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Choosing Wisely: Can past medical decisions impact the allocation of scarce ECMO resources?

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Abbreviations: ECMO—Extra Corporeal Membrane Oxygenation

On a cold night in January 2013, I checked my email and was surprised by the message: “Due to the H1N1 flu epidemic, we cannot support any further ECMO patients as we have reached the limit of our equipment and staffing.” My thoughts went to the expectant mother upstairs, carrying a fetus with an anomaly whose only hope for survival was ECMO. I wondered how I would tell her that the life-support therapy her baby needed would not be available if she delivered tonight, knowing that this resource had been exhausted by patients with potentially preventable illness.

We argue treating ECMO as a scarce resource analogous to donated organs allows for a more prudent approach to its allocation. A policy of withholding ECMO from patients who have refused the influenza vaccine serves two functions: further incentivizing vaccination compliance and more justly allocating scarce resources in times of crisis. Ethical implementation would necessitate widespread education regarding existence of the policy so that those continuing to refuse the vaccine are giving “informed refusal.” Requiring patients who refuse the vaccine during a routine office visit to sign a waiver demonstrating understanding that they may be ineligible for this intervention is one way of accomplishing this. Enacting the policy only when certain criteria are met, such as influenza pandemic or other crisis situations, allows for discretionary and compassionate utilization of ECMO in the absence of overriding demand.

ECMO: Extra Corporeal Membrane Oxygenation (ECMO) is a life-sustaining therapy for patients with severe cardiorespiratory failure. It is a limited resource available in a few hundred centers in the US, each with a fixed number of circuits. As of 2011, nearly half of patients who received ECMO were newborns with respiratory failure. This is the population for whom ECMO was developed and still has the best reported outcomes.¹ Indications have expanded to include pediatric and adult patients with other causes of cardiorespiratory failure; average survival in these age groups is considerably lower, though the risk/benefit ratio and prognosis is variable and based on individual factors. Its use is considered cost-effective for adults and children with reversible disease.^{2,3}

The frequency and severity of complications limits ECMO only to patients with high risk of imminent death. It is *considered* when mortality risk approaches 50%, and *indicated* when it is anticipated to exceed 80%.¹ It is typically allocated among eligible patients using a “first-come, first-served” rule. Within ECMO centers, a fixed number of circuits are available, limited by equipment, specialists who continually oversee it, and blood products. Though transport to other centers can be helpful in localized shortage, transport may be risky or entirely unfeasible, and all centers may be at capacity during pandemics and other widespread crises.

Influenza: Influenza is a prevalent illness with significant morbidity and mortality. In 2009, the H1N1 strain caused aggressive respiratory failure, leading to investigation of ECMO as a rescue therapy for older children and adults.⁴ Subsequently, H1N1 vaccine development offered an effective prevention strategy. During the 2013-2014 influenza season, an estimated 7.2 million cases were prevented by vaccination, resulting in 90,000 fewer hospitalizations.⁵

The influenza vaccine is safe and cost effective. Insurance coverage is mandated by the Affordable Care Act, and it is available outside of the doctor’s office, which may lower the cost of administration.⁶ Nonetheless, fewer than half of eligible patients received the influenza vaccine during the 2013-2014 season,⁷ and a regional study noted the majority of patients who required intensive care from influenza were unvaccinated.⁸ Reasons for non-vaccination include lack of access to preventative health care, philosophical objection, and, importantly, misperceptions about the mechanism or side effects—for example belief that vaccination causes “the flu” or that the vaccine symptoms are worse than influenza infection.⁹ These misperceptions may, in part, be attributable to framing. When obtaining informed consent, physicians must discuss potential risks of the vaccine but not the risks of declining vaccination.¹⁰ This encourages “omission bias”, in which consequences of action (experiencing a complication of influenza vaccine) are judged more harmful than consequences of inaction (experiencing a complication of influenza).

