as considerably provocative and contentious given that his inferences on utilitarian foundations have led to conclusions that advocate for legislation of euthanasia of unborn children, infants and severely handicapped people (Landeweerd, 2004). In the hESC debate, utilitarian arguments have been advanced in support of the research, including justification for the destruction of the human

⁴² This particular quotation of Mill is from his *Utilitarianism* (London 1861) as cited in *Mill's Ethical Writings*, edited by J.B. Schneewind (New York: Collier, 1965).

embryos. The utilitarian arguments which support the research, stand diametrically opposed to the Kantian views advanced by the opponents of hESC research.

Sometimes, the utilitarian argument is advanced with the principle of beneficence in mind. For instance, Nortjé (2007) supports the notion that taking away of human life is not fundamentally wrong, rather saving or enhancing life of a human being is preferable. This is a typical balancing of the principle of beneficence with that of maleficence, as proposed in the Principlism approach. This principle will be demonstrated later on in chapter five. Quoting Brody (1983), Nortjé submits that, "killing is wrong only when it leads to bad consequences" (Nortjé, 2007), and by extension, it can be argued that "saving lives is right only when it leads to good consequences" (Nortjé, 2007). Utilitarians would therefore justify hESC research by the virtue their intended consequences – the saving or enhancement of human life. The other unfortunate consequence, that is, the destruction of embryonic life, is a mere peccadillo – a necessary evil that facilitates good actions.

Strength of Utilitarianism

To start with, utilitarianism offers a single framework of ethics, by which in principle, we may answer any moral question (Reiss, 2002). In any context of moral reasoning, the utilitarian has an answer to the question.

Secondly, utilitarianism has a human and relational face to it. As opposed to deontology, which is largely transactional, utilitarianism takes cognizance of the human attribute of sentience, and therefore, "takes pleasure and happiness seriously" (Reiss, n.d.). This is important in helping demystify ethics as a discipline whose sole occupation is to command humans on what they must and must not do.

Thirdly, utilitarian has its mind made up. Whereas Kantian deontology may fail to give guidance in the situation of two exclusively competing evils, Mills utilitarianism appears to shed some light. In what appears as an antithetical response to Kant's second formulation of the *Categorical Imperative*, the utilitarian *Happiness Imperative* proposes that humans should inherently consider the option which give them the highest degree of happiness, and that the best happiness, according to Mill, is that which is realized only when everyone is happy.

Fourth, utilitarianism acknowledges the impact of decision and actions. The idea that consequences counts is, in a sense, a proper motivation for desirable actions – particularly actions that have moral implications. This applies to both the objectionists as well as enthusiasts of hESC research. To the objectionists, the destruction of embryonic organisms

have consequences, and to the enthusiasts, the neglect patients who could use embryonic substance assistance for therapy, or even the use of embryos themselves are consequential. The difference is what both sides weigh as the desirable consequences.

Finally, utilitarianism leans towards supporting the best interest of the society. Given that the "greatest good for the greatest number of people" is the supporting maxim of this theory, utilitarianism considers the overall benefits of a given action or decision to the greatest number - usually, the society – as opposed to the individual. In the situation of the embryo, supporters of hESC research would not hesitate to destroy the embryos even if they were persuaded that embryos possess personhood. This is a consistent and sustainable logic if the destruction the logic would bring maximum benefits to the majority. hESC research holds promise for transplantation and regeneration therapy. It is a clinical/medical solution to what is presently the highest cause of mortality to human population. Chronic disease situation, globally, is getting out of hand, and hESC research is touted as the therapeutic approach with the best possible results against the scourge.

Weakness of Utilitarianism

There are considerable challenges with the utilitarian theory as the primary determinant of ethical decisions. Four Problems of utilitarianism: *Need for a non-consequential judgement, criterion for calculating consequences, a basis for distributive justices,* and *the limitations of empiricism*. First, utilitarianism as an ethical theory fails the test of philosophical purity as it cannot stand on its own. Though it is proclaimed largely in opposition to normative theoretical positions like the deontological ethical theory, it cannot logically sustain the assaults that it purports to mete on deontology. In fact, it largely depends on a deontological position to make its case. Arthur Holmes argues thus:

If we desire an action A1 to facilitate A2, then to be entirely consequentialist we must have chosen A2 to facilitate A3, and likewise A3 for the sake of A4, and A4 for the sake of A5, and so on. But a chain of consequences that has no end is absurd; why choose that chain and not another? A decision is needed as to what set of consequences to prefer, a decision that cannot be based entirely on consequences because that would take us back again to the infinite regress. A non-consequential decision is therefore needed as to the kind of consequence we are to seek. The quality of consequence is really the decisive thing, not just the quantity; and in actuality the utilitarian wants to maximize consequences of a certain kind, *good* consequences rather than bad. But

deciding what consequences to regard as good is itself a nonconsequential judgement (Holmes, 1984: 42).

Moreover, Bentham's appropriation of the utility principle stands on shallow ground. By equating good with that which is pleasurable, Bentham proposes a hedonistic ethical theory that is not only impossible to comprehend but also difficult to practice. This is largely because "pleasure is a general and vague concept, and that hedonism makes it sound as if we are just passive beings, either pained or pleased" (Holmes, 1994:42). Such a notion would go against Kant's argument for human dignity and worth, given the human's disposition to rational behaviour. Furthermore, Bentham's presupposition that everyone seeks pleasure poses the "isought" problem as it is not possible to extrapolate an "ought" out of a factual and verifiable generalization in and of itself. In an attempt to sanitize Bentham's theory, Mill introduces the concept of higher versus lower pleasures.43 But one would ask Mill his reason for the preference of the higher pleasures. Underlying Mill's argument, one possibly discerns a choice that is not purely consequential but rather what Holmes refers to as an appeal to "the dignity and desirability of what is distinctive about humans" (1994:43). Utilitarians have continued to modify the theory in several ways. Nevertheless, the validity of utilitarianism as a consequentialist theory remains challenged. This is because the demand for a nonconsequential basis for decision-making has persisted. And why is it so? It is largely because to answer the question of which consequences are good requires one to build a nonconsequential premise.

Secondly, beyond the challenge of the inevitability of a non-consequential premise, the utilitarian still faces another challenge – that of determining the criterion for calculating the consequences. Although Bentham proposed the "hedonic calculus"⁴⁴ for computing the rightness or wrongness of an action, the calculus runs into error of reducing quality to quantity, yet the quality of pleasure or good is not something that can be determined by some level of quantification. There is no possibility of absolute quantifiability. If anything, it cannot be established with precision the kind or manner of consequences which should be considered in the calculus – whether intended, predictable or actual. Furthermore, actual consequences cannot help make advance judgements necessary for ethical decision-making, and "empirical predictions concerning social consequences and human happiness are extremely limited in both

⁴³ According John Stuart Mill, the higher pleasures are those that are aesthetic and intellectual, whereas the lower pleasures are those that are physical. Mill argues that humans should prefer the higher pleasures as opposed to the lower ones. To Mill, he'd rather a dissatisfied human than a satisfied pig.

⁴⁴ Bentham's "Hedonic Calculus" posits: for each alternative action or policy we can quantify the pleasure involved in terms of its intensity, duration, certainty or uncertainty, propinquity or remoteness, fecundity, purity, and extent. Then we can likewise quantify the pain... and identify the path of maximum surplus pleasure.

their extent and probability" (Holmes, 1984). How would one measure the prioritization of patient's life over an embryonic life and vice versa? On the one hand, it can be argued plausibly, that the human, with a life threatening condition, is on the edge of life and death and therefore has least potentiality (given that certainty of the therapeutic outcome is unknown) compared to a budding embryo that could possibly live and thrive for many years to come, on the other hand, it can be argued that the life of a living human person has been tested and confirmed and the priority of restoring such a life, when threatened is higher than that of an unknown embryo. Overall, the consequentialist approach has no way of determining with certainty, the net possible outcome of an action. The arguments are based on purely hypothetical situations.

Beyond this, the strenuous requirement for an accurate utilitarian calculation makes the theory reserved for just a few people, for not all the people have the capacity to master the utility formula. It is not even workable in a context of urgency. Even more, the utilitarian requirement that "every possible course of action would have consciously to be analysed in terms of its countless consequences would quickly bring practically all human activity to a stop" (Reiss, n.d.).

Thirdly, utilitarianism reduces justice to dividing the means and possibilities in the society in such a way that pleasure or happiness is provided for as much as possible for all (Landeweerd, 2004). In any case, the utilitarian obsession with the greatest good for the greatest number runs the risk of prioritizing the interest of the society above those of the individuals in a totalitarian way. This kind of thinking obviously trivializes the preference, rights and desires of the minority. If adopted and applied institutionally, there is danger of neglecting the underprivileged, the infants, the very ill, those with various forms of disability, etc. What's more, history has demonstrated that sometimes this value system can and does lead to massive fatality and flaw of human rights and dignity as in the case of the Nazi situation, the apartheid regime and the racial discrimination in the United States. The principle of the greatest good makes it difficult to assure a fair distribution of resources. Take the case of limited supply of organs for transplantation. What criterion would a utilitarian use to determine who gets an organ first and why? Would it be the first come first served or would it be on the basis of other considerations? A hospital in Nairobi Kenya has a limited funding for a cancer patient who needs medical care and yet suffers the constraints of resources. To determine who qualifies for this medical "bursary" the patients are subjected to various examinations including medical and socio-economic tests. Take a case where the situation of Patient A who is materially poor qualifies him for the funding, but a doctor's prognosis of the disease presents limited chances of survival; and Patient B whose socio-economic situation is comparatively better than patient

A, and also has a comparatively better disease prognosis, meaning that if treated, he has higher chances of survival than Patient A. Who would qualify for the funding? A utilitarian calculus would place the advantage on to Patient B, a decision that would obviously disadvantage Patient A, even though it is very clear that this patient is in more need. Would the utilitarian decision be truly and manifestly just in the eyes of the Patient (and his family and friends)?

Finally, Mill is mistaken about the sovereignty of happiness and pleasure. The first difficulty is that of the measurability of pleasure. Reiss (2002) questions: "Is pleasure to be equated with well-being, happiness or the fulfilment of choice? And, anyway, what are the units?" He continues to question whether it is "always the case that two units of pleasure should outweigh one unit of displeasure" (Reiss, 2002). In any case, is it always true that is pleasurable is always what is good, ... and is happiness something that can be defined objectively? (Landeweerd, 2004: 5). Arguably, it is not far-fetched to submit that Utilitarianism does wrong to reduce humans to pleasure-seeking pain-avoiding units of society. Also, Utilitarianism is hardly reconciliable with its emphasis on human rights. The argument that human rights are universal and inalienable requires that such rights are protected by at at all times. Unfortunately for utilitarianism, the consequences of any action determines their morality. Therefore some actions that in other contexts may be deemed inhumane, could be exonarated by the utilitarian calculation from any claims of moral culpability. Sometimes, the utilitarian emphasis on the highest good for the highest number could, and has often led to a violation of the rights of the minority. History attests to this weakness of the utilitarian worldview. Furthermore, Utilitarianism's pretence to pursue the greatest good for the greatest number appears to be an altrusitic pursuit that most naturally would translate into a utopian theory. Utilitarianism's means-to-ends morality is antithetical to Kantian reasoning, particularly as articulated in Kant's second formulation of the Categorical Imperative, where Kant adjures the moral agent to treat human beings not merely as a means to an end but as an end, in and of themselves. Underlying this is the supposition that humans have absolute capacity to predict and control the future outcome of events. If anything, there is no telling how incomplete the human knowledge of possible consequences is (Moodley 2017). Those who oppose hESC research advance this argument, noting that the inconclusiveness of the research makes it impossible to state the benefits with certainty. For the implications of utilitarian theory to the debates on morality of hESC research, we turn to chapter five.

Reflections on the Classical Theories of Morality Within the Unique Context of Biomedical Ethics

Admittedly, the context for biomedical ethics is daunting, given the inevitability of the conflicting obligations that emerge in the conversation all too often. The polarity exhibited by the deontological and the utilitarian ethical perspectives makes bio-ethical decision-making a messy affair. The two ethical theories are diametrically opposed to each other, with each emphasizing a particular element of the bioethical sphere of influence. It helps to understand that the deontological perspective is predominantly patient-centred, whereas the utilitarian position is usually society-centred. It is also instructive to note that although these approaches may be in a perpetual state of conflict, they each hold a substantiating merit and demerit in the biomedical sphere of operations. Biomedical ethicists are therefore well advised to understand their contrasting ethical backgrounds and their capacity to frustrate as well as create discontentment. Acknowledging this situation will enable the healthcare and all relevant biomedical stakeholders strike the needed balance that would establish the desirable congruity necessary for smooth practice.

So then, even as the end justifies the means in utilitarian ethics, obligations are of utmost significance in the deontological ethics. Thus, the consequentialist position of a utilitarian which insists that only the outcome of an act must determine the morality of an act contends with the unfortunate possibility that it could cause harm to some individual even as it explores a net outcome of maximum benefit. What this means is that it would inevitably ignore the principle of non-maleficence as it pursues the virtuous principle of beneficence. This is the kind of quandary that these two classical views of morality puts hESCs research into. At this point it is difficult to determine which theory triumphs over the other in this debate.

Decision-making in bioethics becomes a daunting task in utilitarian situations, where for example decision need to be made and the subject in question is incompetent as would be in the case of a braindead patient. Which one should be saved? The braindead human person or the human embryo?

From the foregoing, one can possibly deduce, as Reiss already has, that there is limited common ground for argumentation on the deontological and utilitarian ethical positions. Reiss asserts that philosophers, however, disagree on the possibility of sustainability of views on "rights and obligations without responsibility for consequences, and no evaluation of consequences without reference to rights and obligations" (Reiss 2002). Quite discernible is

the reality of the two opposing worldviews: deontological and teleological thought systems.45 Landeweerd (2004) comments that the incommensurability of these two worldviews has permeated throughout the whole realm of thought on human existence, including biology, psychology, philosophy and sociology. This is obviously noticeable in the Kantian-utilitarian duel as they play out in the field of bioethics where philosophers have sought to present one over another as the supreme moral standard for making moral decisions. Their apparent incompatibility and seeming eternal duel have convinced many thinkers that there is need for an alternative approach to moral decision making in the field of bioethics.

Considering the inevitable tensions and the consequent complications attendant to the ethical process that relies singularly "on either of, or any one particular ethical approach" (Reiss 2002), it is advisable to consider some other arbitrating approaches. In this case, Principlism framework approach is proposed as a midwifing ethical position that could considerably leverage on the strengths found in the two theories as well as account for the gaps created by the weaknesses of the deontological and utilitarian approaches to ethics. Reiss (2002) proposes consensus building as a framework for resolving ethical tensions.46

The search for consensus is an attractive proposal given its potential for thawing the antagonistic polarity caused by the teleological and the deontological viewpoints. This path must however be taken with the knowledge that there is never any certainty as to the rightness or wrongness brought about or revealed through the consensus approach. It still remains useful in providing an interim solution as the search for a moral absolute continues.

This approach makes much sense in the field of bioethics where there is scarcely any time for debate and dialogue given the reality of its context: that of urgency. When a life and death decision must be made, a theoretical debate is the last thing any decision-maker would be interested in. The triumph of Principlism as an essential assessment tool for engaging bioethicist on the debate on the morality of hESC is expounded further in chapter four where assessments of the arguments on hESC research are made.

⁴⁵ Landeweerd has categorised the two opposing worldviews as those that are deterministic and others that are non-deterministic, or rather a hybrid of traditions that incorporate a certain conception of free will.

⁴⁶ Reiss opines that "there are good reasons both in principle and in practice in searching for consensus. Such consensus should be based on reason and genuine debate and consider long established practices of ethical reasoning. At the same time, it should be open to criticism, refutation and the possibility of change. Finally, consensus should not be equated with majority voting. Consideration need to be given to the interest of the minorities, particularly if they are especially affected by the outcomes, and to those such as young children, the mentally infirm and the non-humans – unable to participate in the decision-making process. At the same time, it needs to be born in mind that while a consensus may eventually emerge there is an interim period when what is more important is to engage in valid debate in which the participants respect one another and seek for truth through dialogue" (Habermas, 1983; Martin, 1999; Reiss, 2002).

