

### MID-ATLANTIC ETHICS COMMITTEE

#### NEWSLETTER

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articles with timely information
about bioethics activities. Each issue
includes a feature article, a Calendar of
upcoming events, and a case presentation
and commentary by local experts in
bioethics, law, medicine, nursing, or
related disciplines.

Diane E. Hoffmann, JD, MS - Editor

# Legal and Ethical Considerations for COVID-19 Vaccination Mandates for Healthcare Workers



As of February 2021, the Food and Drug Administration (FDA) has authorized three COVID-19 vaccines for emergency use. Data show that these vaccines are extremely safe and effective at reducing the severity of COVID-19. Healthcare workers (HCW)—including doctors, nurses, trainees, and nonclinical essential workers—were prioritized for vaccine distribution because of the occupational risk they bear in fighting the pandemic. Although the supply of vaccines is still limited, many HCW have already been vaccinated.

However, some HCW have declined COVID-19 vaccination. Even before COVID, HCW were among the most

hesitant populations towards occupational vaccines, such as the seasonal influenza vaccine. Insufficient knowledge and understanding of vaccines, including concerns about side effects and doubts about effectiveness, are cited as reasons for hesitancy among HCW. (Loulergue et al., 2009) However, vaccine hesitancy among HCW is a matter of public health because HCW are disproportionately exposed to immunocompromised patients, the elderly, and children in their workplace and therefore have a higher risk of transmitting or contracting communicable diseases. HCW are also key connectors of information for the public and have been shown to sway patients' vaccination behavior.

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The information in this newsletter is not intended to provide legal advice or opinions and should not be acted upon without consulting an attorney.

In response to this hesitancy towards the COVID-19 vaccine, many hospitals and other healthcare organizations are considering whether to mandate or require COVID-19 vaccinations for their employees. Employer-based mandates should be assessed both legally and ethically.

There are significant ethical and legal concerns about mandating a vaccine that is still under an Emergency Use Authorization (EUA). The EUA statute does not specifically prevent employers from mandating vaccines that have only EUA status. (21 U.S.C. § 360bbb-3.) However, under the EUA statute, certain conditions must be met before a vaccine is administered. Those who receive the vaccine must be informed that it has been authorized for emergency use, and the "known and potential" benefits and risks must be explained. Moreover, those receiving the vaccine must be informed that they have "the option to accept or refuse administration," as well as of "the consequences, if any, of refusing administration."

There is uncertainty about whether "consequences" of refusing vaccination may include adverse employment actions, including termination or reassignment. However, in the context of the statute, it is likely that "consequences" refers to health-related consequences only, and that all persons to whom the vaccine is administered must be given the "option to accept or refuse" without threat of repercussions. On the other hand, the statutory requirements likely apply only to the entity that actually administers the EUA vaccine, which may

not be the employer. If an employer requires its employees to get the COVID vaccine from a third party—e.g., from a city or county vaccination site—then presumably the employer would not be subject to the statutory requirements.

Nevertheless, the spirit of the EUA statute suggests a commitment to voluntariness that militates against an employer vaccine mandate prior to the FDA's full approval of the vaccine. After all, some COVID-19 vaccines that are currently available are the first to utilize the new mRNA-based technology. So long as there remains significant uncertainty about the risks of the vaccines, mandates seem difficult to justify.

It is likely that some COVID-19 vaccines will soon be granted a full Biologics License Application (BLA) approval by the FDA. Current federal law generally allows employers to mandate vaccines as a condition of employment, so long as they comply with laws prohibiting employment discrimination. (Rothstein, Parmet, and Reiss 2021) Ethical considerations suggest that employers allow broad accommodations for people with medical, religious, and perhaps even moral concerns, even if they are not always legally required to do so.

The Americans with Disabilities Act (ADA) requires that employers provide reasonable accommodation to an employee or job applicant with a disability, unless doing so would pose an "undue hardship" i.e., a significant difficulty or expense for the employer. Under the ADA, a "disability" is defined as "a

physical or mental condition that substantially limits a major life activity." (42 U.S.C. § 12102(2) (A)-(C).)

Courts have generally been skeptical that a vaccine allergy is a disability under the ADA. For example, a federal district court in Maryland denied an ADA claim brought by a medical assistant who had a known allergy to a component of the flu vaccine, and who requested, but was not granted, an exemption from the vaccine mandate imposed by her employer, a major medical center. (Eubanks v. Mercy Med. Ctr., Inc. (D. Md. Dec. 17, 2015).) The court did not accept the plaintiff's argument that "the functions of [her] immune system" constituted a "major life activity," and determined that her allergies did not qualify as a disability under the ADA. The court rejected the plaintiff's claim under Maryland's Fair Employment Practices Act (FEPA) on the same grounds. (Md. Code Ann., State Gov't § 20-601(b)(1).)

This example suggests that the conceptual framework of the ADA is not well suited to vaccination policies. The mere risk of suffering a vaccine-related injury, no matter how great the risk or severe the injury, does not itself impair a major life activity. Such impairment typically occurs only after the vaccine has been administered and the injury suffered, but then an exemption is of no avail. As an ethical matter, therefore, employers ought not rely solely on the requirements of the ADA, but should craft a medical exemptions policy that allows for exemptions even when the underlying medical

condition would not qualify as a "disability" under the ADA.

Title VII of the Civil Rights Act of 1964 prohibits employers from discriminating against employees on the basis of their religious beliefs or practices, and requires employers to accommodate these beliefs and practices so long as the accommodation does not impose an "undue hardship, i.e., something 'more than a minimal burden' on the operation of the employer's business." (29 CFR § 1605.2.) For example, offering to transfer an employee who objects to vaccines on religious grounds to a different organizational role is likely a sufficient accommodation, even if the employee is unhappy with this change.

The Equal Employment Opportunity Commission (EEOC), which administers Title VII, defines "religion" very broadly to include beliefs and practices that are not part of a traditional church or sect. However, the category of religious belief does not include personal preferences, political views, or beliefs about science or medicine. For example, the belief that vaccines "may do more harm than good" is a medical, not a religious belief. The EEOC definition correctly reflects the important autonomy interest that individuals have in being able to live according to their sincerely held religious or non-religious moral beliefs.

