

**EXTRACORPOREAL MEMBRANE OXYGENATION (ECMO) THERAPY IN
INTENSIVE CARE UNITS (ICU) IN SOUTH AFRICAN STATE HOSPITALS:
A NORMATIVE STUDY.**

Name: Susan Murphy

Student Number: 9704409e

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

Date: 18 May 2020

I, Susan Murphy (Student number: 9704409e) am a student registered for the degree of Masters of Science in Medicine in Bioethics and Health Law in the academic year 2019.

I hereby declare the following:

- I am aware that plagiarism (the use of someone else's work without their permission and/or without acknowledging the original source) is wrong.
- I confirm that the work submitted for assessment for the above degree is my own unaided work except where I have explicitly indicated otherwise.
- I have followed the required conventions in referencing the thoughts and ideas of others.
- I understand that the University of the Witwatersrand may take disciplinary action against me if there is a belief that this is not my own unaided work or that I have failed to acknowledge the source of the ideas or words in my writing.
- I have included as an appendix a report from "Turnitin" software indicating the level of plagiarism in my research document.

Signature:

A handwritten signature in black ink, appearing to read 'smurphy', with a large, stylized flourish at the end.

Date: 18 May 2020

Abstract

Objective

Most discussions about the appropriateness of Extracorporeal Membrane Oxygenation therapy (ECMO) in state hospitals have been focused around healthcare economics and cost:benefit. To date, the bioethical considerations of this topic have not been comprehensively addressed. This research articulates the normative ethical considerations which need to be considered when making decisions about government funding of medical therapies in general, and costly life-sustaining therapies, such as ECMO, specifically, in a resource limited environment.

Methodology

This research report uses a normative/philosophical design to apply the ethical theories of Principlism, Responsive Communitarianism and Ubuntu (African Moral Theory) to the question of whether it is ethically justified to embark on ECMO therapy programmes in South African State Hospitals. The report outlines the healthcare challenges currently facing South Africa, and the state hospitals in particular. Within the context described, this research report argues and defends the position that it is not morally justifiable for Intensive Care Units in South African State Hospitals to be implementing ECMO programmes. Finally, responses to the commonly provided reasons in favour of implementing ECMO programmes in South Africa are addressed and rebuttals to these arguments given.

Conclusions

When applying the normative ethical theories of Principlism, Responsive Communitarianism, and Ubuntu (African Moral theory), it is not morally justifiable for South African State Hospitals to be implementing ECMO (Extracorporeal membrane oxygenation), given the current state of national healthcare services.

Acknowledgements

I would like to thank my supervisor, Dr Christopher Wareham for his guidance through the process of writing this research report.

I would also like to acknowledge the support of my Head of Department, Professor L.R Mathivha who allowed me the time and opportunity to embark on this endeavour.

Table of Contents

Introduction	1
 Chapter 1 Healthcare in South Africa at present	4
1.1 The State of Healthcare in South Africa.	
1.2 The State of Critical Care Services in South Africa.	
1.3 Critical Care services in Lower Middle-Income Countries.	
1.4 Components of ICU care in Lower Middle-Income Countries.	
1.5 How does ECMO differ from other organ support therapies currently provided in the ICU's of LMIC?	
1.6 The Perpetual Problem of Scarce Resources.	
 Chapter 2: The normative ethical theory of Principlism and ECMO in South Africa.....	9
2.1 Justice	
2.2 Beneficence	
2.3 Non-Maleficence	
2.4 Autonomy	
 Chapter 3: Responsive Communitarianism and ECMO in South Africa	25
3.1 Communitarianism	
3.2 Responsive Communitarianism and ECMO	
 Chapter 4: African Moral Theory (Ubuntu) and ECMO in South Africa.....	31
4.1 Community	
4.2 Interdependence	
4.3 Solidarity	
4.4 Dignity	
4.5 Social responsibility	
4.6 Community Consultation	
4.7 Prioritizing Dignity	
4.8 Maximising Communal Benefit	

Chapter 5: Addressing the arguments in favour of providing ECMO services in South Africa.....	37
5.1 The obligation to provide “Best care”	
5.2 The “Rule of Rescue”	
5.3 Non-provision of ECMO increases disparities among private and public healthcare users.	
 Conclusion.....	 43
References.....	45
Appendices.....	51

List of Abbreviations

ECMO – Extracorporeal Membrane Oxygenation

ICU – Intensive Care Unit

VA ECMO – Veno-arterial ECMO

VV ECMO – Veno-venous ECMO

ELSO – Extracorporeal Life Support Organisation

Introduction

ECMO (extracorporeal membrane oxygenation), is a life support therapy which uses an extracorporeal (i.e., outside the body) circuit to perform the function of artificial heart and lungs (Veno-Arterial ECMO) or artificial lungs alone (Veno-Venous ECMO) for those patients whose heart and lungs are not able to pump and oxygenate blood adequately by themselves. (1)

The number of centres internationally which offer ECMO has increased from 83 worldwide in 1990 to 391 centres in 2018. (2) One critical care review opines that ECMO has become a standard therapy in critical care, and as its usage increases worldwide, and further advances are made, that it will in future be adopted widely in middle and high-income countries. (3)

This phenomenal growth in both the academic interest in ECMO as well as its use as a therapeutic modality has filtered down to the South African community of critical care specialists too. There has been an increased local interest in implementing ECMO programmes and training of Intensivists (ICU specialists) in the skills needed to run such programmes successfully. (4)

Amongst members of the Critical Care Society of South Africa, there is, however, disagreement amongst practitioners whether it is appropriate or not to be implementing ECMO programmes in government hospitals. (1) It has been a source of debate as to where ECMO should fit into the offerings of critical care in South Africa.

Hospital managers usually make decisions about where to allocate financial resources and hospital budgeting and expenditure. These decisions are taken with consideration of the recommendation of the heads of clinical departments who oversee the running of their units. This devolving of decision-making was evident in the legal case of Soobramoney vs. Minister of Health (17), where criteria for access to a haemodialysis programme were drawn up based on the available resources of the public hospital involved.

To date, most of the discussion about the appropriateness of ECMO in South African State Hospitals has been focused on healthcare economics and cost vs. benefit. Accordingly, the primary ethical consideration which has been considered has been that of distributive justice. Additionally, the legal aspects of the provision of expensive life-sustaining therapies within the context of scarce resources, have been well-discussed. (17) There is a need for a more in-depth exploration of the other ethical issues concerning the implementation of ECMO in South African state hospitals.

In this report, I use a normative approach to articulate and defend the reasons why it is not ethical for Intensive Care Units in South African State Hospitals to be implementing ECMO programmes currently. Normative research, as it pertains to the field of bioethics, makes use of bioethical theories and the moral values which they advocate, and applies them to the research question being addressed.

Firstly in chapter one, I describe the current state of the South African Healthcare System, and summarise the current challenges it faces, including but not limited to shortages of financial resources.

In chapter two, I articulate the normative aspects to be considered when deciding which medical therapies to fund in general, using mainly the normative ethical theory of Principlism. Furthermore, I explain how the Principlism approach provides moral guidance for making decisions about the appropriateness of funding costly life-sustaining medical treatments within the context of a limited resource environment, in particular.

In chapters two to four, I apply a normative approach to evaluate whether it is ethical for South African government hospitals to be embarking on ECMO programmes within the context of our current healthcare system. My argumentative strategy focuses on the normative ethical theories of Principlism, as well as Responsive Communitarianism and Ubuntu (African Moral Theory). I show how each of these normative ethical theories supports the argument that it is not ethically justified to provide ECMO in public hospitals in South Africa.

Finally, in chapter five, I address the arguments which are commonly used to support the use of ECMO in state hospitals. I argue that the provision of ECMO is not essential for providing "best care" and that minimising the inequalities between public and private healthcare services would be best addressed through health programmes other than ECMO. Finally, I argue that there is no moral obligation to prioritise the sickest (Prioritarianism/"Rule of Rescue") when resources could be better used elsewhere.

1. Background: Healthcare in South Africa at present

In this chapter, I address the current state of healthcare services in South Africa, as well as the state of local critical care services. I explain the necessity of care services, even in lower-middle-income countries such as ours. Additionally, I outline the available guidance, which is useful to help make decisions about what kind of therapies should be provided as part of a critical care service within the context of scarce resources. This background is imperative because it allows for the vital context within which to assess whether a proposed medical therapy is ethically justified or not.

1.1 The State of Healthcare in South Africa.

The Health system in South Africa faces many unique challenges. Although economically, South Africa is defined as a lower-middle-income country, when it comes to assessing the health of its population, it is doing worse than many low-income countries. (5) 8.1% of the Gross Domestic Product (GDP) is spent on health, which exceeds the average of 3.96%, which is spent by all lower-middle-income countries. (6)

By 2015, South Africa had not achieved any of its target indicators of the 4th Millennium Development Goal to reduce child mortality, or the 5th-millennium development Goal (Improved maternal health) (7)

Considering the social determinants of health: Only 66.4% of the South African population have improved sanitation, and 16% of the population still have no access to electricity. In rural areas, almost 20% of the population's drinking water has not been filtered or treated. According to the WHO stats for SA (2018), there are 13.7 deaths per 10000, which are directly attributable to unsafe water, sanitation, and hygiene services. This number has increased from last year, and we do not appear to be on track to meet our 2030 Sustainable Development Goal (SDG) target in this area. (8)

State healthcare services mostly comprise infrastructure, which was initially built to serve the minority of South Africa's population. (5) Post-1994, the infrastructure has

not expanded in parallel to the expanding population growth, which has expanded to over 56 million individuals. (6) The socio-economic inequalities within our society mean that we have a unique health profile, unlike that found anywhere else in the world.

We have a burden of poverty-related illnesses such as malnutrition, communicable diseases, and high rates of maternal and child mortality and adolescent pregnancy. (5) Also, HIV is still a huge problem, with HIV prevalence amongst men and women aged 15-49 increasing, and HIV prevalence among pregnant women aged 15-24 remaining almost unchanged. (7) Life expectancy at birth has increased marginally from 57.6 years in 2001 to 61.2 years in 2015. (7)

Additionally, trauma, violence, and injuries make a significant contribution to early death and disability in our population. (5) Current estimations of homicides per 100000 are 33.1 (2016), and age-standardized deaths from injuries (road traffic, violence, self-harm, and accidents) are 80 per 100000 population (8)

Lifestyle-related disease and its related complications such as stroke, and ischemic heart disease, are also likely to become more prevalent if the current trends continue. There has been a steady increase in the number of adults older than 18 years who are overweight and with raised fasting blood glucose over the last five years, and almost 40% of adult females older than 40 years and 15% of adult males under the age of 40 are obese. 46.9% of adults older than 18 years do not get sufficient physical activity, and 35% of the population have raised cholesterol. (8)

1.2 The State of Critical Care Services in South Africa

When it comes to health services, there are 5, 6 hospital beds per 1000 people living in SA (2005 data), and 0.82 physicians per 1000, and 5.23 nurses per 1000 (2016 data) (8) With regards to Critical Care services in South Africa, an audit done in 2005 (9) found that there were 2022 ICU beds in the country. Of these beds, 57% of them are in the private health sector. Only 23% of government hospitals have intensive care/high care facilities, compared to 84% of private hospitals. In government hospitals, the bed: population rates range from 1:20000 in provinces such as Gauteng and the Western Cape, to 1:80000 in other provinces. (9) Comparatively, the USA has 34 beds per 100000 population over 20 years of age. (10)

