

POLICY FORUM

What Should We Learn From Early Hemodialysis Allocation About How We Should Be Using ECMO?

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Abstract

Early hemodialysis allocation deliberations should inform our current considerations of what constitutes reasonable uses of extracorporeal membrane oxygenation. Deliberative democracy can be used as a strategy to gather a plurality of views, consider criteria, and guide policy making.

Introduction

Decision making about how to use new life-saving technologies, especially in life-or-death situations, is often fraught. Debate has long persisted about the appropriateness of hemodialysis (HD) for patients who are elderly and frail.¹ Decisions about use of extracorporeal membrane oxygenation (ECMO)—a machine-facilitated process that oxygenates and circulates blood for patients with impaired heart or lung function—are similarly clinically and ethically complex. In this article, we first examine the growth of ECMO and consider cautionary lessons of early HD allocation deliberations for current decision making about ECMO use. We then highlight a recent multisociety statement that calls for stakeholder input in defining the [boundaries of ECMO use](#) at the end of life. Finally, we suggest that a deliberative democratic process can provide a better way forward in decision making about deployment of new technologies in a health care environment in which costs continue to escalate.

ECMO in Its Adolescence

ECMO has been in clinical use for more than 40 years. In 1944, blood was first oxygenated while passing through cellophane artificial kidney membranes, and the idea of ECMO was born.² In 1972, ECMO was first successfully used to treat an adult with posttraumatic respiratory failure.³ In its first decade of use, however, patients' survival rate was around 10%.³ The next 40 years were a slow period of growth in use of ECMO.⁴ Complications from bleeding, clotting, infections, and resource limitations impaired its regular use in adults until the mid-2000s.⁵ Between 2002 and 2006, for example, fewer than 1000 adults annually received ECMO therapy.⁶ Since 2009, there has been a considerable increase in adult ECMO use, with 18 684 patients receiving ECMO therapy between 2008 and 2014.⁷

Currently, ECMO is used as a bridge to surgical intervention (a temporary modality) or as a bridge to recovery from respiratory and cardiac conditions (even if that time is measured in years⁸) when traditional modalities have failed. Already in development is a small implantable ECMO for bridge to recovery or destination therapy,⁹ so one can easily envision a time in the coming decades in which ECMO will be used increasingly as destination therapy.

Ethical Foundations of Clinical Criteria Used in HD Decision Making

Growth in ECMO use was similar to that of HD between 1940 and 1960. Originally envisioned as a short-term organ support device that would bridge a patient to receiving an organ, HD is now commonly used to manage patients' care for years. In the 1930s and 1940s, HD for acute renal failure was to be complimented with dietary treatment.¹⁰ It is unlikely that early "protonephrologists" envisioned treating end-stage renal disease (ESRD) with HD, as is currently done, but once repeated vascular access was developed in 1960,¹¹ HD became a feasible maintenance therapy. This breakthrough led to the establishment of the first outpatient dialysis center, the [Seattle Artificial Kidney Center](#) (now the Northwest Kidney Centers), in 1962.¹² HD use in treating chronic disease ballooned when Medicare funding for dialysis began in 1972.¹¹ As of 2015, 468 000 patients were maintained on chronic HD.¹³

At the Seattle Artificial Kidney Center, ethics committees helped determine how to allocate limited HD resources. First, a team of physicians (the Medical Advisory Committee) created screening criteria for assessing patients' eligibility for HD in terms of their comorbid conditions and risk factors. Patients who passed this phase of evaluation according to clinical criteria were then evaluated by the Admissions and Policy Committee (a group of Seattle area citizens comprising a lawyer, a clergyman, a housewife, a banker, a state official, and a surgeon), which sought to allocate HD access in terms of patients' *social worth*. This controversial second phase of decision making was one of the first times an organization formally drew upon community input to allocate a scarce resource.¹⁴

An article in *Life* magazine about this decision-making process sparked national debate about whether and how one's social worth should be used to allocate access to medical technologies.¹⁵ At the time of this debate, the clinical criteria were generally seen as necessary and relatively uncontroversial. Since then, however, even the presumed objectivity of clinical criteria has been questioned. For example, challenges to neurological criteria for death have been raised.¹⁶ In this context, deciding the medical appropriateness of treatment outside of true medical futility can be very controversial.

In 2015, the second author (GTB) collaborated on a multiple critical care societies statement to address "potentially inappropriate treatment" in intensive care units.¹⁷ This document considered how clinicians and institutions should respond to patient or

surrogate requests for treatments that clinicians regard as medically inappropriate, an issue that has been a persistent source of clinical ethical complexity. In the 1960s, using HD to treat ESRD in patients with other life-limiting diseases would have been considered a potentially inappropriate treatment. Even today, there is support for the view that dialysis for certain populations is inappropriate.¹⁸ Given the controversy around defining and responding to requests for inappropriate treatment, how should indications for ECMO be assessed and how should ECMO be used?

Democratic Deliberation About Health Technology Uses

The 2015 multisociety statement called for the medical profession to “engage in efforts to influence opinion and develop policies and legislation about when life-prolonging technologies should not be used.”¹⁷ This document further specified that such engagement requires diverse stakeholder input in order to be ethically acceptable in a pluralistic society. What would it look like to gather pluralistic stakeholder input about ECMO use?