Finally, healthcare organizations should consider the disproportionate impact that a vaccine mandate may have on HCW who are members of a minority racial or ethnic group. Data suggest that Black

Americans are much less likely to trust the healthcare system and express willingness to get vaccinated against COVID-19. (Egede and Walker, 2020) Much of this distrust of Black Americans in medicine is rooted in a history of oppression, exclusion, and exploitation evidenced throughout U.S. history, and specifically within American medicine. (Jones, 2021)

For this reason, imposing a vaccine mandate on HCW could disproportionately affect Black HCW, a group that is already underrepresented among doctors, and in some contexts overrepresented among non-clinical essential staff, such as janitors and culinary staff, who are likely to be much lower paid and perceived by managers as easier to replace. (Gaynor and Wilson, 2020)

Moreover, if members of racial minority groups disproportionately refuse to comply with a strict vaccine mandate, and suffer adverse employment consequences as a result, their employer may be liable for race discrimination under Title VII. In particular, an employer's policy that results in a disproportionate number of adverse employment outcomes for members of a certain racial or ethnic group raises a question of disparate impact discrimination, even if the policy is race-neutral on its face. (Cf. Griggs v. Duke Power Co., 401 U.S. 42 4, 91 S. Ct. 849 (1971).)

A mandate that disproportionately impacts Black Americans and other minority and underrepresented populations is ethically problematic whether or not it succeeds in encouraging greater vaccine uptake. If it does succeed, the success could be tainted by the same race-based coercion, paternalism, and exploitation that has long haunted American medicine. If HCW from minority groups choose to refuse vaccination, however, and disproportionately lose their jobs as a result, then the mandate problematically contributes to unjust inequities in employment opportunity.

In conclusion, vaccine hesitancy raises the question of how best to promote COVID-19 vaccine uptake among HCW. Strict mandates, however, without adequate opportunities to opt-out, are difficult to justify. Vaccine mandates ought always to be considered a "last resort" intervention when combatting low vaccine uptake rates, and should be carefully evaluated before implementation. Employer mandates face an even greater justificatory hurdle than government mandates, as they are less effective at promoting public health goals such as herd immunity.

When considering vaccine mandates, employers must consult the law, but they should not assume that whatever is not legally forbidden is therefore ethically permitted. Existing legal constraints sometimes inadequately reflect the ethical considerations that apply to employer vaccine policies. (Parmet, 2018) Before imposing a mandate, employers should consider alternatives such as masking, testing, and discouraging "presenteeism," i.e., coming to work while ill. (Edmond, 2019) Employers should also seek to build voluntary buy-in and understanding, particularly in light of equity concerns, through clear communication and honest engagement with all members of the workplace community. The safest course, both ethically and legally, is to protect patients and workers and effectively reduce workplace transmission through all means possible before considering and implementing mandates.

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## A Conversation about Vaccine Mandates: MHECN COVID-19 Working Group

Early in the COVID-19 pandemic, MHECN established a COVID-19 Working Group to provide a forum for ethics committee members from healthcare institutions around the state to share information about their experiences, challenges, and solutions to problems they have encountered during the pandemic. Topics for discussion have included allocation of scarce medical resources including ventilators, PPE, staff, and treatments such as remdesivir, visitor policies, staff burn-out, allocation of vaccines, and most recently hospital vaccine mandates. In this article we share a summary of the Working Group's conversation on vaccine mandates.

#### **COVID VACCINE MANDATES**



An infectious disease physician at a Montgomery County hospital introduced the topic of whether it is ethically justified to mandate COVID vaccines for healthcare staff after the vaccines are FDAapproved. At his hospital there has been ~70% staff vaccine acceptance. Patients have already asked if staff caring for them have been vaccinated for COVID and if not, some have requested to be transferred to the care of another provider. One can foresee hospitals advertising based on employee vaccination rates, making this a marketing tool, not just a public health measure. He asked for the

Working Group's (WG's) thoughts on the following questions:

Does information regarding vaccine refusal/acceptance pose a breach of privacy/confidentiality? There is a question of whether information about employees' COVID-19 vaccination status is maintained on behalf of the employee health plan and thus covered by HIPAA's privacy requirements. Even if this were true, a waiver could be issued by the employee.

Are vaccine mandates more effective than persuasion or incentives (e.g., paid sick leave)? The WG discussed concerns about the efficacy of a vaccine mandate. For example, it was suggested that flu vaccine mandates for healthcare facility staff have not been shown to produce the expected outcomes of reducing patient morbidity/mortality. Taking into account that we do not currently know to what extent COVID vaccination itself reduces transmission, this may be relevant (a presumed benefit of a vaccinated worker is that he/she is less likely

to infect patients/visitors). In addition, a mandate could disincentivize employers from engaging with staff to hear their perspectives and earn their trust, which could widen gaps in trust that are essential for public health goals to be achieved.

Do vaccine mandates discriminate disproportionately against marginalized communities? Given that there are higher rates of vaccine refusal among communities of color, and persons of color are overrepresented in certain healthcare sectors (e.g., long-term care and ancillary hospital staffing), a mandate could disproportionately affect this already marginalized population by restricting job opportunities for those who prefer to avoid vaccination.

Is there a difference between mandating vaccination for current staff versus new hires? Given that newly hired staff could be told about the vaccine mandate and choose not to take the job, some may see a difference between mandating the vaccine for current staff versus new staff, since the latter would have

received "notice." However, whether one is deprived of getting a job or of losing a current job may not be an appreciable distinction.

Is reduced employee absenteeism a sufficient reason for a mandate? Even if vaccinating staff doesn't reduce patient contagion, there is clearly a benefit in reducing employee absenteeism due to sickness. Reduced transmission is also likely (though not yet demonstrated), and preventing hospitalizations and serious illness of healthcare workers and those who are immunocompromised (e.g., bone marrow transplant patients, NICU babies) is an appreciable benefit, as gaps in COVID protection can be fatal.

Are there valid contraindications to COVID vaccine?

One physician reported that at his hospital, for flu vaccine, which is mandated for staff unless a request is made based on health exemptions, about 1% of staff have a valid contraindication. This is expected to be quite rare for COVID vaccine. Anaphylaxis is very low. A lawyer-ethicist offered that the only appreciable risk at the population level (for staff) is dignitary and emotional, that is, taking away a worker's choice to refuse the vaccine (for whatever reason). They get the benefit of being spared from serious illness/ death, protection from symptomatic illness, and most likely not being a vector within their own household.