Traditional Arguments Against Human Embryonic Stem Cell (hESC) Research

We now turn to the traditional arguments advanced against hESC research – both scientific as well as ethical. Some of these draws closely from the moral status arguments as we shall see in chapter five. Herein though, we will briefly consider the scientific and then the ethical arguments advanced against use of hESCs for research.

Scientific Arguments Against hESC Research

The scientific information is useful and necessary in aiding understanding of the true nature of the embryo. It is foolhardy to discuss and develop a philosophical and consequently policy position on a subject matter whose nature is not clearly understood. This is true of the embryo as is of any other material study. There is need for scientific information which empirically demonstrates the actual status and nature of the single-cell embryo – the zygote. As Dianne Irving has argued:

without this correct scientific information we are *all* precluded from forming our consciences correctly or making morally correct decisions about abortion, human embryo research, human embryonic stem cell research, cloning, formation of interspecies chimeras, germ-line DNA recombinant gene research and therapy, and other related current medical and scientific issues (Irving, 2000).

Generally speaking, putting good science into use provides for a starting point that is commonsensical, and which nurtures meaning thought and conversation, particularly on the subject of bioethics.

Those who oppose hESC research on scientific terms advance medically related arguments. The first argument is that the process is fraught with difficult medical challenges, particularly because hESCs growth are not easy to manage, and that they are most often prone to production of debilitating tumors or even mutate into cancerous cells (Weiss, 2005). If, however, the ESC was to mature into adult cells, the case would have been different. Some scientists argue that even this is still a long shot, given that "even matured hESCs continue to produce tumors" (Condic, 2009).

Secondly, transplanted cells derived from the embryonic organism are prone to rejection given that the recipient's immune system is subjected to persistent attack, consequently necessitating the treatment of the patient with immunosuppressive drugs, which are not only expensive but are also confronted with a myriad versions of side effects. Suggestions to clone human embryos from the patient's own cells in order to overcome the

rejection problem is still beset by the ethical challenge of embryo destruction. This challenge will also be discussed shortly below.

Given the prevailing situation, medically speaking, the current status of ESC research offers merely promises of future cures with no immediate results, and the situation may remain as such until the problems 1 and 2 are resolved. Bernard Lo and Lindsay Parham (2009) are of the opinion that there is need to first establish "evidence of safety and proof of principle through the appropriate preclinical studies in relevant animal models or through human studies of similar cell-based interventions." This might be a possible first step towards resolving the concerns 1 and 2 raised above.

Ethical Arguments Against hESC Research

The deontological argument is advanced against the use of hESC research in transplantation and regenerative medicine. This argument will be explored, followed by a Principlism analysis of the argument.

Deontological Arguments Against hESC Research

The deontological argument advanced against hESC research is that it is morally impermissible to kill innocent persons in order to promote social utility. Consistent with Kant's second formulation of the categorical imperative, that it is morally impermissible to use other human being as a means towards some other person's end. Use of an embryo to develop cures for other human beings is a morally prohibited act. The argument is advanced in this form: "It is morally impermissible to intentionally kill innocent human beings; the human embryo is an innocent human being; therefore it is morally impermissible to intentionally kill the human embryo" (Siegel, 2018). This argument does not fully demonstrate that hESC research is in and of itself, murder since those who use the researchers involved in this activity are not the actual harvesters of the embryo. They may, however, be accused of complicity in embryo destruction. Either way, investigating the morality of embryo destruction is a desirable venture.

Accordingly, the use of embryos in research involves destruction of early human life in order to advance regenerative medicine. This argument is premised on the idea that embryos are human beings. According to this view, "morally relevant human life begins at conception, and therefore the destruction of one human being to save another is not ethically justifiable" (Kerasidou, 2016). The process of harvesting of hESCs entails the extraction of the inner cluster from the blastocyst, an then exposing it to a process of in order to produce a given cell

type. This procedure, it is argued, ends up with the destruction of an early human being (Dignitas personae, 32). Proponents of this position argue that the early life of the embryo are, in fact, real development stages of an actual human being, and not merely some part of a human being. In this case it is arguable, as has already been advanced above, that whereas that the single-cell human embryonic organism, as well as the multicellular developing "human organism" through to the blastocyst stage, is "totipotent", it is unscientific to call it just a stem cell, for indeed, a stem cell is just but a part of an organism. The organism, on the other hand is a whole entity.

There is a unquestionable distinction between the human parts and the embryonic human that is a distinct, and actual human being. In this regard, the question is not about when the human *life* begin, but about "when does the life of every human *being* begin"? The pre-implanted human embryo is an ongoing human life, not a pre-human life, for if it were to find a conducive environment for implantation it would develop into a full human being. On the other hand, if it were not to find a place for implantation, it would die – and that is different from the disintegration that would happen to for example, a human part like an oocyte, a kidney, or a skin cell – which though they possess life would not advance into a human being were they to be implanted into a woman's uterus. If anything, the human embryo formed at fertilization is a new and distinct individual with "a mixture of both the mother and the father's chromosomes" (Carlson, 1994: 31). This fact is not true of other body cells and tissues – even adult stem cells (Carlson, 1994: 31). This view therefore also dispels the argument that the human embryonic organism is just a potential but not a real existing human being, for the human zygote is actually an existing human being.

This view is heavily contested. The first rebuttal to this position is "that monozygotic twinning is possible until around 14-15 days of an embryo's development" (Smith & Brogaard, 2003). If so, then it must be understood that all persons cannot rightly proclaim that their lives began as zygotes. Sample this argument by Siegel:

An individual who is an identical twin cannot be numerically identical to the one-cell zygote, since both twins bear the same relationship to the zygote, and numerical identity must satisfy transitivity. That is, if the zygote, A, divides into two genetically identical cell groups that gives rise to identical twins B and C, B and C cannot be the same individual as A because they are not numerically identical to each other (Siegel, Winter 2018 Edition).

Of course, this argument, admittedly, "does not imply that a zygote is not a human being, or that it has not individuated." As Siegel (2018) argues, it only follows that "if one held

that a condition of an entity's status as an individual human being is that it be impossible for it to cease to exist by dividing into two or more entities. But this seems implausible.... [moreover] the fact that a zygote may divide does not create problems for the view that the zygote is a distinct human being" (Siegel, 2018).

The strongest possible response to the argument that use of hESC in scientific research involves destruction of early human life is the claim that the "preimplantation embryo" has only a "reduced moral status" (National Institute of Health, 1994). By advancing this argument, the proponents cede the objection that the embryonic organism is not a human being. They reason "that species membership is not the property that determines a being's moral status" (Siegel, 2018). They acknowledge that the embryonic organism is indeed a human being but assert that although "the product of fertilization is genetically human, it is not a 'developmental individual" (Grobstein, 1985; McCormick, 1991). To buttress this view, McCormick argues that "the moral status—and specifically the controversial issue of personhood—is related to the attainment of developmental individuality... it should be noted that at the zygote stage the genetic individual is not yet developmentally single—a source of only one individual" (McCormick, 1991).47 It is this purported lack of individuality that denies the human embryo the moral status, which is its apparent ticket for the right to life.

In response, Irving (2000), argues that it is this ostensible "scientific fact" which "grounds their [Grobstein and McCormick] moral claim about the pre-embryo." She contends that 'although the argument may sound scientific, his [McCormick's] embryology is self-contradictory as implantation takes 5-7 days. The "single body axis" to which McCormick refers is the formation of the primitive streak, which begins to take place at 14 days' (Irving, 1999). These two periods should not be confused as "there is absolutely no relationship or interaction between these two cell layers, and so the 'entity' is not a 'developmental individual' yet" (Irving, 1999).

Andrew Siegel (2018) notes that Kuhse and Singer (1992) as well as Tooley (1982) single out "reasoning, self-awareness, and agency as some of the capacities that are necessary for the right to life" while at the same time acknowledge that there is no consensus about these capacities. This argument, by extension, deprives even an infant of the right to life – if at all the capacities espoused are to be concluded as final. This is in and of itself a new problem if found to be true. It poses a problem for the defense of the sanctity of an infant's life, while at the same time inevitably makes it difficult to sustain the argument for the embryo's right to

⁴⁷ For further an extensive reading on how McCormick expounds his argument against the individuality of the embryo see McCormick, 1991: 3.

life, particularly to the deontologists who hold on to the moral agency for the embryo since both human embryos as well as infants lack the said capacities. Although others, like McMahan argue that the non-consequentialist constraints to not kill human infants and adults does not in the same breath, apply to human embryos (McMahan, 2007).

George and Gomez-Lobo's (2002) appeal to two senses of mental capacity is a considerably fair response to Kuhse and Singer. In their view, there exists the *immediately exercisable* capacities as well as the *basic natural* capacities for mental functions, and that the former is an actualization of the latter function that exists at the embryonic stage of life. The argument is that the human embryo's basic nature is the rational nature and that it is not an optimally realizable nature until they are able to begin exercising that reasoning potential, and that there is no justification for ascribing moral worth to some individuals while denying others.

This argument on potentiality creates a greater problem to the deontologist. Sagan and Singer (2007), and Savulescu (1999) have separately argued that potentiality does not imply actuality, and that it does not logically ensue that the embryo with a basic nature – a mere potential is the same as the adult who is already exercising the capabilities that the embryo only exhibited a potential for. Accordingly, therefore, placing moral weight on the embryo's potential and demanding their protection thereof, precipitates an equal obligation to protect the human cells that exhibit considerable potential for development into reasoning being. The problem with such a position, according to Siegel (2018), is that the argument for the protection of trillions of cells is that it is impossible to implement as most people would out rightly reject the idea. Therefore, the argument for potentiality of the human embryo is deemed unsustainable. One may respond that Singer, Savulescu and company are pushing the potentiality argument too far – given that the use of cells for production of actual beings has not come to practice yet. They would be challenged to present their view when this happens. Meanwhile, it is acknowledged, and undeniable fact that the embryo, when implanted and accorded the natural environment for development, would certainly progress into a full human being. There is therefore a distinction between the embryo and the purported cells which makes their potentiality argument fairly plausible than the argument for cell protection. The two are different substances and should remain distinguished in any argumentation on life and protection.

It should be recognized that the deontological arguments prohibiting use of embryonic organisms for research are found to be inconsistent, even incoherent in certain respects. This is because the prohibition against using embryos in research is premised on the Kantian maxim that demands respect for all autonomous persons. As such, Kantians prohibit embryo

destruction arguing that destruction of human life, for whatever reason is morally unacceptable. On the other hand, the same Kantians argue for the justification of capital punishment. The particular act that is common and therefore found contradictory in the theory is the act of murder, that is, killing of an embryo in the first instance, and killing of a capital offender in the second instance. Both entails the termination of human life, in Kantian determination. There is an inconsistent and incoherent flaw in this kind of reasoning. For if there is found even an iota of reason for termination of human life – then building blocks of the *categorical imperative* – which is a normative ethic, will come tumbling down. It may appear that at this point, the Kantians are embracing a consequential framework of thought to boost their argument for capital punishment. What comes out, however, is the fact of the impossibility to coherently and consistently sustain a deontological argument in every life situation. That is why the absolute prohibition against destruction of human embryos cannot be logically sustained. It appears that sometimes, some utilitarian appeal to consequences has merit in the debate. This is true irrespective of whether the Kantian deems the embryo to be a person with moral status or not. Indeed, if there is any Kantian justification for the murder of a capital offender – one certified as fully autonomous human person – for whatever reason, that "Kantian" exceptional clause that allows for such exceptional unethical action can be equally extended the use of human embryos in research. After all, Kantians advance a utilitarian argument for capital punishment with the moral justification that it benefits the society. That argument for societal beneficence is also true in hESC research as it aims at reducing, even possibly eliminating some medically related aspects of human suffering. Both scenarios entail the death of a human person, deontologically speaking. In fact, capital punishment entails the causing of death of a uncontested autonomous human persons with full moral status, whereas, hESC research entails the death of just a potential human person, at best, and an organism at worst – that is if we consider the further end of the spectrum in the personhood and moral status debate. The difference is much larger, thereby warranting justification of hESC research in special circumstances (that will be discussed in chapter six).

Conclusion

The classical theories of morality, that is, deontological and utilitarian theories, are insufficient in resolving the moral dilemmas that present themselves as conflicting obligations in the bioethical enterprise in general, and in the hESC research in particular. Decision making in both the utilitarian and the deontological domains become herculean when both are used to

confront the same moral question. In the context of hESC research, the two theories are in conflict regarding the moral permissibility or culpability of the use of human embryos in scientific research. On the one hand, Kantian deontology prohibits use of other humans [embryos] as a means towards an end, whereas the utilitarian position appeals to the principle of beneficence thereby obligating moral agents to perform acts that profit from the destruction of embryos. Since these views are perpetually in conflict, a theory that consolidates the best possible outcomes from both position is espoused.

What emerges from this discourse is that the deontological argument against the use of hESC in research is strongly dependent on the view on the moral status of the embryo, and particularly, the argument for the personhood of the embryo. We have seen from the arguments advanced above that the personhood argument for the embryo cannot find consensus, both from the scientist and the philosopher. This kind of argumentation makes it difficult to agree with either the deontologist who argues against use of embryonic organisms for scientific research on the basis of their perceived moral status or with the opponent who argues against moral status. This is because none of the arguments advanced from either side can just be wished away at will. For this reason, we turn to the Principlism framework in chapters four and five, as an approach to assess the validity of the deontological argument – and particularly we seek to determine whether apart from the moral status debate, a solution, even if only temporal, can be found that either totally prohibits or fully permits the use of hESC research in transplantation medicine. In the next chapter, we will employ the Principlism framework as a tool for assessing the moral suitability or otherwise, of using hESC research in transplantation medicine.

Chapter 4: Assessing Arguments Against the Use of hESCs Research in Transplantation and Regenerative Medicine

This chapter will focus on the arguments against pursuing HES Cells research in Transplantation Medicine. Based on bioethical reflections on Principlism, the study will focus on the possible ethical reasons as to why HES Cell Research should not be pursued, and whether alternative remedies may be preferable. The scientific and moral suitability of these alternatives will be explored. My aim will be to apply Principlism to bioethics, particularly in relation to the use of Human Embryonic Stem cells in research and transplantation medicine. This is the core of this thesis, and therefore, a pitch will be made for the moral suitability of Principlism over other theories in making assessments against the use of hESC research and its relevance to transplantation and regenerative medicine. However, the study must first attempt to address the sticky question of the moral status of the embryo before making any other argument. The ethical issues raised in this study are acutely dependent on the moral status of the embryo and their use in scientific research. It is this subject that we turn to in the immediate section of this study.

The Moral Status of an Embryo

The primary ethical concern with regards to hESC research is not necessarily the use of stem cells but rather the source of the stem cells, and more specifically, the need to destroy a human embryo for extraction of cell lines. This need to destroy embryos for the purpose of harvesting the necessary "ingredients" requisite for successful stem cell research and therapy is what births the moral status debate. Thus, underlying the scientific and ethical arguments against using embryos for research is the question of its moral status. It is asked, what is the moral status of an embryo? Related to this question is that of when the human being begins. Is an embryo a person? Is it an autonomous person, so much so that its destruction is to be understood as directly proportional to commitment of murder? Who has the authority to define the moral status of an embryo – the scientist or the philosopher? Finally, is the moral status ascribed or is it inherent? This paper does not attempt to give a new response to the moral status debate. It will rather consider the arguments advanced in the debate and then attempt a middle ground solution to the moral debate. Again, this is done through the employment of Principlism as a critical assessment tool for consensus and justification of the decisions made in the hESCs conversation.

