MEDICAL ETHICS ADVISOR®

For 25 years, your practical guide to ethics decision making

October 2013: Vol. 29, No. 10
Pages 109-120

IN THIS ISSUE

Ethical concerns with emerging neurotechnologies.....cover

Why clinicians often under-utilize ethics consults.....111

Update on judicial interventions in transplant decisions.....113

Ethical considerations with mandatory flu vaccinations.....114

Use ethical approaches with impaired clinicians 115

Statement of Financial Disclosure:
Arthur R. Derse, MD, JD (Consulting Editor), **Shelly Morrow Mark** (Executive Editor), **Leslie Hamlin** (Managing Editor), and **Stacey Kusterbeck** (Contributing Editor) report no consultant, stockholder, speakers' bureau, research, or other financial relationships with companies having ties to this field of study.

AHC Media

"Neurohype" is one ethical concern with BRAIN initiative

Time is right for bioethicists to tackle issues

There is no shortage of ethical considerations involving the Brain Research through Advancing Innovative Neurotechnologies (BRAIN), a $100 million initiative launched by President Obama that aims to uncover new ways to treat, prevent, and cure brain disorders. "There are already many serious ethical considerations with respect to neurotechnologies. The BRAIN initiative might mitigate some of those concerns, while reporting of it could exacerbate some others," says **Henry T. Greely**, JD, director of the Stanford Center for Law and the Biosciences and chair of the steering committee at Stanford Center for Biomedical Ethics, Stanford, CA.

"This is a concerted effort to advance our understanding of neuroscience," says **Thomas Cochrane**, MD, MBA, senior ethics consultant at Brigham and Women's Center for Bioethics and assistant professor of neurology at Harvard Medical School in Boston. "Specifically, a coalition of scientists would like to characterize human neuroanatomy down to the level of connections between individual neurons and groups of neurons."

Better understanding of normal brain function is expected to lead to better understanding of disease states, then to new treatment strategies for those diseases, and possibly the opportunity for enhancement of normal function.

EXECUTIVE SUMMARY

Many ethical considerations will be examined with The Brain Research through Advancing Innovative Neurotechnologies initiative, including privacy, moral responsibility for one's actions, stigmatization and discrimination, and ensuring protection of vulnerable populations. Some other key ethical issues are:
- insufficient evidence of safety of efficacy of treatments;
- excessive "hype" that can result in unrealistic expectations;
- whether neurotechnologies will be translated into clinical care in a reasonable timeframe.

"Like any major scientific advance, big advances in neuroscience have the potential for great good and also for harm," says Cochrane. "The good news about these questions is that we've got a little time — not a lot, but some — to think carefully about them, before the really big disruptive changes come."

In the conversation about the BRAIN initiative, bioethicists must find a middle ground between excessive hype and excessive skepticism, says **Erik Parens**, PhD, senior research scholar at The Hastings Center in Garrison, NY.

Medical Ethics Advisor® (ISSN 0886-0653) is published monthly by AHC Media, LLC, One Atlanta Plaza, 950 East Paces Ferry Road NE, Suite 2850, Atlanta, GA 30326. Telephone: (404) 262-7436. Periodicals Postage Paid at Atlanta, GA 30304 and at additional mailing offices.

POSTMASTER: Send address changes to Medical Ethics Advisor®, P.O. Box 550669, Atlanta, GA 30355.

AHC Media, LLC is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

AHC Media, LLC designates this enduring material for a maximum of *18 AMA PRA Category 1 Credits™*. Physicians should only claim credit commensurate with the extent of their participation in the activity.

This activity is intended for acute care physicians, chiefs of medicine, hospital administrators, nurse managers, physician assistants, nurse practitioners, social workers, and chaplains. It is in effect for 36 months from the date of publication.

Opinions expressed are not necessarily those of this publication. Mention of products or services does not constitute endorsement. Clinical, legal, tax, and other comments are offered for general guidance only; professional counsel should be sought for specific situations.

SUBSCRIBER INFORMATION

Customer Service: (800) 688-2421 or fax (800) 284-3291, (customerservice@ahcmedia.com). Hours of operation: 8:30 a.m.-6 p.m. Monday-Thursday; 8:30 a.m.- 4:30 p.m. Friday.

Subscription rates: U.S.A., one year (12 issues), $499. Add $17.95 for shipping & handling. Outside U.S., add $30 per year, total prepaid in U.S. funds. Discounts are available for group subscriptions, multiple copies, site-licenses or electronic distribution. For pricing information, call Tria Kreutzer at 404-262-5482. Back issues, when available, are $83 each. (GST registration number R128870672.)

Interim Editorial Director: **Lee Landenberger**.
Managing Editor: **Leslie Hamlin** (404) 262-5416 (leslie.hamlin@ahcmedia.com)
Executive Editor: **Shelly Morrow Mark** (407) 614-5185 (shelly.mark@ahcmedia.com).

AHC Media

EDITORIAL QUESTIONS

Questions or comments? Call Leslie Hamlin at (404) 262-5416.