1.3 Critical Care Services in Lower-Middle-Income Countries.

Critical care services are undoubtedly necessary for both low and middle-income countries. (11) They are essential wherever acute, life-threatening, reversible illnesses exist in a population. In the setting of acute trauma, severe infectious diseases such as pneumonia and malaria, endocrine emergencies such as DKA (Diabetic Ketoacidosis), surgical emergencies, and obstetrical emergencies, the provision of critical care services to these patients allows for recovery, generally with excellent outcomes. Indeed, the WHO mandates that any hospital which performs surgery and anaesthesia should have an Intensive care unit. (11) There are various grading systems to grade the different levels of care that may be provided by an Intensive care unit. In South Africa, Intensive care units are graded from Category 1, which is mostly high care, where patients require intensive monitoring without organ support, to Category 3, which is a tertiary ICU facility providing multidisciplinary intervention, ventilation, renal replacement therapy, and haemodynamic support. (12)

1.4 What components of ICU care should be available in such LMIC?

It is recommended that the components of each ICU be designed in accordance with local financial constraints, needs of the population it serves, and within the human resources which it has available. (11) Baker proposes that critical care services are essential in low and middle-income countries, and should be set up rationally, such that they "prioritize basic and cheap therapies and fit into a coordinated service that benefits all critically ill patients"(11)

1.5 How does ECMO differ from other organ support therapies currently provided in the ICUs of LMIC?

As explained in the introduction, ECMO (extracorporeal membrane oxygenation), is a life support machine which acts as an artificial heart and lungs (Veno-arterial ECMO) or just artificial lungs (Veno-Venous ECMO) for patients whose heart and lungs are not able to pump and oxygenate blood adequately by themselves. The kinds of patients who need ECMO are those for whom all other medical therapy has usually failed and without ECMO will usually not survive their illness. (1)

The current available medical literature demonstrates that the best clinical outcomes for patients put on ECMO occur in those units which have high volumes of patients placed on the therapy. Centres which do more than 30 cases per year have lower mortality rates compared to those who do less than 6 ECMO cases per year. (2) This is not surprising as it is a complex therapy that requires experienced providers and is human resource-heavy. It is not clear what all the factors are which contribute to good ECMO outcomes, and volumes alone are not the only important factor.

ECMO is a costly therapy to provide. (14) Not only is the equipment expensive (both the machine used, and the consumables required), but there are also other costs to consider. ECMO patients have long admission times to ICU, which adds to the cumulative cost. Also, an ECMO service has significant human resources requirements – patients sometimes requiring two nurses per ECMO patient, as well as a perfusionist present to oversee the therapy, and specialist surgeons available in the event of complications occurring. Placement of the ECMO cannula requires cardiothoracic surgeon and cardiac anaesthetic support. It also requires the skill of an Intensivist trained in the management of these patients.

While outcomes for ECMO patients have improved over the last decade, the average overall survival to discharge is 55 %. (13) Outcomes are better in neonatal and paediatric compared to adult pulmonary outcomes. (13)

1.6 The perpetual problem of scarce resources.

The problem of scarce resources within healthcare systems is not unique to LMIC. Even high-income countries, which have efficient national health insurance programmes, face the problem of scarce resources, and how to decide on the allocation of these scarce resources is a perpetual challenge.

The British courts, ruling in a case involving the NHS, made the point that "the reality is that resources can never be unlimited." (15) Even in the South African Constitution and the Bill of Rights, section 27 states that "everyone has the right to have access to health care services, including reproductive health care; sufficient food and water; social security..." (1) and section 27 (2) goes on to say that the state has to take "reasonable legislative and other measures, within its available resources, to achieve the progressive realization of these rights" (16)

In the case of *Soobramoney v Minister of Health (Kwa-Zulu Natal)* (17), the constitutional court judgement, in this case, emphasized this fact that the provision of healthcare services must be within available resources. The judgement in the case of Mr. Soobramoney and his request for haemodialysis stated that " Given this lack of resources, and the significant demands on them that have already been referred to, an unqualified obligation to meet these needs would not presently be capable of being fulfilled" Where resources are limited, it is inevitable that there will be a limit to what healthcare and medical therapy the government is able to provide to the population. Judge Sachs, in the *Soobramoney* case, noted that "the rationing of access to life-prolonging resources is regarded as integral to, rather than incompatible with, a human rights approach to healthcare."

The philosopher, Ronald Dworkin makes the valid point that "We should not treat healthcare as a bottomless pit to the detriment of other social goods" (18) State financial resources will never be sufficient fund all the healthcare therapies that every single person needs. The fixed financial allocation means that hard decisions need to be taken as to how the financial resources are allocated. The question of how these decisions should be made is a difficult one to answer. Rationing is necessary, but answering the question of how to do this and how to make decisions about what therapies to prioritise within our healthcare service is challenging. (19)

In summary, I have outlined the challenges facing the South African Healthcare System currently, as well as some of the particular challenges involved in providing critical care services within the context of the economic challenges facing Low and Middle-income countries. I have highlighted the perpetual problem of limited resources, which exist within all healthcare systems. This groundwork provides an essential foundation for the following chapters, which will use the normative theories of Principlism, Responsive Communitarianism, and Ubuntu to argue that it is unethical to provide the hyper-expensive life-sustaining therapy of ECMO in South African State Hospitals.

2. The normative ethical theory of Principlism and ECMO in South Africa

In this chapter, I outline the normative ethical theory of Principlism and its components of Justice, Beneficence, Non-Maleficence, and Autonomy. Each of these components are considered individually, as they apply to the moral implications of implementing ECMO programmes in South African government hospitals at present.

Principlism is a normative ethical theory that is commonly used for ethical decision-making in medical ethics. Beauchamp and Childress first described this approach to ethical decision-making. (20) It considers four principles in ethical decision making, namely, Beneficence, Non-Maleficence, Autonomy (respect for persons), and Justice. These four principles together are considered to be foundational elements of "common morality" and provide a framework for approaching bioethical challenges/dilemmas. Beauchamp and Childress emphasise that the four principles are, however, not complete, but merely provide direction and guidance for discussion and ethical decision making. (20)

Although Beauchamp and Childress emphasise that no one principle is more important than another, in practice, it does occur that there may be a conflict between different principles. In these instances, balancing of the various principles should occur, and usually, one or more principles emerge as dominant. (20)

I now consider each of the principles in Beauchamp and Childress's Principlism approach, as they apply to whether it is morally right to implement ECMO programmes in South African government hospitals at present.

2.1 Justice

The principle of Justice includes not only distributive justice, although in the context of healthcare ethics, this is often the most common aspect of justice that is discussed. Accordingly, in this report, I will focus predominantly on the discussion of distributive justice.

Aspects of rights based justice, such as the right to access to healthcare, and the right to dignity and bodily integrity are also important, as is legal justice.(16)

In the healthcare setting, distributive justice pertains to how health resources are allocated. Such resources should be distributed in an equitable and fair manner, such that all members of a community derive benefit from them. It concerns itself with not only the priorities identified by the healthcare service, but also how resources are allocated to meet these needs. A necessary component of distributive justice is that expensive therapies and certain health services may need to be rationed. (20)

In this section, I first outline the importance of ICU care as part of the package of primary health care, which should be available to all members of the South African population, as a fundamental human right. Secondly, I address the moral obligation incumbent on medical practitioners to utilize ICU resources in a way that does not disadvantage other users of this resource, but rather, generates maximum benefit for those who require such care. Thirdly, I discuss why, in the context of limited ICU resources, it is essential that such resources are rationed and managed fairly. Finally, I address the economic considerations concerning the costing of ECMO and its potential benefits.

Each person has the right to life and health. Additionally, section 9 of the Bill of Rights of the Constitution of the Republic of South Africa says that all people are equal and should enjoy equality of all rights and freedoms. (16) In the context of scarce medical resources, where it is factually impossible for every person to receive the healthcare that they may need, what does it mean to treat people like equals? Dworkin makes the argument that "the right to equal treatment is the right to an equal distribution of some opportunity or resource or burden." (37) (Page 227)

In attending to the health needs of the population of South Africa, ICU care should be part of a package of health care that is available to all. ICU care is defined as "the caring for patients with a high severity of illness which potentially threatens their life, bodily integrity or other vital functions, through a multidisciplinary health care team which responds to that threat in a well-organized and sustained manner and providing this care in a geographically defined location: the ICU" (12) (38)

ICU care tends to be highly valued by society collectively, as the survivors represent the success of modern technology

I agree with Dworkin and argue that in South Africa, each member of the population should have the opportunity to access ICU care when they require it. The difficulty is, as outlined in section one, that the current ICU resources do not meet the current need requirements and so rationing of the allocation of such ICU resources is necessary. Several individuals have proposed different strategies for how to make these decisions about the allocation of scarce resources and funding. Persad and Wertheimer argue that "there are no value-free medical criteria for allocation" (pg. 423) (38) and maintain that it is impossible to allocate resources based on clinical or scientific facts alone. (39) Ethical principles and values are needed to make decisions about resource allocation, in addition to clinical and scientific facts.

What is the fairest way of rationing ICU resources? Some, such as Kliemt, maintain that priority should be given to those who are the most severely ill, within any healthcare system. (40) He coined the term "Akutprinzip," which means that the higher the acute threat to life which a condition causes, the higher the priority in treating it within the public healthcare setting. (40)

Others agree with this sentiment. Nord proposes that urgent, life-saving therapies should deserve extra weight, because an unexpected premature death (as opposed to someone who knows they are dying), deprives that individual of achieving the plans and hopes and dreams which one had intended for one's life, and therefore deserves extra merit, regardless of how old the patient is or how good/bad their quality of life will be after being "rescued"(41)

The tricky part is, as Dan Brock puts it: "there seems no objective, principled basis for determining how much priority to give the sickest, that is, how much aggregate health benefits should be sacrificed to treat or give priority to the sickest. Instead, the most one can say is that most people and many theories of distributive justice have a concern both for maximizing overall benefit with scarce health resources and for helping the worst off or sickest, but there is great indeterminacy regarding the proper trade-off between these two concerns when they are in conflict."(42) (Page 10)

Locally, the Critical Care Society of South Africa has opted for a more pragmatic standpoint as the basis of their consensus document on ICU Triage. The document recommends that "Triage decisions in SA should be made on the basis of achieving the greatest medical benefit from the available ICU resources. Patients should be prioritized such that those with the greatest likelihood of incremental medical benefit from ICU admission are given priority for admission" (43) This concept of "incremental medical benefit" is intended to mean that it is not only the sickest but those who are both very sick as well as most likely to benefit from ICU care, who should be prioritized for ICU admission.

A utilitarian (consequentialist) argument would additionally, also favour the allocation of ICU resources in a manner which would accommodate the most considerable number of critically ill patients who need ICU care, as possible.

Many of the therapies provided in the context of the intensive care unit are expensive. ECMO is no different. It is challenging to summate the cost of ECMO comprehensively. (35) The full cost of ECMO needs to include not only the in-hospital costs but also the costs incurred pre-transfer to an ECMO centre, as well as the costs incurred for long-term follow-up, medical services, and neurodevelopmental therapy services which may occur. (44)

A systematic review of US and international in-hospital costs of ECMO demonstrated a wide variation of total in-hospital costing varying from USD 42554 to 537554 per patient. (44) The variation in cost occurs because of the heterogeneous type of conditions for which ECMO is utilized. Higher costs occurred for infants post repair of Congenital Diaphragmatic Hernia and with cardiac conditions and lower costs for respiratory conditions. This same systematic review demonstrated variability in the duration of ECMO treatment, with mean durations ranging between 5.1 and 11.4 days on ECMO therapy in US studies and a median of 9 (1-28) days in non-US studies. There was also variability in the distribution of total costs. In some centres, the costs of medical personnel contributed to the most considerable cost of the therapy (82% in one instance), and in other centres, the hospital stay was the most significant contributor to cost.