Deciding on the Moral Status of the Embryo

It is impossible to discuss the ethics of the use of embryos in scientific study without commenting on the issue of their moral status. The question of the moral status of the embryo is usually preceded by that of their origin, and, closely by the question: whose word is the final one with regards to verifying their origin and being? These questions necessitate two others, namely: "when does a human being begin?" or for some, "when does the physical dimension of a human being begin?" (Irving, 2000). Also worthy of consideration is the concern about the competence of the persons to guide on answering these questions – the physician? Politician? Bioethicist? Philosopher? Theologian? Is the fact of the embryo a political, or a phenomenal, or a spiritual-theological, or sociological, or scientific reality?

Since the primary focus of this thesis is not necessarily on the personhood of the embryo, some of these debates will only be mentioned in passing. For instance, the debate on the most competent person to guide on the status of the embryo will not be exhausted. Instead, this study will go directly into the author's favoured view on who reserves the intellectual authority to guide on the true material status and understanding thereof, of an embryo.

Although this is debatable, it is espoused that the scientist – specifically, the embryologist, is endowed with the material facts and instruments that could aptly guide conversation on the material status of the embryo, particularly with the regard to beginning of life. This view is objected to, by among others, Van Niekerk, who from a personal conversation with this author argues that "the question is not on the person with the authority to determine the moral status of the embryo but rather what arguments are advanced in the debate." Whereas this is agreeable, this author is of the opinion that for an informed debate to be realised, there are certain material facts that cannot be merely conjectured. The particular biological or physical composition is necessary to understanding their status, even if only in a limited sense. One way of doing good philosophy is on using sound instruments for ascertaining the veracity of our arguments. Empirical verifiability is therefore one of the agreeable ways for establishing facts in philosophical conversations. It is in this sense, therefore, that the expertise of an embryologist is coveted in establishing certain physiological facts regarding the embryonic organism. This, in the opinion of this author, is not directly proportional to conferring upon the embryologist the absolute authority of determining the moral status of the embryo. It is an acknowledgement of their vital instrumentality in aiding a guided conversation. This is necessary because a key aspect of the issue at hand is strictly a scientific question that should "be answered by objective, empirical facts demonstrated by the science of human embryology" (Irving, 2000). Irving sensationally proclaims that "the question as to when the physical

material dimension of a human being begins via sexual reproduction is a strictly scientific question, and fundamentally should be answered by human embryologists—not philosophers, bioethicists, theologians, politicians, x-ray technicians, movie stars, obstetricians and gynaecologists" (Irving, 1999). Yet in embracing this position it must be recognised and be defended that "the question as to when a human *person* begins [is, however,]48 a philosophical question" (Irving, 1999).

The embryologist has the intellectual instruments for investigating and ascertaining (it is hoped) the true and particular material status of the embryonic organism and therefore give clarity on its physical and material status. In other words, it is contended here that the material status of an embryo is not an issue to decide on. Rather, it is a fact to establish or discover. It is not an opinion, perspective or view to be advanced. The moral status of an embryo on the other hand is one that must be deliberated upon establishment of the essential material facts and evidence.

Although the embryologist should instruct us on the biological and material specifics of the status of the embryo, it is however, far-fetched to argue that they reserve the last word on the moral status, and consequent scientific use of the embryo. Indeed, they provide reasonable, factual and meaningful information which must be considered and employed in a multi-disciplinary environment, particularly when considering their use in human-advancing scientific research. Therefore, it is desirable for the embryologist, philosopher, bioethicist, theologian, and physician to put their heads together and brainstorm objectively on the moral status of the embryo, as well as the appropriateness of their use in scientific research. This collaborative adventure is worthwhile as it puts together a multi-perspectival effort in resolving an enduring human dilemma, and problem of the day. The multi-perspectival approach helps establish the moral status as well as objectively weigh the pros and cons attributed to the use of the embryo in scientific research. The Principlism framework approach to bioethical decision-making finds its usefulness in such a setting as it employs deliberative judgement in its pursuit of a reflective equilibrium when weighing the different thoughts and principles presented by the diverse bodies of thoughts, some of which are in tension. It also helps with bringing unanimity in the making of desirable and justifiable decisions. The approach would allow for the incorporation of the valid views of the physician, philosopher, and the bioethicists as they consider the implications of the empirical facts adduced by the embryologist. With this settled, we turn to the conversation on the moral status of the embryo.

Debate on the Moral Status of the Human Embryo

The debate on the moral status of the embryo is tied to the question of personhood. Those who object to the use of the embryo in hESCs research argue that the practice is equivalent to murder as it involves the destruction of living human persons. Those who oppose this view advance the argument that embryos do not have inherent personhood. This argument against the personhood of the embryo takes the form: "1). The immediate product of fertilization is not a human being yet; or 2) the product may be a human being but not a person yet, [specifically human person]" (Irving, 2000). In other words, the respect, dignity and worth ascribed to an early human embryo is directly proportional to its biological progress and development.49

Such an argument poses difficulty to the anti-embryonic research community who contend that embryonic organisms are human persons right from the beginning of fertilization. In fact, there is an argument advanced in the world of science, particularly among embryologists, that the "early human embryonic stages are really developing stages of a whole human being, not just part of a human being" (Irving, 2000). They contend that the biological objects are not just stem cells as is argued by their opponents. Irving asserts that although these biological objects are totipotent, they are not just stem cells. She writes: "While it is true that the single-cell human embryonic zygote, and the multi-cell developing human organism up to the blastocyst stage, is "totipotent" (relatively speaking), it is not scientifically true... that it is just a stem cell" (Irving, 2000).50 In other words, regardless of the biological growth stage, the scientific facts of human embryology ascertains the existence of the embryonic organisms as whole human beings, whether or not one makes the "theoretical argument that 'there is no whole human being yet, or whether it is argued that there is no 'person' there yet" (Irving, 2000). This position dispels the pre-embryo myth – that scientific obfuscation in reference "to the early stages of the developing human embryo" (Irving, 2000).

The defenders of the moral status further argue that the developing embryonic being is not just a "potency"51 to develop later into a human being for it is already a living human being. Irving rejects the terms potency and potential as pure philosophical terms that should not be

⁴⁹ Dianne Irving observes that the former NIH Human Embryo Research Panel Report and the NBAC Report have variously expressed that the respect and dignity due to the early human embryo evolve in degrees as the biological organism evolves through its developing biological stages (Irving, 2000).

⁵⁰ Irving uses the example of Dolly – the now infamous sheep that was cloned. She says: "Take for example the 'Dolly' experiment. The skin that was used as the donor cell was just part of the mother sheep, not the mother sheep herself. Or, a skin on Joe's face is not Joe; it is just a part of Joe. To destroy the skin cell on Joe's face is not to destroy Joe. But to take out Joe's guts and insides does destroy Joe. Thus, Irving equates the destruction met on human embryos who are used as sources of stem cells or gene fragments used in some somatic and germ line gene therapy research (Irving, 2000).

51 A potential human being

included in a scientific journey of investigation. It may be objected that the "early totipotent or pluripotent 'cells' will not become 'mature human organism' 'unless and until it is implanted'" (Irving, 2000). The response, according to Irving, is that such an objection "is scientifically false and misleading ... [since] the single-cell embryonic human zygote and all of its early developmental stages is already a human being (which is a human organism), regardless of whether or not it is implanted" (Irving, 2000).

So, this debate rages on and on. One would think that If the embryologist was to confirm that the embryo is a living organism, then the other group of thinkers are free—even obligated to inquire as to what kind of living organism it may be. A living organism whose parental material is derived from a living human being, and who upon nurture to its logical conclusion should grow into a full human being should plausibly be considered a human being – not a possible human being.

It is noteworthy, to consider that the moral status is not given, assigned or ascribed – it is discovered. Whatever, decision we come up with upon consideration of scientific facts, as well as by deliberation across disciplines, the enduring truth that must stand proclaimed is that the embryo's moral status is not assigned – it is discovered. Discovery connotes unearthing or establishment, and therefore demands exploration. It implies pre-existence. It is an establishment of actual state of being, that is, finding things that are as they are, not making up descriptions, definitions and ideas of things based on individual thoughts.

As is observed, the debate on moral status rages on with arguments and counterarguments advanced from both sides of the divide. The implications of the arguments on the moral status are equally sharp and sweeping. For instance, there are those opposed to embryo use in hESC research who maintain that human embryos should be accorded equal moral status to fully developed humans. On the other hand, those who support use of embryos argue that embryonic organisms have no moral status. According to this group, the embryonic organisms lack relevant characteristics that define beings with moral status. Yet some who consider embryos to be of the same moral status as other biologically alive entities recognize that embryos just have lesser moral status than human persons and therefore permit their use in research. Still there are those who believe that although the embryo has either lesser or no moral status at all, they still ought to "be treated with respect or that there are certain limits to what may be done with a human embryo" (COMMITTEE FOR PEDIATRIC RESEARCH, 2012). Finally, there are those who though believe in the moral status of the embryo, argue that the interest of those who could benefit from future developed treatments supersede the wishes of those who condemn the embryo use – particularly the embryos that are facing disposal.

Some Concluding Remarks on the Personhood and Moral Status Debate

There are sufficient arguments advancing personhood of the embryo as there are those debunking the same. It seems there is a stalemate posed by the views advanced on either side, and this debate does not show signs of ending soon. This author does not find an ultimate knockdown argument that justifies the triumph of either sides, even if only tentative. As such, this thesis proposes a middle ground position that would enable society to advance on with other related matters while the debate ensues. It would seem reasonable enough to hold on to the respectability doctrine of the embryonic organism – whether or not they are confirmed human persons with moral status. At least, there is no doubt as to the fact that embryos are living organisms whose biological make ups are directly derived from biological substances (or components) of living autonomous human persons. Whether or not they are human persons, or just beings imbued with the potential to become fully established creatures of the species homo sapiens sapiens. They may not share the same moral status and consequent worth of equal treatment as of established human persons, but they, undoubtedly, are self-existing embryonic human organisms. Just that mere fact of their existence – as biological products, substance, or materials derived from human persons accords them some recognizable status worthy or respect. What we ought to agree on is the entailment of respect – that is whether the respect of human embryos confer upon them the right to infinite livelihood. The question as to what respect for the embryonic organism is, ought to be settled amicably. Even more, whether there are degrees of respect – and what exactly is the essential substance of respect, and whether there is remarkable difference between the respect ascribed to the embryo and that to the fully developed human person with recognized moral status.

With such concession we can proceed on to affirm respect of the embryo – whether or not we consider them autonomous human person. The problem this admission raises in the context of hESC research is that which Nico Nortje (2007) has asked in his DPhil thesis, namely, "how do we *simultaneously* confer respect on the embryo *and* [at the same time] proceed with research that requires the destruction of embryos...?" (Nortjé, 2007: 90). The idea of embracing the Principlism framework in bioethics may be the starting point for answering this question. Principlism as a moral framework approach seeks to thaw the contentious positions held by opposing ethical worldviews. It holds that a good ethical process is done in an irenic environment and that it shuns tendencies towards obstinate dogmatism. Van Niekerk et al quotes Gibson (2007) who has illustrated this idea beautifully as she weighs in on the moral status of the embryo:

'Ethically acceptable uses of the embryo have to be worked out in a way that acknowledges that the human embryo is both something that may have considerable moral status and something that may well not have considerable moral status Just as we should approach the use and destruction of the human embryo with "fear and trembling'; so too should we approach the prevention of its use in the same way. By researching on the human embryo, we may well be destroying something that has considerable moral status; by preventing research on the human embryo we may well be failing to alleviate the suffering of children and adults whom [sic] most certainly do have considerable moral status, for no good reason' (Gibson 2007: 377: Van Niekerk, 2013: 29).

The irenic substance in the Principlism framework accords the opportunity to look at moral dilemmas with a conversational eye – an eye that seeks to dialogue with the intent of problem solving – as opposed to that which seeks to debate in order to justify one's position. Principlism argues that on the one hand there is A, and on the other hand there is B, and that both A and B should be brought to a point of mutual co-existence. This is distinct from the way the classical theories of morality function. Deontology, utilitarianism, and even virtue ethics somewhat hold onto some normative reasoning, akin to arguing that it is either my way or the highway. Such an approach does not serve the interest of the bioethical enterprise.

Having considered the sticky question of personhood vis-à-vis moral status of the embryonic organism, we now turn to the assessment of the traditional arguments advanced against use of hESC research in transplantation and regenerative medicine. It is at this point in the thesis that we begin the employment of Principlism as an assessment tool for the arguments against hESC research, and later consider the arguments for use of hESC research in chapter five.

A Principlism Assessment of the Arguments Against hESC Research

The moral status of the pre-implanted embryonic organisms may never be concluded with finality, and debates regarding the morality of stem cell research rages on. It is worth recognizing that this is an ongoing debate, and anyone engaged in the conversation should be cognizant of and sensitive to the differing moral positions. This study is weary of the debate on the moral status – and particularly the ethical considerations inherent in the hESC research. Yet, the study also recognizes the potential benefit of future discoveries to humanity, some of whose viability are being confirmed as some studies move to clinical trials phase. Given the ongoing ethical debates, a framework approach that recognizes the quandary – whether to invest in a technology that may save many lives in future, or to protect what is understood as

human life – is proposed, not as a way that gives final answer to the moral dilemma, but as one that enables progress on the research beyond the moral status debates. This thesis proposes the use of Principlism as a moral assessment tool that should enable bioethicists and scientist to progress on with the hESCs research without shutting down the ongoing debate on moral status. The four principles are used to assess the arguments posed in the debate – both for and against use of hESC research. These principles are respect for autonomy, beneficence, nonmaleficence, and justice. The previous chapter has discussed the origins, meaning and use of the four principles. This chapter will forthwith embark on their use as assessment tools to the arguments advances in the hESC research debate.

Principlism seeks to bring equilibrium into problematic moral situations in the bioethical enterprise. The bioethical environment is one that does not enjoy the luxury of time, and thus cannot wait for moral warriors to wrestle each other to the ground before decisions can be made. It is an environment of life and death and each moment counts. Decisions have to be made—decisions that would either lead to life or death. As is in the case of hESC research and with particular reference to their use in transplantation and regenerative medicine, the debate on the morality of the use of the human embryo as the source of the coveted pluripotent stem cells appears like it will not come to an end soon. Therefore, the bioethicist is placed between deciding on whether to continue with the debate further, endorsing the destruction and use of the embryos in research, or rejecting the whole stem cells project all together.

It has been demonstrated that the global status of the noncommunicable disease burden is a mess that needs fixing, and that stem cell research, and particularly hESC research holds the potential for the ultimate control of the spiralling disease burden. Since all other approaches to ethics have brought a stalemate, particularly in the arguments advanced in the embryonic status debates, the Principlism framework approach is proposed to be a possible deal breaker in the conversation. The main question to be considered here is under what circumstances is hESC research permissible?

How does Principlism reflect on the hESC research debate? Can Principlism resolve the impasse on hESC research? That is the real thrust of this thesis. The remaining parts of this study will consider the Principlism's interaction with the arguments for and against hESC research. Each principle will be used to assess the traditional arguments for and against the research. Particularly, the specification and applicability of each principle vis-à-vis the subjects in the debate, that is the embryo and the donors will be considered. This is consistent with B&C's assertion that the principles need "specification in particular contexts to function as a practical guide to conduct, [as] appropriate specification will incorporate valid exceptions"

(Childress, 2013: 107). The manner of interrogation will be through the asking of myriad clarifying questions that assess the claims or arguments on either side of the divide. The principles under consideration are respect for autonomy, beneficence, nonmaleficence, and justice, respectively.

Respect for Autonomy: Whose Autonomy?

