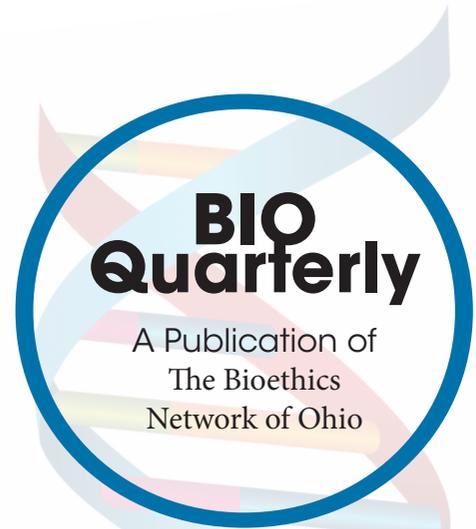


BENO



● Responsible Allocation of Medical Resources for the Chronically Ill



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Hospitals in the Cleveland area and throughout Ohio continue to spend significant proportions of their budget on individuals at the end of life. Previous research demonstrates that one subpopulation, the chronically critically ill (CCI), regularly suffers from severe and often irreversible illness with significant medical costs in the final stages of life. The components of health status that indicate chronic critical illness are subject to debate, though most definitions center on prolonged mechanical ventilation (PMV), which regularly designates that most acute conditions have been addressed but significant irreversible maladies still exist. [1-2] There is some ambiguity pertaining to when ventilation moves from acute and short-term to 'prolonged', with the standard threshold being 21 consecutive days at >6 hours per day. [2] Tracheostomy represents another marker of chronic critical illness if performed after four days or more of mechanical ventilation (MV). [1]

CCI patient populations are subject to poor outcomes in terms of mortality and overall quality of life. A 2008 study on patients undergoing more than 21 consecutive days of mechanical ventilation found that in-hospital mortality rates were as high as 41%, with an overall one-year mortality rate above 50%. [1] In addition to pervasive



continued on page 2...

CONTENTS

Uterus Transplantation and Research Ethics: A New Evaluation of Equipose

5

Venture Capital and Implications for Ethical Implementation

7

Welcome New BENO Members

8

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Responsible Allocation of Medical Resources for the Chronically Ill

continued from page 1...

mortality in and outside of the hospital, the CCI population overwhelmingly experiences serious deficiencies in higher levels of functioning. This often leads to the need for around-the-clock caretaking, suggesting that the chronically critically ill are unlikely to recover in a meaningful way in most circumstances. [3]

What makes the CCI a population of financial concern is the significant allocation of resources towards this patient population that results in proportionally marginal outcome improvement. By utilizing mortality and spending data from previous literature, Cox et al. performed simulations to elucidate cost-effectiveness of interventions. [4] Patients undergoing >21 days of PMV in 2007 survived on average 2.6 years at an additional cost of \$143,808 compared to ventilation withdrawal, meaning that treatment of the 'base-case' patient cost \$55,460 per life-year extended. [4] Adjusting for medical inflation, additional costs in 2019 hover around \$200,000 total and \$77,000 per life-year extended. Further, patients classified under the >21 day

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definition had an ineffective care rate at 47% while those with short-term MV only received ineffective care 10% of the time. Donahoe defines medical interventions as 'ineffective' when hospital costs reach over \$100,000 but one-year mortality rates of around 50% continue to persist. [5]

Local hospital spending based on the Medicare diagnosis related groups (DRG) designations paints a bleak picture for overall cost control and responsible resource utilization. [6] DRGs 003 and 004 both code for >96 hours of MV and the performance of a tracheostomy. [7] The main difference between these two codes is that DRG 003 denotes the additional performance of a major surgery or ECMO, while DRG 004 does not include any surgery. [1, 3] In 2015, the Cleveland Clinic discharged 122 patients charged under DRG 003. On average, the hospital bill for these cases came to \$577,298.47. In turn, Medicare and out-of-pocket mechanisms combined covered \$159,342.20. Thus, the Cleveland Clinic was covered for only 27.6% of its total costs for care of these individuals. The DRG 004-associated costs are more modest due to the removal of significant surgery resources, but the trend is similar. The hospital charged Medicare on average \$319,925.13 while being reimbursed a total of \$79,264.68 from the program and beneficiary. These numbers do not solely encompass the CCI, however, there is precedent of using DRG 003 (previously 541) as a definition of PMV. [3] Other healthcare institutions in the Cleveland area, including University Hospitals, experienced the same relative trends pertaining to these DRGs.

Local hospitals in Northeast Ohio, like the Cleveland Clinic, face serious resource burdens in regard to caring for the chronically critically ill due to the high costs associated with extended mechanical ventilation and chronic disease as a whole. Understanding that the United States spends more than any other developed nation on healthcare but nonetheless experiences

significant disparities in access, balancing the treatment of the CCI with considerations of cost-effectiveness and the downstream reductions in resources for other patients must, at the very least, be a subject of serious deliberation.