Wide variability in the distribution of cost for disposable items, medications, equipment, pathology and radiology, and surgery is evident. (42)

When considering the current costs of ECMO, it is essential to remember that many of the medical therapies which are commonplace in the ICU today, such as renal dialysis and mechanical ventilation, were very expensive too when they were first introduced. (35) Over the years, however, they have become more affordable as well as more effective, with better outcomes and better costing per life-year saved. The same may very well occur with ECMO – with it becoming more affordable in the future. Neonates and paediatric patients, additionally, because they have many years of life ahead of them if they survive ECMO, will demonstrate a lower cost per life-year saved, with an estimation in one study of 4190 USD per life-year saved. In other words, it may be more cost-effective to provide ECMO for this sub-group of patients. (35)

Fleck argues that when it comes to the cost of medical therapies, any decisions about medical distributive justice need sound medical facts to base them on. (24) In his paper, he gives the example of HIV positive patients who receive combination ARV therapy for the rest of their lives. While the expense of such therapy is about a third of the cost of that of expensive cancer drugs, these patients receive their medication for decades. In contrast, the chemotherapy drugs are usually for a much shorter period, albeit that they are 3x the cost. However, he rightly argues, life expectancy and the amount of socially productive life years generated needs also to be considered, as well as the chance of successful cure from such expensive cancer therapies. (24) The issue of expensive cancer therapy drugs needs to be considered within the broader context of other expensive life-prolonging therapies, all vying for a slice of the budget pie.

With this in mind, one could make a compelling argument for providing hyper-expensive therapies that provide significant benefit. The argument falls flat if the same therapy is hyper-expensive and provides minimal benefit.

In summary, when considering the ethical principle of Justice, I have argued that ICU care is an integral part of a comprehensive health care package and should be available to all those who need it.

When it comes to rationing the available ICU resources fairly, there is a moral obligation to try to help as many individuals who can benefit from critical care services as possible and to do so in a way that is also as economical as possible, maximizing the benefit obtained for the cost output. It is not ethical for institutions to initiate ECMO programmes when, at present, all those who need ICU care are currently not able to access that care, and when doing so will increase the demand for ICU care, without simultaneously providing the extra funding and capacity needed.

This argument by Peter Mack is worth keeping uppermost in our minds when considering distributive justice and the allocation of resources within the context of medical science and advancements.

Medicine is a costly science, but of greater concern to the health economist is that it is also a limitless art. Every medical advance created new needs that did not exist until the means of meeting them came into existence. Physicians are reputed to have an infinite capacity to do even more things and perform more expensive interventions for their patients so long as any of their patients' health needs remain unfulfilled. The traditional stance of the physician is that each patient is an isolated universe. When confronted with a situation in which his duty involves a competition for scarce medications or treatments, he would plead the patients cause by all methods, short of deceit. However, when the physician's decision involves more than just his patient or has some commitment to public health, other issues have to be considered. He then has to recognize that the unbridled advocacy of the patient may not square with what the economist perceives to be the most advantageous policy to society as a whole.(45) (page 63)

2.2 Autonomy

Autonomy means a person's ability to "self-rule." The first pre-requisite for autonomy, according to Beauchamp and Childress, is that there must be some intentionality on behalf of the individual in question. "Intentionality" is understood, in philosophical terms, to be a characteristic of all acts of consciousness, distinguishing them from 'physical' or 'natural' phenomena. (21)

Secondly, that individual must have an adequate understanding of what their decision entails, and finally, there must be no controlling factors, either externally or internally, which influence the decision being made. (20)

When considering autonomy, in the context of decision-making about medical therapies, it seems apparent that everyone should be able to make informed decisions about the care that they wish to receive. This respect for persons is the bedrock for the informed consent process. Accordingly, it would, therefore, follow that should individuals want to have access to ECMO as a medical therapy, and they consent to the procedure in an informed manner, having understood the risks involved and the potential benefits and complications, then they should receive it. However, this would be an over-simplification. Even in countries with abundant financial resources, patients do not receive therapy, which they wish to receive just because they want it. Best practice guidelines, evidence-based medicine, and treatment protocols exist in every medical specialty to outline which treatments are appropriate and beneficial, and the circumstances and prerequisites for their use.

Additionally, Beauchamp and Childress emphasise that "respect for autonomy has only prima facie standing, and competing moral considerations sometimes override this principle" (pg. 107). (20) Beauchamp and Childress highlight that autonomy should not be "excessively individualistic" to the degree that it fails to take into consideration the truth that individuals exist within a society and that one's individual choices and actions have an impact on society at large. (20) The implication is that while patients should be allowed to make informed choices about the treatments they receive, there are some circumstances where it is justifiable to limit the choices available. Specifically, if one's choices require funding for an expensive and scarce therapy within a healthcare system that is already underfunded, then it may be justified to deny that treatment.

This kind of limitation of an individual's autonomy, for the good of society as a whole, does currently occur in certain instances within healthcare. In the context of outbreaks and communicable diseases that pose a risk to the community, a patients' autonomy may be impaired through isolation until they are no longer infectious, even if they do not consent to such isolation.

In this instance, the limiting of an individual's autonomy is for the health of the society in general, protecting them from infection.

There are those, such as the bioethicist, Gillon, who maintain that "respect for autonomy should be 'first among equals' "in the Principlism approach. (22) (pg. 307) Moreover, this viewpoint is commonly supported, particularly in western societies, where the resolution of the conflict between different principles in a manner that autonomy over-rides the other principles. (23) However, the risk of allowing autonomy to dominate the other three principles carries the risk of turning Principlism into a rather individualistic approach, with the emphasis on "self," "self-rule" and "self-interest." This kind of approach is inevitably not going to meet the needs of the community at-large. Callahan argues that autonomy is not just about the right to make independent choices. There must also be some consideration of what the effects these decisions will have on the community at large. (24) Furthermore, he argues that "the first set of questions to be raised about any ethical problem should focus on its social meaning, implications, and context, even in those cases which seem to affect individuals only" (23) (pg. 287)

From what has been discussed about distributive justice in the first part of this chapter, and now the principle of autonomy/self-determination, it is clear that these two principles are inevitably going to conflict with one another, especially in the context of scarce resources. Fleck argues that it is not possible to get just outcomes with regards to distributive justice if each individual decides what they think is best for themselves. (24) Instead, it is necessary to have a "social agreement" to determine what is just and fair. He elaborates further that this "social agreement" requires the participation of members of the community /society to agree by deliberation and to use rational arguments. (24)

It may be possible to obtain some agreement between these two conflicting principles, by using John Rawls' "original position" The "original position" is part of John Rawls' social contract theory and it concerns itself primarily with social justice. (25) The idea is to imagine that one could be any person in a given society, hence the idea of a "veil of ignorance" – one could be from any socioeconomic status, race, cultural group, etc. It is then from this imagined position of impartiality that autonomous decisions that affect society as a whole are made.

The point of placing oneself in this position is to attempt to ensure that one's decisions, in addition to being autonomous, are also as fair and just as possible. When one imagines oneself in this position, the idea is to remember that one could be any member of society – therefore, it would be in one's best interest to ensure that any decisions being made are as fair, just and impartial as possible for all members of society, not only the wealthy and the privileged.

In summary, when considering the principle of Autonomy as it pertains to ethical decision making, it is clear that autonomy does not translate to one being able to choose to receive any medical therapy which one wishes to receive. Rational decision making is necessary, which includes adhering to best medical practice guidelines. Additionally, any decisions made about medical procedures that are funded by the government must have some consideration of social justice and what the effects of such decisions will be on the greater society. For these reasons, it may also be necessary to limit the autonomy of an individual, particularly within the context of scarce medical resources.

2.3 Beneficence

According to the principle of beneficence, common morality dictates that we have a positive obligation to "do good" to other human beings. The moral requirements of individuals extend beyond merely not causing harm to others (non-maleficence). Preventing harm to others, including removing potential harms and actively intervening to prevent harm, is also considered to be part of beneficence. (20) The medical profession has always maintained that its primary purpose has been to "do good" – right from the origins of the Hippocratic Oath. The Health Professions Council of South Africa states that "Health Care Practitioners should act in the best interest of patients even when the interests of the latter conflict with their self-interest" (26) Patient care, and doing what is in the best interest of one's patient are understood to be the primary responsibilities of medical practitioners. (26)

Concerning beneficence, the question which begs to be answered is whether or not healthcare practitioners have the same moral obligation to always demonstrate beneficence to their patients in the same way that they are obligated to always act with non-maleficence? (20)

Some philosophers, such as Bernard Gert, argue that non-maleficence is a definite moral obligation, and while beneficence is morally commendable, it is not obligatory. (28) In other words, it may be ethically acceptable to not always act in a way that provides benefit to individuals (or patients, in the context of medical practitioners), provided one has not actively caused harm by doing so. This concept is termed "impartial adherence." (20) What this means that unlike non-maleficence, which must be followed impartially, the principle of beneficence does not need always to be adhered to impartially at all times, and failing to adhere to it is neither legally prohibited nor grounds for legal punishment. (20)

Additionally, it needs to be clarified to whom medical practitioners are required to demonstrate beneficence. Is it only to the patient in their immediate care? Does it extend to both the patient in their immediate care as well as their future patients? Or is it perhaps to the patient in their immediate care, their future patients, as well as other patients using the healthcare services collectively? To consider beneficence as being a principle to be applied for the patient in one's immediate care only is possibly a rather narrow-minded application of the ethical principle. I argue that the principle of beneficence should apply to both current and future patients under the care of a medical practitioner, as well as to all potential healthcare users. I will address this further under the discussion of Responsive Communitarianism (Chapter 4) and Ubuntu (Chapter 5).

For now, however, I will consider beneficence as it pertains to the individual patient: Since ECMO is a life-saving therapeutic intervention for those who need it, it generally does provide benefit to these individuals. In most circumstances, not providing ECMO to these patients almost will almost always result in death. The reason for this is because, at present, there are no other alternative therapies available as a substitute, once a patient is at the point of requiring ECMO therapy. (3) ECMO is usually used in patients with a high risk of mortality where other modalities of conventional therapy have failed by working as a modified heart and lung machine. (3) Even with a mortality rate of around 45%, this is still better than certain death. (13)

However, ECMO alone is not a cure-all. Experts in the field of ECMO highlight that, as a therapeutic intervention, it should be viewed as a "bridging therapy."

In other words, it is a therapeutic modality that provides support to the body as a "bridge" to either recover from the disease process or, failing that, the transplant of a new, functioning organ. There is no rational argument that would justify it being used as a "bridge to nowhere." (29)(30) This point is a crucial consideration in the South African healthcare service, where there are currently no government hospitals where heart, lung, or heart/lung transplants are performed, and so there is no option of ECMO being a bridge to transplant.

Also, internationally, according to the Extra-Corporeal Life Support (ELSO) registry, between 2002 and 2012, 52% of Veno-Arterial (VA) ECMO runs were discontinued as a result of organ failure or a diagnosis incompatible with life. (13) In other words, worldwide, 52% of cases of VA ECMO runs end up, in essence, being "a bridge to nowhere." (30) This information is essential, as it is unlikely that local outcomes will be superior to these international outcomes where, for every 1 out of 2 VA ECMO cases, the therapy ends up being futile.

We can infer from these facts that there may, therefore, be a significant chance that ECMO, if performed in government hospitals, has a high possibility of indeed ending up being a "bridge to nowhere." This outcome would be undesirable, and significantly curtails potential benefit to such patients, thereby conflicting with the principle of Beneficence.