In considering respect for autonomy in hESC research, the first important question is: whose autonomy? Is it the embryo's? The embryo donor's? The gamete donor's? And, in what ways are their autonomies respectable? Given B&C's instruction "that to respect autonomous agents is to acknowledge their right to hold views, to make choices, and to take actions based on their values and beliefs" (Childress, 2013: 106), how would this be considered with respect to the embryonic organism? Is the embryonic organism capable of holding views, making choices, and taking actions based on their values and beliefs? (Ebbesen, 2015). Are they even capable of holding values and beliefs? In the arguments advanced against the use of hESC research in transplantation and regenerative medicine, the overarching ethical problem is that of the moral status of the embryo and by extension therefore, respect for its autonomy. For if indeed it exhibits inherent personhood with moral status, then the embryo is correspondingly worthy of respect. Yet, the debate rages on as to whether the embryonic organism is a person with moral status, or just another object without inherent personhood, and therefore with little, reduced, or no moral status. It has been considered that this debate is active and ongoing without indication of imminent resolution, and is therefore not capable of immediate determination. We will however, examine whether the embryo is respectable and how that would play out if it were to be accorded that status. The study will also look at the question of respect with regards to the donor – both male and female.

Respect for Autonomy of the Embryo?

Respect for autonomy would require, perhaps, the informed consent of the embryo. But is the embryo capable of consent, let alone informed consent? Beauchamp and Childress' explication of this principle is solid. They aver:

The principle of respect for autonomy can be stated as both a *negative* and a *positive* obligation. As a *negative* obligation, the principle requires that autonomous actions not be subjected to controlling constraints by others... as positive obligation, the principle requires both respectful treatment in disclosing information and actions that foster autonomous decision-making (Childress, 2013).

What would be some of the controlling constraints that the embryo may suffer and that which the principle of respect for autonomy protects them from? It is held that specification of the principle, with the goal of appropriating their applicability as functional guides of conduct would demonstrate how they yield to the "rights and obligations of liberty, privacy, confidentiality, truthfulness, and informed consent" (Childress, 2001: 64). What rights and obligations of liberty does the embryo warrant? Who is this embryo that is entitled to privacy, confidentiality, truthfulness and informed choice?

Assuming that the arguments for moral status, and the corresponding argument for the respect of the human embryo are entertained, how would such respect be demonstrated? The assumption here is that moral status is not granted, and that it is inherent, and therefore, cannot be given or taken away. If this be the case, and if the embryo is certified as to inherently possess moral status, then it also follows that it qualifies for moral respectability. In which case, there would be a moral obligation to not just acknowledge that respect, but to also demonstrate the respect. So, how would that play out, in practice? How do we demonstrate respect to the embryo? Some would say, by acknowledging the sanctity of their lives – therefore, by not subjecting them to wanton destruction, or by not using them as a means towards other people's ends. That is to say, with respect to hESC research, embryos should not be destroyed for the purpose of harvesting the pluripotent stem cells so as to enable the continued survival of other human species.

Very well, that argument may be made. The Kantian would seem to make a compelling case for the respect of the embryo, even from a Principlist perspective. It gives a fairly convincing reason as to why the embryo should be deserving of respect. The argument however, leaves a few gaps that makes it impracticable. One would first ask the exact and particular meaning of respect as advanced by the Kantian in this scenario? For example, when you say that you have given me a minute, there are two things that ought to happen. First, is that I must be able to comprehend the fact of the granted minute. Secondly, I should be able to accept or reject that minute – in other words, there should be capacity to experience the fact of the granted minute. A minute is understood as a sixty second period or duration. It is an expression of a time frame. Of course, it cannot be physically conveyed because it is not materially tangible. It however, can be measured. Therefore, if I was given a minute, I should be able to experience a sixty second wait (for whatever reason the minute was granted). The one minute may be a period granted to me to execute a certain action or command, or maybe a grace period before the giver of the minute can execute other actions or decisions that he has determined. Either way, it is supposed to be a reasonable and comprehensible concept or notion

that I am supposed to acknowledge and respond to according to my autonomous determination. Now, if the embryo is autonomous and entitled to respect, it follows that the embryo must correspondingly possess the requisite capacity to comprehend, acknowledge, and appropriate that respect. Respect for the embryo's autonomy would be the one that enables it/he/she to direct how they may want or desire to be treated. Perhaps in the case of IVF, respect for the autonomy is the one that grants it the autonomous decision to choose which uterus it may desire for its implantation, and this is never the case – even if the embryo possessed the capacity to express such desires. The embryo cannot independently, and purposely desire to or personally communicate its desire. The sum total of the treatments mete on the embryo – whether IVF, cloning, stem cell extraction, or mere disposal – are results of other persons' expression of their autonomy. For "an autonomous individual", according to B&C, "acts freely in accordance with a self-chosen plan, analogous to the way an independent government manages territories and sets its policies" (Childress, 2013: 101). Liberty52 and agency53 are some of the conditions deemed mandatory for autonomy. We never find an embryo's autonomous decision regarding their continued existence in their embryonic form or transition thereof to another form (developmentally speaking) they may desire. Embryos have no capacity for independence from controlling influences, let alone the independence itself. They also exhibit no capacity for intentional action whatsoever. They also have no capacity for competence - a requisite ingredient for appropriating autonomy. The treatments met on embryos are usually an expression or indication of the autonomous decisions of the human subjects that handle them, and not the embryos' decisions. Such actions reflect other human's autonomy imposed on the embryo, and not the embryos' autonomy. It is in this sense that this study finds it inconsistent to argue for the autonomy and respect of the embryo, when the actual expression of that respect and autonomy is an outright impracticality.

Another aspect for respect for authority would entail respectful treatment of the embryo with regards to disclosing information of the intent to use them for research, clearly delineating the positives and the negatives of the research, and spelling out the desired as well as expected outcomes. The embryo should, on the other hand, possess the capacity to accept or reject their use in the research. This is akin to circumstances of organ donation where an individual, perhaps, a parent decides to donate an organ to their ailing child, with the full knowledge that the harvesting of such an organ would mean the end of their lives. The parent who has been thoroughly briefed on the implication of such a decision, upon his own internal deliberations,

⁵² Independence from controlling influences

⁵³ Capacity for intentional action

deems it morally desirable to rescue their ailing child, even though it means their death. That is the kind of informed consent that respect for autonomy of the embryo would imply. As we have seen, this is both a biological as well as a situational impossibility – the embryo does not, and will never have the capacity to comprehend information regarding the use of their stem cells for transplantation and regenerative medicine, let alone communicate such consent. In this case, the embryo does not pass as a full, autonomous, and consenting individual. The principle of respect for autonomy cannot be applied to the embryo, who is the main subject in the hESC research ethics debate. When the questions are rightly considered, one finds it very difficult to procure the same rights ascribed to individual persons onto the embryo.

It can be argued that just as adults are presumed to be competent unless there is reason to believe otherwise, children and infants are deemed incompetent and incapable of giving informed consent. In such cases, there is always the designation of a surrogate decision makers who stands in the gap for such incompetent persons. Such arguments could be advanced as applicable to embryos – that is for those who deem them to exhibit moral agency – and that they deserve representation by competent persons who will take their (embryos') best interests at heart. This argument, however, raises the question of who is the designated surrogate decision maker on behalf of the embryo. Is it the donor, the state, or the researcher? What is the criterion for making this determination? Or perhaps, the preceding question should be whether there is need for surrogate decision makers for the embryo. Does the embryo have a corresponding moral value akin to that of an infant or a child? This is doubtful, and the argument continues in a circular motion.

There are other implications of the respect for autonomy principle, but which are not relevant to this study given the impossibility to progress the arguments on the autonomy of the embryo beyond this point. Perhaps, exploring the respect for autonomy of the donors may break the deadlock on the morality of the use of the embryonic organism in stem cell research. Although justification for the respect for autonomy of the embryo cannot be established and effected, there is likelihood that the three other principles can provide a useful guide on the morality of hESC research. It is notable that "obligations to respect autonomy do not extend to persons who cannot act in sufficiently autonomous manner—and who cannot be rendered autonomous—because, for instance, they are immature, incapacitated, ignorant, coerced, or exploited" (Childress, 2013: 108). B&C counsels that it cannot be presumed from the foregoing, that "these individuals are not owed moral respect" as they have "assigned moral status that prevent them from harm-causing conditions…" (Childress, 2013: 108). This is the beauty of Principlism, one principle alone may not determine, by itself, the morality of a

decision. Consideration of the remaining principles, weighing them upon each other, through the use of reflective equilibrium, a moral guide would be found. This is exactly the course of this study. However, before considering the remaining three principles, this study will briefly consider a Principlist assessment of the autonomy of the donors, to see if they can break the moral deadlock on the respect for autonomy vis-à-vis the imperative for moral respect debate on hESC research.

Respect for Autonomy of the Donors: Gametes and Oocytes?

Since the embryo is deemed incompetent, and therefore without capacity for informed consent, it can be argued that the donors, by virtue of their participation in the supply of vital biological material for the development of the embryos, should play a distinctive role in the determination of their use. In other words, some form of surrogacy may be ascribed to the donors just as parents or guardians of incompetent children are permitted to make decisions regarding treatment of their incompetent kin. This view holds that the donors may decide whether or not the embryos produced from their biological materials should or should not be destroyed for the purpose of extracting the hESCs for research on transplantation and regenerative medicine. Even this view has ethical problems and cannot be determined that easily. The same questions asked of the embryo's status are asked again of the donors: are the donors (gamete and oocyte) autonomous and obligated to informed consent regarding the use of hESC in research and transplantation medicine? Are they deserving of respect? Whose autonomy is imperative: the male, or the female donors? What do you do when both donors are not in agreement on how to treat the embryo? There is no doubt that the adults donating their biological parts for embryonic production are competent adults, and therefore capable of informed consent, unless otherwise established. It is standard practice to presume the competency of all adults. Assuming the informed and consenting adults agree on what to do with the embryos, how would they know what is best for the embryo? On whose interest would they understand themselves to be acting when they choose the destruction or preservation of the embryo? In the event that they refuse to accept the use of embryos in research, what would they intend the embryos to be used for? How long would they preserve the embryos? If they were to cease to exist [assuming they both die], who would be the next surrogate decision maker on the use of the embryos? Would advance directives be applicable in this context? And is the infinite preservation of the embryos feasible?

The first problem is that of assigning surrogacy to the embryos as demonstrated by the questions asked above. First, there is no knowing between the donors who has the ultimate decision-making authority, whether the male or female donor. Secondly, even if they both were to be assigned a joint authority, it would be hard to find them in agreement on what to do with the embryos. And even if they were to agree, they would not know what is the exact best interest of the embryos for they have no capacity to communicate with, and obtain accurate knowledge on the exact desire of the embryos. Too many questions will remain asked, and very few answers will be found in this context. Ultimately, the presumption that the donors reserve authority on what to do with the embryos is the closest we can get to applying informed consent, and by extension, the principle of respect for autonomy. Even with this admission, the donors would only speak on the fate of the remnant embryos procured for IVF and which are destined for destruction, nevertheless. The logical conclusion for the donors would be to sign them up for research in order to serve altruistic purposes rather than allow for their destruction. Either way, research or not, such embryo lives are destined to end, and therefore, it would be found most beneficial to use them in a cause that may be of benefit to the greater humanity.

So far this study on the assessment of the morality of hESC research by use of the respect for autonomy principle establishes that it is not easy to coherently, consistently, and comprehensively sustain the arguments against the use of embryos for stem cell research. First, the moral status, and consequent autonomy and competence of the embryo cannot be established whatsoever. There is therefore no established autonomy of the embryonic organism that other moral agents in the conversation are morally obligated to uphold. Although it is held that the argument for respect of the embryo by virtue of its existence of a unique organism is plausible and sustainable. In other words, it could be universally considered immoral to destroy embryos just for the sake of it – whether they exhibit moral status or not. The virtue of their association with the human person grants them some level of respectability. Therefore, creation of embryos just for the sake of destruction in order to harvest stem cells may be considered a morally reprehensible behaviour. However, the use of "left-over" embryos, upon consent of the morally competent surrogate decision makers, who are the donors, should be deemed morally acceptable. These donors must be thoroughly informed, and be allowed to make their decisions without an iota of external influence.

Nonmaleficence (First Do No Harm) Assessment

It is without doubt that this is the most employed bioethics principle advanced by those who oppose hESC research. B&C explains that "the principle of nonmaleficence obligates us

to abstain from causing harm to others" (2013: 150). This principle echoes the maxim *primum non nocere*: "Above all else [or first] do no harm (Childress, 2013). In Kantian deontology, the first formulation of the *categorical imperative* requires that we treat persons as we would require them to treat us. If we would not desire, and or require to be harmed in any way, so should we not cause harm to other persons. The embryonic organism has life that can be destroyed. That is why some ethicists hold on to the doctrine of moral reprehensibility against agents who commit, abet, or support the destruction of embryos.

In the explication of the principle of nonmaleficence, B&C admit that this is one of the principles that find acceptance in so many types of ethical theories. Citing William Frankena (Frankena, 1973: 47) as an example, B&C demonstrate how the principle is sometimes merged with the principle of beneficence to form one principle. They however, maintain that the principles must be separated as "conflating maleficence and beneficence into a single principle obscures critical moral distinction as well as different types of moral theory" (Childress, 2013: 151). This is because the obligations derived from the two principles are distinct. Typically, nonmaleficence, according to B&C, "overrides other principles" (Childress, 2013), although they also admit that "the weights of these moral principles vary in different circumstances" (B&C, 2001: 115). This example highlights the superiority of Principlism as a bioethical framework, as it does not presume priority of any moral principle above the others. This approach promotes contextual intelligence, and it allows the handling of each case on its own presented merits.

For the purpose of practicality and usability, the principle of nonmaleficence is specified into certain rules – which seems to have a universal appeal – which give justification to the principle. Rules like, "1. Do not kill, 2. Do not cause pain or suffering, 3. Do not incapacitate, 4. Do not cause offense, 5. Do not deprive others of the goods of life.... are prima facie, although not absolute" (B&C, 2013: 154). These are general rules and notions to take into consideration whenever the principle of nonmaleficence is invoked.

How then does the principle of nonmaleficence respond to the arguments against hESC research? The overarching subjects in the principle of nonmaleficence is that of harm and injury. The idea of harm, in the context of embryonic organisms in research, connotes the "thwarting, defeating, or setting back of some party's interests…" (Childress, 2013: 153). More specifically, the idea of causing injury and death is in view when we talk about nonmaleficence in the hESC research debate. The destruction of the life of the embryo when harvesting the coveted pluripotent stem cells for the purpose of research and therapy is viewed by some ethicists as a harmful exercise. The question is, to whom is the exercise deemed harmful? The

embryo is deemed to have no capacity for sentience and therefore cannot claim injury, nor can injury be claimed on its behalf by any third party. The biologist, particularly the embryologist, should help answer the question whether the dismembering of the parts of the embryo is a physically injurious exercise. In any case, the embryos that are the most likely candidates for extraction of pluripotent stem cells are the excess remnants left behind after IVF procedures for fertility patients. These cells are after all destined to disposal if they are not assigned further use. The very fact that they face extinction whether by destruction during harvesting of the stem cells or by mere systemic neglect and disposal betrays the argument against their use. It is not clear what harm or injury would be ascribed to an embryo used in research that is not applicable to embryos merely destroyed or left to perish upon completion of an IVF procedure. Moreover, any embryo that does not possess properties of personhood – particularly sentience, cannot claim absolute injury.