*Is a COVID vaccine mandate ethically justified?* 

The consensus of the group is that there is more benefit from ensuring that all staff are vaccinated and although the answer to "can a vaccine mandate be implemented" is "yes," the question of "should a vaccine mandate be implemented" needs to be considered from all angles. It is comparable to the flu vaccine mandate. Is there an opt-out for anyone? Will staff declining vaccination be stigmatized? Isn't it ethically preferable to engage staff and try to get their buy-in?

A hospital chaplain noted that we all live in a community, and there are inevitable conflicts between respect for autonomy and promoting the common good; there are times autonomy can be justifiably overridden. While the harm is not trivial, it can be reduced if people feel like they have been heard/respected enough for that conversation to be had by them or people who look like them. Of note, no religious body has come out against COVID vaccines.



An emergency planning expert noted that in previous epidemics (e.g., Ebola, HIV/AIDS) there were similar concerns; everyone has an opinion (s)he should not be afraid to voice. Leadership has learned they need to gather those opinions to form a marketing campaign to support their decisions. Based on what we know so far, there will be a lot of people refusing a vaccine. It is not clear

whether, even when supply is adequate, we will reach herd immunity. Healthcare is one of the few sectors that will be put out in front of this to make this decision. Which groups will be mandated to get vaccinated? Teachers, healthcare workers, airline employees (i.e., those in unavoidable close proximity to those they serve)?

A physician echoed the need to have conversations at the C-suite level to achieve procedural justice, and to include diverse representation in these conversations. She underscored that how administrators do this matters; a mandate may be OK but that doesn't absolve leaders from talking with rather than at employees.

A law professor suggested that the word "mandate" is negatively laden and might be replaced with another term. However, another lawyer in the group warned of the dangers of euphemisms, and that honesty is important.

A physician mentioned that her hospital was reluctant to impose vaccination with the threat of termination. However, many companies and healthcare facilities appear to be moving toward mandates.

The WG agreed vaccination must be part of a multi-prong strategy, and that a variety of individuals should be at the table when deciding whether it should be mandatory, from janitors and kitchen workers to nurses and physicians.

## **COVID-19 Vaccine Ethics Forum Focuses on Interprofessionalism, Equity, and Faith**

On November 10, 2020, MHECN co-sponsored the Seventh Annual Interprofessional Forum on Ethics and Religion in Health Care: Unraveling Vaccine Science, Faith, and Public Discourse. Vaccine researcher and University of Maryland (UMB) School of Medicine faculty Dr. Matthew Laurens gave an overview of COVID-19 vaccines being tested in clinical trials.

Deanna Tran, with the UMB School of Pharmacy, reviewed causes of "vaccine hesitancy," mostly resulting from misinformation and myths, for example, that vaccines cause autism or overload the body's immune defenses (science has debunked both positions). Dr. Tran called for a multidisciplinary approach to overcome vaccine hesitancy by role modeling vaccine adoption and using motivational interviewing techniques and outreach efforts to educate patients and the public about vaccine efficacy and safety.

Trudy Henson, Public Health
Program Director at the Center
for Health and Homeland Security
and an adjunct professor at UMB's
Carey School of Law, reviewed
the law and policy considerations
for COVID-19 vaccines that
become available, such as how
to fairly allocate vaccines that
are in short supply, and whether
mandating vaccination would be
justified or effective. She provided
background information on existing public health powers, such

as those articulated in the 1905 Supreme Court case Jacobson v. Massachusetts, while emphasizing that vaccine mandates might not be the only or most effective policy approach. While highlighting the importance of promoting vaccination through encouragement and example, Henson also spoke on the potential pitfalls of strongly encouraging or even mandating vaccinations should demand exceed supply, which occurred with the H1N1 vaccine in 2009. Responding to questions after her presentation, she also discussed the likelihood of vaccination becoming a condition of employment for some frontline healthcare workers, explaining that while such requirements were likely to be permissible, especially for private employers, those mandates were likely to be delayed due to questions of supply.



Yolonda Wilson, Fellow with the National Humanities Center and Encore Public Voices, addressed how systemic racism has harmed—and continues to harm— Black and Brown people by way of their being more susceptible to suffering serious and fatal

COVID-19 disease and having poorer access to COVID-19 research, testing, treatment, and vaccination opportunities. For example, researchers may simply assume that Black people don't trust science and won't volunteer for research trials, rather than enlisting their feedback about how to gain their trust and cooperation. Ken Berkowitz, Special Advisor with the Veterans Health Administration's National Center for Ethics in Health Care, reviewed data showing that healthcare facility flu vaccine mandates for staff have not achieved better outcomes compared to voluntary flu vaccination. Given that vaccination rates are lower among persons of color, this raises the question of whether vaccine mandates unfairly disadvantage persons of color. Individual liberty should be preserved if persuasion can effectively promote trust that vaccines are in an individual's best interest and that of their community.

Rabbi Shmuel Silber of Suburban Orthodox Toras Chaim offered a Jewish interpretation of the tension between faith and science. God has control over everything – both the pandemic and the science that creates remedies to cure and eradicate disease. When there is tension between the needs of the community and the individual, the community always wins out. This is a view focused on individual responsibilities to create a society that benefits every individual. If a vaccine is found to be safe and

effective, there is an obligation to take the vaccine. The overwhelming majority in the Jewish community are "pro-vaccine" for this reason. A Jewish approach to vaccine allocation would use a similar calculus to identify what is best for the community (for example, prioritizing frontline healthcare workers who are in the greatest danger and who can preserve others' well-being).

Bowyer Freeman, Senior Pastor at New St. Mark Baptist Church,

proposed that science and religion work together to help us better understand our human nature. Pastor Freeman's background in genomics gives him a unique perspective on this issue. For example, new genetic advances may benefit some and exacerbate social disparities for others. In order for COVID-19 vaccine science to benefit all, it must be adopted by the majority to achieve the goal of herd immunity. Trust is key. Indeed, pastoral care, clinical ethics, and medicine require a foundation

of trust. Pastor Freeman referred to this as "trust economics," a term not intuitively aligned with religion. However, considering that "economics" involves the production, consumption, and transfer of wealth, a spiritually-informed approach recognizes that wealth and health are intertwined, and that when large portions of the community are left behind, societal wealth is elusive. This is something we have seen first-hand during the COVID-19 pandemic.