Deliberative democracy (DD) is one model for gathering [stakeholder input](#) about value-laden and often controversial topics. Amy Gutmann and Dennis Thompson have defined DD as “a form of government in which free and equal citizens (and their representatives) ... justify decisions in a process in which they give one another reasons that are mutually acceptable and generally accessible, with the aim of reaching conclusions that are binding in the present on all citizens but open to challenge in the future.”¹⁹ DD involves asking a small representative sample of stakeholders (selected by an organizing body for a given value-laden topic and a DD facilitator) to come together to agree upon a response to a controversial question or policy. DD requires a structured process that allows for open information sharing among all parties and requires a skilled facilitator in the DD process.¹⁹

Governments and large institutions have used DD to inform health policy. In Great Britain, the National Institute for Health and Care Excellence (NICE) has employed a Citizens Council.²⁰ This body of 30 members of the public represents the demographic makeup of Great Britain and is assembled to give input on topics that NICE has chosen.²¹ (See Table for topics recently deliberated upon by the NICE Citizens Council.)

Table. Sampling of Topics Deliberated Upon by the National Institute for Health and Care Excellence Citizen Council

How should NICE assess future costs and health benefits? ^a
In what circumstances should NICE recommend interventions where the cost per QALY is above the threshold range of £20 000 to £30 000? ^b
Is there a preference to save the life of people in imminent danger of dying? ^c
Are there circumstances in which the age of a person should be taken into account when NICE is making a decision about how treatments should be used in the National Health Service? ^d
Abbreviations: NICE, National Institute for Health and Care Excellence; QALY, quality-adjusted life year. ^a From National Institute for Health and Care Excellence Citizens Council. ²² ^b From National Institute for Health and Care Excellence Citizens Council. ²³ ^c From National Institute for Health and Care Excellence Citizens Council. ²⁴ ^d From National Institute for Health and Care Excellence Citizens Council. ²⁵

In the early 2000s, the Romanow Commission on the Future of Health Care in Canada also convened a series of DD-based conversations with almost 500 representative Canadian citizens on health reform in Canada.²⁶ These sessions helped inform a final government report that recommended sweeping changes to encourage the sustainability of Canada’s health care system.²⁷

Although the strong centrally managed health care systems of Canada and Great Britain differ in important ways from the individualistic and decentralized health structures in the United States, these 2 examples of DD informing health policy align with the multisociety statement goal of “engag[ing] in efforts to influence opinion and develop policies and legislation about when life-prolonging technologies should not be used.”¹⁷ So how could a DD-based approach to ECMO use proceed in the United States?

Operationalizing DD for ECMO

There is precedent in the United States for policy making concerning difficult value-laden health care decisions. The Organ Procurement and Transplantation Network (OPTN) coordinates organ allocation through the United Network for Organ Sharing (UNOS). OPTN allows public comment on proposed policy changes but does not use a true DD process in discussions regarding policy changes. Allocation of transplant organs is analogous to deployment of scarce technological resources like ECMO—both involve highly value-laden decisions with many stakeholders and life-or-death consequences.

The Extracorporeal Life Support Organization (ELSO) is “an international non-profit consortium of health care institutions who are dedicated to the development and evaluation of novel therapies for support of failing organ systems.”²⁸ Its origins parallel

the early development of UNOS in that it consists of a registry “to support clinical research, support regulatory agencies, and support individual ELSO centers.”²⁸ ELSO could coordinate DD processes to inform policies regarding ECMO deployment by convening stakeholder participants (likely to include citizens, physicians, and payers) and a DD facilitator. Potential questions for DD facilitators to ask participants in a DD process could include the following:

1. Which, if any, comorbid conditions are absolute contraindications to ECMO use?
2. Should a quality-adjusted life year (QALY) analysis inform ECMO use?
3. Should ECMO use be limited to regional ECMO centers?

Establishing prospective criteria based on responses to these questions by participants in a DD process could help generate robust and thoughtful engagement regarding the clinically beneficial limits of ECMO; help avoid current idiosyncratic bedside clinical decision making about when to recommend ECMO; and be used as the basis for refining national professional guidelines for ECMO use. Such a process and the resultant guidelines could also be used to inform broader debates about the social and cultural relevance of technology use at the end of life.

ECMO Guidelines

The rise of ECMO as extracorporeal organ support—with future potential for organ replacement therapy—shares many similarities with the rise of HD. Just as in the early days of HD, criteria for [appropriate use of ECMO](#) remain vague and undefined. Lessons from early decision making about HD use and subsequent shifts in social attitudes about intensive care suggest that set boundaries for new technology use in health care should be prospective and transparent, include multiple stakeholders or their representatives, and be open to challenge and revision as the technology matures and as clinical, social, and cultural norms evolve. As we have suggested here, DD-based approaches to policy making offer one strategy for including stakeholders’ voices in refining guidance for bedside clinicians about how and when to use ECMO. This technology is currently in its adolescence—rapidly growing, developing, and testing the boundaries of its potential—and ECMO policy making should be informed by many and applied broadly to help clinicians help patients.

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