

Extracorporeal membrane oxygenation therapy in intensive care units in South African state hospitals: A normative study

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The use of extracorporeal membrane oxygenation (ECMO) in critical care is gathering momentum internationally. There is interest in it being included within the offering of critical care services in South African (SA) state hospitals. Most discussions about ECMO's appropriateness in state hospitals have focused on healthcare economics and cost: benefit ratio. To date, the bioethical considerations of this topic have not been comprehensively addressed. The present research aims to articulate some of the normative ethical considerations when making decisions about government funding of medical therapies in general, and costly life-sustaining treatments such as ECMO specifically, within a resource-limited environment. We used a standard normative/philosophical design and applied the ethical theories of responsive communitarianism and *ubuntu* (African moral theory) to investigate whether it is morally justifiable for intensive care units in SA state hospitals to be implementing ECMO programmes at present. We concluded that both responsive communitarianism and *ubuntu* advocate that when considering expensive therapies that extend or save lives, such as ECMO, it is essential to consider the collective effect of such treatments on the community – the benefits as well as burdens. Accordingly, considering the National Department of Health's current state, it is ethically unjustified for ECMO to be included in the current critical care service in state hospitals at present.

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The field of medicine ... is overwhelmingly non-communitarian in the sense that it rarely concerns itself with the common good.
Amitai Etzioni^[1]

ECMO (extracorporeal membrane oxygenation) is a life-support therapy that 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 patients whose heart and lungs are not able to pump and oxygenate blood adequately by themselves.^[2]

The number of medical centres internationally that offer ECMO has increased from 83 worldwide in 1990 to 391 centres in 2018.^[3] 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, it will, in the future, be adopted widely in middle- and high-income countries.^[4]

This phenomenal growth in both the academic interest in ECMO and its use as a therapeutic modality has generated interest among the South African (SA) community of critical care specialists, with at least two state-funded hospitals in the Western Cape Province and three in Gauteng Province offering ECMO to specific groups of patients.^[2,5]

It remains debatable where ECMO should fit into the offerings of critical care in SA owing to the unique challenges that the health system faces.^[6] By 2015, SA had not achieved any of its target indicators on either the 4th millennium development goal (MDG) to reduce child mortality, or the 5th (improved maternal health).^[7]

Critical care services are arguably an essential component of healthcare services in any country.^[8] They are essential for acute, life-threatening, reversible illnesses in a population. The World Health Organization mandates that any hospital that performs surgery and anaesthesia should have an intensive care unit (ICU).^[8] Concerning critical care services in SA, there is a discrepancy in ICU bed availability between the private and state-funded healthcare services. A 2005 audit found that 57% of all ICU beds nationally were located in the private sector, and only 23% of government hospitals have intensive care/high care facilities, compared with 84% of private hospitals.^[9]

Methodology

A standard normative/philosophical approach was taken to address the question of whether or not it is ethical for ICUs in SA state hospitals, in their current state, to implement ECMO programmes. A PubMed search was performed for literature using the following MeSH headings: extracorporeal membrane oxygenation; cost-benefit analysis; clinical ethics; and healthcare quality, access and evaluation.

The normative ethical theories of responsive communitarianism and *ubuntu* (African moral theory) were chosen because they were deemed suitable for application to the ethical issue under discussion. Secondly, they were considered a good fit for the SA context in that they fit the moral thinking of a significant number of the stakeholders affected. Finally, they provide an alternative to the principlism approach, which is most commonly used by clinicians when considering ethical issues in medicine. A summary of these two normative ethical theories is provided in Table 1.^[1,10-14]

Table 1. Ubuntu v. responsive communitarianism

<i>Ubuntu/African moral theory</i> ^[12-14]	<i>Responsive communitarianism</i> ^[1,10,11]
<ul style="list-style-type: none"> • 'An action is right just insofar as it promotes shared identity among people grounded on goodwill; an act is wrong to the extent that it fails to do so and tends to encourage the opposites of division and ill-will' (Metz)^[12] • There is a global context to an individual's existence • Dignity, respect and human rights of all people prioritised • Interdependence between individuals and their communities recognised • Personhood is developed through communal relationships • Solidarity and responsibility towards members of the community • Maintaining community harmony is an important ethical mandate 	<ul style="list-style-type: none"> • Recognises individual autonomy as well as common good of the community without compromising either • Some choices can only be effectively made at the community level • Interventions that diminish autonomy may be justified if they provide significant benefit to the community • Social meaning and implications provide the primary context for ethical decision-making

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Discussion

Responsive communitarianism and ECMO

Considering all the issues of importance to any given community is complicated. To simplify them, it is helpful to consider the six-step framework proposed by Nancy Kass,^[15] namely:

- 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 programme?
- Can burdens be minimised? Are there alternative approaches?
- Is the programme implemented fairly?
- How can the benefits and burdens of the programme be fairly balanced?