It is undeniable that the overall ECMO survival rates have steadily improved over the 47 years since the first patient was placed on ECMO. (31)(32) For the past 30 years, the Extracorporeal Life Support Organization (ELSO) has kept a registry of the outcomes of ECMO runs done worldwide, including information from 170 ECMO centres. The reports from this registry are publicly available. (13) The outcomes are significantly better for paediatric patients placed on ECMO (both respiratory and cardiac indications) than for their adult counterparts (predominantly respiratory). (13)

These continued improvements in outcomes are encouraging, and survival rates will likely continue to improve over the next decade. Undoubtedly, medical practitioners are advocates for the best interests of their patients, and so ECMO is very appealing as a therapy for the most desperate and dying.

Nancy Jecker, however, eloquently reminds us that "patient advocacy does not support 'doing everything'; rather, it justifies helping the patient." (33) (Page 71) When considering beneficence, it is not sufficient to consider that the therapy is life-saving. Consideration also needs to be given to the ability for an individual to enjoy and participate fully in that "saved life," and in this way, should provide benefit (beneficence) without causing further unbearable harm or suffering (non-maleficence). I will elaborate on this further in the next section.

In summary, I have shown that the principle of beneficence (doing good) means that physicians should always try to do good for the patients that they treat. However, the obligation for beneficence is not as strong as the obligation for non-maleficence. Additionally, the principle of beneficence as a moral requirement should not be applied narrowly: it should be applied as meaning to do good for all patients. Finally, the concept of beneficence should extend beyond mere survival, but rather, what is considered to be a "good outcome" needs to include consideration of the whole picture both whether patients can recover and be removed from the ECMO machine, as well as how the survivors experience their subsequent daily lives.

2.4 Non-maleficence

The principle of non-maleficence states that common morality requires us to "do no harm." This would include both refraining from causing harm, as well as engaging in any activity which could cause harm to a person. (20) According to Beauchamp and Childress, and as mentioned previously, "obligations of non-maleficence are usually more stringent than obligations of beneficence"(20) (page 151) It is considered morally wrong to harm others by causing suffering, incapacitating an individual, or impairing their enjoyment of the "goods of life" (20)

Several immediate complications may occur with ECMO therapy, which may result in patient morbidity or death. (34) These complications may occur as a result of the therapy itself, following the surgical procedures of cannulation and de-cannulation, the concomitant failure of other organ systems that may occur, as well as complications from the anticoagulation therapy which is required during the extracorporeal circulation of blood. (32)(3)(34) Complications occur more frequently with VA (veno-arterial) ECMO, than VV (venovenous) ECMO cannulation.

Most serious complications are bleeding, including cerebral haemorrhage, as well as cerebral ischaemia, which may result in considerable neurological morbidity.

(35)(31)(3)

Survival to hospital discharge is how the success of ECMO has been traditionally assessed to date. (32) However, a better indicator of success may be the measure of the quality of life that these survivors go on to achieve – including both functional, neurological, and psychological recovery. (32) There is a paucity of data looking at this in particular. At the moment, there is no consensus on what constitutes "good long-term outcome" for these patients. Additionally, there is no useful data on what the actual long-term outcome of these patients is after they make it to hospital discharge. (32)

In one cohort of paediatric patients who survived after ECMO, one-third of them had neurodevelopmental problems that required specialist intervention services. (31) Research on neonatal ECMO survivors using functional MRI of their brains demonstrates that there appears to be a degree of subtle brain injury to the hippocampus, as indicated by a loss of hippocampal volume, which occurs in these patients. This results in memory deficits and learning problems as they get older. Impairments in verbal memory as well as visuospatial memory appear to occur, as well as attention deficits, which manifest through school-going years and adolescence. (31)(32)

Other long-term complications may also occur in these patients. In another cohort, 32% of children had at least one sign of chronic kidney disease when followed up to 8 years of age, after ECMO survival. Decreased exercise tolerance may also be seen in these patients at school age. (31) (32)

These long-term needs of ECMO survivors need to be considered when deciding whether or not to implement ECMO programmes in state hospitals. (32)(31) What kind of outcomes will be acceptable to the parents of these children, or the survivors themselves? When faced with the possibility of death, most would likely, at that point, accept the possibility of "life at any cost."

However, the neurological and other morbidities subsequently experienced by such survivors may result in them experiencing "unbearable lives," which would not be in keeping with the principle of non-maleficence and would be morally wrong. (32)

It is necessary to interrogate whether, after surviving ECMO, these patients (especially children) will have access to the kinds of long-term therapy, psychosocial support, and special schooling that they will need. In our current state schools and healthcare services, these kinds of needs are not well provided for or accommodated at present. To knowingly embark in the pursuit of a therapy where the necessary support and resources for survivors is lacking would conflict with the principle of non-maleficence.

Additionally, Nancy Jecker argues that "if the quality of outcome to be achieved falls well below a threshold considered minimal.....the claim that one is 'rescuing' the patient is dubious" (33) (page 71). Furthermore, she argues that in such instances, "a more honest telling might be: harming the patient, wasting resources, feeding false hope, disregarding professional standards, failing to show courage, being seduced by technology, neglecting to focus on palliative care, being co-opted by the family, refusing to acknowledge medicines limits, denying a patients impending death" (Page 71) (33)

Does non-intervention by medical rescue therapies for dying persons constitute maleficence? I argue that it does not. Not intervening is merely allowing the disease process to run its full course, naturally. We do not always need to "rescue" the dying. (36) It is possible to provide ongoing medical care while at the same time not providing ECMO to these patients. I argue that it adheres more to the ethical principle of non-maleficence to provide only supportive care, analgesia, and palliation to those who are facing life-threatening illnesses, for whom there is minimal chance of recovery without artificial heart/lung support. Additionally, this approach would also provide the least harm to the patient by limiting both their short and long-term suffering.

In summary, the principle of non-maleficence would support not introducing ECMO programmes into the state healthcare service at this present time, because the

healthcare service is inadequately resourced at present to firstly provide the heart/lung transplants which ECMO is often a bridge for, and secondly, to support the long term medical, psychological, educational and therapeutic needs of survivors. For those patients for whom ECMO therapy is necessary, it would be appropriate to provide ongoing support and palliative care to alleviate suffering. It is not necessary to always "rescue the dying." Non-maleficence may advocate not doing so.

Conclusion: Principlism

In conclusion, using the normative ethical theory of Principlism to consider whether it is ethically acceptable to be implementing ECMO programmes in South African state hospitals, I have put forward the following arguments:

When considering justice and fairness, it is not ethical for state hospitals to initiate ECMO programmes when, at present, there are limited ICU resources, and the current demands for ICU care exceed the availability of services. Before such programmes can even be considered, there needs to be an increase in both the funding and the capacity of the state Intensive Care Units. Access to ICU care for those who need it is an essential medical service. Managers of these ICU services must ration such services in a manner that they can help both those patients who are the sickest, and who are likely to derive the greatest benefit from such a service. Additionally, they must do this in a way that maximizes the benefit obtained for the greatest number of individuals for any given cost output. In doing so, and considering 'beneficence' for critically ill patients, the considerations should not only be for the needs of the current patients in the ICU, but also for those future patients who will need to utilize the services. In this way, resources should be stewarded rationally and fairly. Implementing ECMO programmes in state hospitals in their current capacity will be expensive. It will also place increased demands on an already over-stretched service. This would mean that other, far more cost-effective treatments would not be provided to patients who are likely to derive more significant benefit from such treatments. For these reasons, it should not be implemented.

Patients who receive ECMO would almost certainly die without the therapy, and so providing it does provide benefit to these patients immediately. However, survival rates to hospital discharge are about 45%. (13)

In the South African context, for those whose lives are saved by ECMO, there is a genuine possibility of it ending up being "a bridge to nowhere," due to the absence of State transplant programmes which perform heart, lung or heart-lung transplants. Additionally, many short and long term complications accompany ECMO therapy, which has the potential to impair long term quality of life. (32) These chronic medical needs will place extra demand on the healthcare service, and the long term learning needs of paediatric ECMO survivors may not be adequately addressed in government schools. These complications cause ongoing suffering and harm and conflict with the ethical principle of non-maleficence.

Although autonomy implies that patients should be able to receive the medical treatment they choose, when the healthcare system is funded by the government entirely, then any funding decisions about expensive therapies such as ECMO must consider what the effect of funding such therapies will be, in terms of consequences for other users of the healthcare service. I argue that in the case of ECMO, individual autonomy should be limited so that funding can be channelled to health needs, which benefit a higher number of individuals in the community. I will progress this argument further under the next section, "Responsive Communitarianism."

3. Responsive Communitarianism and ECMO in South Africa

In this chapter, I argue that any decision-making about the allocation of medical resources cannot be considered separately from what may be deemed to be a community's collective social responsibility. Furthermore, when the issue considered is the relevance and need for funding an ECMO programme within the government-funded healthcare system, consideration must be given as to how such a decision will impact both the functioning of the existing healthcare service, as well as how its implementation will impact the society in general.

3.1 Communitarianism

Whitehouse makes the point that, in its original form, the field of bioethics concerned itself with society as a whole, including all the parts that make it up, as well as the environment in which we live and work (46). Over some time, however, somehow, this broad scope of bioethics has narrowed. The consequence is that bioethics has developed an almost myopic focus on autonomy and the best interests of the individual predominantly and occasionally at the expense of all else. Whitehouse emphasizes that "Bioethics as a profession needs to shift its gaze from principles such as autonomy and professional recognition to relationships in community, intuition and public and environmental health." (Page 30)(46)

Callahan explains how communitarianism views society by using the analogy of an ecosystem. (23) Within an ecosystem, the optimal wellbeing of that ecosystem relies on continued healthy interactions amongst plants and other plants, as well as plants and the environment that they live in and the animals, both small and large, which co-habit with them. Each plant needs a healthy and balanced ecosystem for it to remain alive, healthy, and flourish. Similarly, all human beings exist within communities, both small and large. Communities may comprise small nuclear families, large groups of related individuals, or even entire neighbourhoods. Communities may also include those who are unrelated but share a common interest such as religious groups, ethnic groups or those of similar sexual orientation. Most individuals will belong to more than one community, with smaller communities existing within more strong communities, which is referred to as nesting. (47) Within each community, there will be common ideas of what constitutes a "good life," and

these ideas may differ from community to community and even within the different communities which an individual finds themselves "nested" in. In this way, no person exists in isolation. Being in communities means the things which affect us on an individual level, will also have some effect on the community at large. Likewise, the decisions which we make as individuals do not exist in isolation and separate from the community which we inhabit, but they affect it too.

Communitarianism is community-centred. Etzioni distinguishes between two different types of communitarianism: 'authoritative communitarianism' and 'responsive communitarianism.'⁽⁴⁷⁾ Authoritative communitarianism is simplistically explained as being the polar opposite of an autonomy-centred approach. This approach focusses on prioritizing the community's best interests, often at the expense of individual desires or needs. Responsive communitarianism, however, of which Etzioni is a proponent, tends to be a more balanced communitarian stance. It recognizes both the autonomy of individuals, as well as the common good and needs of the community, without compromising the needs of either. The common good is defined as "those goods that serve the shared assets of a given community."

Responsive communitarianism advocates a more balanced, integrative approach. It recognizes that "autonomy can only be a part of the story about how we are to live together, how we are to make families and communities that support the growth of love, enduring loyalties, and compassion." (Page 33) ⁽⁴⁸⁾. In the responsive communitarian approach, one's individuality is not erased by belonging to a community. However, instead, the community helps an individual to grow and develop in a manner that the best interest of both individual and community dovetail together.