Anita J. Tarzian, PhD, RN MHECN Program Advisor

The <u>recording</u> and slides of the November 10 forum are available on <u>MHECN's website</u>, under Workshops and Conferences.

#### Allocating Scarce Medical Resources at Hospitals in Maryland



In response to the COVID-19 pandemic and the possibility of resource shortages, Maryland's five largest health systems (The Johns Hopkins Health System, the University of Maryland Medical System, MedStar Health, LifeBridge Health, and Luminis Health) partnered to develop guidelines and processes for the allocation of scarce resources (ASR). These five hospital systems, or the "5H," engaged with multi-disciplinary working groups to recommend a series of factors that should be considered in deciding who should receive scarce resources during a pandemic such as COVID-19. The resulting draft framework, published as "Operational Recommendations for Scarce Resource Allocation in a Public Health Crisis" and referred to herein as the 5H ASR Framework, seeks to enhance survival and maximize treatment benefits for as many patients as possible when resources are scarce while prioritizing ethical considerations. The 5H ASR Framework includes triage plans for eight scarce resources: ventilators, blood

products, ICU beds, ECMO, dialysis, convalescent plasma, remdesivir, and hydroxychloroquine.

Acknowledging that the COVID-19 pandemic is not over and that future pandemics are possible, the Maryland Health-care Ethics Committee Network (MHECN) has worked with representatives of the five health-care systems to make the 5H ASR Framework available to Maryland hospitals and the public. The purpose of dissemination is to make the community aware of choices that would be made by hospitals if these medical resources were in short supply.

In February 2021, MHECN's COVID-19 Working Group collected feedback on the 5H ASR Framework from MHECN members (including healthcare ethics committee members) and contacts through its listserv and encouraged broader dissemination. MHECN received twenty-one responses, reflecting a wide variety of healthcare professions including physi-

cians, clinical ethicists, social workers, and palliative care providers. Approximately eighty percent of respondents were familiar with ASR frameworks, nationally, for pandemic triage during crisis situations. However, respondents were far less familiar with the 5H ASR Framework and the 2017 proposed ASR framework which the current 5H ASR draft is based on. Of the scarce resources included in the 5H ASR Framework and in the survey, survey respondents had the highest familiarity with ventilator allocation. The high familiarity with ventilator triage plans was expected since mechanical ventilators were identified as a possible scarce resource early in the pandemic.

Since the 5H ASR Framework is based on distributive justice with equitable and standardized practices, fairness in triage decisions is critical. When asked which components of the 5H ASR Framework are the most critical for ensuring fairness in ASR triage decisions, respondents identified the availability of palliative care and hospice services for patients not eligible for limited lifesaving resources as a top concern. Respondents also indicated the importance of clear communication between healthcare providers and patients and their families about the ASR process. Another primary concern was avoiding biased decision-making based on age, race, or disability.

Looking towards implementation,

respondents were somewhat confident that limited life-saving resource decisions would be fair if Maryland hospitals use the 5H ASR Framework during the pandemic under crisis standards of care. Although respondents appeared optimistic, there were underlying concerns that decisions would still be biased even if the 5H ASR Framework is followed. One respondent stated that "there may be clinicians who figure out how to bypass the framework." Another stated that "[m]ost people will try to do their best to be fair, [but] there will be some problems in achieving this completely." Respondents expressed concerns about the successful implementation of the framework in the chaotic emergency room setting where there may not be sufficient time for review, stating that "[t]he use of a framework will be very important to avoid ad hoc decision making, which is known to be more biased."

Numerous comments addressed the need for a clear anti-discrimination statement in the draft to emphasize that allocation decisions should not be based on age, disability or quality of life and life-cycle concerns. One respondent commented that "decisions should be made on objective, evidence-based predictions on survival to discharge and no decisions should be made based on the patient's perceived quality of life." Apprehension that people with disabilities may be disfavored under the framework has been a longstanding point of concern for various stakeholders, as even neutral language meant to avoid discrimination can produce disparate outcomes.

MHECN's Working Group believes it is important to continue public engagement and incorporate stakeholder concerns as the 5H ASR Framework circulates among Maryland hospitals. The MHECN survey provided elucidating insights into the health community's familiarity and views of the 5H ASR Framework. MHECN hopes to continue to seek out stakeholder input and concerns from the general public. It would be useful to better understand the public's familiarity and perspectives on resource allocation for both community input and transparency in potentially difficult resource allocation decisions. No ASR framework will be perfect, but MHECN seeks to provide feedback to the 5H drafters that includes different perspectives and responds to community priorities to further ethical principles of justice, transparency, participation, and accountability.

The proposed ASR framework and related documents are available on MHECN's website.

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#### **CASE PRESENTATION**

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One of the regular features of this Newsletter is the presentation of a case considered by an ethics committee and an analysis of the ethical issues involved. Readers are both encouraged to comment on the case or analysis and to submit other cases that their ethics committee has dealt with. In all cases, identifying information about patients and others in the case should only be provided with the permission of the patient. Unless otherwise indicated, our policy is not to identify the submitter or institution. We may also change facts to protect confidentiality. Cases and comments should be sent to MHECN@law.umaryland.edu.

#### CASE STUDY FROM A MARYLAND HOSPITAL

Baby L, an infant of about 24 weeks gestation, is delivered precipitously en route from the emergency room to the Labor and Delivery suite. The infant has poor respiratory effort and is bradycardic to 60 bpm. She is stimulated and mask-bagged. She is intubated shortly after birth and transferred to the NICU after being briefly shown to her mother.

The father is called and immediately came to the hospital to see his newborn infant. Updates are provided to the mother who remains in the Labor and Delivery suite.

The parents are both devout Jehovah's Witnesses. Because of their faith, they are adamant that Baby L not receive any blood products. The mom tells one nurse: "If you give her blood, I will not take her home with me."



Although most of the mother's family lives in Africa, she has strong social support from other family members who live nearby. A patient advocate affiliated with the Jehovah's Witness community also provides support for the mom at the hospital.