The United States subscribes heavily to the rule of rescue, the doctrine that “the imminence of death demands that we rescue the doomed.” [8] The intuition is that the worst off will die or suffer first if we do not care for them quickly. In context of the CCI, the principle becomes an imperative to expend resources on these patients. However, the fact that the CCI population experiences poor health and abysmal prognosis without treatment does not unequivocally justify the aggressive allocation of resources toward them. [9] One harmful assumption that lies within a “sickest first” approach is that potential to improve is uniform. [10] For example, if patient A is twice as ill as patient B and both can benefit from a treatment equally, then it is obvious that patient A should have priority for the intervention, but if the treatment will extend A’s life by 3 months and B’s life by 2 years, it would be myopic to prioritize A. Arguing that significant allocation towards the CCI is justified solely because they have the most ‘room for recuperation’ seems shortsighted and ignores the fact that many of these individuals are extremely unlikely to recover.



Perhaps a better alternative to the status quo is a maximization principle, often centered on utilitarian constructs. A life-year maximization principle lacks a consideration of quality, which most would agree is a fundamental component of optimizing utility in a society. Consider the aforementioned scenario again, with the same conditions. This time, however, the two years of treatment-extended life for B involve technology dependence and minimal consciousness while the three months of life for A can be spent doing whatever he or she values. Is it fair to equate one month spent in an ICU with one month spent interacting with family and friends? Treating every case as equal in regards to benefit seems problematic, and at the very least, insufficient.

In working towards a policy or guideline to alleviate resource burdens pertaining to the CCI population, it appears unadvisable to let a single moral framework or principle dictate the entire evaluation. Need, prognosis, and quality are all ethically legitimate dimensions that require particular consideration. There is no mechanism to determine when small benefits provided to an entire

population begin to outweigh life-saving measures for individuals, especially when these efforts may not extensively improve health status. [11] Additionally, utilitarianism’s judgments concerning the vulnerable and suffering are antithetical to the values of the medical community. To say that the hospitals have a moral imperative to provide all resources to the CCI simply because this patient group currently experiences the worst health statuses is insufficient. Further, to argue that the CCI are not entitled to these machines, staff, and beds because their outcomes are severely hindered and doing so draws resources away from healthier populations is also myopic on its own. In the end, a policy designed to address allocation issues pertaining to the CCI must successfully balance patient need with other relevant considerations.

The aforementioned trends and assertions altogether justify the responsible development of a hospital policy designed to reduce wasted resources and, secondarily, protect physicians from families who dissent to the withholding of care even when such interventions will be ineffective. At the center of a hospital procedure for CCI utilization is the determination of criteria under which care can be justifiably withheld. To come to such a conclusion, administrators and physicians must first discern when exactly interventions fail to uphold the purpose of either improving health status or aiding in the achievement of a subjective quality of life. Based on the previously discussed data, 14 days of PMV appears to be an appropriate cutoff. Many individuals who are not weaned by this point will suffer extensive cognitive deficiencies and potentially face indefinite institutionalization. [1]

A prudent hospital policy pertaining to the CCI would allow the medical team to refuse placing a tracheostomy following 14 days or more of PMV if such an approach will yield both indefinite institutionalization and a minimal probability of functional improvement. This proposal is rooted in the notion that performing a tracheostomy with the *sole* purpose of getting the patient out of the ICU and into another care facility is not only unnecessary, but also potentially harmful to an individual’s well-being. The purpose of this policy is not to discourage the performance of tracheostomies on the CCI as a whole: they can be a vital step in working towards recovery and becoming independent of any ventilator support. However, cases will arise in which the family of a continually intubated patient

continued on page 4...

who has already suffered serious cognitive decline will still request a tracheostomy. The use of *medical team refusal* rather than *prohibition of the practice* ensures that, in cases where a patient's physicians believe that the tracheostomy can have tangible benefits, it is performed without regulatory difficulties.

For ideal implementation, the CCI tracheostomy hospital policy should include exceptions for religious and philosophical objections.

For ideal implementation, the CCI tracheostomy hospital policy should include exceptions for religious and philosophical objections. This guarantees that those who have strong feelings on death and end-of-life in general are not forced to undergo a process that they deem as wrong for whatever reason. The decision makers will have the opportunity within a time frame of 48 hours to coordinate a transfer to another facility with full cooperation from the medical and administrative team. Such an exemption safeguards against the obstruction of religious and moral values but still allows the hospital in question to uphold the policy.