Griffiths and West speak of "choices that cannot be effectively made except at the level of the community." ⁽⁴⁹⁾(pg. 1098) To this effect, they have proposed a "balanced intervention ladder" explicitly about public health measures. ⁽⁴⁹⁾ As one moves along the ladder, there exists a continuity from measures which are autonomy-enhancing, such as public education programmes, to those which are autonomy diminishing, such as removing unhealthy foods or ingredients from shops.

Most of those measures, which are autonomy diminishing, are those that are of significance to public health, such as compulsory isolation of patients with infectious diseases. For those actions, which are autonomy diminishing to be acceptable, the resultant health benefits must be deemed sufficiently beneficial to both individuals and society, in order to justify the loss of personal autonomy

Therefore, it is apparent that responsive communitarianism acknowledges that individuals do not exist in isolation, but within entire communities. In this way, it is a more holistic approach. The general state of health and wellbeing of these communities has an impact on the health and wellbeing of each individual who exists within their community. This balanced approach, combining the best interests of both individuals and the community that they live in, with neither overriding the other, is appealing, because of its emphasis on social responsibility and other-centredness..

3.2 Responsive Communitarianism and ECMO

The responsive communitarian approach has merit, especially when contemplating expensive life-sustaining therapy such as ECMO. All patients who utilize the government healthcare service benefit from a service that is well-managed and in which resources- are utilized in a manner that provides benefit to all health users. All patients will benefit from a healthcare system in which finances and resources are well stewarded. Rationally, prioritising the "common good" is the right thing to do, even if it does not necessarily benefit oneself immediately. The reason for this is because the benefits to the community of health care system users will be impacted positively in the long term.

ECMO is a costly therapy, as outlined in the previous section. How should the decision about whether ECMO would be of benefit to the community at large be made? Health economists propose that cost-effectiveness is the most crucial consideration when deciding on which health priorities would produce the most significant benefit to society. Health economists make use of the QALY (quality-adjusted life year), and the CUA (cost-utility analysis) when assessing the merits of health treatments in this way. They refer to the concept of an "opportunity cost" of a health intervention.

The definition of the opportunity cost of investing in any given health intervention is "the health benefits that could have been achieved had the money been spent on the next best alternative intervention or healthcare programme" (50) (page 1551)

Taking the opinion of the health economists alone, then the value of ECMO can be assessed simply by assessing one or all of these cost-effectiveness indicators. (51)(52) However, cost, utility, and life years are not the only things that need consideration when assessing the value of medical therapy. There may be other issues of importance to consider, from a communitarian perspective, such as whether or not the proposed intervention has particular value because it targets groups which have suffered significant past health loss, or whether the intervention has potential to reduce inequalities which are associated with health, or whether the intervention has the potential to reduce later catastrophic health expenditure. (53)

Taking into account all the issues which are of importance to any given community is complex. In an attempt to simplify the issues of importance, it is helpful to consider the 6-step framework proposed by Nancy Kass. This framework was initially described as a tool to assist with decision-making when considering the implementation of new healthcare programmes. (54). It is also helpful to evaluate the potential value which any given healthcare programme or therapy may provide to communities and, in this way, links into the responsive communitarian approach.

The six-step framework consists of the following steps:

- What are the health goals for the programme (for the public)?
- How effective is the programme in reaching its goals?
- What are the known or potential burdens of the program?
- Can burdens be minimized? Are there alternative approaches?
- Is the program implemented fairly?
- How can the benefits and burdens of the program be fairly balanced?

Using this framework suggested by Nancy Kass, it is possible to apply these six questions to assist with deciding whether an ECMO programme should be implemented in government hospitals. (54)

Health Goals of Programme.

The health goals for the ECMO programme can be inferred from existing programmes elsewhere. (55) These would include: supporting the heart and lungs or lungs only of patients with reversible life-threatening conditions.

Potential burdens of programme

There are numerous potential burdens of the programme: the most significant being the financial cost of such therapy, which I have outlined in the previous section. The therapy is also human resource-intense – requiring specialized doctors, as well as ICU nurses and perfusionists, trained in overseeing the therapy. The incidence of concomitant morbidities is also significant, and patients on the programme may need other organ support, such as dialysis and mechanical ventilation. As previously mentioned, the length of stay in ICU and, therefore, bed occupancy may be a long duration.

Efficacy of programme

In terms of programme efficacy – as previously mentioned, best outcomes occur in centres which perform large numbers of ECMO runs (>30 per year) (2), which would mean that successful programmes would require high numbers of patients to get "good" outcomes. What constitutes "good outcomes" at present is an overall survival to discharge remains around 50%, which means that patients have a 1 in 2 chance of dying even with the ECMO therapy.

Can programme be implemented fairly?

Such programmes would only be able to be implemented in hospitals that have the required support services. Very few hospitals would be capable of supporting such a programme. Access to such therapy would only be available to those who can access these hospitals. Since the therapy is time-sensitive, some would not be able to access ECMO even if they need it and would potentially benefit from it.

It is clear that using this 6 step framework, an ECMO programme would not be justifiable when considering the needs of the community. Despite this, there is continued support for ECMO, even though mortality rates for this therapy are high. This is likely to be because these patients are the most desperately ill of all – the dying.

It is this severity and the sudden threat to life, which has resulted in ECMO receiving support as a health priority in developed nations. However, I would argue that it is not appropriate to allow the severity of the illness to skew health priority setting in this way – that those who are most ill have the medical interventions which they need prioritized, even when by comparison to other interventions which may be more productive, they underperform.

The field of medicine, Etzioni notes, tends to be "overwhelmingly non-communitarian in the sense that it rarely concerns itself with the common good" (47) (page 18). This is true. Medical practitioners tend to revel in progress within the field of medicine and place their focus on personal achievements and progress. This general attitude and approach drive the implementation of programmes like ECMO in lower-middle-income countries, which still need to achieve the goals of implementing essential health interventions.

It is not only medical practitioners who are to blame for pushing the agenda of novel and exciting (albeit expensive) therapies. In surveys of public opinion, non-medical people too, highly value those interventions which are life-saving for severely ill patients, even when they may not be cost-effective. (56)

In summary, responsive communitarianism advocates a rational decision-making process, as opposed to moral dialogue. Instead, when it comes to decisions about therapies that extend life or save a life, a "threat to life cannot be the sole condition of priority. Sometimes interventions with marginal benefits and extremely high costs should not be prioritized". (53) The collective effect of such expensive therapies on the community at large needs to be considered. The answers to Nancy Kass's six questions, as discussed above, demonstrate that the responsive communitarianism approach would not advocate the implementation of expensive therapeutic interventions, which are neither cost-effective nor fair (not all members of the community can access them). Instead, resources would be more appropriately distributed to health interventions that are accessible to a greater number of individuals within the community, and which results in better outcomes for the cost incurred.

4. African Moral Theory (Ubuntu) and ECMO in South Africa

Ubuntu presents us with an ethical perspective that is common to many African cultures and has much in common with responsive communitarianism. Just like responsive communitarianism, it too emphasizes the importance of the wellbeing of the entire community and the common good of all participants in society. (57) Ubuntu is a distinctly African moral theory, and even though it has much in common with responsive communitarianism, its distinct African origins, and the five pillars of which it comprises, make it essential to consider when engaging with ethical dilemmas in African communities. In particular, the emphasis on the dignity of each person is unique to Ubuntu.

The five pillars of Ubuntu, as proposed by Himonga, are community, interdependence, solidarity, dignity, and responsibility. (58) I will discuss each of these in turn, before explaining how they would likely influence decision-making about the appropriateness of ECMO in state healthcare institutions.

4.1 Community

Ubuntu emphasizes the importance of relationships and community. Additionally, the ethical theory recognizes that all human beings exist "nested" within multiple community groups – both large and small. These relationships and communities are not only meaningful because they are necessary for survival and meeting physical and emotional needs, but also because it is through these relationships that one becomes a complete person. Desmond Tutu explained Ubuntu as the idea that "a person is a person through other persons." (59) Elsewhere it is explained that being an individual must include being with others. Human relationships within the communities that people live and work in are considered to be the essential foundation of the Ubuntu philosophy.

4.2 Interdependence

The Ubuntu ethical theory emphasizes interdependence as opposed to the independence of individuals. Members of interdependent social communities tend to view the communities or groups which they are a part of as extensions of themselves. (60) Within these types of communities, there is an emphasis on social responsibility and common purpose.

Maintaining harmony amongst the members of the group is essential, as is showing mutual respect for one another and prioritizing the needs of the collective.

Cohesiveness and unity of the group, as well as a social duty, is emphasized and valued in these kinds of communities.

According to Ubuntu, the freedom of one individual is relative to the freedom of others within the community. In this way, one's autonomy is not cancelled because one belongs to a community, but instead, there exists a balance between individual autonomy and the wellbeing of the community. Accordingly, the priorities set within any community would be to attend to the needs of the community at large – those things that are both directly good for the members of the group, as well as those things which help them to lead better and healthier lives. Therefore, the priorities of health institutions and policies, according to Ubuntu, would be to focus on helping each individual to live full, healthy, dignified lives.

4.3 Solidarity

Solidarity is defined as "unity or agreement of feeling or action, especially among individuals with a common interest." (61) Social solidarity is the social bond that unifies human beings together in an association which they agree and consent to be a part of, and which is of importance and value to themselves. (62) Within these groups, there is a shared concept of what is perceived to be "common good," and there is an implicit understanding that each member of the group will act on behalf of the group as a whole, or each other, to achieve the recognized common good.

4.4 Dignity

Ubuntu particularly emphasizes the inherent dignity of each human being, and this dignity comes from the relationships within a given community. (63)

In *S v Makwanyane and Another* (CCT 3/94)(64), the Constitutional Court of South Africa ruled that capital punishment was incompatible with the constitution's affirmation of human rights. In this constitutional court judgement, reference was made to Ubuntu and, in particular, to the way that Ubuntu recognizes that each human being is entitled to dignity, respect and that each human life carries value. (64)

Similarly, each person within a given community must treat the other members of that community with dignity and respect, and recognize the value of human life.

4.5 Social Responsibility

The concept of social responsibility is the obligation in which members of a society or community have to act in a manner that produces benefits for the community at large. Each member of a community has some duty and responsibility to make sure that they contribute to the common good.

Therefore, with the understanding of how community, interdependence, solidarity, dignity, and responsibility underpin the normative ethical theory of Ubuntu, I argue that the priorities which Ubuntu would emphasise when considering the implementation of ECMO programmes would be first, community consultation, secondly ensuring that decisions taken do not undermine the dignity of patients within the healthcare system, thirdly, using resources rationally to maximise communal benefit, and finally, prioritizing those interventions which would maximise the health of the population. Such interventions would not be limited to healthcare alone but would include all aspects of what is required for people to live full and healthy lives.

4.6 Community consultation

Community consultation would be a priority to understand how communities view expensive life-sustaining therapies such as ECMO. This nature of community consultation and engagement is the first principle of the Batho Pele principles. (65) There is no published data about how South African citizens feel about the so-called "rule of rescue" – which is the use of medical resources to rescue the most ill patients. However, In the UK, the NICE citizen's council report about the viewpoints of ordinary citizens and the "Rule of Rescue" in the context of healthcare resource allocation is valuable to read. (56)

Most of the ordinary citizens on the NICE citizen's panel accepted the Rule of Rescue and agreed with the preference for saving the lives of those who were immediately at risk of dying, over saving many future lives through public health prevention programmes.

Most, however, agreed that the application of the "Rule of Rescue" should be within certain limitations and proposed factors for the NHS to consider when deciding when to apply the "Rule of Rescue."