At 24 hours of age, the infant remains critically ill but fairly stable. She is active and alert, her labs are not suggestive of infection, her perfusion and color are good, but she remains on respiratory support. The staff remain cautiously optimistic about the

baby's prospects. However, the parents' refusal of blood products quickly becomes a worry, as staff anticipate the clinical trajectory of the infant and her associated need for blood transfusions. Wanting to draw upon every supportive resource to help give the baby a fighting chance, the baby's primary nurse requests an ethics consult. She, in collaboration with the NICU team, wants to be proactive, avoid last-minute scrambling, and explore every conceivable remedy. She wants to know if the healthcare team would be able to give the infant a blood transfusion if necessary to save her life or avoid serious health problems.

How should the ethicist or ethics committee respond?

#### Comments from a Neonatologist/Bioethicist

Advances in neonatal medicine continue to improve the survival of infants with severe medical conditions, including infants born extremely premature. Yet the morbidity and mortality related to extreme prematurity are substantial in the United States and similar countries with intensive neonatal care. Data from the National Institute of Child Health and Human Development (NICHD) suggest that for infants born at 24 weeks the average survival is 50%. Among infants who survive to 18 months of age, one-third to one-half have moderate to severe neurodevelopmental impairment. (1)

The infant in this case has several additional risk factors. The gestational age seems uncertain ("about 24 weeks") which is crucial; if for instance her gestational age is really closer to 23 weeks, the average survival decreases to 30% and as many as 80% of survivors have moderate to severe neurodevelopmental impairment. (1) The cause for premature labor in this case is not disclosed to us, but one of the most common triggers is infection. Infection will increase both neonatal morbidity and mortality; we are told the infant's labs and clinical status are reassuring for no infection, but the infant was just born 24 hours ago. Another concern is that this infant was presumably born outside the hospital with delayed admission to an ICU. Rarely do Emergency Medical Technicians who respond to 911 calls have the equipment and training needed to resuscitate an extremely premature infant. The

resulting hypothermia, inadequate oxygenation and ventilation, hypotension and infection exposure all increase morbidity and mortality. (2) For example, we are told that the initial infant heart rate was ~60, often a trigger for neonatal CPR, but are not told if CPR was performed.

It is with the above factors in mind that we must interpret the clinicians' "cautious optimism" that this infant will do well. Clinicians are poor at determining prognosis for individual premature infants. (3) Key to this case are the odds of anemia and severe thrombocytopenia. As many as 80% of premature infants get red cell transfusions. Their anemia results from immature and impaired erythropoiesis and frequent blood draws, in addition to the common complications of sepsis, bleeding, and need for surgery. (4) Over 60% of premature infants get platelet transfusions for severe thrombocytopenia which, if untreated, can lead to intracranial hemorrhage and further neurologic insult. (5)

While the need for transfusion is common in extremely premature infants, there are data to suggest that overzealous transfusion may also be associated with intraventricular hemorrhage, necrotizing enterocolitis, and retinopathy of prematurity. (6) Ongoing research is focused on determining optimal thresholds for transfusions for these infants. (7)

In this case, the religious beliefs of the infant's parents raise the question of whether it is possible, and of value to the infant, to avoid all transfusions. Jehovah's Witnesses believe that the Bible forbids taking of blood and that those who do will be shunned from the community and endanger their souls.

(8) The parents here indicate that they will abandon the infant if she receives a transfusion.

While adults generally have autonomy to make decisions about refusing life-sustaining therapies for themselves, parents cannot always make similar decisions for their children. Parent decisionmaking neither falls squarely within the concept of autonomy nor surrogate decision-making. The principle of "best interests" is often applied to parent decisionmaking for children, others use the guidepost of "avoiding harm." The ethical and legal latitude given to parents who refuse treatments for a child often hinge on whether the treatments are emergent. If emergent, the child's interests generally prevail, and physical/physiologic interests are given greater value than spiritual interests.

We are told that the medical team is acting to avoid such an emergent situation, asking the ethics consultants to assist with aligning the parent and medical team goals. Medically, there are several proactive approaches that may minimize transfusion need. Clinicians can pay meticulous attention to whether a lab needs to be drawn from the infant, optimizing her blood volume. There are data to suggest that transfusion protocols may reduce the use of blood products by standardizing lab orders and

thresholds for responding to anemia. (9) Intravenous iron can be added. Studies of erythropoietin have mixed results for extremely premature infants but could be considered, if the locally-available formulation is acceptable to the parents. There are fewer options to proactively manage severe thrombocytopenia. Treatment with recombinant factors would be possible, though the limited data in this population raises concerns for unproven/experimental therapy in a very vulnerable patient. Some medical centers have expertise in "bloodless" medicine and surgery and could be consulted for additional strategies; again, relevant data is limited for extremely premature infants. The <u>Jehovah's Witness website</u> offers other supports for clinicians seeking blood-conservation strategies for Jehovah's Witnesses.

These proactive medical strategies should be paired with proactive ethical and legal strategies. The team must gather information about this particular family's beliefs regarding specific blood products—not all Jehovah's Witnesses have exactly the same beliefs. It is unclear in the above case whether the parent(s) are also from another country; if so, the interplay of religious and cultural beliefs deserves exploration. It is important to explore whether these parents believe that their religious culpability is averted if the clinicians actively override the parents' wishes and transfuse the infant based on medical necessity. If this is consistent with with their beliefs, this, in combination with meticulous efforts to minimize transfusion need, may be an agreeable common ground. The family may need reassurances of confidentiality to minimize risk of censure by their community. Many hospitals have a Jehovah's Witness liaison to assist clinicians and families in these scenarios.

When common ground cannot be found, clinicians need to know whether their state has relevant legal cases/ statutes relevant to transfusion practices for Jehovah's Witnesses, particularly for cases involving sick minors. (10) Some states may allow physicians to override parent refusal of transfusion in emergencies; some may protect physicians from liability if they accede to parent refusal of transfusion. Some hospitals may encourage seeking a second opinion and then transfer to a center willing to follow the parents' wishes. It should be noted that the transfer of an extremely premature infant at 24 hours of age risks additional morbidity/mortality, so this option for this infant would need to be considered very carefully.

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#### **Comments from a Healthcare Attorney**

We are presented with the case of an infant of 24 weeks' gestation. Her parents are described as devout Jehovah's Witnesses who are opposed to blood transfusions. Baby L is critically ill but fairly stable after birth, and the ethics committee has been asked by the baby's nurse to consult on the baby's care in order to avoid lastminute scrambling.