"The brain is one very important organ in a very complex body, which interacts with still more complex local and global environments," says Parens. "Making headway in understanding one part of that vast system will be fascinating. But it won't be a panacea any more than mapping the human genome was."

Safety and efficacy

The Presidential Commission for the Study of Bioethical Issues will examine broad ethical concerns for human and animal participants in neuroscience research, as well as the societal implications of discoveries that could arise from the BRAIN Initiative, according to communications director **Hillary Wicai Viers**. These include questions relating to privacy, personal agency, moral responsibility for one's actions, stigmatization and discrimination, and the appropriate use of neuroscience in the criminal justice system.

"As important research is done that has the potential to shape what we know about conditions like Alzheimer's and Parkinson's — and other diseases that afflict tens of millions — careful reflection on the ethics of neuroscience will help establish appropriate interventions on the human brain, she says.

It is necessary to ensure protection of vulnerable populations, such as individuals with cognitive impairments, and educate a wider range of researchers, ranging from linguists to economists, who might not be familiar with human participants research protections.

Greely says the biggest concern right now is "neurohype" — lots of excitement coupled with insufficient evidence as to what neurotechnologies can realistically do. "There is lots of activity going on without a lot of good evidence that it works," he says. "People aren't paying enough attention to what exactly has been shown to work, and what could plausibly work within a realistic timeframe."

It's not yet known whether cranial stimulators work for anything other than FDA-approved purposes, or what their safety is like for anything else, for instance. "And optogenetics is a wonderful research tool for doing neuroscience in mice, but a lot of the reporting seems to gloss over the difficulties of going from mice to human," says Greely. "Safety and efficacy is not just a regulatory issue. It's an ethical issue."

Timing of treatments

It is unclear whether neurotechnologies developed and articulated under the BRAIN initiative will be

translated into clinical care within a reasonable window of time. "We must be equally concerned about the ampliative claims and underestimated potential adverse effects that prompt over-expedience in moving novel technologies to the clinical forefront," says **James Giordano**, PhD, chief of the Neuroethics Studies Program at Edmund D. Pellegrino Center for Clinical Bioethics at Georgetown University Medical Center in Washington, DC. Concerns include unanticipated mid- to long-term effects, and the relative benefits, burdens, and harms incurred by either omission or commission. He recommends bioethicists take these steps:

- Realistically assess the capabilities of neurotechnologies.
- Develop approaches to either prevent problems, or resolve them early.
- Consider what areas and types of neurotechnology are being subsidized, fortified, and advanced.
- Assess how these developments will affect local, regional, national, and global societies, economics, and politics.

Greely says that in some cases, expectations for neuroscience in medicine have been somewhat disappointing. It was hoped, for example, that in the fifth edition of the *Diagnostic and Statistical Manual of Mental Disorders*, there would be more physical indicators of mental illnesses. "I think people hoped you could do an MRI [magnetic resonance imaging] and see OCD [obsessive-compulsive disorder] or see autism, and we can't," he says. "The brain is a really complicated physical organ, and we haven't been able to see those yet."

In the clinical setting, bioethicists can help doctors to confront unrealistic expectations. "People hoping for miracles are likely to be disappointed," says Greely. "They may be seeing beautiful brain images in magazines, but it is not yet at a stage where it helps very much with medical treatment."

Cochrane expects the controversy will come to an end when treatments are developed for the diseases in question, or when it's determined what prognostic value these tests have, and for which patients. Meanwhile, he says, "it's the medical ethicist's job to keep the excitement over these new technologies in perspective." ■

SOURCES

- **Thomas Cochrane**, MD, MBA, Senior Ethics Consultant, Brigham and Women's Center for Bioethics, Assistant Professor of Neurology, Harvard Medical School, Boston. E-mail: tcochrane@partners.org.
- **James Giordano**, PhD, Chief, Neuroethics Studies Program, Edmund D. Pellegrino Center for Clinical Bioethics, Georgetown University Medical Center, Washington, DC. Phone: (202) 687-1160. E-mail: jg353@georgetwon.edu.
- **Henry T. Greely**, JD, Director, Stanford (CA) Center for Law and the Biosciences. Phone: (650) 723-2517. E-mail: hgreely@stanford.edu.
- **Erik Parens**, PhD, Senior Research Scholar, The Hastings Center, Garrison, NY. Phone: (845) 424-4040 ext. 224. E-mail: parense@thehastingscenter.org.

Give clinicians good reasons to call for ethics consults

Begin with relationship-building

The consensus is, "Ethics consults are useless." "They never give us any answers." "They always side with the family."

Clinicians often under-utilize ethics consults because they believe they're unhelpful or overly time-consuming, says **Autumn Fiester**, PhD, director of the Clinical Ethics Mediation Program at University of Pennsylvania's Perelman School of Medicine in Philadelphia.

Unfortunately, there is some truth to these negative perceptions. "Sometimes, people have had bad experiences with ethics consults in the past, and that makes them decide it's not very helpful," acknowledges **Benjamin Wilfond**, MD, director of the Treuman Katz Center for Pediatric Bioethics at the Seattle (WA) Children's Research Institute.