However, if we considered properly, the rules specifying the principle of nonmaleficence – "1. Do not kill; 2. Do not cause pain or suffering; 3. Do not incapacitate; 4. Do not cause offense; and 5. Do not deprive others of the goods of life" (B&C, 2013), – then it may be argued that the dismembering of the embryos during stem cell harvesting robs them of their lives, effectively rendering them lifeless. That process of rendering a living organism lifeless is known as killing. Of course, it has been submitted earlier that the embryo is devoid of sentience and therefore we cannot claim that the killing process causes them pain and suffering. In addition, destruction of the embryo goes beyond incapacitation as it completely annihilates the organism. This annihilation may be a good thing or may not be a good thing for the embryo – but from their (embryo) standpoint, we will never know. As to whether offence can be caused to an embryo is not in question since the embryo has no rational capacity. It cannot be offended in any way. Finally, the obligation to not deprive others of the goods of life may apply to the embryo if we deem them to be autonomous persons with moral worth. The compelling question for those who make arguments in favour of this obligation must answer the question as to whether the embryonic organism has the rational capacity to claim knowledge and experience of the goods of life. So, the obligation violated, is the one that prohibits killing. But as is argued elsewhere, some of the obligations are not absolute because the principles must be weighed upon another to determine what is morally preferable. Maybe it is possible that causing the destruction of an embryo, if there are justifiable reasons, could be a good thing after all. It is like when utilitarians argue for murder in self defense. Generally speaking, murder is a morally reprehensible act, however, the circumstances upon which murder is committed may determine the morality of the action. As the utilitarian may argue,

there are circumstances where taking away of another life is the morally acceptable thing to do. Beyond the hypothetical scenarios, such an argument has recently been advanced in practical life. The justification for the killing of Osama bin Laden as a legitimate government policy is an example. Another example: what if somebody who does not wish me well loosened the tires of my car while I had stopped at a convenience store, and upon return, I continue driving at a reasonable speed within the prescribed legal limits. Suppose, that while driving, one tire comes off and rolls off the road instantly killing an innocent pedestrian. Whereas it may be argued that I killed the individual by the virtue of the fact that I was operating the vehicle whose tire came off and caused the death, morally speaking, I am not even remotely complicit, leave alone responsible for the death of the pedestrian. It may be a sad event that a pedestrian has died, but it is not my moral responsibility. If anything, I may be considered a victim of attempted murder by persons known or unknown to me. It would be the task of the law enforcers to investigate and find the morally responsible person – the one who deliberately loosened my car tire.

From the forgoing, it would seem that advancing the argument of harm against the embryo would be daunting – maybe even, impossible. Perhaps, reconsidering the moral agent in this case may change the reasoning. What if it is argued that the moral agents harmed in the use of embryos for research is the donor? The donor may claim emotional and psychological harm. They may argue that there is a general moral wrongness of killing, as Singer [quoted by Nortje (2007)] has claimed, that it leads to unintended consequences which are very negative side effects. The emotional and psychological turmoil endured by those close to the deceased – that is friends, colleagues, and relatives – are burdensome overflow accruing from the fact of death. The fact of death is an inevitability, and there is no knowing whether death is in and of itself a good or bad thing, as there is nobody with a credible report of the ultimate status of expired persons on the other side of life. To the dead, death is just that – death. To the persons left behind, there is an emotional gap left by the deceased that the friend and kin cannot cover. This experience of loss by the bereaved is the unintended consequence of death that makes killing morally reprehensible. By the same token, the death of an embryo does no particular harm to the embryo, for their status beyond death is undocumented – whether good or bad. However, for those with emotional attachment, destruction of the embryo is by extension, a deliberate causation of harm [to the *donors*] as they are left behind nursing emotional wounds. How far this argument of emotional wounds caused to moral persons by death of an embryo is a subjective situation that is only explainable by such claimants of emotional pain and loss. Indeed, how much loss would one claim from the destruction of an embryo that they never

knew in person? What kind of relationship can be entered with an embryo? Is the feeling of loss a true state of mental and psychological being, or an imagined state imposed upon oneself? This question cannot be conclusively answered philosophically for there may be as many opinions as are person involved in the debate. It is however, deemed a morally desirable thing to respect the feelings of persons who ascribe emotional lose to the destruction of embryonic organisms whom they claim attachment to.

Finally, we consider the rule of double effect (RDE)54 which may be "invoked to justify claims that a single act, which has one good effect and one harmful effect (such as death) is not morally prohibited" (Mangan, 1949; Cavanaugh, 2006; Childress, 2013: 164). B&C notes that the "RDE incorporates an influential distinction between intended effects and merely foreseen effects" (Childress, 2013: 164). Use of embryos for research has two effects, the intended one being development of regenerative therapy for curing debilitating medical conditions, and the foreseen being the destruction of embryos in the process of harvesting pluripotent stem cells. In assessing the morality of hESC research, this doctrine would consider the "four conditions or elements that must be satisfied for an act with double effect to be justified" (B&C: 2013: 165). These will include

- 1. The nature of the act;
- 2. The agent's intention;
- 3. The distinction between means and effect; and,
- 4. Proportionality between the good effect and the bad effect (Childress, 2013).

The first condition requires the act to be good or at least to be morally neutral, independent of its consequences (Childress, 2013). This criterion is met, and considered morally accepted, considering the fact that the consequences of hESC research is intended to bring life to several humans who suffer various ailments potentially curable by hESCs related technology. Moreover, many ethicists will consider the act to be considerably morally neutral as well as good. The second condition requires that "the agent intends only the good effect, not the bad effect. The bad effect can be foreseen, tolerated, and permitted, but it must not be intended" (B&C, 2013: 165). Indeed, the sole intention of hESC research is not the destruction of embryonic organism, rather it is the extraction of the pluripotent stem cells that are useful for research on regerative medicine. Of course the bad effect, that is destruction of the embryo is foreseen. It can be tolerated and even permitted, considering the inevitability in the process of meeting the desired consequence of extraction of the pluripotent stem cells. Destruction of

⁵⁴ As in all the determinations of Principlist assessments, this part of the thesis will draw largely from Beauchamp and Childress (2013).

the embryo is just an inevitable consequence but not a desired or intended one. This criterion, therefore, also meets the moral permissibility threshold. The third criterion requires that "the bad effect [should] not be a means to the good effect (B&C, 2013: 165). Unfortunately, this criterion falls short of the moral permissbility threshhold as the bad effect, that is, the destruction of the embryo, is the inevitable means of the good effect, that is the extraction and procurement of the pluripotent stem cells for the purpose of research on regenerative medicine. Finally, the fourth criterion demands that "the good effect must outweigh the bad effect" (B&C, 2013: 165). This criterion calls for mastery of the utility calculus, for there is need to calculate the outcomes of the act. The first, almost impossible task is that of determining the units of measurements. How do we count and weigh the consequences – bad and good? If one embryo is destroyed, is it considered equal to the death of one individual? And if that be the case, can it be argued that the death of one individual facilitates the extraction of vital cells (whose unit of measurement is unknown) which will lead to the potential salvation of many lives? This fourth criterion posses many questions and problems of practicality and usability of the criterion. It is prone to subjective evaluation of the consequences, and an agent may choose to see the moral consequences that meets his moral presuppositions and goals. In sum, RDE gives a partial direction on the path to judicious assessment of the morality of hESC research. Considered alongside other principles by means of reflective equilibrium, it may somewhat provide a definite answer to the question at hand. In the meantime, this study finds the criterion inconclusive for determining the moral justification of hESC research in transplantation and regenerative medicine.

It is therefore concluded that there is no empirically verifiable justification or rational justification for the argument that destruction of the embryo for whatever purpose, but more specifically, for hESC research causes harm to the embryo. The embryo lacks the essential qualities that establishes it as an object of harm. The contesting donors and other persons sympathetic to personhood of the embryo arguments may however claim harm as a result of destruction of the embryos. It is important to note that the claim to harm does not necessarily entail a corresponding experience of actual harm. Therefore, the principle of nonmaleficence absolves persons interested in hESC research from moral impropriety as long as they demonstrate respect to persons who may feel offended by their position. With this conclusive remark, we now turn to beneficent assessment of the arguments against hESC research.

Beneficent Assessments

The "principle of beneficence refers to a statement of moral obligation to act for the benefit of others" (B&C, 2013: 203). Beauchamp and Childress continue to note that the ethical theory of "utilitarianism is systematically arranged on a principle of beneficence" (B&C, 2013: 203) and that benevolence was, during the period of Scottish Enlightment, the centrepiece of common morality theories of David Hume and Francis Hutcheson. Furthermore, B&C maintain that "obligations to confer benefits, to prevent and remove harms, and to weigh an action's possible goods against its costs and possible harms are central to moral life, [although].... the principles of beneficence are not sufficiently broad or foundational that they determine or justify all other principles" (B&C, 2013: 203). This view hold, as opposed to classic utilitarians, that the principle of utility, although valuable, is not the sole fundamental principle of ethics but rather just one among a number of prima facie principles, and therefore it doesn't singularly determine the overall balance of moral obligations (B&C, 2013). It is therefore construed that conduct that is beneficent is probably ideal rather than obligatory, and it is, of course, uncertain where to draw the line between the moral ideal of beneficence and obligatory requirements of beneficence.

Beneficence and nonmaleficence have sometimes been confused as of being one and the same thing. It is also important to acknowledge and therefore, distinguish the rules of beneficence from those of nonmaleficence. B&C records the prima facie rules of beneficence as:

- 1. Protecting and defending the rights of others,
- 2. Preventing harm from occurring to others,
- 3. Removing conditions that will cause harm to others,
- 4. Helping persons with disabilities, and
- 5. Rescuing persons in danger (B&C, 2013: 205).

These rules 56 are distinct from those of maleficence as opposed to nonmaleficence, they are positive requirements; do not require impartiality; and "generally, do not provide reasons for legal punishment when agents fail to abide by them" (Childress, 2013). The principle of beneficence and its specification through the enumerated rules above must be considered

⁵⁵ The explication of the principle of beneficence is entirely derived from the works of Beauchamp and Childress (2013), unless otherwise state.

⁵⁶ B&C lists the "rules of nonmaleficence are: 1. Do not kill, 2. Do not cause pain or suffering, 3. Do not incapacitate, 4. Do not cause offense, 5. Do not deprive others of the goods of life, are prima facie, although not absolute" (B&C, 2013). It is also noted that the "rules of nonmaleficence are 1. Negative prohibitions of action, 2. Must be followed impartially, 3. Provide moral reasons for legal prohibitions of certain forms of conduct."

appropriately within their defined contexts. Therefore, their uses and applications vary considerably.

With this background information on the principle of beneficence, the study now proceeds to consider it in making assessments on the arguments against use of hESC research in transplantation medicine. As in the assessment on the principle of respect for autonomy, we ask again, whose beneficence is in focus when deliberating the use of human embryos in scientific research? The embryos? The donors? The potential recipients of hESC-related therapy? People who are generally offended by hESC research? We will make this assessment by looking at the applications of the five rules that specify beneficence. We will ask the five questions and assess their interaction with each of the agents in the case. We start with the embryos, then the donors, then potential patients, and finally persons that are generally offended by hESC research.

Beneficent Assessment of Embryos

The first rule is the requirement to protect and defend the rights of others. The use of the word others, here, is presumed (for the purpose of this argument) to mean persons, particularly human persons.57 For the purpose of this argument, it is held, as already discussed in this thesis, that regardless of view on personhood, respect for the embryo by the virtue of its inherited human biological composition, grants it a graduated level of respectability. Therefore, a following argument can be advanced that that which is potentially respectable ought to receive that respect. In the same breath, being accorded respect includes protection of status, and therefore, the embryo's right and status as a human organism ought to be protected and defended. The second rule requires the prevention of harm from occurring to others. Indeed, if there is a right to protect and defend, it should logically ensure that persons with such rights should be prevented from harm. Harm is anything that may be debilitating to the livelihood of an individual – whether physical or psychological. Earlier in addressing the embryonic relationship with regard to the principle of nonmaleficence, we established that the embryonic organism has no sentience or rationale. Therefore, they can't experience physical pain, psychological pain or mental pain. It is not feasible to say that there is harm done to the embryo. If this argument is sustained, then it also answers the third rule which requires that moral agents should remove conditions that will cause harm to others. If there are no harms to prevent from

⁵⁷ The personhood and moral status debate is inconclusive on the actual status of the embryo as the acceptability or deniability of the embryonic moral status is pegged on positions taken regarding personhood – and this is an ongoing debate – as well as whether personhood status is conferred state that is granted or an intrinsic state that exists a priori and therefore is discovered.

occurring to the embryo, then it cannot be consistently argued that there are objects or conditions that may cause harm to the embryos. In which case, this study finds that moral agents are under no obligation to remove conditions that may cause harm to the embryo as there is no established capacity for harm. Should we help persons with disabilities? Yes. That is the requirement of the fourth rule. Does the embryo meet the status of disabled persons? Although there are people who may argue that they do, in this thesis, it is held that since their personhood remains a contested matter, it is inconsistent to either ascribe personhood on the one hand, or to deny it on the other hand. It is sustained that they are living organisms of special status, and whom are deserving of respect. That respect is perhaps akin or similar to the help given to persons disabled in some way, but it is not directly proportional. It is therefore asked, what kind of help may an embryo require? Is it habitat? The virtue of an embryos being, and its continued existence is preceded by the placement and sustenance of the necessary conditions, that is conducive environment, for its inception and existence. There is no further help it requires with regard to habitation that it does not have already. The same argument can be advanced of nutritional requirement. Finally, the fifth rule requires moral agents to help persons in danger. What kind of danger would the embryo be exposed to? Being in danger is directly proportional to facing harm. Since it has be argued above that no potential harm can be projected towards the embryo, it necessarily ensues that there is no danger upon which they could be said to be in. There are those who argue that discontinuation of their existence is a dangerous thing for them. We argue that death is not a dangerous thing, for nobody knows exactly what lies beyond death. The problem with death lies in the process of dying. When the cause and process of death is painful and undignifying then, the dying subject, at the moment of dying experiences pain – danger or harm. However, when the death has happened, the deceased is no longer in pain and therefore unharmed, and in no danger. We further argue that the embryo, because of lack of sentience, rationale, and self-awareness, cannot experience harm – even in the process of their disintegration, or discontinuation – or whatever it is that leads to or is equivalent to their death. It has been argued that those who experience harm in the situation of death are the living persons associated with the dead person, and who are pained by the discontinuation of the being of such deceased subjects. Not much is known about the immediate and ultimate fate of the dead persons. As a matter of fact, at the point of death, their personhood is relinquished and they become objects – disposable, like any other object without use – immediate or future. This is true of the embryonic organisms as well. The process of their dying does not pain or harm them in any way, and when they are done dying, their fate is unknown, and really those who fret about their death do it for mostly psychological reason.

There is no other foreseeable reason. Such are the harmed persons – they could be donors or any other persons resistant to the ideas of embryos use in research. Curiously, such persons do not object to the fact of the inevitability of death, including their own. Death is sure to come – to persons and to embryos – ultimately.

In sum, advancing the idea of beneficence towards the embryo is unsustainable, philosophically. The starting point is in the contested matter of their status, and this reflects on every other discussion that eventually involves them and their treatment. On the barest minimum, this thesis advocates for their limited respectability on special grounds already stated. But since even this idea of limited respectability of the embryo is a contested matter, and since the operationalisation of Principlism requires that we not only make specification, but also seek a reflective equilibrium, this assessment finds that the defense of the status and consequent right of the embryo cannot be a normative rule. Therefore, we must consider other agents in this dialogue.

Beneficent Assessment of Embryo Donors

So, the next group of persons in the debate would be the donors. We ask, are donors competent human persons with moral status and rights that are worthy and deserving of defense and protection? Of course, yes. If so, then, with regard to the embryo debate, what right do they hold or reserve? First, the principle of respect for autonomy demands that they [donors] are thoroughly informed of all that the process and products and purpose of the hESC research entails. They cannot be coerced into donating embryos against their wills. The principle of nonmaleficence also protects them from unnecessary harm – physical or psychological. This principle prohibits the use of their biological parts against their will as this may lead to psychological torture. They benefit from protection of unfair treatment and psychological torture. Their right to knowledge and informed consent is protected and defended, and so is their right to not experience harm by virtue of psychological torture. This however, applies only to the use of embryos that they have donated, and not the use of all embryos available – even those donated by other subjects. So, here we conclude that the first rule of the principle of beneficence prohibits use of embryos in scientific research, or for any other purpose that they may not have authorised, and is therefore against the donor's will. It however, does not prohibit the use of other embryos simply because they object to it. Their right is directly and only tied to the embryos for which they are the biological parents.