It is critical to note that, at "about" 24 weeks' gestation, Baby L is in the "periviable" window. Any infant of 24 weeks' gestation has a number of critical care decisions that need to be made, of which the transfusion issue is only one aspect. Baby L is within the window when a number of infants do not survive or only survive but with significant and permanent limitations, even if they do receive transfusions.

I would recommend that a social worker first talk to the parents to learn more about their values, priorities, religious beliefs, cultural values, family or religious community pressure, and understanding of their daughter's clinical situation. The person meeting with the parents should know that Jehovah's Witnesses are generally supportive of modern medicine, except for the transfusion issues. The person should also be aware that different Witnesses have differing interpretations of the prohibition on blood transfusions—for example, some Witnesses allow the transfusions of plasma but not whole blood, while others prohibit all blood products. Social workers are often better at interviewing patients than busy members

of the care team, who can make parents feel defensive or pushed, sometimes causing them to become more adamant. If possible, it could be helpful to interview the parents separately to allow for candid one-on-one communications, as sometimes one parent may be afraid to state his or her own views or to ask questions in front of the other. During all phases of the treatment process, the parents should be provided with the best available information as to the baby's clinical situation so that they can make the most informed decisions about all aspects of the baby's care, not just those pertaining to the transfusion issue.



The American College of Obstetricians and Gynecologists ("ACOG") published a position paper in October 2017, called the "Obstetric Care Consensus." The ACOG statement describes periviable as 20-26 weeks and notes that, while a number of factors can influence viability, it is a very complex and ethically challenging area. It notes no "bright line," but, rather, gives a range of outcomes based on various factors and analyses. The statement notes that very small differences in gestation can materially affect outcomes, i.e., if "about 24 weeks" is really closer to 23 or 25 weeks, the clinical outcomes can

vary significantly. After reviewing various clinical issues, the ACOG article discusses the importance of family counseling, "giving the patient [mother] and her family the opportunity to express their values and preferences." The article talks about the importance of interdisciplinary perspectives and coordination to ensure consistent messaging, including acknowledgement when data are uncertain and consensus cannot be obtained. "It is important that the healthcare team provide accurate, balanced, and unbiased information and guidance." (p. e195)

The ACOG statement also notes that, because different providers may have differing views and the treatment teams may vary or rotate, "it is preferable that institutions develop consensus guidelines regarding counseling about outcomes and a general approach to resuscitation of the periviable newborn... The family should be counseled regarding short-term and long-term consequences that are anticipated in the context of evolving clinical findings for their newborn...When a decision has been made to withhold or withdraw life-sustaining treatment after birth, the newborn should receive individualized compassionate care that is directed toward providing warmth, minimizing discomfort, and allowing the family to spend as much time with their newborn as desired."

The consistent theme in the ACOG statement is that decisions regarding periviable newborns should generally be made by the patient

and her family, giving them as much support, information and time as is reasonably available.

An article published in 2021 from the aptly-named "UpToDate.com" concurs, noting that "most infants" survive over 26 weeks and few survive below 22 weeks, so the difficult range is 22-26 weeks.

They note the difficulty in precisely calculating gestational age and the several factors that affect survivability within the window.

While the statute relates to abortion rights, Md. Code Ann Health-Gen. 20-209 uses a medical definition of viability—that of when the attending physician finds, using her best medical judgment based on the particular case, that there is a reasonable likelihood of survival outside the womb.



Once the parents have been interviewed in the most comfortable manner possible, they should be invited to meet with the ethics committee (or ethicist) in a non-confrontational forum for a discussion as to how to best care for Baby L. Given Baby L's birth within the window of periviability, the threshold question of whether to provide aggressive or comfort care should be addressed first, aside from the transfusion issue. If the decision is to provide aggressive care, additional decisions need to be made, including a discussion regarding transfusions.

Critical members of the treatment team should also be present so as to provide important clinical information.

The meeting should seek to promote dialogue and to problem-solve, rather than to push anyone's agenda or to dissuade the parents from their religious beliefs.

It is possible to obtain a court order to override the parents' wishes as to transfusion issues, and I have done so in appropriate occasions when an infant would be otherwise viable and may be in need of a transfusion that overrides a parents' religious beliefs. Typically such orders name a hospital administrator as emergency guardian of the person with the limited authority to be able to consent to transfusions, are obtained for very short windows of time (144 hours), and are sought, whenever possible, with appropriate advance notice to the parents and with counsel appointed for the infant. They are often scheduled for a subsequent hearing after the initial period has expired, but subsequent hearings are often moot. In some cases, the administrator never has to consent to a transfusion, as every reasonable effort is made to avoid the transfusion, both for clinical reasons and due to the parents' objections.

We do not know all the facts in this case that would be available in a real situation. However, given that Baby L is reportedly in the midst of the periviable period, I would counsel the hospital to try to defer to the parents' decision-making, based on as much objective information as time and the patient's situation will allow and a discussion of the parents' beliefs and priorities, so long as the decisions are made within the boundaries of the law and Hospital policy.

Sigrid C. Haines Partner Whiteford, Taylor & Preston

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American College of Obstetricians and Gynecologists; Society for Maternal-Fetal Medicine. Obstetric Care consensus No. 6: Periviable Birth. Obstet Gynecol. 2017 Oct;130(4):e187-e199. doi: 10.1097/AOG.0000000000002352. Periviable birth (Limit of viability). https://www.uptodate.com/contents/periviable-birth-limit-of-viability.

Md. Code Ann. Health-Gen. 20-209

#### What the Ethicist and Ethics Committee Did



After a chart review, the ethics director's first call was to legal and then he proceeded to Labor and Delivery to meet the mother. They talked about the wonder of birth, the challenges ahead, her love for her infant, and how she wanted everything done to save the life of her baby; the one exception being administering blood products. The ethics director asked if she would like a visit from one of the hospital chaplains to provide spiritual support. After being assured that the ministry would be provided in the name of Jesus and Jehovah, she gratefully agreed. The ethicist assured the mother that she and her infant would receive the best care possible and that he would remain in regular contact. She smiled and expressed her gratitude.