Make your presence known

Clinical ethicists can reach clinicians through presentations, grand rounds, and brochures. However, simply being "present" can have a bigger impact. "Ethicists need to be seen as part of the everyday working environment, not as ancillary or anomalous," says **D. Micah Hester**, PhD, chief of

EXECUTIVE SUMMARY

Clinicians often under-utilize clinical ethics consults because they believe these to be unhelpful and time-consuming, but bioethicists can counter these misperceptions with education and by building relationships in clinical areas. To encourage clinicians to call for ethics consults:

- spend time in clinical areas regularly;
- have informal discussions about cases;
- encourage clinicians to call for any challenging case.

the Division of Medical Humanities at University of Arkansas for Medical Sciences and clinical ethicist at Arkansas Children's Hospital, both in Little Rock. He recommends these practices:

• Spend time in clinical areas, either by rounding in the department or informal visits.

• Have regular discussions — weekly, monthly, or quarterly — with different clinician groups. For example, have informal case discussions with house staff and fellows, or start a journal club with a service group.

• Instead of promoting consultations, promote "debriefings" — after-the-event discussions with medical, nursing, and affiliated staff.

"All of these help break down barriers by developing familiarity and comfort with consultants and ethical reflection," says Hester.

Bioethicists at Treuman Katz Center for Pediatric Bioethics have found that when they round on certain units frequently, those units make more calls for ethics consults. "When you are comfortable with people, it makes it more likely they will call you when things get complicated," says Wilfond.

Twice a year at Seattle Children's, cases from ethics consults are presented at grand rounds by the person who called the consult, with an outside commentator discussing the approach that was taken. This reminds people that ethics consults are useful, says Wilfond.

"Clinicians are more likely to call if they know that the person doing the ethics consult has the appropriate expertise, and is sensitive to time pressures in the clinical environment," says **Hannah I. Lipman, MD, MS**, associate director of the Montefiore-Einstein Center for Bioethics in Bronx, NY. Here are some practices that can encourage clinicians to utilize ethics consults:

• Remind clinicians that consults can help with any challenging case.

Any ethically challenging case should bring the possibility of an ethics consultation to the mind of clinicians, just as readily as heart-related challenges bring a cardiology consult to mind, says Hester.

In many hospitals, it is commonly "high-stakes" end-of-life and/or critical care cases that generate ethics consults. "But clearly, ethics affects the wide range of medical practices, both in- and outpatient," says Hester.

Since most ethics consults involve end-of-life decision-making, the family and clinical team are often already at loggerheads. "In my view, consults should be called at the first sign that the doctor-patient or doctor-family relationship is breaking down," says Fiester.

• Educate clinicians that consults don't necessarily need to be formal and time-consuming.

To educate clinical areas on this, Wilfond developed a one-page flyer about the consult service. "Some consults are big meetings and others are conversations," he says. "But even for conversations, we try to do consults in person whenever possible. It's another way of building relationships."

When a conflict arose within the care team about the best approach for a particular patient, the physician involved was initially very opposed to involving ethics. Wilfond suggested a conversation instead of a formal consult.

After a half-hour discussion, it appeared as though nothing was resolved. "But afterward, the primary nurse and physician ended up continuing the conversation by themselves, and came up with a plan," says Wilfond. "We clearly got things going, but they finished it on their own."

• Be prepared to explain the role of the ethics consultant.

Clinicians are sometimes unsure of the consultant's role. "They might think we're going to slow a case down or take control over the care of their patient," says Lipman.

She routinely explains to clinicians that the consultant's role is primarily that of mediator with ethics expertise, with the goal of bringing parties to consensus, rather than substituting for the primary team. "We help the clinical team and patients and families understand the bioethics implications of the choices in front of them," says Lipman. "We're there to help support them in understanding the ethics issues."

The team uses consults to teach approaches to common ethics dilemmas, which clinicians can draw upon in future cases. For instance, clinicians often expect a "yes" or "no" answer when they call about complex discharge cases. "We explain that we are not answer-oriented; we are process-oriented," Lipman says. "We tell them the things they need to consider when determining how to honor the patient's values as much as possible, and still ensure a safe discharge."

Some clinicians avoid ethics consults because they are concerned about a phenomenon known as the "ethics police," says Hester. "That the consultant will swoop in and tell everyone what is right and wrong."

Clinicians may need to be told that ethics consultations aim more at facilitating discussions and clarifying values. Hester informs clinicians that ethics consults can help in these ways:

• Consults can reduce length of stay and costs because protracted problems get resolved earlier than if no consult is called;

• Physicians report that consults aid in clearer communication;

• Patients and families note that they feel more included in their care and appreciate having complex issues simplified for better decision-making.

"What patient isn't helped when his or her physician better understands what values are being traded on during the relationship?" asks Hester. "If ethics consults can facilitate better communication, the patient is the beneficiary." ■

SOURCES

• **Autumn Fiester**, PhD, Department of Medical Ethics & Health Policy, Perelman School of Medicine, The University of Pennsylvania, Philadelphia. Phone: (215) 573-2602. E-mail: fiester@mail.med.upenn.edu.