Using this framework, it is possible to evaluate the benefit that a proposed programme, such as ECMO, would bring to a community. I explore in detail four of these questions below, and briefly address the other two in the concluding comments of this article.

The health goals for the ECMO programme can be inferred from existing programmes elsewhere, including supporting the heart and lungs or lungs only of patients with reversible life-threatening conditions.^[16]

Potential burdens

Like many of the therapies provided in ICUs, ECMO is expensive. The expense pertains to financial and human resource requirements, and to summate the cost of ECMO comprehensively is challenging.^[17] One systematic review demonstrated a wide variation in total in-hospital cost and variability in the cost of disposable items, equipment, pathology, radiology and surgery between different hospitals.^[18]

Life expectancy and the amount of socially productive life-years generated also must be considered, and the chances of successful cure from such expensive medical therapies.^[17,19] Health economists use the QALY (quality-adjusted life-year) and CUA (cost-utility analysis) to assess the merits of health treatments. However, it must be emphasised that QALYs have yet to be validated for use in critical care.^[20] A compelling argument could be made for providing expensive therapies that provide significant benefits, but it would fail if they are excessively expensive and provide minimal benefit.^[21]

Other issues of importance to consider, apart from cost and health economics, include whether or not the proposed intervention has

particular value, because it targets groups that have suffered significant past health loss, or whether it could reduce inequalities associated with health or reduce later catastrophic health expenditure.^[22]

The medical complications that may occur with ECMO therapy and patient morbidity or death are also essential to consider.^[23] These may be consequences of the treatment itself, surgical procedures involved, or other organ systems' concomitant failure.^[23,24] Serious complications include haemorrhage and ischaemia, which may result in considerable morbidity.

Survival to hospital discharge has been the traditional assessment of the success of ECMO. However, a better indicator of success may be measuring survivors' quality of life – including functional, neurological and psychological recovery.^[24] Useful data are not available on the long-term outcome of these patients after hospital discharge, nor consensus on what constitutes a 'good' long-term outcome.^[21]

In one cohort of paediatric patients who survived after ECMO, one-third of them had neurodevelopmental problems that required specialist intervention services.^[25] Research on neonatal ECMO survivors using functional magnetic resonance imaging of their brains demonstrates subtle brain injury to the hippocampus. This results in memory deficits, learning problems, impairments in verbal memory and attention deficits, which manifest through school-going years and adolescence.^[20,24] Other long-term complications may also occur in these patients, such as chronic kidney disease and decreased exercise tolerance.^[20,24]

These long-term needs of ECMO survivors must be considered when deciding whether or not to implement ECMO programmes in state hospitals. It is necessary to consider whether, after surviving ECMO, these patients (especially children) can access the needed long-term therapy, psychosocial support and special schooling within the government health and education services. Severe neurological morbidities may result in 'unbearable lives'.^[20]

Nancy Jecker reminds us 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.'^[26] Furthermore, 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.'^[26]

Efficacy

As ECMO is a life-saving therapeutic intervention for those who need it, it generally benefits these individuals. In most circumstances,

not providing ECMO to them will almost always result in death. At present, there are no alternative therapies available once a patient requires ECMO therapy.^[2] Even with a mortality rate of around 45%, this is still better than certain death.^[27]

ECMO outcomes have also improved over the last decade, although the average overall survival rate to discharge remains 55%.^[27] The best clinical outcomes for ECMO patients occur in units with high volumes of patients placed on the therapy (>30 per year).^[3] This is expected, as complex therapy requires experienced providers and is human-resource heavy.

However, ECMO experts highlight that as a therapeutic intervention, it is a bridging therapy, supporting the body temporarily to either recovery or, failing that, transplantation. No rational argument would justify it being used as a 'bridge to nowhere'.^[28,29] This point is a crucial consideration in SA, where there are currently no government hospitals where paediatric heart, lung or heart/lung transplants are performed. However, there is one centre in the Western Cape Province where they are performed for adults.

Internationally, according to the extracorporeal life support (ELSO) registry, between 2002 and 2012, 52% of veno-arterial (VA) ECMO runs were discontinued due to organ failure or a diagnosis incompatible with life.^[27] This means that worldwide, 52% of cases of VA ECMO end up being a 'bridge to nowhere'. As it is unlikely that local outcomes would be superior, there is a high possibility of ending up being a bridge to nowhere.

Can the programme be implemented fairly?

Such programmes could probably only be implemented in very few hospitals with the necessary support services, and would only be available to those who could access these hospitals. The time-sensitive nature of the therapy would mean that some potential patients would not access ECMO even if they needed it and could benefit from it.

State financial resources will never be sufficient to fund all the healthcare therapies that every person needs. A necessary component of distributive justice is that expensive therapies and certain health services may be rationed.^[30] We are reminded that 'we should not treat healthcare as a bottomless pit to the detriment of other social goods.'^[31]

The issue of scarce resources within healthcare systems is not unique to low- and middle-income countries. High-income countries, which have efficient national health insurance programmes, also face the problem of scarce resources, and deciding on their allocation is a perpetual challenge.^[32,33] Furthermore, would it be morally right for institutions to initiate ECMO programmes when, at present, all those who need ICU care cannot access that care, and when doing so will increase the demand for ICU care without simultaneously providing the extra funding and capacity required?