Meanwhile the hospital's legal and risk management offices were examining what options might be available. There was not an appetite for going to court to try to get a judge's emergency ruling to allow the hospital to administer blood products. They felt there was not sufficient precedent in the state of Maryland. Thus the initial legal recommendation was to invoke the emergency treatment section of the Maryland Health Care Decisions Act (MHCDA). The attorney's thinking was:

1) The treatment would be of an emergency nature; 2) The people authorized to give consent would not be immediately available; and, 3) Without the treatment there would be substantial risk of death. That approach, however, did not resonate with the clinical care team as the mom was still a patient in Labor and Delivery and the father was just a phone call away, and it would take a bit of time to actually get blood delivered to the unit. Of course the parents were available for decision-making. In response, the ethicist reached out to a law professor who was familiar with the MHCDA for a collegial discussion and opinion. She recommended that we reconsider going to court making the argument that it was an emergency as the infant could decompensate at any time. This opinion was relayed back to the hospital attorney and he was asked to reconsider his recommendation. When it became apparent to legal counsel that treating under the auspices of the parents being unavailable to provide consent was not a viable approach, he agreed to explore the option of going to court. Risk management was going to explore options as well, and the ethicist was going to engage in another conversation with the baby's mother, as they had established a warm and trusting relationship.

Meanwhile, the staff continued to worry as the infant remained in critical condition and they knew that the time was approaching when blood transfusions would be necessary. All involved were caring for Baby L not just with skill and determination, but with kindness and concern.

During a lengthy conversation, the baby's mother once again affirmed that blood products were not to be used. She and the ethicist openly discussed how seriously ill her beloved daughter was and that soon the physicians would likely be at a point where they would need to provide blood in order to save the life of the child. She was directly asked what are we to do when that point comes? She replied: "Well that would be a decision that YOU make." A door seemed to be opening. Asked if she would accept the doctors' decisions, she said, "Yes." A preliminary conversation then took place about allowing the care team to become the medical decision-maker regarding what treatments would be necessary to potentially save the life of Baby L. Several follow-up discussions were held throughout the morning and afternoon, and the mother affirmed each time that she would allow the medical providers to make decisions about necessary treatments. These discussions were documented in the chart.

Next, the Patient Care Advisory Committee (PCAC) process was explained by the ethicist to the mother and she accepted the invitation for herself and her husband to attend the meeting. She was informed who the participants would be: COO as designee of the hospital president, SW, physician who is not the attending, director of risk management, senior nursing director, chaplain, and ethics director as moderator. She was informed that the recommendations of this group would be implemented by the hospital. If she and her husband disagreed they would have the right to take the matter to court and ask a judge to reverse the decision or they could seek a transfer of the patient.

The process began with a meeting between the care team and the PCAC, the purpose of which was to discuss the clinical details. The consensus recommendation of the PCAC was strong and clear: given that Baby L was most likely to need life-saving transfusions, there was a medical necessity for the care team to have that treatment available to use. The PCAC would present that decision to the family.

The PCAC meeting was held with Baby L's parents immediately thereafter. Although this situation was taking place during a time when most meetings were being held via Zoom, the PCAC felt that face-to-face interaction was essential. After introductions, the medical situation was updated for the family. They were again informed about the baby's anticipated need for blood products.

The Committee members explained that they had reached a consensus that blood products are likely to become medically necessary in order to provide optimal care for their baby. The parents understood the situation and indicated that they did not want to contest either the decision or the treatment plan. They proceeded to explicitly ask that the clinical care team become the decision-maker, not just for blood-related decision-

making but for all treatments. Each stated they trusted that whatever decisions were made would be in the best interests of Baby L. They indicated that all they were asking for at this point was to be kept informed of what treatments were being provided and to receive regular updates on how their daughter was doing.

When the outcome of the meeting was shared on the NICU the relief was palpable among the staff. They were caring for the infant with dedication, skill, and tenderness, and with some emotional investment. In the week to come, Baby L's medical condition waxed and waned. For the most part she remained in critical condition—on respiratory/temperature/ and feeding support, moderately increased heart size with apnea/brady-cardia/desaturation episodes, and continuing anemia. That said, she also remained reassuringly active.

Thirteen days after being born, however, Baby L developed hydrocephalus. Two days later she was transferred to a regional pediatric hospital where she remains in critical but stable condition as of this writing. The ethics notes, which describe the agreed-upon process for making decisions, especially in regard to blood products, accompanied her.

### **Comments from the Hospital's Ethics Director**



The ethical dilemma is fairly straightforward. There is obvious tension between respecting the autonomy of the parents as decision-makers and honoring their firmly held religious beliefs and protecting the welfare of a vulnerable, critically-ill infant who cannot speak for herself. The care team, regularly assured the parents that we would always respect their faith but that our primary goal was to give Baby L the best chance to survive and be as healthy as possible. From very early on, the team,

with unwavering commitment, acted on the moral obligation to be a voice for the infant who could not advocate for herself, respecting but giving less weight to the autonomy of the parents in preference to the welfare of the baby.

In an ironic and parallel fashion the parents were also working out their own internal moral dilemma. They had to grasp two opposing pathways at once: live by their faith and do the right thing for their baby. These were not synchronistic courses of action. As the parents were struggling to find a way to reconcile the conflicting options, they began to see how the agreed-upon solution offered them a way for bending but not breaking their faith while giving their daughter the very best chance at life. In never having been required to give consent for blood products they would be relieved of some shame and guilt, as well as moral culpability.

Recently, the Senior Nursing Director remarked, as we were discussing Baby L's current condition at [the pediatric hospital], "I hope after she is fully stabilized, she will come back to us. She will get great care at [the pediatric facility]. Here she will receive great love."

#### A few salient take-home lessons loom large:

- The all-hands-on-deck approach, which was activated early on, was helpful.
- Building trust across a cultural divide is essential. This requires time and being mindfully present at the bedside.
- Being creative and relentless in considering options and approaches can be useful.
- Applied ethics entails rolling up one's sleeves and engaging with all of the important stakeholders in interdisciplinary collaboration. It extends far beyond philosophical and theoretical approaches to resolving problems.
- Sometimes love works, even in the high-pressured environment of modern healthcare.