• **D. Micah Hester**, PhD, Chief, Division of Medical Humanities, University of Arkansas for Medical Sciences, Little Rock. Phone: (501) 661-7973. E-mail: DMHester@uams.edu.

• **Hannah I. Lipman**, MD, MS, Associate Director, Montefiore-Einstein Center for Bioethics, Bronx, NY. Phone: (718) 920-4630. E-mail: hlipman@montefiore.org.

• **Benjamin Wilfond**, MD, Director, Treuman Katz Center for Pediatric Bioethics, Seattle (WA) Children's Research Institute. Phone: (206) 884-8355. E-mail: benjamin.wilfond@seattlechildrens.org.

Ethics of judicial intervention in transplant decisions

In a highly publicized case of a 10-year-old child with cystic fibrosis, a federal judge ordered that both the girl and an 11-year old boy with cystic fibrosis be allowed to compete on an equal basis with adults for lungs from adult donors.

Shortly afterward, the executive committee of the Organ Procurement and Transplant Network (OPTN) declined to pursue an emergency change to give the same advantage to all children in need of lungs. Instead, the committee voted to approve a modification to the lung allocation policy, granting pediatric patients the ability to request an exception and be considered in the adult pool.

Stuart C. Sweet, MD, PHD, medical director of the Pediatric Lung Transplant Program at Washington University School of Medicine in St. Louis, MO, says these two important ethical questions arose from this scenario: Is the policy wrong, and if so, should it be changed so that anybody who wants to do what this child asked to do, could? Should the decision-making be taken out of the court's hands and put in the hands of medical professionals?

The OPTN executive committee decided there were not enough data to show that there is a clear impact to the pediatric population to warrant making a change to the policy. They also decided that the decision-making about whether any given case that challenged the policy should come to the OPTN and be heard by a review board, and not be left for the courts to decide.

"The Court accepted that compromise, and vacated the injunctions once both children had their appeals under the new policy heard and approved by the lung review board. The temporary restraining orders were allowed to expire," Sweet says.

EXECUTIVE SUMMARY

A court recently ordered that two pediatric patients with cystic fibrosis be allowed to compete on an equal basis with adults for lungs from adult donors, but transplant experts say judicial intervention risks disrupting a system based on public trust. Some ethical considerations:

• Not every child waiting for a lung transplant has access to resources such as representation by an attorney.

• Changing the entire lung allocation policy through an urgently convened review would have confounded a carefully constructed allocation policy.

• There wasn't a compelling argument that the population of children in that age group was being placed at risk, to warrant wholesale changes to the policy.

Ethical principle of allocation

Reviewing the fairness of an organ allocation policy through the experience of *any* individual transplant candidate's case could lead to an unbalanced emphasis of justice concerns at the expense of utility considerations, says **Alexandra K. Glazier**, Esq., vice president and general counsel at the New England Organ Bank in Waltham, MA.

This is because utility as an ethical principle of allocation requires system-wide measurement, says Glazier, and the analysis of utility is especially critical in a system faced with a significant organ shortage. "Any child awaiting lung transplantation can request an exception if medically appropriate," she says. The 10-year-old in the reported case was granted an exception and subsequently transplanted twice. It has been reported that both sets of lungs were from adult donors.

Sweet says one reason it's ethically questionable for the courts to get involved in an individual case is because not every child waiting for a lung transplant has access to resources such as representation by an attorney.

In addition, changing the entire lung allocation policy through an urgently convened review would have confounded the careful construction of allocation policy developed through a publically transparent and deliberative process, argues Glazier.

"The circumvention of organ allocation through judicial appeals creates the opportunity for cases that are emotionally appealing, such as rescuing children, and may undermine the main ethical directive of an equitable allocation system to maximize the public good and achieve justice," says Glazier.

System placed at risk

The message that lawsuits are a mechanism for more favorable organ allocation runs the risk of disrupting a stable system based on public trust. "To overturn a carefully crafted policy based on information that was primarily provided by the plaintiff is problematic," says Sweet. "For the court to do that, when only hearing one side of the equation, places the whole system at risk."

There was no vehicle for medical professionals to hear the case, adds Sweet, and there wasn't a compelling argument that the population of children in that age group was being placed at risk to warrant wholesale changes to the policy. Since the OPTN had not envisioned this particular scenario coming up when the policy was developed, there was no existing process for a review board to hear the case.

The discussion about pediatric access to lungs has not included consideration of how often transplantable pediatric lungs are rejected by transplant surgeons, notes Glazier, perhaps due to regulatory pressures related to transplant program outcome measures.

"In making this decision, the lungs provided to the child would be taken away from an adult who might not survive to receive the next offer," says Sweet. "It is not a trivial decision for the court to make." ■

SOURCES

• **Alexandra K. Glazier**, Esq., Vice President/General Counsel, New England Organ Bank, Waltham, MA. Phone: (617) 244-8000. E-mail: Alexandra_Glazier@neob.org.