The detailed viewpoints expressed by this group of lay individuals who contributed to the NICE citizens council report shows quite clearly that amongst such ordinary citizens there is a tension that exists between wishing to do what they feel is the right thing to do (rescue the most ill and desperate) and the desire for a utilitarian stewarding of available health resources (doing the most considerable amount of good for the highest number of healthcare users). The impression gained from the document is that ordinary citizens felt that while there should be some special attention to those who are the most ill and who need expensive therapies, at the same time, such therapies should be cost-effective, should not produce burdensome costs to the national healthcare system, and therefore to society at large, and there should be a significant improvement to the recipient's quality of life for the national healthcare service to consider funding them.

These suggestions are sensible and rational. If these suggestions are applied to ECMO in South African state hospitals, then this therapy should not be provided because, as previously argued, it does produce burdensome costs to the healthcare system, and therefore to society at large. Additionally, the survival outcomes are inadequate for such a costly therapy, and survivors may subsequently have a worse quality of life after the therapy.

4.7 Prioritizing Dignity

Qobo says, "People should be placed at the beginning, centre, and end" when it comes to making decisions. (Pg. 426) (66) Ubuntu mandates that all decisions about healthcare resource allocation should be mindful of the fact that all human beings have inherent worth and value and deserve personal treatment that is dignified and respectful. Human beings should not be treated as a means to an end in decision-making.

My interpretation of this is that Ubuntu would want every human to have access to the best medical care possible.

However, as I have already discussed in the first section of this manuscript, there are limitations to what can be provided, and this is a fact that cannot be ignored. So how does the Department of Health make the best decisions about public health policy, allocation of resources, and funding priorities within the framework of Ubuntu? I argue that indeed, this would mean that many of the more technologically advanced and expensive medical therapies cannot be implemented without first addressing those basic needs which are essential to the good health of a population - clean water, sanitation, access to uninterrupted supplies of chronic medication, eye care, nutrition, mental health services. That is not to say that these sorts of public health interventions should be the only priorities. Access to intensive care services and life-sustaining therapies is also necessary. However, it is not rational to have the latter without providing the former.

Treating patients with dignity also includes not causing unnecessary suffering – by prolonging life where there is little chance of a successful outcome, and denying them a dignified death. In the case of ECMO, instead of allowing patients to die with dignity and minimal suffering, these patients would instead be subjected to uncomfortable invasive procedures, be heavily sedated such that they are unaware of their surroundings, their bodies subjected to numerous procedures and artificial machines to possibly recover, but with no likelihood of organ transplant should they survive.

4.8 Maximising communal benefit

Recognizing that all the health needs for every person cannot be accommodated for, all the time and that there are limitations to what the government healthcare service can financially afford to provide, difficult decisions concerning what can be funded or not, need to be made. I argue that Ubuntu would prioritise funding for those therapies which maximise the benefit to the community's wellbeing and produce the most considerable number of healthy members of the population. With this in mind, rationally, it is not possible to justify implementing ECMO programmes which are very expensive, save very few, at a high cost, and with considerable morbidity. It would be more prudent to channel such funding to medical interventions, which are less costly, provide better outcomes, and help a higher number of individuals.

In summary, Ubuntu emphasises the dignity and worth of each human life – and accordingly, actions that potentially prolong life but do so at the expense of one's dignity or depriving others in the community of a dignified life, are not acceptable. Decisions taken should take into account the wishes of the community and should maximise the benefit to any given community. Accordingly, Ubuntu would not consider ECMO to be a priority for healthcare funding, where its funding ends up burdening the community without providing significant benefit to the quality of life of recipients.

5. Addressing the arguments in favour of providing ECMO in South Africa.

In the first three sections, I have outlined the current state of critical care services in South Africa, as well as argued the case for not implementing ECMO programmes in South African government hospitals, using the normative ethical theories of Principlism, Responsive Communitarianism, and Ubuntu. In this section, I will now address some of the arguments given in favour of providing ECMO services in South African State Hospitals. The three main arguments usually presented are first, that doctors working in ICU's have a moral obligation to provide the best care to patients, in line with international standards. One of the premises of this argument is that increasing the provision of ECMO may improve overall outcomes over time. Secondly, that the "rule of rescue" mandates helping the most ill patients. Finally, the argument that is not providing an ECMO service in state hospitals will increase the disparity of care, which currently exists between private and state-funded healthcare services.

5.1 The obligation to provide "best care."

This has been one of the more compelling arguments provided in support of ECMO in state hospitals and is also the reason why ECMO has gained such momentum within the critical care community over the last decade. (13) With the increased utilization of this therapy, more and more data and studies about ECMO and its outcomes are being published and presented at international congresses and in peer-reviewed journals. Additionally, the uses of ECMO have expanded significantly, to include things such as E-CPR which is ECMO that is placed during CPR for patients who have had cardiac arrests, as rescue therapy for the stopped heart. Stories from survivors appear in popular newspapers and magazine articles and are re-told at medical congresses, generating awe and wonder at modern technological advancements from laypeople and doctors alike.

It is therefore unsurprising that intensivists working in the ICU, being advocates for their patients, would want to have access to this kind of therapy – which can save the most desperate, dying individuals and gift them with life. Also, many of these intensivists would argue that there is an obligation to provide medical therapy, which is in line with the best clinical practices and international standards of care.

They argue that the government healthcare system can indeed afford such therapy if it were to manage the monetary resources efficiently allocated to them.

I agree with this argument in part – that intensivists do have an obligation to provide the best standards of care to their patients and that they should strive to provide patients with the highest standards of clinical practice, based on medical evidence. However, there is also a need to be rational and understand that there is a relationship that exists between the obligations of medical doctors and the means available to them to fulfil such obligations. Immanuel Kant reminds us of the ethical imperative that "ought implies can," and where there is no means or ability to do so, then we are not obligated to fulfil the "ought." (67) This means that if resources, financial or otherwise are limited to the degree that we are unable to fulfil our obligations to our patients, there are limitations to what we can provide. This is also the case where conflict exists between equally weighted obligations.

Additionally, as mentioned previously, the issue is much more complicated than ECMO being able to keep a person alive. It is necessary to be mindful of the cost incurred to both the patient and the community for a life saved – the morbidities which result from the therapy, and the ongoing medical and supportive requirements that these patients need.

The responsive communitarian approach reminds us that in any healthcare system, the wellbeing of that system should be the concern of everybody. Those physicians caring for patients in the ICU have obligations that extend beyond just the care of the patient in front of them. There are obligations upon all those within the healthcare system – both users as well as providers and administrators, to steward the resources in a manner that benefits the most considerable number of healthcare users as possible.

Healthcare administrators and the provincial and national governments also must not waste financial resources but to administer them in a manner where they are stretched to provide maximum benefit.

5.2 The "rule of rescue."

I have referred to the "rule of rescue" earlier in this report. The "rule of rescue" is a social value that mandates that we "must attempt to rescue an individual when that individual's death is imminent." (68) Jonson coined this term, and he elaborates in the following way:

We throw a rope to the drowning, rush into the burning buildings to snatch the entrapped, dispatch teams to search for the snowbound. This rescue morality spills over into medical care, where our ropes are artificial hearts, our rush is the mobile critical care unit, our teams the transplant services. The imperative to rescue is undoubtedly of great moral significance, but the imperative seems to grow into a compulsion, more instinctive than rational. (68) (Page 174)

Jonson goes on to argue further that the "Impulse to rescue is almost always well-intentioned; however, it is not always rationally or ethically defensible" (68) (page 174) I fully agree with this statement, and also, argue that there is no ethical obligation to follow the "rule of rescue." There is no moral directive to save the sickest when more benefit could be done for more people with the same resources. While it may be morally admirable and well-intentioned, as well as displaying the virtues of kindness to rescue desperate individuals, it is not rational. Hope says that those who would choose to rescue one individual over several demonstrate a 'callousness' and 'lack of imagination.'" (69) (Page 182)

There are some, such as Schone-Seifert, who argue that the rule of rescue may become acceptable in certain instances, for example, when the victim is identifiable, and there is a risk of acutely impending death, and the intervention has a reasonable chance of resulting in survival with excellent outcomes. (40)

According to the principle of justice, however, ethical decision making is required to be neutral. There should be no role for partiality. When considering the importance of the wellbeing of the entire community, as valued in the responsive communitarian and Ubuntu normative ethical theories, then justice is of great importance, especially when faced with making decisions that have ramifications for entire groups of individuals in the context of limited resources.

Cookson et al. argue that the state does not have an obligation to pay for any life-saving benefits and that not doing so does not violate their human rights in the same way that not providing them with access to essential healthcare services, for example, would be. He argues that "resource constraints are likely to prevent any Rule of Rescue from assuming the rigidly inviolable character of a human right, as it will never be possible to afford all technologically feasible medical rescues"(70)(Pg. 543)

Therefore, the "rule of rescue" is not absolute, and justice requires impartiality in decision making. So why do physicians feel the moral imperative to rescue so profoundly? Possibly because there are special obligations placed on doctors by society to do whatever they can to help their patients who are in need as a result of the special relationship and history that exists between them. However, this virtuous inclination to save patients should not allow irrational behaviour. (40)

The Department of Health, as the funder of the healthcare budget, has to serve the entire population. Furthermore, while 'care ethics' may say that doctors have a special relationship to their population, the same is not valid for national departments and policymakers.

Another reason why the "rule of rescue" is irrational is because death is a certainty faced by all people eventually – and for each person at the end of their lives, their deaths are "imminent." Therefore, "imminent death" is neither exceptional nor unique to be experienced by a few, but rather, something we will all face. (70) Hope reminds us that "no treatment is, strictly speaking, 'life-saving' since none of us is immortal. Treatments are at best 'death postponing'" and so to this effect, the rule of rescue should be rejected in determining the allocation of health resources."(69) (pg. 181)

Following on this, instead of the "rule of rescue," perhaps our thoughts should be reframed from "leaving someone to die" but instead to "not removing the risk of dying." When contemplating providing expensive life-sustaining therapies, the questions we should ask are not "what is the worth of human life?" but rather "what is the worth of preventing death?" (71)

Additionally, adhering to the rule of rescue would be discriminatory against those "statistical victims" who are faceless. Cookson argues that it is unfair to arbitrarily discriminate in favour of those who are facing immediate danger and are visible and easily identifiable and discriminating against those who are not known but who may need assistance in the future. (70)(71)

In summary, there is no moral imperative for physicians and healthcare policymakers to adhere to the "rule of rescue" when it conflicts with other ethical principles. Additionally, following the 'rule of rescue' is irrational as well as not in keeping with the ethical principle of justice and can even be argued to be unfair and discriminatory. Therefore as an argument in favour of providing ECMO therapy, it fails.

5.3 Non-provision of ECMO increases disparities amongst private and public healthcare users.

Another argument in favour of providing ECMO in state hospitals is that because ECMO is already available in private hospitals, not providing it to state patients will serve to increase further the disparities which exist between public healthcare users (more impoverished individuals) and private healthcare users (wealthier individuals) (20) Part of the vision and drive for the National Health Insurance Bill in South Africa is the desire to create a healthcare system that does reduce these inequalities and gives access to all South Africans, the healthcare services they need. Many would argue that this would mean that the same therapies, such as transplants, ECMO, expensive immunotherapy for cancer, should be provided to government healthcare users too. This is undoubtedly an admirable, albeit lofty aim. In its current proposal, the NHI Bill proposes a "Formulary" of therapies and treatments which will be provided, although no details are available as to what will be included in this formulary. (72) Universal health coverage will probably be limited in terms of what hyper-expensive therapies it will be able to provide to its citizens, including hyper-expensive therapies such as immunotherapy and second-line chemotherapy drugs. Medical schemes will likely continue to provide these more expensive complimentary services to those who can pay for them.