#### **CALENDAR OF EVENTS**

#### 2021 Webinar List

#### **Children's Mercy Kansas City**

#### **Brown Bag Workshops\***

### Use of Tertiary Care Pediatric Emergency Department for Over-the-Counter Medications Tuesday April 27, 2021

Cassandra Newell, MSN, CPNP, RN, CPN, Pediatric Nurse Practitioner, Emergency Department, CMKC LeChelle Nelson, RN, CPN, MSN, CPNP-BC, Critical Care Nurse Practitioner, Emergency Department, CMKC

### Rates of Positive Suicide Screens among the Emergency, Inpatient and Outpatient Clinics at a Tertiary Care Children's Hospital

Tuesday May 18, 2021

Fajar Raza, MBBS, Pediatric Ethics Fellow, CMKC Shayla Sullivant, MD, Child & Adolescent Psychiatrist, CMKC

#### Do Reasons Matter? Rethinking Pediatric Treatment Disagreements

Tuesday June 22, 2021

Amy Caruso-Brown, MD, MSc, MSCS, Associate Professor of Pediatrics and Bioethics & Humanities, SUNY Upstate Medical University, Syracuse, NY

\*All Brown-Bag Workshops take place from Noon – 1PM CDT. For non-employees of Children's Mercy, please contact Jeremy Garrett (jgarrett@cmh.edu) and Jennifer Pearl (jepearl@cmh.edu) via email (preferably at least 3 business days in advance) if interested in attending.

#### **Pediatric Bioethics in the Shadow of COVID Symposium**

Wednesday, May 5, 2021 9:00 am CDT

The COVID-19 pandemic raised complicated ethical issues for children and those who care for them. Children's Mercy Bioethics Center will host a symposium to discuss these complex ethical issues. Thought leaders in pediatric bioethics and health policy will reflect on the successes, failures and surprises that arose and that likely will continue with the COVID-19 pandemic. Register here.

#### **Columbia University**

#### Racing with Vaccines: Data, Narratives, and Ethics

With Robert Klitzman (Bioethics), Danielle Spencer (Narrative Medicine), and David Kreutter (Applied Analytics). Watch the recording here.

**COVID-19 Related Webinars** compiled by the Columbia University Department of Medical Humanities and Ethics can be found here.

#### **CALENDAR OF EVENTS (cont.)**

#### **Hastings Center**

Hastings Center President Mildred Solomon was a featured speaker on Included: <u>The Disability</u> <u>Equity Podcast</u> of the Johns Hopkins University Disability Health Research Center. Read the transcript here.

<u>Advancing Social Justice, Health Equity, and Community</u>. The Daniel Callahan Annual Lecture, with Duke professor Patrick Smith and Hastings Center president Mildred Solomon, was held February 9, 2021. Click here to watch the Zoom event.

#### **Johns Hopkins**

#### On the Outrage of Black Mothers: Healing the Past in the Present

<u>Tuesday, Apr 20, 2021</u>, 12:00 - 1:00 pm EST

#### **Ethics For Lunch**

The Many Faces of Trust During the Pandemic: Watch the Video

Ethical Challenges of Effective Pain Management in Patients with Severe Cancer Pain and Substance

Use Disorder: Watch the Video

#### **University of Maryland Carey School of Law**

#### The Rothenberg Health Care Law & Policy Speaker Series

**Challenges in Equitable Allocation of SARS CoV-2 Vaccine** 

Professor R. Alta Charo, the Warren P. Knowles Professor of Law and Bioethics at the University of Wisconsin at Madison.

Watch the recorded presentation <u>here</u>.

#### The Politics of Public Health Regulation

Joshua M. Sharfstein, Vice Dean for Public Health Practice and Community Engagement and Professor of the Practice at the Johns Hopkins Bloomberg School of Public Health Watch the recorded presentation here.

#### **Eradicating Systemic Racism in the Government's Pandemic Response**

Professor Ruqaiijah Yearby, Executive Director and Co-Founder of the Institute for Healing Justice and Equity Center for Health Law Studies and Professor at the Saint Louis University School of Law Watch the recorded presentation here.

#### **CALENDAR OF EVENTS (cont.)**

#### **Michigan State University Bioethics**

#### Healthcare Artificial Intelligence Needs Patient Data: Who "Owns" the Data About You?

Adam M. Alessio, PhD, Professor, Department of Computational Mathematics, Science, and Engineering; Department of Biomedical Engineering and Radiology; Institute for Quantitative Health Science & Engineering, Michigan State University.

View Recorded Webinar

#### **Maternity Care Deserts in Rural Michigan**

Andrea Wendling, MD, Director of Rural Medicine and Professor of Family Medicine, Michigan State University College of Human Medicine.

View Recorded Webinar

#### Is Seeking Information on Social Media Harmful to Your Health?

Anjana Susarla, PhD, Professor of Information Systems, Michigan State University Eli Broad College of Business.

View Recorded Webinar

#### **Controversies and Complexities in LGBTQ Health Care**

Emily Antoon-Walsh, MD, MA, FAAP (she/her), Seattle Children's Hospital Regional Pediatric Hospitalist; Clinical Assistant Professor, Department of Pediatrics, University of Washington. Barry DeCoster, PhD (he/him), Associate Professor of Bioethics and Philosophy, Department of Population Health Sciences, Albany College of Pharmacy and Health Sciences. Henry Ng, MD, MPH, FAAP, FACP (he/they), Center for LGBTQ+ Health, Transgender Surgery and Medicine Program, Cleveland Clinic Foundation.

View Recorded Webinar

#### **Washington State University**

"Bioethics Grand Rounds: Health Professional Rights and Obligations During Pandemic" April 28th, 2021, Noon-1:00pm PST Matthew Wynia, PhD, MPH & Heidi Malm, PhD Register Here

The Law & Health Care Program Maryland Healthcare Ethics Committee Network University of Maryland Francis King Carey School of Law 500 W. Baltimore Street Baltimore, MD 21201

The Maryland Healthcare Ethics Committee Network (MHECN) is a membership organization, established by the Law and Healthcare Program at the University of Maryland Francis King Carey School of Law. The purpose of MHECN is to facilitate and enhance ethical reflection in all aspects of decision making in health care settings by supporting and providing informational and educational resources to ethics committees serving health care institutions in the state of Maryland. The Network attempts to achieve this goal by:

- Serving as a resource to ethics committees as they investigate ethical dilemmas within their institution and as they strive to assist their institution act consistently with its mission statement;
- Fostering communication and information sharing among Network members;
- Providing educational programs for ethics committee members, other healthcare providers, and members of the general public on ethical issues in healthcare; and
- Conducting research to improve the functioning of ethics committees and ultimately the care of patients in Maryland.

MHECN appreciates the support of its individual and institutional members. MHECN also welcomes support from affiliate members who provide additional financial support.

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