Hospitals can often be considered closed-off systems: distributing resources towards one cause (time, beds, money, etc.) draws them away from another. The chronically critically ill, by nature of the categorization, will continue to suffer from some of the most serious health burdens, ranging from continual intubation to significant declines in cognitive and functional ability. These incredible reductions in health status may justify

the allocation of additional resources over non-emergent patients and other less urgent initiatives, though it does not necessitate a myopic adherence to such a principle. A prudent balance of relevant factors is beneficial not just for healthier patients and less drastic causes, but also for CCI patients themselves. A policy designed to reduce the incidence of tracheostomies that serve a minimally beneficially purpose can contribute to alleviating these serious resource burdens. Hospitals in Northeast Ohio will continue to face distributive dilemmas, particularly in regard to the CCI and end-of-life patients. However, the development of reasonable and meaningful policies can contribute towards incremental improvement in the end likely benefitting patients and physicians throughout the system.

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● Uterus Transplantation and Research Ethics: A New Evaluation of Equipoise



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Since the first clinical trial success in Sweden in 2014, uterus transplantation (UTx) has been growing, leading to many clinical trials across the world and throughout the United States. [1] As these trials continue and the reality of UTx as a therapeutic intervention comes to fruition, more thorough analysis of the ethics surrounding the process is warranted.

Clinical equipoise is an oft-cited standard for evaluating the ethical legitimacy of proposed medical experimentation. The standard of clinical equipoise is satisfied when the medical community is genuinely uncertain whether an experimental intervention is superior to proven interventions for the same condition. While clinical equipoise was first proposed as a standard for randomized controlled trials, clinical equipoise has since been applied to other areas of medical research, including transplant research. In 2016, Testa *et al.* provided the first analysis of UTx closely focused on equipoise. They compared the risks and benefits incurred by each individual affected by the UTx to the risks taken on by gestational surrogates as a comparator way of achieving motherhood with a genetic linkage to the child and concluded that living-donor UTx satisfied the standard of clinical equipoise at that time. [2] Since that publication, UTx has advanced. A woman with a UTx from a deceased donor has given birth to a healthy child, [3] new surgical techniques are being utilized, [4] and more children have been born to donor-recipient mothers. [5] These developments necessitate an updated analysis.

The first child to be born to a woman who received a uterus transplant from a deceased donor was delivered in 2016. [3] Prior to this point in time, all UTx successes resulted from trials utilizing living donors. Recovering uteruses from living donors necessitated serious conversations about the harms suffered by these donors in the process. Now that viable uteruses can be recovered from deceased donors, is it still ethical to proceed with clinical trials utilizing living donors?

Prior research suggested that the risks associated with living-donor uterus recovery would be akin to the risks associated with a radical hysterectomy. These risks would include ureteral, bladder or rectal injury, as well as iliac vessel damage or pelvic nerve damage. [2] While these risks and others are plausible, few such complications have actually been reported in living donors. Even in the absence of complications associated with hysterectomy, recovering a uterus for transplant is a long surgery: the original Swedish trial reported an average operating time of greater than 11 hours, with average time under general anesthesia exceeding 12 hours for donor surgery. [1] Extended periods of anesthesia have well-known risks. [6, 7]



However, UTx is now utilizing new surgical techniques that decrease risk. In Baylor's clinical trial, the reported length of time in surgery for living-donor hysterectomy ranged from 480 to 540 minutes (8 to 9 hours), with an average of 330 minutes spent operating (5.5 hours). Most of the time spent operating was on the dissection of the uterine veins, but these trials ultimately exhibited success in uterine grafts that relied solely upon the utero-ovarian vein for venous outflow, so that the most time-consuming part of the recovery procedure may actually not be necessary in the future. [2, 4] Decreased length of surgery would reduce risks associated with general anesthesia. So too would less invasive surgical techniques: a team in China has already successfully performed a robotic assisted UTx with a surgical time of only 6 hours. [8] If the standard of care in UTx were to include minimally invasive surgical

continued on page 6...

techniques, this would have substantial impact on reducing the risk profile of living-donor UTx. [5, 9]

Still, clinical equipoise requires evaluation of risks and benefits for all stakeholders involved. This means we must also consider risks to the children born to donor-recipients. Risks to children born to donor-recipients is a complicated topic as individuals may debate fetal personhood, and the risks to the fetus in UTx are imposed by nature of the procedure and cannot be eliminated. While we can largely bracket debates about fetal autonomy, since the intention of UTx always is to bring about the birth of healthy,



living babies, we must still address risks to the fetus. While realized risks to infants born of UTx so far have been minimal, mainly prematurity and low birth weights, [2] potential risks to the fetus in utero as a result of maternal use of immunosuppressive therapies do exist. [10-12] Because of this we must ask ourselves, can we prioritize autonomy of patients, and respect their own volition for this procedure (UTx), as enough to determine it is morally justifiable? I believe in UTx trials we can do just that, as the risks to the fetus are minimal and immunosuppressant use in pregnancy is largely considered safe by the medical community. [13]