The second rule regards the prevention of harm from occurring to others. If the donors have a right to determining the use of their donated biological substances then they correspondingly reserve the right of protection against harm. The kind of harm that is possibly experienced by the donors would be exposure to psychological or mental turmoil as a result of the use of their donated biological substances (embryos) against their will or in a manner they disapprove of or that which they deem immoral. For psychological or religious reasons, they may regard embryos as human persons or just objects deserving of protection. Violating their conscience on this matter and advancing the use of [their] embryos again their will is harmful and therefor morally perilous to them. It causes them psychological harm on the bare minimum, and this ought to be prevented. It must be emphasised that this argument is consistent to the extent that the subject of discussion is the particular embryos donated by the particular donors. Donor A cannot object to the use of embryos donated by donor B – whether donor B sanctioned their use or not.

The foregoing arguments regarding the protection and defense of the donors' rights to determine the use of their donated biological products as well as to prevent them from any related psychological harm therefore demands the fulfilment of the third rule, namely, that moral agents remove conditions that will cause such harm to the donors. The use of this rule in this context calls for further specification. Sometimes harm does not come to people, but rather people put themselves in harm's way. In everything that happens, there is a considerable percentage of individual responsibility, this cannot be advanced to other moral agents apart from the donor. However, those harms that may come on the way of the donor as a consequence of deliberate exposure by secondary moral agents must be expunged by all means possible. This means that if donors object to the use of their embryos, they must also provide means of their protection. They must not only specify how they would have these embryos protected, but also provide necessary resources to preserve them ad infinitum. This is bordering on an impossibility, for even if they can provide the specifications required, they cannot do this beyond their own death, which is sure to come. The question is do they object to use of the embryos in ways they disapprove for as long as they live or even beyond their deaths? And if beyond their deaths how does this cause them harm? If the protection is up to the time of the donor's death, what does it do to them knowing that at some point the embryos will be used in a way they disapprove, or that the embryos will die? Again, the argument can be made that even parents know that the children they sire will one day die – what they are committed to is to keep them alive to the extent that they can as parents. So again, with the embryos, their continued existence, as embryos or developed human persons will someday come to an end.

The requirement to remove conditions that may cause harm to a donor in relation to the destruction or unapproved use of their embryos can only be met temporarily. It is not possible to sustain *ad infinitum*.

The fourth and the fifth rules – the requirement to help persons with disability and to rescue persons in danger – do not apply to the donors. There is no known or perceived disability that donors may experience in relation to the use of embryos for scientific research since the principle of respect for autonomy and the principle of nonmaleficence already takes care of them in the sense that the embryos cannot be used without their expressed informed consent, and therefore not deliberate harm can be brought their way. In the same breath, they are in no known danger and therefore require no rescue whatsoever.

In sum, the principle of beneficence does not establish the sustainability of an absolute objection against the use of hESCs in research. It finds that it is morally unacceptable to use the embryos in a manner not consented or deemed undesirable by the donors, and that this is only in so far as the use of the particular embryos donated by the particular donors is concerned. Otherwise, the principle of beneficence, even in relation to the donors, does not object to the general use of embryos in scientific research.

Beneficent Assessment of the use of Embryos in Relation to Potential Beneficiaries of hESC Research Therapy

The third group that may advance the principle of beneficence is the potential beneficiaries of hESC research therapy. These are the person for whom the debate on the use of embryos for research is made sustainable. The Scientists have indicated that there are various ailments that are potentially curable by the employment of hESC in clinical use. There are quite a number of noncommunicable diseases which are said to be incurable by means of conventional medicine. As we have seen in chapters one and two, it is argued that the noncommunicable diseases have raised the intensity of the disease burden globally. Scientists, however reason that the global disease burden is not insurmountable if they are allowed to test the curative potential of the hESCs to their logical conclusion, devoid of the legal and moral prohibitions that is slowing down progress in the research. This is the situation that has motivated this study, and we seek to establish whether ESC research conducted for the benefit of other humans is a morally sustainable scientific adventure.

In order to critically assess the plausibility of the arguments that prohibit hESC research, the third agent will be considered. Again, as in the previous cases, the principle of positive beneficence, as specified by the *prima facie* rules of obligations will be considered. Therefore, this assessment begins with the first and the second rules, namely the requirement of moral agents to protect and defend the rights of others, and the requirement to prevent harm from happening to others. The principle of beneficence holds that "to benefit a fellow human being is fundamental to moral life" (Niekerk, 2017: 38). This obligates the moral agent to "always try to maximize the net aggregate of good and to minimize suffering" (Niekerk, 2017). Following this, it is observed that a patient, like all human persons, is an autonomous person with established moral status, and therefore whose right to life is worthy of protection and defense, and who should correspondingly, be protected from harm. Considering W.D. Ross' (1930) assertion, as recorded by B&C, that general beneficence "rests on the mere fact that there are other beings in the world whose conditions we can make better" (Childress, 2013: 21), a patient with a debilitating medical condition is owed an obligation of beneficence. A physician is a moral agent who by virtue of their training and position in society, is charged with the responsibility of saving lives. Therefore, a patient is entitled to medical care and treatment by the physician who is available and has the capacity to treat, and also has necessary equipment to facilitate the process. Further to the physician's obligation to provide medical and clinical services to a patient who not only expresses desire for treatment, but also seeks

that treatment, the physician is obligated to pursue the best possible and available method of treatment that would best meet the goals of such an individual. In this case, the treatment of a patient whose condition, is deemed only treatable by use of hESCs is morally entitled to that kind of procedure. The physician, who is competent in regenerative therapy has a moral obligation to support and pursue that medical strategy that would bring the desired results to the patient as long as the materials and equipment for use are available, including the use of hESC for therapy. The assessment also finds that the case of a patient's beneficence is also supported by the third, fourth and fifth rules, namely, the moral agents' requirement to remove all conditions that will cause harm to the patient, help persons (patients) with disabilities, and rescue persons in danger. The physician is obligated to remove diseases-causing conditions that are already causing harm (pain) to the patient. They should help the patients who are temporarily disabled by the disease. Finally, they are obligated to rescue the patients who are in danger of the incapacitating disease.

The assumption, is that the promised potential of the hESC in regenerative medicine is confirmed. However, we are aware that research on hESC is an ongoing activity whose final potential is yet confirmed. What this means is that studies that seek to provide ultimate cure to illnesses should then be sustained, at least for their beneficent potential. The question that ought to be asked is not whether researches on hESC researches are morally permissible but rather what guidelines allow for morally appropriate ways of undertaking the research. It is not a whether to proceed case, but rather how to proceed.

It may be argued, in contestation to the submissions above, that sometimes the requirement for the patient's beneficence is in contradiction to other moral subject's right of respect for autonomy, and or even nonmaleficence. This is an argument that may be advanced by those who generally feel wronged by the use of embryos for research, particularly based on religious and moral convictions. In response, it is noted that "the moral offence to those who accept the full humanity of the embryo should be balanced against the potential benefits for future sufferers" (Siegel, 1999; Meilaender, 2001; Guido Pennings, 2004). This is the requirement of Principlism as a framework for determining the best moral decisions when confronted with a dilemma of sorts. Thus, McGee and Caplan have argued that "people who believe that embryos are full moral persons should not be able to dictate the research agenda of the whole community" (McGee and Caplan, 1999). The idea is not to dismiss the fears and concerns of those in opposition but rather acknowledge and respect, even sympathise, with their alternative views and concerns while still holding to an ethic that is not swayed by just one group's subjective approach. A reflective equilibrium will be reached upon considerations

of the spefications of the various principle and upon weighing them, a point of consensus is reached. Note that, it is not argued that opposing hESC research is a morally wrong view, rather, it is argued that upon weighing of the matter at hand based on the principle of beneficence, there is stronger justification for embracing the use of embryos in research than for prohibiting their use. There is more potential future benefit for society if the research is carried to naught, than when it is left in limbo. Moreover, it is sustained that, there are embryos that have been created, particularly for in vitro, and whose donors have achieved their primary goal of fertility treatment, and whose future are in limbo. They may be used in future to treat other couples with infertility cases, or they may be discarded. It is these embryos that are destined for destruction by lieu of discardment that this study proposes their use in research. If anything, they get to be destroyed anyway. The way of research is a more dignifying and beneficent way, than the way of mere destruction. As B&C have observed, "if morality does not demand this much beneficence, it is difficult to see how morality imposes any positive obligations at all" (Childress, 2013). This thesis agrees with B&C that "even if competing obligation exists... requirements of beneficence will in some cases override it" (Childress, 2013).

In considering the beneficence accorded to the beneficiaries of hESC research, paternalistic attitude towards embryo donors opposed to their use for research is morally prohibited. It is noted that "the primary goal of clinical research is scientific understanding that can lead to sound clinical interventions" (Childress, 2013), and that such interventions are subject of compassionate overture. Though it is "compassionate and justified to provide some investigational products [such as embryonic stem cells for regenerative research] for therapeutic use, it is generally not obligatory to do so" (Childress, 2013). Embryo donors may or may not allow the use of their donated biological substances for clinical research. They are, in this case, not compelled to extend beneficence or altruism to stem cell lines and the potential research beneficiaries. We now turn to the Principle of justice.

Using the Principle of Justice to Assess the Morality of hESC Research in Transplantation and Regenerative Medicine

What is justice? Beauchamp and Childress' proposal is that "justice is interpreted as fair, equitable, appropriate treatment in light of what is due to or owed to persons" (Childress, 2013). As opposed to popular notions, "justice must be understood in more than just legal terms" (Kidha, 2012). Brian McLaren, while quoting Will and Lisa Samson, "submits that

justice is 'acting right in our relationships'" (McLaren, 2009; Kidha, 2012). According to this view, "justice is the right use of power while injustice is the abuse of power" (McLaren, 2009). In a Newspaper article in 2012, this author submitted that,

Certainly, justice happens when power and authority between people is exercised in conformity with universally agreed highest standard of moral excellence. As we pursue our own well-being, there is need to acknowledge others and pursue their well-being and dignity. This is not a constitutional or legal issue; it is attitudinal. It is an attitude that inspires a tendency to look kindly upon otherness (Kidha, 2012).

With regards, to bioethics, the concept of justice is closely tied to the idea of *distributive justice* – the notion that "fair, equitable, and appropriate distribution of benefits and burdens determined by norms that structure the terms of social cooperation" (B&C, 2013: 250). Moreover, it is conceived that "the scope of *distributive justice* "includes policies that allot diverse benefits and burdens such as property, resources, taxation, privileges, and opportunities" (B&C, 2013: 250).

In assessing the suitability or morality of hESC research through the lenses of the principle of justice, this thesis takes cognizance of the counsel of B&C who posit that with regards to applicability in clinical research, *distributive justice* transcend the idea that justice entails the consideration "of risks and burdens of research and the need to protect subjects from harm, abuse, and exploitation" (B&C, 2013: 250). It further agrees with the notion that the focus has shifted to the possible benefits of the clinical trials, while de-emphasizing their risks. Accordingly therefore, "justice as fair access to research—both participation in research and access to the results of research—became as important as protection from harm and exploitation" (Levine, 1996; B&C, 2008; B&C, 2013). Moreover, it is herein acknowledged that "no single moral principle is capable of addressing all problems of justice" (B&C, 2013). They have to be specified and balanced within their defined contexts.

The scope of this thesis does not allow for further explication of the idea of justice. It should however, be noted that there are, as B&C claims, six theories of justice that come into play in conversations regarding distributive justice. They are divided into two: *traditional theories*, and *recent theories*. Traditional theories include the *utilitarian*, *libertarian*, *communitarian* and *egalitarian* approaches, whereas the *recent* theories include *capabilities* and *well-being* theories. According to B&C, the mechanism of resource distribution will largely depend on the theory of justice a society subscribes to. This thesis observes that this is a major weakness of Principlism as a framework for moral determination. It does not present a cogent criterion for decision-making in matters regarding justice, as it presents a plethora of

theories to choose from. This takes away the general idea of Principlism as a framework approach for prompt decision-making. In addition, the presentation of many theories of justice takes away the general idea of universal applicability of moral theories. This criticism is not without the acknowledgement of the difficulty experienced in moral decision making in situations of life and death.

The moral determination of just distribution of resources in the ethics of hESC research is therefore confronted with a plethora of decision making criterion. In which case, each moral agent may claim a theory that promotes their particular interest. The thesis will briefly consider how each of the four traditional theories of justice would interact with the moral agents in the hESC scenario.

Considering the Utilitarian Theories of Justice

The first theory to consider is the *utilitarian* theory which as B&C notes, "emphasizes a mixture of criterion for the purpose of maximizing public utility. What this means is that when it comes to pursuit of justice, "we [must] seek to produce maximal balance of positive value over disvalue—or the least possible disvalue, if only undesirable results can be achieved" (Mill, 1969; B&C, 2013: 254). Typical difficulty with all utilitarian thoughts is the question of measuring utility. This difficulty with mastering and appropriating the utility calculus makes the theory an esoteric adventure reserved for a few. An ethical position that cannot be appropriated by the masses is difficult to apply. It is important to take this into consideration as we use the utilitarian principle to assess the justice element in the ethics of hESC research.

How does the idea of maximal balance of positive value relate to the [person] of the embryo in hESC research? The nudging question is whether is it just to use embryos for research. Given that this kind of embryonic use involves their destruction, the question asked therefore, is whether destroying the embryo does any justice to it. What obligations of justice are owed to the embryo? These questions are best settled in the concluded argument that the personhood of the embryo is in question and therefore, cannot be used as a criterion for determining decisions. Yet, justice and value cannot be owed to that which possesses unknown status. So then, even in weighing the other biomedical ethics principles as they relate to the use of the embryonic organism in research, it is difficult to question, for example whether justice is done to their autonomy, for they have no established autonomy. Can it be said that justice is done to them with regards to the principle of nonmaleficence? Again, it has been argued that no harm can be extended to that which has no sentience, rationale, and capacity for self-

awareness. What about beneficence? What obligation is owed to the embryo? There are no known obligations of respect for autonomy, nonmaleficence, or beneficence that ought to be met by moral agents, and which failure to meet constitutes injustice. Strictly speaking, the utilitarian calculus has no applicability in the justice debate regarding the embryo other than that which compels the obligations to preserve them (embryos) and obligations to advance medical research for the benefit of human preservation and advancement. At the end of the day, the enduring question is how do we measure and prioritize obligations to the embryo? Should the embryos be kept alive and stored until a use other than those that cause their destruction arises? "Which is more important: conducting stem cell research that might result in new medical cures or not destroying the potential life of human embryos involved in this research?" (Jerit, 2013: 667). The demand of justice pierces at the heart of the matter, namely "the protection of nascent life [vis-à-vis] the alleviation of pain and suffering" (Jerit, 2013).

Considering the Libertarian Theories of Justice

These are theories that typically 'recognize "just and natural rights" to liberty' (Locke, 1960; Childress, 2013). Unlike utilitarianism, "a libertarian interpretation of justice focuses not on public utility ... but on unfeterred operation of fair procedures and transactions under conditions of law and order" (B&C, 2013: 255). Robert Nozick, according to B&C, "argues for a theory of justice in which government action is justified if it protects citizens' liberty and property rights" (B&C, 2013; Nozick, 1974). Therefore, "justice consists in the operation of just procedures, [and] not in the production of just outcomes such as an equal distribution of health resources" (B&C, 2013: 255) . This system guarantees the property rights of investors in healthcare, liberty rights of physicians, and holds that society is not morally obligated to provide welfare. The obvious flaw of libertarianism is that its emphasis on transactionalism, thus making it distinctly individualistic. This further undermines the idea of relationships in community. Its advantage is that there is no boundary for how far one can rise in society. The more aggressive and enterprising a person is the more their potential for accumulating material wealth. Wealth to be used at one's will and pleasure – another recipe for an unbalanced society. It is the kind of fabric an unjust society is made of, as it forms the building blocks for facilitating slavery.