Within the healthcare system as it exists in its current format, however, I argue we cannot pretend that the disparities between the public and private healthcare sector are not already enormous and that the state budget is woefully inadequate to manage the current demands of the healthcare service as it is at present without adding in the additional expenses of these kinds of hyper-expensive therapies. That is not to say that the inequalities do not need redress; however, it would be more rational and prudent to recognize that the best approach would be to utilize resources to minimize these inequalities in the areas which are most likely to have the most significant impact on the health of the population as a whole, and on the highest number of healthcare users — to this effect, channelling resources into the management of chronic illnesses such as diabetes and hypertension, screening and early diagnosis of cervical and breast cancer, good antenatal care, better immunization coverage, and ensuring uninterrupted supplies of medications such as essential drugs, antibiotics, and antiretrovirals. Other public health initiatives such as reducing teenage pregnancy, improving the number of communities with safe drinking water and sanitation, and addressing prevention programmes for trauma such as burns, drownings, and road traffic accidents, are also important.

In summary, in this chapter, I have argued that while intensivists should aspire to provide the highest standards of care to their patients, a pragmatic approach requires recognition of the limitations in which medicine is practised in South Africa. Also, I have shown that there is no moral imperative to adhere to the "rule of rescue" when it conflicts with other ethical principles. Finally, I acknowledge the need for a redress of the inequalities which exist between the current private and public health services. However, I have argued that resources would be better allocated to public health initiatives, rather than in the implementation of ECMO programmes.

Conclusion

In conclusion, I have provided a summary of the current place, which ECMO occupies in the international critical care community, and how the interest in this therapeutic modality has been kindled amongst critical care physicians locally.

Additionally, I have outlined the current state of healthcare services in South Africa (this may change in the event of the NHI being implemented nationally). In particular, I have highlighted the burdens incumbent on the existing healthcare services. Whether or not the Department of Health is doing an excellent job of how it manages its financial resources is beyond the scope of this report. It is notable, however, that the Special Investigation Unit's report Proclamation R21 of 2010 published on 14 May 2010 and released on 29 March 2017 to the public, reported more than 1.2 billion Rands spent on irregular, fruitless, wasteful and unauthorised expenditure by the Gauteng Department of Health. (73)

Considering this current state of affairs, I would argue that even if one believes that NHI will be implemented nationally soon, ECMO should not be on the available offerings from the National Health Department. In the arena of critical care services, it is clear that the department of health needs to make progress in terms of expanding infrastructure available for critical care services, as well as producing more critical care trained nurses to support the anticipated expanded resources as priorities.

This position is supported by the normative ethical theories of Principlism, Responsive Communitarianism, and Ubuntu (African Moral Theory), as I have argued. ECMO is both a scarce and expensive, life-sustaining therapy. The government does not have a moral obligation to provide this expensive, life-sustaining therapy to all citizens, even if it is an effective therapy and is available to those who can pay for it in the private healthcare sector.

Finally, I would like to concede that while the current circumstances within the National Department of Health should not allow ECMO as a therapeutic offering, the idea of a public-private partnership with financial support from private business entities to fund such expensive services as ECMO, transplants, and other hyper-expensive therapies to the population at large, is appealing.

Should this route be pursued, then it is clear from the available literature that ECMO should be performed in the first instance at dedicated ECMO centres where there is a concentration of skills and expertise to ensure the best possible outcomes as well as the lowest cost. Also, explicit guidelines would need to be developed, restricting the therapy to those who are likely to have good outcomes, as suggested by Schone-Seifert, those with expected reasonable outcomes.

As things stand, however, the provision of ECMO is ethically unjustified in South African public hospital intensive care units at this point.

References:

1. Richards G, Joubert I. Extracorporeal membrane oxygenation (ECMO). SAJCC. 2013 Jul; 29(2):7-9.
2. Barbaro RP, Odetola FO, Kidwell KM, Paden ML, Bartlett RH, Davis MM, et al. Association of hospital-level volume of extracorporeal membrane oxygenation cases and mortality. Analysis of the extracorporeal life support organization registry. Am J Respir Crit Care Med. 2015 Apr 15; 191(8):894–901.
3. Butt W, MacLaren G. Extracorporeal membrane oxygenation 2016: an update. F1000Res. 2016 Apr 26; 750(5):1-6
4. Thomson D. Poster: Initial experience of extracorporeal membrane oxygenation service at a tertiary academic centre: A case series of 7 patients. SAJCC; 2017 Nov; 33(2): 70
5. Coovadia H, Jewkes R, Barron P, Sanders D, McIntyre D. The health and health system of South Africa: historical roots of current public health challenges. Lancet. 2009 Sep 5; 374(9692):817–34.
6. 2016 Statistics South Africa Report [Internet]. [cited 2019 Feb 24]. Available from: cs2016.statssa.gov.za
7. Statistics South Africa. Millenium Development Goals Country Report: South Africa 2015 [Internet]. 2015 [cited 2019 Feb 24]. Available from: www.statssa.gov.za/MDG/MDG_Country%20Report_Final30Sept2015.pdf
8. South Africa: Factsheet of Health Statistics 2018. World Health Organization; [Internet]. 2019 [cited 2019 Feb 24]. Available from: www.who.int/gho/countries/zaf/country_profiles/en/
9. Scribante J, Bhagwanjee S. National audit of critical care resources in South Africa - transfer of critically ill patients. South Afr Med J. 2007 Dec; 97(12):1323–6.
10. Wallace DJ, Angus DC, Seymour CW, Barnato AE, Kahn JM. Critical care bed growth in the United States. A comparison of regional and national trends. Am J Respir Crit Care Med. 2015 Feb 15; 191(4):410-416.
11. Baker T. Critical care in low-income countries. Trop Med Int Health. 2009 Feb;14(2):143–8.
12. Guidelines for Intensive Care in South Africa . SAJAA 2006 Jan (1):1-8
13. ECLS Registry Report [Internet]. 2019 Jan [cited 2019 Feb 22]. Available from: <https://elso.org/Registry/Statistics/InternationalSummary.aspx>

14. Crow S, Fischer AC, Schears RM. Extracorporeal Life Support: Utilization, Cost, Controversy, and Ethics of Trying to Save Lives. *Semin Cardiothorac Vasc Anesth*. 2009 Sep; 13(3):183–91.
15. Wright, Katharine. Funding pressures in the NHS: an ethical response. Nuffield Council of Bioethics; 2014 May.
16. Constitution of the Republic of South Africa. 1996.
17. Soobramoney v Minister of Health (Kwazulu-Natal) (CCT32/97) ZACC 17; 1998 (1)
18. Dworkin, R. *Sovereign Virtue: The Theory and Practice of Equality*. Harvard University Press; 2000.
19. Hunter D. Hyper-expensive treatments. Nuffield Council of Bioethics; 2011 May.
20. Beauchamp TL, Childress, JF. *Principles of Biomedical Ethics*. 7th Edition. Oxford University Press; 2013.
21. Siewert, Charles. Consciousness and Intentionality. In: *The Stanford Encyclopedia of Philosophy* [Internet]. Spring 2017 Edition. Available from: <https://plato.stanford.edu/archives/spr2017/entries/consciousness-intentionality/>.
22. Gillon R. Ethics needs principles--four can encompass the rest - and respect for autonomy should be "first among equals." *J Med Ethics*. 2003 Oct 1; 29(5):307–12.
23. Callahan D. Principlism and communitarianism. *J Med Ethics*. 2003 Oct 1; 29(5):287–91.
24. Fleck LM. Just Caring: Health Care Rationing, Terminal Illness, and the Medically Least Well off. *J Law Med Ethics*. 2011 May; 39(2):156–71.
25. Freeman, Samuel. Original Position. In: *The Stanford Encyclopedia of Philosophy* [Internet]. Summer 2019 Edition. Available from: <https://plato.stanford.edu/archives/sum2019/entries/original-position/>
26. *Guidelines for Good Practice in the Health Professions (Booklet 1)*. HPCSA; 2016.
27. Jecker NS. Integrating medical ethics with normative theory: Patient advocacy and social responsibility. *Theor Med*. 1990 Jun; 11(2):125–39.
28. Beauchamp, Tom. The Principle of Beneficence in Applied Ethics. In: *The Stanford Encyclopedia of Philosophy* [Internet]. Spring 2019. Available from: <https://plato.stanford.edu/archives/spr2019/entries/principles-beneficence/>

29. Pope TM. Medical Futility Blog: ECMO as a Bridge to Nowhere 2015. [Internet] [cited 2019 Nov 29]. Available from: www.bioethics.net/2015/06/ecmo-as-a-bridge-to-nowhere/
30. Mulaikal TA, Nakagawa S, Prager KM. Extracorporeal Membrane Oxygenation Bridge to No Recovery: Pushing the Limits of Patient and Family Autonomy: When Is Enough Enough? *Circulation*. 2019 Jan 22; 139(4):428–30.
31. IJsselstijn H, Hunfeld M, Schiller RM, Houmes RJ, Hoskote A, Tibboel D, et al. Improving Long-Term Outcomes After Extracorporeal Membrane Oxygenation: From Observational Follow-Up Programs Toward Risk Stratification. *Front Pediatr*. 2018 Jun 26; 6:177.
32. MacLaren G, Fortenberry J, Tibboel D, Laussen PC. Universal Follow-Up After Extracorporeal Membrane Oxygenation: Baby Steps Toward Establishing an International Standard of Care. *Pediatr Crit Care Med*. 2017 Nov; 18(11):1070–2.
33. Jecker NS. The Problem with Rescue Medicine. *J Med Philos*. 2013 Feb 1; 38(1):64–81.
34. Makdisi G, Wang I-W. Extra Corporeal Membrane Oxygenation (ECMO) review of a lifesaving technology. *J Thorac Dis*. 2015 Jul; 7(7):E166-176.
35. Crow S, Fischer AC, Schears RM. Extracorporeal Life Support: Utilization, Cost, Controversy, and Ethics of Trying to Save Lives. *Semin Cardiothorac Vasc Anesth*. 2009 Sep; 13(3):183–91.
36. Jox RJ, Schaider A, Marckmann G, Borasio GD. Medical futility at the end of life: the perspectives of intensive care and palliative care clinicians. *J Med Ethics*. 2012 Sep; 38(9):540–5.
37. Dworkin, R. Taking Rights Seriously. Universal Law Publishing Co Ltd; 2005.
38. Dünser MW, Baelani I, Ganbold L. A review and analysis of intensive care medicine in the least developed countries. *Crit Care Med*. 2006 Apr; 34(4):1234–42.
39. Persad G, Wertheimer A, Emanuel EJ. Principles for allocation of scarce medical interventions. *The Lancet*. 2009 Jan; 373(9661):423–31.
40. Schone-Seifert B. The "Rule of Rescue" in Medical Priority Setting: Ethical Plausibilities and Implausibilities. In: *Perspectives in Moral Science* [Internet]. 2009 [cited 2019 Nov 29]. Available from: <https://pdfs.semanticscholar.org/6481/83bd0c095363568e4368715240e9069537d6.pdf>