• **Stuart C. Sweet**, MD, PHD, Medical Director, Pediatric Lung Transplant Program, Department of Pediatrics, Washington University School of Medicine, St. Louis, MO. Phone: (314) 454-4131. E-mail: Sweet@kids.wustl.edu.

Ethical arguments strong for mandatory vaccination

Patients' welfare is key

Public health interventions that are mandatory and infringe on personal liberty and autonomy *can* be ethically justified — but only if the interventions are reasonably safe and effective, voluntary participation has failed, and many people will be harmed if the intervention does not occur, according to **Alan R. Fleischman**, MD, clinical professor of epidemiology and population health at Albert Einstein College of Medicine. "I believe mandatory flu vaccination programs for health care professionals meets these criteria, and should be widely implemented," he concludes.

The Centers for Disease Control and Prevention surveyed 2,348 health care providers in April 2012 and found that 66.9% reported having had an influenza vaccination for the 2011–2012 season.[1]

The main ethical concern in the debate regarding mandatory influenza vaccination of health care workers is the potential tension between protecting patients' welfare and restricting workers' liberty, says **Armand H. Antommaria**, MD, PhD, FAAP, director of the Ethics Center at Cincinnati (OH) Children's Hospital Medical Center.

"Given their role, health care workers have an ethical obligation to be vaccinated," says Antommaria. "Unfortunately, voluntary vaccination programs have not been sufficiently effective."

Flu epidemics continue to kill large numbers of people each year, and while immunization is not fully protective against the flu, it greatly diminishes the likelihood of infection and attenuates the severity of the illness, says **Alan R. Fleischman**, MD, clinical profes-

EXECUTIVE SUMMARY

Mandatory influenza vaccinations for health care workers can be ethically justified because the vaccine is reasonably safe and effective, voluntary participation has failed, and many people will be harmed if it does not occur, according to bioethicists.

- Infected health care professionals frequently transmit influenza to vulnerable patients.
- Health care professionals are ethically obligated to prioritize patients' well-being.
- Voluntary programs haven't resulted in a substantial majority of workers being immunized.

sor of epidemiology and population health at Albert Einstein College of Medicine in Bronx, NY.

"Overriding the strongly held principle of autonomy should only be considered when an individual's decision directly injures others," he says. Studies show that infected health care professionals frequently transmit flu to vulnerable patients, which can result in very serious illness and death.[2]

"In addition, the vaccine appears to be safe, with very few serious acute reactions or long-term complications," says Fleischman. "These are the facts that must be taken into account as one discusses the question of mandatory immunization in health care workers."

Putting patients first

Another ethical consideration is the obligation of health care professionals to behave in a manner consistent with ethical codes of practice, which clearly prioritize patient interests over personal concerns and well-being. "The ethical principle of beneficence asks each health care professional to maximize benefits to patients and minimize harms," says Fleischman. "This principle even requires professionals to place themselves at some level of risk to protect the interests of their patients."

Serious efforts to educate and incentivize health care workers to obtain immunizations have not resulted in a substantial majority of workers being immunized. "Whether this is misunderstanding the risks of immunization, fear of shots in general, or a fatalistic belief that 'whatever will be will be' when it comes to illness, health care workers, particularly nurses and aides, have not voluntarily agreed to annual immunizations in sufficient numbers to counter the argument for requiring vaccination as a prerequisite to employment or work," says Fleischman.

Mandatory immunization programs have been successful in various hospitals, nursing homes, and health care systems, resulting in close to 100% rates of vaccination.[3,4]

"To be fair, such programs should allow individual workers to opt out for personal medical reasons," says Fleischman. "Workers should be compensated for any lost wages or costs that might result from an acute or long-term complication of the mandatory immunization program."

As for what types of exemptions should be granted, Antommaria says policies might legitimately exclude workers without direct patient contact, but should treat all workers with direct patient contact equally.

"For example, penalties for noncompliant physicians should be as stringent as penalties for noncompliant janitorial staff," says Antommaria.

If conscientious objections are prohibited, medical exemptions must be justified because they also place patients at risk, he adds. "Granting nonmedical, conscientious objections does not fundamentally undermine the goals of mandatory immunization programs," says Antommaria. "If you prohibit such exemptions to protect patients, you have to explain why you are willing to grant medical exemptions which also place patients at risk." ■

REFERENCES

1. CDC. Influenza vaccination coverage among health-care personnel—United States, 2010–11 influenza season. *MMWR* 2011;60:1073–7.
2. Wendelboe AM, Avery C, Andrade B, et al. Importance of employee vaccination against influenza in preventing cases in long-term care facilities. *Infection Control and Hospital Epidemiology* 2011;32:990-997.
3. 2007 National Influenza Vaccine Summit Immunization Excellence Awards: Virginia Mason Medical Center's Mandatory Vaccination Campaign. 2007. Presentation at Flu Summit; April 20, 2007; Atlanta, GA. Available at: http://www.preventinfluenza.org/summits/2007/Session_Four/Hagar_2007.pdf.
4. Mandatory flu vaccination program achieved almost total compliance. March 23, 2009. Available at: http://www.pediatricsupersite.com/view.aspx?rid=38084.