This kind of justice theory gives way to the ultimate thinking of Thrasymachus (Plato, 1982) and Nietzsche which advocates for the position that might is right. It definitely puts the embryonic person at a position of disadvantage, for woe unto the one who has no strength or

capacity to protect themselves. The thinking of Nietzsche buttressed the resolve of Hitler and his Nazi experimentations on human persons. This theory does not obligate the physician to provide healthcare to those deserving, merely because it is the right thing to do, but rather the question the physician would ask is "what is in it for me?" A medical practitioner acting on such a frame of mind may not feel constrained to pay fidelity to processes. Yet, it is not merely that things are done that make such actions right, but also that due processes are followed in getting such right things done. The end does not necessarily justify the means, but that the end and the means must work in unison to bring out a desired good for all. Libertarian ethics cannot be used to successfully evaluate the morality of hESC research as it does not have a favourable view for community that is usable in a pluralistic context.

Considering the Egalitarian Theories of Justice

This is the theory that "all humans must be treated as equals because they are created as equals and have equal moral status" (B&C, 2013: 256). With respect to the application and usability of this theory in health policy and practice, B&C points at Norman Daniels'58 argument "that health care is special and that fair opportunity is central to any acceptable theory of justice" (B&C, 2013: 256). The theory recognizes positive societal obligations to reduce or eliminate barriers that prevent fair and equal opportunity, and obligations, that extend to programs or correct of compensate for disadvantages. The beauty of this theory is in the communal and relational outlook and pursuit. It takes cognizance of the essence of human existence – community, and promotes such just values that recognize, at the bare minimum, the fact of existence of humanity, and at best the distinct value of the species homo sapiens sapiens as found in their interactions within society. Humanity is indeed, in and of itself, an intrinsic good, and when well nurtured brings out the best in society. Compared to libertarian notions that border on greed and animalist survivalist tendencies, this theory aptly considers the fact of human existence, and their purpose as posited by Socrates in his campaign for the examined life. The implications for this view to hESC research applies as it does to national as well as international health policies. It protects the fundamental right to good health and thus obligates the physicians to do whatever is in their power to protect and prevent from harm, persons with debilitating medical conditions. hESC research potential is therefore recognized and supported for its future worth – its potential for preservation and advancement of human well-being – to society. The moral reservations of persons against hESC research are not

neglected. Because of the considered equality of persons, their concerns are registered and acknowledged as legitimate even if not ultimate. Ultimately, Principlism as a moral framework does not proclaim finality in decision making, rather it holds onto the principle of tentativeness. If one day, upon weighing and counter weighing of the values, the positions of such persons are found agreeable, then the Principlist will find no difficulties adjusting to the new knowledge. This, in and of itself, is a fruit of an egalitarian justifiable system of ethics.

Considering the Communitarian Theories of Justice

The final theory considered within the biomedical ethics principle of Justice is communitarianism. "Communitarianism is a social philosophy that, in contrast to theories that emphasize the centrality of the individual, emphasizes the importance of society in articulating the good" (Etzioni, 2015: 1). The communitarian system is pluralistic, broad, and encompasses a variety of conceptions of good as presented in diverse moral communities. The communities define the acceptable standards of morality. With regards to justice, the communitarian system resolutely condemns the concept of prioritization of individual rights over the common good. In biomedical ethics, some communitarians would argue that "members of a community should be willing to provide others [with] objects of lifesaving value when they can do so at no cost to themselves" (B&C, 2013: 258). Beauchamp and Childress notes Daniel Callahan's communitarian principle that "we should enact a public policy from a shared consensus about the good of society rather than the basis of individual rights" (Calahan, 1990; B&C, 2013: 258). It is held "that societies cannot be based on one normative principle, and that both individual rights and the common good are major sources of normativity, without either one being a priori privileged" (Etzioni, 2015: 1). This theory does well to consider the good for society in their pursuit for justice and ethical decision making. Communitarianism is also favourable to pluralistic societies where diverse views are largely considered when public policies are constructed. As opposed to the utilitarian theory, it is simple, straight forward, and is designed to guide moral decisions and actions in a contextually intelligent manner. The difficulty with communitarianism is that it avoids the question of normative standards. In the long run, there has to be an agreeable moral standard that guides all conduct in society.

With regards to its relationship with the hESC research, the theory encourages a continued deliberative "process of moral dialogue, which occurs when a group of people engage in a process of sorting the values that will guide their lives" (Etzioni, 2015). What this makes possible is the creation of a safe environment of weighing diverse moral persuasions

within a safe community context where the good of all moral agents is taken into consideration. Thus communitarianism's possible triumph in the hESC research is its acknowledgement of diversity and its encouragement of dialogue. The problem, however, is that it does not give the moral agents a framework for decision making, particularly in a context demanding of immediate directions. The need for continuation of the hESC research is immense, and dialoguing over its morality cannot go on *ad infinitum*. A moral theory of justice should be able to guide on the right way to go when it is called upon. Communitarianism, does not afford this since it would present as many views as are persons in the dialogue. It beats the logic of Principlism, which seeks to enable tentative moral decision making for the purpose of facilitating life, while moralist continue to play with ideas.

Conclusion

Stem cell research is not necessarily the problem per se, but rather the source of the stem cells for the research. This means that the controversy regarding hESC research is centred primarily around the question of personhood and consequent moral status of the embryo. It is however, apparent that the moral status controversy is not about to end soon. The standoff on the moral status will continue being an encumbrance to hESC research until such a time that a decision is made. This is not an acceptable position either. It is the view of this study that a solution be provided – one that recognizes the concerns of the embryo defenders but also acknowledges the need for continuation with research involving human embryos because of the immense therapeutic potential they hold for human lives. Somehow, the survival of the human species depends on a solution to the chronic disease menace, of which, hESC research is the most promising. Principlism as a framework for determination of the ethical implications of bioethical activities has shown that this equilibrium can be met. By weighing the moral dilemma against the four principles, the study shows that although the debate on the moral status is important, it found that the debate need not stymie the research whose results would be beneficial for society. The principles also find merits and demerits in the arguments fronted by both the deontologists and the utilitarians in the hESC research conversation. Acknowledging that no ethical theory is better than the other in resolving the impasse, through a Principlism assessment, this thesis suggests that the research should be allowed to continue but within a defined framework with clear guidelines on how the process should ensue. This way, a compromise is built upon which the concerns of those involved in the conversation are gradually addressed, even as the debate concerning the moral status and personhood of the embryo continues. Chapter five of this thesis is an analysis of the implications of the

Principlism assessment of the arguments against the hESC research, with recommendations and concluding remarks on the way forward for the research.

Chapter 5: Analysis of the Principlism Assessments, Recommendations and Concluding Remarks

This chapter will first summarize arguments in favour of pursuing hESC research in transplantation and regenerative medicine. It will then make an analysis on the matters arising from the Principlism assessment on the arguments against hESC research. Using the Principlism framework, the study will strive to establish the moral appropriateness of using HES Cells in Transplantation Medicine. The goal is to determine the benefits of the therapies afforded through hESC research. The first step in this chapter is to look at the arguments that support hESC research, before turning to the Principlism assessments. Finally, recommendations and guidelines on appropriate use of hESCs will be attempted.

The Major Arguments in Favour of hESC Research in Transplantation and Regenerative Medicine

1. Human Preservation and Advancement: Arguments for Therapeutic Potential

The medical and scientific benefits of hESC research are enormous. Stem cell research, in general, provides avenues of comprehending the "basic mechanisms of human development and differentiation, as well as the hope for new treatments for diseases such as diabetes, spinal cord injury, Parkinson's disease, and myocardial infarction" (Bernard Lo, 2009). Nortjé, citing Okarma, notes the unique ways that SC treatment works as compared to normal medicine:

The treatments that are foreseen on the basis of human embryonic stem cell research are expected to work in fundamentally different ways from normal drugs and to have a different effect on the body. Medicinal drugs are often successful because of their ability to alter aspects of a cell's metabolism. However, drugs cannot cause the growth of new, healthy cells that will actually replace damaged cells (Okarma, 2001:4; Nortje, 2007: 14)

The prevalence of noncommunicable disease burden has spiralled, globally, and it seems conventional medicine is not the solution, while on the other hand hESC research provides a promise, as we have seen in chapter one and two of this thesis. The fact that hESC research offers promise of cure and preservation of the human person is a compelling reason for pursuing research using embryonic biological parts.

2. The case of "doomed embryos"

There are three options regarding the fate of the spare embryo that remain after fertility treatment: they could be stored for future use by the individuals for whom the embryos were

created; they could be donated to other infertile couples; they could be donated for research; or they could be discarded. It can be argued that it is morally permissible to make scientific use of the embryos that have been elected for discardment, as long as permission for the scientific use has been obtained after the decision for discardment. Siegel (2018), quoting Curzer (2004) submits "that it is morally permissible to kill an individual who is about to be killed by someone else where the killing of that individual will help others" (Siegel, 2018). If anything, "the researchers who derive hESCs from embryos that were slated for destruction do not cause their death, [rather] the decision to discard the embryos causes their death; research just causes the manner of their death" (Green, 2002; Siegel, 2018) akin to the way the hangman is not morally liable for the execution of a convict on death row as he is just implementing a judicial decision, for which he has no control. These arguments derive from the presumption "that the decision to discard spare embryos prior to the decision to donate them to research entails that the donated embryos are doomed to destruction when researchers receive them" (Siegel, 2018).

3. Benefitting from Moral Wrongs

The impermissibility for destruction of human embryos does not necessarily prohibit all research with hESCs. Sometimes, moral wrongs may prove beneficial. In such instances, it may be considered morally acceptable to derive benefits from situations of such kinds. Citing Robertson (1988), Siegel makes the argument "there is nothing objectionable about transplant surgeons and patients benefiting from the organs of murder and drunken driving victims" (Robertson, 1988; Siegel, 2018). Moreover, "if there are conditions under which a researcher may use hESCs without being complicit in the destruction of embryos, then those who oppose the destruction of embryos could support research with hESCs under certain circumstances" (Siegel, 2018). Even as Curzer (2004) "argues that a researcher who benefits from the destruction of embryos need not sanction the act any more than the transplant surgeon who uses the organs of a murder or drunken driving victim sanctions the homicidal act" (Siegel, 2018). The obvious response to this argument is that the two cases are not analogous equivalents, and as Siegel admits, "there is a [striking] difference between the transplant case and the hESC research case" with regards to the moral wrongness of the latter, given that hESC research "systematically devalues a particular class of human beings", whereas organ transplantation "is largely socially accepted and legally permitted" (Siegel, 2018).

4. Morally Relevant Humans?

There are those who hold that morally relevant humans are those who exhibit certain characteristics such as self-awareness and language, and therefore the embryonic organism is not recognisable as a human with moral status. The reason is, they argue, "possessing such

characteristics is what makes life morally valuable and thus the destruction of human embryos is morally permissible" (Singer, 1982; Bortolotti L, 2005; Kerasidou, 2016;). This argument holds that the embryo is not a human person with a corresponding moral status. Those who hold this view, like Sandel, insist that the embryo cannot be accorded moral status by the virtue of their biological composition. Sandel argues that:

it is important to be clear about the embryo from which stem cells are extracted. It is not implanted and growing in a woman's uterus. It is not a fetus. It has no recognizable human features or form. It is, rather, a blastocyst, a cluster of 180 to 200 cells, growing in a petri dish, barely visible to the naked eye (Sandel, 2007:9).

This thesis has determined that the debate on the moral status is at the moment, indeterminable by the ethical theories or perspectives in use. It is much safer to hold that the embryo is human organism though not necessarily a human person, and that their threshold for respect is not necessarily commensurate to that of a human person. In any case, respect for persons does not imply that such persons cannot be "killed" as there are circumstances where the respectful thing to do to some persons is to assist them in dying – if that was their wish.

5. Human Embryonic Stem Cell Therapy is not a Mere Potentiality: There is Proven Success in Clinical Use

In spite of the arguments claiming the indeterminateness of the hESCs research – that the therapeutic value is pegged on mere potentialities – there are reports of ongoing clinical use of the technology. According to Watt and Driskell (2010), those who deride SCR on account of the uncertainty of future efficacy, given the potentiality arguments, stand corrected of such notions. There are accounts of "haemopoietic stem cell transplantations as the oldest therapy that is most widely used" (Perry and Linch, 1996; Austin et al, 2008). Moreover, "organ transplantations have depended on the understanding of immune rejection" (Watt and Driskell, 2010). There are other proven clinical therapies associated with Stem Cells, for example, the use of limbal Stem Cells in the restoration of visions in patients suffering from chemical destruction of the cornea as reported in various publications (De Luca et al, 2006; Aradi, 2019; Muchangi, 2019; Omollo, 2019). Some "clinical trials involving grafting of brain tissue from aborted foetuses into patients with Parkinson's disease and Huntington's disease" have also been conducted with considerable success (Dunnett et al 2001; Wright and Barker, 2007; Watts and Driskell, 2010).

Analysis of the Principlist Assessment Regarding use of hESC Research in Transplantation and Regenerative Therapy

As has been discussed, the most dividing issue with respect to hESC research is the question of personhood and moral status of the embryo, and consequent moral culpability or otherwise, of research on human embryos. On the one hand, there is the view that hESC research is a continued perpetuation of the egregious disrespect for personal autonomy, while on the other hand, lies the view the hESC research holds the key to a future nirvana of revolutionary transplantation and regenerative medicine. Its potential as a source of replacement tissues coveted for their ability to restore organ tissues of human persons suffering from debilitating medical condition is hailed as a beneficent imperative for the society at large. The two views have been debated for years and still there is no sign that the debate will soon be resolved.

Meanwhile, human society is confronted with the inescapable reality of a rising disease burden that is increasingly becoming incurable by traditional medicinal practice. Traditionally, medicinal drugs have worked by way of altering aspects of a cell's metabolism. What regenerative therapy, a potential cure effected by the unique properties of the pluripotent stem cells, offers is a replacement and repair of the debilitating tissues and organs. This is attributed to the stem cells capacity for self-renewal and differentiation into respective organ cells thereby effectively replacing the stubborn cells in the various organs.

This magical therapy is however, fraught with encumbrances in lieu of the ethical and legal obstacles generated by the nature the research. Yet such motivations on the morality of the research need not hinder progress on the scientific pursuit of a cure for most debilitating human diseases of our times. This study, confirms as many others, that the employment of the traditional theories of ethics in the determination of the morality of the research has played a considerably great role in fuelling the debate on hESC research, thereby grinding its progress almost to a halt. The divergent public opinion, on the two views – deontological, and utilitarianism – present an eternally conflicting worldview that has no potential for resolution. A different ethical framework is therefore necessary for approaching the dilemma on hESC research. This study, has, in this regard, employed the Principlist framework in determining the morality of the research. The central premise upon which the research centred was on the inevitability and indeterminacy of the personhood and consequent moral status of embryonic organism, which in turn stifles progress on the research. The debate has stifled progress of this

research by standing on the way of decision making as to whether continued use of human embryonic organisms should be permitted or not.

By shifting the debate from the personhood and moral status of the embryo to addressing concerns of the changing societal wellness status precipitated by the spiralling conditions of the noncommunicable disease burden across the globe, a need for consensus building is consequently established. It is confirmed and affirmed that there is urgent need to join hands together in fighting the diseases that are threatening to annihilate humanity. This study, confirms that hESC research shows the most promising potential to deal with this emerging threat.

Principlism, as a framework approach has been used to show that although the morality of the process is indeed in question, even indeterminable, its desired goal and possible achievements far outweigh the concerns of morality. In effect, Principlism does not settle the morality question, but rather locates it as a tentative inconvenience that is overridden by the tentative need for urgent solutions. In a sense, Principlism is a theory of tentativeness. It is a theory of moral tentativeness, as it allows persons of opposing worldviews to temporarily lay aside the intricate value issues so dear to them, in order to jointly confront a more compelling issue that threatens their existence. In this sense, Principlism is a theory of mutuality as its goal is to foster mutual co-existence of persons in society. The beauty of the Principlism approach is that it does not demand a moral conversion from the moral agents. Neither does it require the moral agents to denounce their philosophical leanings, although it encourages them to openmindedly engage opposing worldviews with freedom to convert should new and compelling information require that kind of response.