UTx has come a long way in a short time and the risks associated with the practice are significantly diminishing as the practice is further refined. Even though we have learned since Testa et al. that deceased-donor UTx is feasible and eliminates the risk of harm to the donor, reductions of the risks associated with living-donor UTx since Testa et al, mean that the balance of risks and benefits still does not clearly favor deceased-donor UTx. UTx remains in a state of clinical equipoise between living and deceased donor UTx, and as such we urge that both living- and deceased-donor UTx remain ethically

defensible. Furthermore, we have verified the need to address the risks to the potential infants born via UTx, but recognized the risks to this stakeholder are largely considered minimal. We support placing increasing value on the autonomy and benefits of the donor-recipients, in which case we can see clinical equipoise being satisfied within the practice of UTx, thus adding moral justification to the continuation of clinical trials.

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● Venture Capital and Implications for Ethical Implementation



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The landscape for private healthcare in Ohio and across the nation is rapidly changing. Private equity firms, which use funds from institutional investors hoping for profit, own an increasing number of practices. The amount of money involved in healthcare-related private equity deals increased by 187% from 2010 to 2017. [1] Private equity firms buy practices from private owners in cash, retain the other employed physicians (typically at a lower compensation rate), and increasing reimbursement by improving contracted payment rates with improved bargaining power. The private equity firm's ultimate goal is to sell the practice to a larger private equity firm, typically within 5 to 7 years, for 20-30% more than the first private equity firm paid. This has become a common phenomenon in particular outpatient specialties such as orthopedic surgery, ophthalmology and radiology.

There are several ethical concerns regarding private equity firms' acquisition of practices and how it pertains to the corporatization of medicine. Since the intended goal is eventual resale of the practice at a higher value to a larger venture capital group, profits are emphasized, with the concern that this is at the cost of patient care. Oftentimes, the private equity firm will advertise to a prospective physician interested in selling their practice that the project is "physician-owned" or "physician-operated", but this may simply be a holding company the firm uses as a physician dominant subsidiary. Ultimately, the parent company is responsible for all final decisions pertaining to office culture and bylaws, and may have few or no physicians in leadership roles. [2]

In dermatology, a field which represents 1% of practicing physicians in the United States, 15% of practices were owned by private equity firms in 2015; this number is sharply rising. [3] In such settings, providers have been reported to be pressured into providing increased numbers of procedures, sell in-office products, and refer to associated groups or laboratories. [4] Some specialists have reported no such changes in their groups and state that the practice model and culture is left unchanged, and may even experience an improved practice flow given a larger group's bargaining capabilities for physical materials and insurance deals within the office.

The private equity model also may prove to be harmful to young physicians. Profits from the sale of

a practice to a private equity firm go exclusively or almost exclusively to the practice owners, who in selling earn 3-13 times their prior earnings before interest, taxes, depreciation, and amortization. Non-practice owners reap no benefit from the sale of the practice, even as they are often the main source of profit after the practice's sale to the private equity firm. Young physicians who joined their group under a partnership track type model will either have to abandon that goal if the practice is sold by joining private equity, as even partial ownership options are usually not available in this model, or starting anew at a different practice. Many private equity firms entice new graduates from residencies with high salaries in their first year, which will drop to below standard compensation if the physician is not able to maintain a certain level of productivity, either by seeing patients themselves or supervising one or multiple midlevel providers, which is often a hallmark of private equity-owned practices. Younger physicians may find it difficult to open independent practices as private equity firms begin to control and dominate market share, making it more difficult to negotiate contracts with insurance providers. Similarly, older physicians are more likely to have leadership roles in state and national specialty organizations, which may pose a conflict of interest if they have an ownership role in private equity, particularly if organizations pass bylaws facilitating the entry of private equity into their specialty.

There is an imperative need to educate patients and providers on the new model of private equity practice and the changes the model portends. More and higher quality information is needed to ascertain if these groups have any effect on quality of care, and what effect they will have on the healthcare system as a whole in the future. In the interim, the increasing role of private equity firms in medical practices should not be passively regarded as incidental to the health care those practices provide. Furthermore, patients should be informed about the changes in how they pay for health care and the possibility that private equity firms may not share physicians' fiduciary commitments to their patients.

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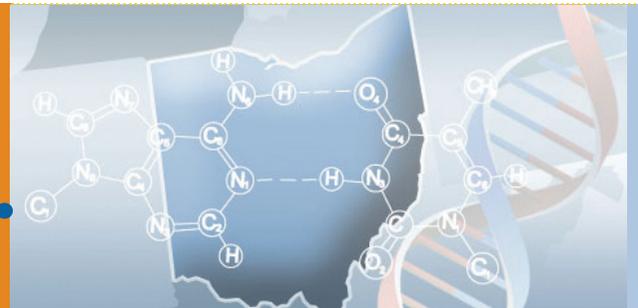
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