The Ethical Dilemma: There is a *prima facie* duty to treat patients with every resource regardless of personal decisions they made prior to becoming ill. This duty came to the national consciousness with the publication in *Life* magazine of the story of the Seattle “God Committee” which determined allocation of the few dialysis machines available, often utilizing ‘social utility’ criteria. Distribution of scarce resources is a long-standing topic of ethical debate¹¹ and healthcare rationing strategies are often considered ethically suspect. Criteria such as age, social standing, and instrumental value of the patient seem discriminatory in our egalitarian society. The first-come-first-served model is effective in situations requiring rapid decision-making; little

needs to be known about the patient and each patient is provided equality of opportunity. Unfortunately, this approach inadequately addresses the concept of fairness, as an infant deprived of ECMO has more potential and years of life ahead of her than an adult who may have already lived half or more of her life and could not have opted for a safe and efficacious preventative intervention.

A possible solution to the dilemma of ECMO shortage in H1N1 pandemic is to withhold ECMO for influenza complications among those who declined vaccination. This could be achieved by developing and publicizing a policy making vaccine refusal a criteria used in ECMO triage decisions in crisis situations, and having competent adult patients sign a waiver acknowledging their understanding of this policy when declining immunization. Vaccinated adults, minors, those with medical contraindications to vaccination, without access to preventative healthcare, or not competent to make decisions would retain access.

Is this ethically permissible? Historically, past decisions have been considered in allocation of limited health resources. Solid organs for transplantation are a limited resource for which demand greatly outweighs supply, and some have argued that patients with alcoholic liver disease should be deprioritized.¹² Though no position is endorsed by the United Network for Organ Sharing, most transplant centers will not list alcoholic patients unless they comply with designated abstinence criteria. Reasons for abstinence criteria are both medical and ethical, as it improves transplant success and reassures decision-makers that the organs are not misallocated. This has been criticized by those who argue that continued alcohol use is not a choice but a manifestation of underlying disease. Vaccine refusal, however, is not an illness.

The question becomes whether it is morally acceptable to deny a patient a potentially life-saving therapy in order to reserve the resource for another anticipated to need it, not whether unvaccinated adults are deserving of life-saving health care for severe complications of influenza. If adequate resources existed, denying a patient desired ECMO therapy on the basis of vaccination status would be impermissible and violate the principles of beneficence and non-maleficence; physicians should not be arbiters of medical care or pass judgement on patients based on past decisions. However, currently and foreseeably, ECMO remains a limited resource. In shortage, different principles come into play: autonomy and justice. The question becomes, "are patients entitled to make decisions about their own health care against physician recommendation of if those decisions imperil others?"

We acknowledge that the impracticalities of instating such a waiver are significant: some patients do not decline vaccination, but rather are never offered it; others may refuse both vaccination and the waiver. Enforcement would also be difficult—determining the degree of shortage warranting ECMO rationing, and consistently applying allocation schemes would be complex and morally distressing. But we propose this as an approach to shifting the nature of informed consent for influenza vaccine away from a neutrally-offered option whose refusal is respected as equally valid as acceptance. Though some patients thoughtfully decline vaccination based on value systems that weigh medical interventions as worse than illness or death, many simply lack understanding of Bayesian probabilities, and have misplaced fears and miscalculated risks. It seems illogical to desire the risk/benefit profile of ECMO therapy as treatment for life-threatening respiratory failure, but not that of vaccination for prevention of influenza altogether. Engaging patients in a discussion which requires them to view their decisions not only in the context of public health, but also in personal consequences of opting-out, may lead to reconsideration of risk assessment about future events and acceptance of vaccination. It also may clarify values of non-interventionists who truly desire neither vaccination nor ECMO.

Our proposal withstands analysis within multiple ethical frameworks. Providing therapy to patients for whom ECMO has most consistently proven effective and have the most life-years to gain satisfies the consequentialist theory of utilitarianism. Within a non-consequentialist framework (Principle of Fairness), a scarce resource is justly distributed, prioritizing those unable to prevent their illness. And although vaccination may be viewed as desirable but not morally imperative, in agent-centered theory (Virtue Ethics), participation in herd immunity may be considered obligatory, as contribution to the health of the general population is the virtuous action.

Conclusion: Personal autonomy over health decisions is highly valued, but consequences of decisions may adversely affect others. The “first-come, first-served” allocation model leads to a conflict between autonomy and distributive justice. Having those who refuse influenza vaccination waive access to future ECMO therapy for subsequent influenza complications would require competent adults to acknowledge the potential consequences of their decision, clarify values, and permit more just allocation of this limited resource.

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