41. Nord E, Daniels N, Kamlet M. QALYs: some challenges. *Value Health J Int Soc Pharmacoeconomics Outcomes Res.* 2009 Mar; 12 Suppl 1:S10-15.
42. Brock, Dan W. Ethical Issues in the Use of Cost Effectiveness Analysis for the Prioritization of Health Care Resources [Internet]. Brown University; [cited 2019 Nov 29]. Available from:
<http://www.nyu.edu/gsas/dept/philo/courses/bioethics/Papers/EthicalIssues.PDF>
43. Joynt GM, Gopalan DP, Argent AA, Chetty S, Wise R, Lai VKW, et al. The Critical Care Society of Southern Africa Consensus Guideline on ICU Triage and Rationing (ConlCTri). *South Afr J Crit Care.* 2019 Aug 22; 35(1b):53.
44. Harvey MJ, Gaies MG, Prosser LA. US and International In-Hospital Costs of Extracorporeal Membrane Oxygenation: a Systematic Review. *Appl Health Econ Health Policy.* 2015 Aug; 13(4):341–57.
45. Mack, Peter. Utilitarian Ethics in Healthcare. *Int J Comput Internet Manag.* 2004; 12(3):63–72.
46. Whitehouse PJ. The Rebirth of Bioethics: Extending the Original Formulations of Van Rensselaer Potter. *Am J Bioeth.* 2003 Nov;3(4):26–31.
47. Etzioni A. Authoritarian versus responsive communitarian bioethics. *J Med Ethics.* 2011 Jan 1; 37(1):17–23.
48. Murray, Thomas H. Communities need more than autonomy. *Hastings Centre Report* (24)1994 p. 32–3.
49. Griffiths PE, West C. A balanced intervention ladder: promoting autonomy through public health action. *Public Health.* 2015 Aug; 129(8):1092–8.
50. Palmer S, Raftery J. Economics notes: Opportunity cost. *BMJ.* 1999 Jun 5; 318(7197):1551–2.
51. Marseille E, Kahn JG. Utilitarianism and the ethical foundations of cost-effectiveness analysis in resource allocation for global health. *Philos Ethics Humanit Med.* 2019 Dec; 14(1):5.
52. Understanding costs and cost-effectiveness in critical care: report from the second American Thoracic Society workshop on outcomes research. *Am J Respir Crit Care Med.* 2002 Feb 15; 165(4):540–50.
53. Norheim OF, Baltussen R, Johri M, Chisholm D, Nord E, Brock D, et al. Guidance on priority setting in health care (GPS-Health): the inclusion of equity criteria not captured by cost-effectiveness analysis. *Cost Eff Resour Alloc.* 2014; 12(1):18.

54. Kass NE. An ethics framework for public health. *Am J Public Health*. 2001 Nov; 91(11):1776–82.
55. Initiating an Adult and Paediatric Extracorporeal Membrane Oxygenation (ECMO) Program in a Developing Country: Challenges, Successes, Opportunities and Road Ahead. *J Cardiol Curr Res* 2016 Nov 25; 7(2).
56. NICE (National Institute for Health and Care Excellence) Citizens Council Report: What are the societal values that need to be considered when making decisions about the trade-offs between equity and efficiency? 2014 May. Citizens Council Reports No 17.
57. Metz T. Toward an African Moral Theory. *J Polit Philos*. 2007 Sep; 15(3):321–41.
58. Himonga C. The Right to Health in an African Cultural Context: The Role of Ubuntu in the Realization of the Right to Health with Special Reference to South Africa. *J Afr Law*. 2013 Oct; 57(2):165–95.
59. Tutu D. *No Future Without Forgiveness*. New York: Random House; 1999.
60. Costandius, Elmarie. Independent and Interdependent concepts of self: A meeting of worlds. *Acta Acad*. 41(2):158–79.
61. Cambridge English Dictionary. In. Available from: dictionary.cambridge.org/dictionary/english/
62. Rehg W. Solidarity and the Common Good: An Analytic Framework. *J Soc Philos*. 2007 Mar; 38(1):7–21.
63. Metz, T. Ubuntu as a moral theory and human rights in South Africa. *Afr Hum Rights Law J*. 2011; 11(2):532–59.
64. *S v Makwanyane and Another* (CCT3/94) 1995 (3)SA 391; (1996) [Internet]. Available from: saflii.org/za/cases/ZACC/1995/3.html
65. The Batho Pele Vision [Internet]. DPSA; [cited 2019 Dec 2]. Available from: dpsa.gov.za/documents/Abridged%20BP%20programme%20July2014.pdf
66. Qobo M, Nyathi N. Ubuntu, public policy ethics and tensions in South Africa's foreign policy. *South Afr J Int Aff*. 2016 Oct; 23(4):421–36.
67. McConnell, Terrance. Moral Dilemmas. In: *The Stanford Encyclopedia of Philosophy* [Internet]. (Fall 2018). Available from: plato.stanford.edu/cgi-bin/encyclopedia/archinfo.cgi?entry=moral-dilemmas
68. Jonsen AR. Bentham in a box: technology assessment and health care allocation. *Law Med Health Care Publ Am Soc Law Med*. 1986 Sep; 14(3–4):172–4.

69. Hope T. Rationing and life-saving treatments: should identifiable patients have higher priority? *J Med Ethics*. 2001 Jun; 27(3):179–85.
70. Cookson R, McCabe C, Tsuchiya A. Public healthcare resource allocation and the Rule of Rescue. *J Med Ethics*. 2008 Jul; 34(7):540–4.
71. Lübke W. Appeal to the Rule of Rescue in health care: discriminating and not benevolent? *Med Health Care Philos*. 2019 Mar; 22(1):53–8.
72. National Health Insurance Bill [Internet]. Jul 26, 2019. Available from: www.gov.za/sites/default/files/gcis_document/201908/natioinal-health-insurance-bill-b-11-2019.pdf
73. Investigation into certain affairs of the Gauteng Department of Health. Proclamation R21 of 2010. 14 May 2010. [Internet] [cited 27 Jan 2020] Available from: www.corruptionwatch.org.za/wp-content/uploads/2018/06/SIU-Report-on-Proclamation-R21-of-2010-02.pdf.

Appendix A: Turnitin report

Turnitin Originality Report Processed on: 28-Jan-2020 10:56 AM SAST ID: 1247604940 Word Count: 14622 Submitted: 1 a0004197:Final_Final.docx By Susan Murphy	
Similarity Index 5%	Similarity by Source Internet Sources: 2% Publications: 1% Student Papers: 3%

1% match (student papers from 15-May-2018) <u>Submitted to University of Witwatersrand on 2018-05-15</u>
< 1% match (student papers from 13-Nov-2019) <u>Submitted to University of Pretoria on 2019-11-13</u>
< 1% match (publications) <u>N. S. Jecker. "The Problem with Rescue Medicine", Journal of Medicine and Philosophy., 2012</u>
< 1% match (Internet from 16-Jan-2020) https://jme.bmj.com/content/medethics/34/7/540.full.pdf
< 1% match (student papers from 07-Nov-2013) <u>Submitted to University of KwaZulu-Natal on 2013-11-07</u>
< 1% match (Internet from 04-Nov-2011) http://www.stias.ac.za/projects/7_social_econ_justice/documents/abstracts/sandra_liebenberg.pdf
< 1% match (student papers from 30-May-2018) <u>Submitted to Zambia Centre for Accountancy Studies on 2018-05-30</u>
< 1% match (Internet from 30-Aug-2019) http://png-assets.s3-website-eu-west-1.amazonaws.com/doc/2012/121025ochealthbrrr.htm
< 1% match (student papers from 23-Jun-2016) <u>Submitted to University of Cape Town on 2016-06-23</u>
< 1% match (student papers from 08-Dec-2019) <u>Submitted to Seminole Community College on 2019-12-08</u>
< 1% match (student papers from 09-Dec-2018) <u>Submitted to University of Stellenbosch, South Africa on 2018-12-09</u>
< 1% match (student papers from 26-Oct-2006) <u>Submitted to University of Central Florida on 2006-10-26</u>
< 1% match (Internet from 29-Nov-2005) http://jme.bmjjournals.com/cgi/content/full/27/3/179
< 1% match (student papers from 16-Jul-2011) <u>Submitted to University of Bradford on 2011-07-16</u>
< 1% match (Internet from 21-Jul-2019) https://www.gov.za/sites/default/files/gcis_document/201409/4thesr0.pdf

Appendix B: Ethics Waiver

UNIVERSITY OF THE
WITWATERSRAND,
JOHANNESBURG



FACULTY OF
HEALTH SCIENCES

PROTOCOL ASSESSORS MEETING

Candidate Full Name: Susan Murphy

Student Number: 97044092 Date: 17.7.2019

School / Department / Division: Bioethics

1. Type of study (tick all that apply):

- ☐ Quantitative
- ☐ Qualitative
- ☐ Mixed Methods
- ☐ Laboratory
- ☐ Clinical
- ☐ Other, please specify

Normative study

2. Is title of the study appropriate (preferably fewer than 20 words)?

☒ Yes

☐ No

Comments: _____

3. Are the study objectives clear and linked to the research aim and title?

☒ Yes

☐ No

Comments: _____

4. Is the design of the study appropriate to meet the study objectives?

☒ Yes

☐ No

Comments: _____

11 March 2019/MP

5. Are the proposed methods and tools appropriate to meet the research objectives?

Yes

No

Comments:

Make sure detailed description of ECMO.

Make recommendation public private partnership

6. Is the study feasible within the resources of:

a) The applicant?

Yes

No

b) The department?

Yes

No

c) The time frame?

Yes

No

7. If this is a PhD protocol assessment:

a) Is the content original?

Yes

No

b) Does the content show the scope and depth of a PhD?

Yes

No

Comments:

Do you recommend:

i. Additional revision/amendment of the protocol? Please be specific on the recommendations being made:

ii. The appointment of the proposed Supervisor?

Yes

No

Nominee/s:

11 March 2019/MP

- iii. The appointment of the proposed Co-Supervisor/s and/or additional co-supervisors?

Yes	No
-----	----

Nominee/s: _____

- iv. Has the Chair of the Assessor Group signed the RECOMMENDATION FOR APPOINTMENT OF SUPERVISOR(S) OF RESEARCH REPORT, DISSERTATION OR THESIS form? Please attach.

Yes	No
-----	----

- v. Has the Chair informed the student and supervisor about the Wits ethics requirements, and that if required, they must have either a Wits Human Research Ethics clearance certificate or a Wits Animal Research Ethics clearance certificate?

Yes	No
-----	----

- vi. Based on the protocol provided (including any proposed changes by the protocol assessor group), does the student require:

1. Human Research Ethics clearance certificate
2. Animal Research Ethics clearance certificate
3. No human or animal ethics certificate is required
4. Unclear, will seek appropriate guidance from the HREC/AREC committees

Yes	No
Yes	No
Yes	No
Yes	No

- vii. Has the Postgraduate student and supervisor/s signed the ethics declaration form

Yes	No
-----	----

Overall recommendation regarding the protocol:

- i. Revision of the protocol to the satisfaction of the Supervisor (**NB: if HoD approval is also required, please specify**):
(**Candidate:** one copy, list of corrections with page numbers and Supervisor approval letter – submit to PG Office).
- ii. Revision of the protocol to the satisfaction of the Assessor Group/Chair:
(**Candidate:** one copy, list of corrections with page numbers, Supervisor approval letter – submit to PG Office and PG Office to forward to the Assessor Group Chair).
- iii. Revision of the protocol and resubmission of the revised protocol to the next Assessor Group Meeting:
(**Candidate:** six copies, list of corrections with page numbers, Supervisor approval letter – submit one copy to PG Office / 5 to school assessor group administrator / for PhD, all six copies to be submitted to the PG Office).
- iv. Candidate goes ahead (no revision required):

Yes	No
-----	----

Yes	No
-----	----

Yes	No
-----	----

Yes	No
-----	----

11 March 2019/MP

Details of Assessors:

Name:	Email:	Sign:
Denise Franssen	denise.franssen@wits.ac.za	D. Franssen
Jeanine Vellema	Jeanine.Vellema@wits.ac.za	J. Vellema

Details of Assessor Group Chair:

Name:	Email:	Sign:
Lize Maree	Lize.maree@wits.ac.za	L. Maree

Date: 17/7/2019