SOURCES

• **Armand H. Antommaria**, MD, PhD, FAAP, Director, Ethics Center, Cincinnati (OH) Children's Hospital Medical Center. Phone: (513) 636-3656. E-mail: armand.antommaria@cchmc.org.
• **Alan R. Fleischman**, MD, Clinical Professor of Pediatrics/Clinical Professor of Epidemiology and Population Health, Albert Einstein College of Medicine, Bronx, NY. Phone: (917) 439-6364. E-mail: arf@fleischmann.net.

Bioethicists obliged to help impaired clinicians

Peers reluctant to report

Clinicians are typically reluctant to report impaired colleagues, while impaired clinicians are often in denial about the problem.

"For the colleagues of impaired clinicians, a significant ethical challenge is to prioritize the primacy of patient *and clinician* welfare over other legitimate fears and concerns," says **Catherine V. Caldicott**, MD, FACP, program director of the Professional/Problem-Based Ethics (ProBE) Program, offered by the Center for Personalized Education for Physicians, Denver, CO.

Colleagues may feel that approaching a peer about impairment is disloyal. "However, as part of medicine's contract with society, they have a professional responsibility to hold themselves and their colleagues accountable to high standards of conduct," says Caldicott.[1] Here are some ways in which bioethicists can play a role:

• Keep your involvement separate from that of legal, risk management, administrative, or any other aspect of the process.

"Blurring or overlapping of the bioethicist with any of these other functions creates confusion among clinicians as to the role of the bioethicist, and can destroy trust in the bioethicist," says **Marianne L. Burda**, MD, PhD, a Pittsburgh, PA-based ethics consultant and educator.

• Ensure that the confidentiality and privacy of impaired clinicians is respected, the same as with any other individual seeking medical care and treatment.

"Lack of confidentiality and privacy, or the perceived lack of these, can be a major barrier to impaired clinicians seeking treatment," says Burda.

• Assist administrators in creating a confidential process for reporting and investigating concerns or observations about impaired clinicians.

"Colleagues covering up for an impaired clinician can put patient care at risk, creating an unethical situation," says Burda.

Impaired clinicians who remain unreported or unassisted can suffer consequences to their ability to practice, families, professional relationships, and self-esteem that are worse than the shame, embarrassment, and possible restrictions on their licenses that may result if their impairment is reported, says Caldicott.

• Be clear about the distinction between a professional ethics issue and a clinical ethics issue.

M. Sara Rosenthal, PhD, director of the program for bioethics and chair of the Hospital Ethics Committee at University of Kentucky in Lexington, says that generally, clinician impairment is a professional ethics issue that should not directly involve a clinical ethics service. "The issue is entangled with employment and HR issues that are completely outside a clinical ethicist's role or purview," she explains.

Rosenthal says a good clinical ethics service should have a "referral rubric" for handling a range of professional ethics issues, including impairment and/or clinician incompetence. "Typically, the chief medical officer would handle such an issue. The role of the clinical ethicist would be to refer the situation to the appropriate individual," she adds.

• Offer health care professionals advice on how to proceed when an impairment is suspected or observed in a colleague.

A concerned co-worker experiencing moral distress over how to approach, support, or report an impaired clinician may seek the guidance of the institutional ethics committee or consultation service. "A bioethicist can help that person develop the moral courage to act by thinking through the ethical justification for approaching or reporting the impaired clinician," says Caldicott.

If the impaired clinician contacts the clinical ethicist directly to discuss his or her impairment, then Rosenthal says the clinical ethicist should take these steps:

• Point out the ethicist's professional ethics obligation to report the situation to the chief medical officer, as opposed to promising confidentiality to the clinician who has come forward;

• Offer to support the clinician by accompanying the clinician to a meeting to self-report;

• Facilitate locating institutional or state resources for the clinician to get help;

• Offer to accompany the clinician to a medical appointment, should that clinician feel isolated and require such support.

In cases where a clinician comes to discuss a possibly impaired colleague, Rosenthal says the clinical ethicist can do the following:

• Help the colleague to understand when it is appropriate to report — usually at the point where patient safety is compromised;

• Offer to report the impairment. "Patient safety would be a priority over the political comfort of the consult requestor," says Rosenthal. ■

EXECUTIVE SUMMARY

Bioethicists can help clinicians who suspect a colleague may be impaired by giving advice on how to proceed and assisting in creating a confidential process. To help the impaired clinician:

- offer to accompany the clinician to a meeting to self-report;
- facilitate locating resources for the clinician to get help;
- offer to report the impairment.

REFERENCE

1. Cruess SR, Cruess RL. Professionalism and medicine's social contract with society. *Clinical Orthopaedics* 2006;449:170-176.

SOURCES

• **Marianne L. Burda**, MD, PhD, Pittsburgh, PA. Phone: (724) 933-0265. E-mail: burdam@duq.edu.
• **Catherine V. Caldicott**, MD, FACP, Program Director, The Professional/Problem-Based Ethics Program, Denver, CO. Phone: (303) 577-3232. E-mail: ccaldicott@cpepdoc.org..