African moral theory (ubuntu) and ECMO in SA

Concerning *ubuntu*, 'people should be placed at the beginning, centre, and end' when making decisions.^[13] *Ubuntu* mandates that all healthcare resource allocation decisions should be mindful that all people have inherent worth and value, and deserve a personalised treatment that is dignified and respectful. Human beings should not be treated as a means to an end in decision-making. 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.

Following *ubuntu* principles, community consultation would be essential before deciding on implementing an ECMO programme in state hospitals. There are no published data on how South Africans feel about healthcare resource allocation. However, when UK citizens gave their viewpoints on the issue of healthcare resource allocation, a tension existed 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). They felt that while there should be some special attention to those who are the most ill and need expensive therapies, such therapies should also be cost-effective, and not produce burdensome costs to the national healthcare system and society. There should be a significant improvement to the recipient's quality of life for the national healthcare service to consider funding them.^[34]

Ubuntu leans toward prioritising health interventions that maximise communal wellbeing through the rational and responsible use of resources.^[13] Such interventions should not be limited to healthcare alone, but include all aspects of what is needed for individuals to live full and healthy lives. Therefore, it would not be rational to implement costly programmes that save very few, at a high cost and with considerable morbidity. All patients using the government healthcare service should benefit from a well-managed service in which resources are stewarded towards less costly interventions, provide good outcomes and help the greatest number of individuals.

Addressing counter arguments

There have been several compelling counter arguments to support the use of ECMO in state hospitals. As more literature about ECMO and patient outcomes becomes available, and its use as a therapeutic modality has escalated worldwide, SA intensivists, as patient advocates, argue that there is a duty incumbent on them to provide their patients with medical treatment that is in keeping with international standards of care. They further argue that the state healthcare system could afford these therapies if it were to manage the monetary resources allocated to them efficiently.

This argument is valid; however, the obligations of medical doctors need to be viewed in the context of the ability to fulfil them. 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'.^[35] In other words, 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.

The cost of ECMO includes not only the cost of the therapy itself, but those costs incurred by the patients and community afterwards, including consequent morbidities and ongoing medical needs. The responsive communitarian approach reminds us that in any healthcare system, the wellbeing of that system should concern everybody.^[1] As such, intensivists caring for patients in the ICU also have obligations that extend beyond the care of the patient in front of them.

The 'rule of rescue' is a term coined by Jonsen.^[36] It describes a social value that mandates that we 'must attempt to rescue an individual when that individual's death is imminent.'

According to the principle of justice, however, ethical decision-making must be neutral, and there is no role for partiality.^[30] *Ubuntu*

and responsive communitarianism place great importance on justice, especially when faced with making decisions that have ramifications for entire groups of individuals in the context of limited resources. There is no moral directive to save the sickest when more benefit could be done for more people with the same resources.

Additionally, the 'rule of rescue' is irrational because death is a certainty faced by all people eventually – and for each person at the end of their lives, their death is imminent. Therefore, imminent death is neither exceptional nor unique, to be experienced by a few, but rather, something we will all face.^[37] We are reminded 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.^[38]

Adhering to the rule of rescue is also discriminatory against those statistical victims who are faceless. Cookson^[37] argues that it is unfair to arbitrarily discriminate in favour of those facing immediate danger who are visible and easily identifiable, and discriminating against those who are not known but who may need assistance in the future.^[39]

It is also argued by some that because ECMO is available in private hospitals, the non-availability of it to state patients further increases the disparities that exist between public healthcare users (more impoverished individuals) and private healthcare users (wealthier individuals), and this is unjust.^[30] This is true. It is also true that the current state healthcare 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 inequities do not need redress; however, the best approach would be to utilise other financial resources to minimise these inequities in areas that are most likely to have the most significant impact on the health of the population as a whole, and the highest number of healthcare users. This would most likely involve directing financial resources to expand healthcare capacity and public health initiatives.

Conclusion

Both responsive communitarianism and *ubuntu* advocate that in 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 prioritised.^[22] The collective effect of such expensive therapies on the community at large – the benefits and the burdens – must be considered. Therefore, considering the current state of the National Department of Health, it is ethically unjustified for ECMO to be part of state hospitals' medical offerings.

However, a public-private partnership with financial support from private business entities to fund services such as ECMO, transplants and other hyper-expensive therapies to the population at large is appealing. Should this route be pursued, the literature clarifies that ECMO should be performed in the first instance at dedicated ECMO centres with a concentration of skills and expertise, to ensure the best outcomes and the lowest cost. Explicit guidelines must also be implemented, restricting the therapy to those likely to have the best outcomes.^[40]

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