Principlism recognizes four principles upon which moral dilemmas can be approached: Respect for autonomy, nonmaleficence, beneficence, and justice. All these are used to determine the morality of the hESC research by considering the merits and demerits of supporting or violating each principle when specifications have been made to effect their application in the defined contexts. We now turn to how the principles of biomedical ethics deliberated on the matter of hESC research and its moral applicability.

The Principle of Respect for Autonomy

Personal autonomy is a universal human right declared by the united nations declaration of human rights and is supported by other relevant conventions. It is therefore agreed that everyone has a right to life. This author, however, holds that the right to life does not

correspondingly necessitate an obligation to live. It merely requires moral agents to respect another moral agents' desire – to live or otherwise. In other words, a moral agent X is not necessarily required to force upon another moral person Y a need to live if the moral person Y, has clearly expressed a desire not to continue living. In the event of a debilitating illness that causes pain and anguish, if the moral agent Y directly expresses desire to discontinue living, then moral agent X has no moral authority to stand on the way of moral agent Y by insisting that the decision of Y is wrong. Of course, this argument is only relevant to established moral agents. It may not necessarily be applied to the embryonic organisms since their personhood is in question, and since they obviously do not show any traits or capacity for desirability of anything. Embryonic organisms have no known desires nor capacity for desire. It would therefore be a futile argument to insist on the respect for the embryo's right to life. However, this does not mean that moral agents make decisions on the continuation or discontinuation of the existence of embryonic organisms, in whatever the developmental stage they may be in. It is affirmed that the desires of the embryo are simply not knowable in the same sense that other moral persons are distinct and knowable. There are moral agents who may hold the view that all living organisms have an intrinsic desire for continued existence and preservation, and that such a desire, being true of all living organisms, is correspondingly true of embryos. This view affirms that embryos may or may not be human person, but that does not necessarily obviate respect of their existence. Their very virtue of existence, first as living organisms, and secondly, as living human organisms necessitates respect for their existence. This does not necessarily confer equal rights and obligations towards them but rather espouses a sort of graded obligation and a graded respect. What it means is that they do not necessarily have a right to life in the same way the UN declaration of human rights contends for human person, but that respect for their existence necessitates their continued existence, in their natural habitat, undisturbed, unless there is a compelling reason that may necessitate interference with the status quo. This argument is the same one extended to the preservation of forests and trees, and indeed, all forms of wildlife. Naturally, destruction of the environment is frowned upon. We know by empirical means, that environmental degradation inevitably leads to the lowering of the quality of life of human persons, and that preservation of the environment is a moral obligation in the best interest of the human person. However, there may be once in a while, unique, compelling situations and events that overrides the obligation to, for example, not to cut a tree, or not to kill a wild animal in its habitat. In this sense, it is consistent to argue that a moral agent may recognize and respect the principle of environmental preservation, and will and desire, and even make efforts to apply that principle in their daily lives. Yet that moral agent may

sometimes be under moral obligation to overlook that principle under very special circumstances. Sometimes, need may arise to cut a tree or to kill a lion that has escaped from the jungle and is killing domestic animals, as well as portending potential danger to the human persons in that community. It is understood that such actions may be undertaken, not as a norm, but as extraordinary circumstance, demanding necessary responses. This does not mean a forfeiture of the principle of respect for environmental preservation.

In the same breath, it can be argued that personhood of the embryonic organism or not, they deserve some degree of respect. A degree of respect, not corresponding to the same respect and worth accorded to mature human persons, but respect (graded respect), nonetheless. And that demonstrating respect, including the respect for their continued existence, does not obliterate the possibility of terminating or discontinuing their existence where that action (of terminating their existence) is in the interest of the moral agent or society at large. In other words, the principle for respect for autonomy applies to the embryonic person to the extent that their discontinued existence is not necessitated by an urgent and necessary event essential to human and societal need. It also means that the respect for the views of persons opposed to hESC research are respected, although not necessarily complied to. As we have seen, extraordinary circumstances may obligate moral agents to ignore other conditions which may be deemed necessary for other moral agents. Such decisions are come by through the process of weighing and balancing options and circumstances.

Such respect for autonomy extends to all other moral agents that are involved in the hESC research debate in one way or the other. The donors respect for autonomy can be achieved by acknowledging and ensuring that their informed consent or otherwise, is obtained before engaging in research using biological products donated by them. The same applies to patients who are beneficiaries of hESC research. They must give consent in order to be recipients of human body parts or tissues derived from other human organisms. No one should be compelled to receive treatment using biological substances donated by other humans against their wills. In the same breath, the physician who performs such therapies must not undertake the exercise under coercion. If a physician has a moral conscience that disagrees with the research, they must not be compelled to effect the therapy. Although, it is argued that sometimes other principles like nonmaleficence may override the applicability of this principle – just like other cases apply. One such case is where it is a life-saving exercise that can only be performed or undertaken by the physician, then it could be argued that he has a compelling duty to save human persons and society.

In conclusion, the principle of respect for autonomy is important and applicable in the hESC research debate and can be used to temporarily stymie any prohibitions against the research as the search for a better consensus continue. This is because such decisions are taken into consideration having weighed the immediate circumstance, and having considered their urgency and significance to human persons and society's best interest in the immediate. Such decisions are not held as normative absolutes but as tentative way forward, acutely aware that when new and better information is procured, the decisions are subject to change.

The Principle of Nonmaleficence

This principle demands that no harm is done to moral persons, unless it is absolutely inevitable. This principle, like all the others in this study, was found to be in need of specification. And What is specification? Beauchamp and Childress define specification as "a process of reducing the indeterminacy of abstract norms and generating rules with action-guiding content" (B&C, 2013: 17). Specification is very needful in appropriating this principle in hESC research context because of the nature of moral conflict the research generates. Thus, specification would help reduce the circumstances of conflict to a more manageable level. In general, the principle prohibits harming other moral agents. But the context of hESC research is ambiguous about the definition of the moral person against whom harm is prohibited. Moreover, it does not define the contexts upon which harm are correspondingly desired, or even obligated. This means that the principle of double effect is found inevitable.

Through specification, the moral agents for whom possible harm could be potentially met is narrowed down to the donors, researchers, and beneficiaries of hESC research. The question as to whether human embryos could be harmed is entertained, and the study concluded on the indeterminacy of the argument given the unknown moral status of the embryo. Therefore, this study pleaded partial and temporal agnosticism on the potential knowability of the personhood and status of the embryo, and its consequent designation as a person capable of harm. Drawing from the respect of authority arguments, it is determined that although it is not possible to establish whether or not human embryonic organisms could be harmed, there is merit in prohibiting arbitrary destruction of embryos. Special circumstances, could however, permit use of the embryos, which necessitates their destruction. But such special circumstances must be few and far between. It is proposed that this principle of nonmaleficence against the embryonic person must guard the research from falling into the slippery slope pathway. Other persons against whom harm is prohibited include the donors, the researchers and physicians,

as well as the beneficiaries of hESC research. It must not be intended that any person is arbitrarily forced on harm's way.

By what means could such agents be harmed? The nature of harm is determined according to each agent. Persons generally averse to hESC research may claim harm when their consciences beat them for condoning or not speaking against what they are convinced is a morally inappropriate behaviour. Such persons, however, are counselled to take solace in the fact that they are not perpetrators of the "morally inappropriate" events or procedure, whether directly or through complicity. You don't take responsibility for moral action of others when they perform actions that you find morally wrong, whether religiously motivated or for any other reason. Embryo donors are wronged and consequently harmed when the embryos they have donated for fertility purposes are used for research against their will. They are however supposed to know that the process of IVF produces surplus embryos which will inevitably need discardment, and that they may elect to either donate them for research or to other infertile persons needy fertility treatment, but that ultimately there would always be some surplus embryo subsequent to the process that would ultimately face destruction in one way or the other. They shouldn't therefore feel harmed by such destructions if in the event, such embryos are discarded or used in research. If anything, argues Guido Pennings and André Van Steirteghem, "'Nothing is lost' by destroying the embryos that had already been lost with the decision of the parents" The use of the embryos for research determines how the destruction occurs but not whether it will occur (Outka, 2002; Childress, 2002; Pennings & Van Steirteghem, 2004: 1063). It is akin to the thousands of gametes and oocytes that don't make it to implantation and are subsequently destroyed during the natural process of procreation, and persons normally do not mourn reproductive organisms destroyed in such natural circumstances. Finally, beneficiaries of hESC research are usually seen as the ultimate benefactors of the research. They are seldom perceived as persons against whom harm could be done, yet it is not far from true that they could be harmed if therapeutic procedures emanating from research of this kind are conducted upon them, procedures that they disapprove of. Obeying the principle of respect for autonomy is usually an insurance against violating the principle of nonmaleficence to such persons.

The Principle of Beneficence

The principle of beneficence is always stated positively and is conceived as the desirability to treat moral persons in ethically respectful manners, first by obeying the no harm

principle, and secondly – and by extension, correspondingly – extending good actions that ensure well-being towards them. In hESC research, the principle does no way extend to the embryonic organism whatsoever. There is no benefit the research extends to the embryos other than what the nonmaleficence principle prescribe – that is – avoiding destruction of embryos by all means where possible. The same argument corresponds to donors of embryos, apart from the very first event that necessitates the product of surplus embryos of whom this debate is a consequence of. The donors' fertility needs are granted beneficence if they succeed in their fertility quest. It is the process of such quests that put forth the question of just treatment of the surplus embryo arisings from the beneficent efforts of treating their infertility. There is hardly any conceivable beneficent action that can be extended to embryo donors which emanates from the hESC research. The primary beneficiaries of hESC research are the patients to whom regenerative therapy necessitated by the products of embryonic organisms are granted. The principle of beneficence extends the courtesy of sustained well-being and preservation of life to such patients whom debilitating disease would vanquish had there been no stem cell therapy upon which to latch. It is thus the argument of this thesis that stem cell researched is not only justified, but is also encouraged by the principle of beneficence. This principle, upon specification and balancing, provides the necessary ground for holding onto the doctrine of the utility over kantianism in the stem cell debate. The principle of beneficence [of the benefitting patients and society] overrides that of respect of autonomy and maleficence [of the embryo and donors] in hESC research. The "moral offence to those who accept the full humanity of the embryo should be balanced against the potential benefits for future sufferers" (Siegel, 1999; Meilaender, 2001).

The Principle of Justice

The principle of justice obligates the fair and just treatment of all moral persons at all times. In the context of hESC research, it asks the twin questions of who ought to receive the benefits of the research and who ought to bear the burdens? (Nortje, 2007). The principle of justice, in the context of this study would recommend that patients with debilitating medical conditions who need hESC therapy should not be prohibited from accessing such services. The idea that just and fair treatment ought to be extended to those who are owed extends to patients in need of hESC therapy as it does to the donors of embryos who are of necessity, producers of the embryos, as a result of a therapeutic intervention designed to cure their infertility. That donors are recipients of justice, they are best persons to extend acts of justice to other persons

in needs. Indeed, much is required from those whom much is given. Recipients of justice must be advocates of mercy.

Recommendations and Concluding Remarks

The debate on the ethics of hESC research represents a diversity of perspectives, which is normally expected in a pluralistic world such as ours. Although diverse perspectives are respectfully represented in the ongoing debate, it is also acknowledged that not all the perspectives are allowable or contemporaneously incorporable into policies and legislations that provide directions to society on the use of hESC research. A moral impasse need not ensue from the standoff necessitated by opposing moral views on the research. For all intent, and particularly for academic purposes, the debate is encouraged for the primary purpose of informing thought and direction. The debate need not, however, stymie progress on the research which has capacity to transform medical practice forever. This thesis establishes that the Principlism framework approach offers just the conducive environment for facilitating dialogue that allows free expression of divergent views while at the same time managing the process of research by playing the arbitrating role between opposing worldviews in a way that promotes research prioritization and continuity while at the same time managing the delicate moral concerns of the stakeholders with vested interest in the research. The idea of common morality as espoused in the principles of biomedical ethics is the facilitative even playfield upon which such an irenic dialogue is carried out. In acknowledgement and appreciation of the contribution of Principlism towards the management of the conversations on hESC research, this study makes a few recommendation on the way forward.

1. Acknowledging and Appropriating the Imperative for Mutuality

Mutual coexistence is a principle of beneficence that promotes the well-being and interests of all persons resident in a community. Both enthusiasts and objectionists of the HESC research practice agree, on the basis of common morality, that that the preservation and continued existence of mankind is a desirable and noble objective. Both recognize the debilitating effects of some diseases not currently treatable by conventional medicine. Both recognize the possibility of a therapeutic intervention that may bring hope to the sustainability of humanity, once again. This mutuality obligates persons of differing philosophical persuasions to join hands in mitigating against a common threat to their continued livelihood and existence. The perspective on mutuality is also a perspective on unity in adversity. When times get rough, mankind must join hands in confronting the global challenges that threaten

the very fabric of their existence. The global status of noncommunicable disease burden indicates that society is under threat of diseases such as cancer, and that fighting cancer must come out as a priority above pontificating over moral values and virtues. Put the other way, our moral persuasions stand supreme in public debate when they confront and address common challenges affecting society, whether or not persons affected think like us.

2. Advocate for Policies that Foster Human Preservation while Reducing Harm to Research Subjects

hESC research is mostly done for purposes. Given the crisis of human health explained in some of the preceding chapters, the goal should not be a sadistic intention to denature human embryonic organisms, rather, it is a desire to provide effective treatment options against debilitating medical conditions. Therefore, research should gradually focus on reduction of morally offensive practices such as destruction of embryos. The present inevitable use of embryos for research is recognised and accepted, although is sustained that it is seldom the ideal. There is hope that alternative approaches will yield to research that does not objectify persons, nor debilitate them. This calls for tolerance from both the hESC research enthusiasts and the objectionists. It is hoped that in due time, pluripotent cells would be procured without necessarily destroying embryonic organisms.

3. Embracing an Ethic of Moral Tentativeness and Multi-perspectivalism

Moral tentativeness is a learning ethic, and is typically conversational. It encourages a thorough thinking through issues and making appropriate decisions based on available information, acutely aware that the finite nature of humanity may not allow the moral agent to see all angles, all views and all possibilities all the times, and that in the event that some new information or "superior reasoning" [as Van Niekerk puts it] emerges, we should be willing to revise our position. In this sense, the ethic is also multi-perspectival as it encourages a thorough determination of, humanly speaking, knowable possibilities antecedent to moral decision making. Such an ethic allows for the possibility of tentative moral compromise. Moral compromise is possible when certain factors are in view: 1) factual uncertainty, 2) moral complexity, 3) the need for a relatively immediate decision or action, 4) the need to maintain a continuing cooperative relationship, and 5) a scarcity of resources (Zubin Master, 2012). A moral agent contemplating decisions on hESC research would benefit from multiple perspectives including those of an embryologist who would offer factual information on the scientific composition of the embryonic organism. They would be driven by a desire for social interest and justice, and would be cognizant of the tumultuous bioethical context.

Knowledge of the various contesting theories of ethics would also prove beneficial in discerning the moral complexity of the decisions to be made.

Conclusion

hESC research portends enormous benefits and potential for human preservation and enhancement. The goal of hESC research should be for the benefit of human and societal health and well-being and not mere sport or idle speculation. The promise of hESC research on the potential development and production of life-saving treatments, as well as efforts of reducing human suffering is rewarding attitude that ought to be prioritised. The Principlism framework approach for moral decision making establishes that the beneficent value of the research is mostly in the best interest of society and therefore most of the times, supersedes other concerns of moral status. While doing so, it recognises that in a pluralistic society, other members' concerns, however minute they may be deemed to be, are important and should be taken into consideration always. Thus, the study finds that the contention on the morality of the embryonic destruction is a fair concern, although it does not outweigh the primary concerns of the research - that is development of a therapy that will save lives and reduce suffering. It recognizes the several dimensions which allow a continuum of positions about research, and suggests that hESC research should continue but with a focus on reducing the reliance on human embryos. It is hoped that ultimately, science will find a therapy that is completely independent of use of the embryonic organisms. In the meantime, the freedom of scientific research and the obligation to relieve human suffering should guide the decisions on hESC research.

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