• **M. Sara Rosenthal**, PhD, Director, Program for Bioethics/Chair, Hospital Ethics Committee, University of Kentucky, Lexington. Phone: (859) 257-9474. E-mail: m.sararosenthal@uky.edu.

Controversy stimulates informed consent debate

Widespread discussion generated

In May 2013, the U.S. Office for Human Research Protections (OHRP) determined that a large multisite clinical trial comparing the effects of differing levels of oxygen supplementation for neonates failed to obtain proper consent from the parents of enrolled infants in the Surfactant, Positive Pressure, and Oxygenation Randomized Trial (SUPPORT).[1,2]

The OHRP stated that the amount of oxygen provided to a participant might have been different than the amount that would have been provided had the baby not participated in the study. "Therefore, there might be increased or decreased risk of severe retinopathy of prematurity/blindness, brain injury, or death in either of these two groups, which it stated should have been disclosed in the Risks section of the informed consent form," says **Marilyn A. Fisher**, MD, MS, associate professor of pediatrics at the Center for Biomedical Ethics Education and Research at Albany (NY) Medical Center.

In a June 2013 letter, a group of bioethicists urged the OHRP to withdraw its notification to the institutions that they failed to meet regulatory informed-consent requirements, in particular regarding reasonably foreseeable risks of enrollment in the study.[3] These were some of the group's concerns about the OHRP's conclusion:

• **Numerous experts disagreed about the OHRP's claim that subjects in the low oxygen group were at higher risk of dying.**

"There were prior studies that showed no increase in mortality from those oxygen levels, including levels considerably below those in the study," says **Norman Fost**, MD, MPH, professor of pediatrics and bioethics at the University of Wisconsin's School of Medicine and Public Health in Madison. The study was reviewed by an expert committee at the National Institutes of Health, more than 20 institutional review boards (IRBs), and numerous co-investigators, none of whom agreed with OHRP's opinion about the risks, he adds.

"Even if there had been evidence prior to the study of increased mortality from the lower oxygen levels, there was no reason for believing infants in the study were more likely to be maintained at the lower levels than infants outside of the study," says Fost.

• **The consent form did state that there might be an increased risk of death by joining the study.**

This was stated in a section addressing another part of the study — comparing different techniques of assisted ventilation by randomized assignment. "As with most consent forms, this one could have been written more clearly," acknowledges Fost. "But it is not the case that parents who read the consent form would be unaware of the risk of death."

• **The OHRP's decision to charge numerous experts and institutions with non-compliance seemed inappropriate to many critics.**

"In the view of the critics, this should be based on something more substantive than a disagreement about the clarity of a consent form, which was approved by dozens of committees including hundreds of thoughtful individuals," says Fost.

Possible turning point

The ORHP subsequently amended the letter. As a result, the investigators have been at least temporarily exonerated of a charge that they failed to comply with federal regulations.

"The institutions involved have been spared from whatever sanctions OHRP might have been considering," says Fost. "Parents involved in the study may get some relief from the concern that the physician investigators caring for their children did not deserve their trust."

The controversy stimulated wide discussion about the OHRP's approach to compliance issues, however, including the process by which they make these judgments, and the substantive criteria used to distinguish disagreement from non-compliance. "This could be a turning point in longstanding concerns about what

EXECUTIVE SUMMARY

Bioethicists disagreed with the U.S. Office for Human Research Protections' position that a large multisite clinical trial failed to obtain proper consent from the parents of enrolled infants. Some current concerns involving consent:

- Potential research subjects may perceive real or imagined coercion.
- Physician investigators may experience conflict of interest.
- The process for obtaining consent is often inadequate.

many see as a dysfunctional regulatory system, inhibiting and discouraging important research that could benefit future patients," says Fost.

The ability to read and understand the written consent form may be affected by vision, language barriers, intelligence, level of education, amount of time available to peruse the informed consent form, pain, anxiety, and availability of health care professionals and friends or family with whom to discuss the informed consent form, Fisher says.

"Some investigators have gone so far as to administer an exam to potential subjects to ensure that they clearly understand these important issues regarding a proposed study, before allowing enrollment into the study," notes Fisher.

Process often inadequate

Potential research subjects may perceive real or imagined coercion when the study investigator approaching them about study participation is also one of the health care providers caring for the patient. "Potential subjects may fear retribution, in the form of provision of inferior health care, if they decide to not participate in a study," says Fisher.

Additionally, physician investigators may experience a conflict of interest between their desire to administer the therapies in the best interest of each individual patient and their desire to help future patients by enrolling patients into research studies, and to benefit their careers by publishing the study's results.

"There is a role for bioethicists in the development of, and monitoring of, human research studies," says Fisher. "With regular review of existing studies, bioethicists working on IRB committees may be able to ensure that the rights of human research subjects are protected." Bioethicists working on IRB committees can make suggestions to ensure that all the key elements of the informed consent are met, for example.

It is well-documented that the process for obtaining consent for clinical research, as well as routine clinical care, is often inadequate, says Fost.

"Patients and potential subjects often do not understand the key elements that should inform their decisions," says Fost. "There is no requirement in the regulations to assess or document whether subjects understand these elements, and therefore there is typically no evidence or documentation of whether or not a decision to 'consent' to a study is truly informed."

One contributing factor to this gap, says Fost, is the increasing length and complexity of consent forms, driven largely by concerns about being charged with non-compliance and severe sanctions. "There is substantial research on how to obtain more effective and meaningful consent, such as the use of interactive computer programs, or simply using shorter and simpler consent forms," says Fost. "One can hope that the SUPPORT controversy will stimulate discussion that will lead to a more effective consent process." ■

REFERENCES
1. Carlo WA, Finer NN, Walsh MC, et al. SUPPORT Study Group of the Eunice Kennedy Shriver NICHD Neonatal Research Network. Target ranges of oxygen saturation in extremely preterm infants. *N Engl J Med*. 2010;362(21):1959-1969.
2. Kuehn BM. Neonatal trial criticized for inadequate consent. *JAMA*. 2013;309(20):2087.
3. The OHRP and SUPPORT. *N Engl J Med* 2013. [Epub ahead of print]

SOURCES

• **Marilyn A. Fisher**, MD, Associate Professor of Pediatrics, Albany (NY) Medical Center. Phone: (518) 262-5421. E-mail: fisherm@mail.amc.edu.
• **Norman Fost**, MD, MPH, Professor, Pediatrics and Bioethics, School of Medicine and Public Health, University of Wisconsin, Madison. Phone: (608) 263-8562. E-mail: ncfost@wisc.edu.

Ethics in forefront of move to control medical costs

Physicians have obligation to all patients

From an ethical point of view, few would argue against the need to reduce harmful treatments or treatments that don't provide any benefits, since providers have a duty not to harm and a duty not to be wasteful. "The harder ethical case is the need to reduce, avoid, or not to adopt those treatments that are very costly but provide only very small benefits," says **James Dwyer**, PhD, associate professor of bioethics and humanities at State University of New York (SUNY) Upstate Medical University in Syracuse.

Dwyer says there is a need to develop fair and reasonable ways to address this category of cases, and a need to provide everyone with treatments that are very effective and reasonably priced. "In the United States, we have really failed at this," he says. "There are many reasons for the interest in controlling the costs of medical care. There may be some bad reasons, but there are plenty of good reasons."

Dwyer challenges the idea that the physician's duty is always and only to one particular patient. "This idea

is modeled on the advocacy that lawyers provide to a client in a criminal case. Whether or not that is the right model for criminal justice, it just doesn't fit medicine," he says. "Physicians always have more than one patient, and more than one concern."

Although the individual patient may be their primary concern, physicians need to take into account other patients, other people, public health, and the health care system, argues Dwyer. "Sometimes they need to advocate for their patients, but they also have a duty of stewardship and fairness. We need to develop practices and systems that also help them to fulfill those duties," he says.

As health care resources get progressively more constrained, there will be a call by governmental and private health care plans to reduce unnecessary or wasteful care, says **Michael Weber**, MD, professor of medicine at SUNY Downstate College of Medicine in Brooklyn, NY. "While on the surface, these calls for restraint would appear very reasonable, they can create the specter of rationing," he adds. "Of course, this has already been happening for many years."

The denial by payers of requests for newer drugs or for diagnostic or surgical procedures, although quite often justified on legitimate medical grounds, can create the impression that financial considerations outrank optimal patient care. In some settings, the use of practice guidelines, which by necessity are often based on selective interpretations of evidence, can be used or misused to restrict access to more costly care. "These actions can create an ethical dilemma in which cost-saving measures are enforced under the guise of 'best practices,'" says Weber.

Perhaps most troubling of all from an ethical viewpoint, says Weber, are schemes whereby health plans provide personal financial rewards to those medical practitioners who demonstrate skill at minimizing costs, and impose pressure on practitioners if they appear to be over-utilizing diagnostic or therapeutic resources. "Bluntly put, these financial strategies can have the appearance of putting clinicians into adversarial relationships with their own patients — surely a troubling conflict of interest for medical professionals," he says.

It cannot be denied that there is a meaningful degree of waste and abuse in the utilization of health care resources, and it is entirely necessary that these unacceptable practices be reined in, acknowledges Weber. "The best approach is an open and transparent public discussion on how this can be most fairly and honestly achieved, without resorting to heavy-handed and questionable cost-saving strategies," he says.

Growing awareness

Much of the movement toward parsimonious medicine will be internally driven by practicing clinicians and patients, rather than externally driven by regulatory requirements, predicts **J.S. Blumenthal-Barby**, PhD, MA, assistant professor of medicine and medical ethics at Baylor College of Medicine in Houston, TX.

"We see this in the Choosing Wisely campaign, where professional medical societies are working come up with lists of unnecessary, wasteful medical tests and procedures," she says. "And patients are becoming more aware of and comfortable with the idea that sometimes less is more."

Patients and physicians are getting on board with parsimonious medicine less because of reasons of social justice, or saving resources for others, and more for reasons of personal and professional well-being, according to Blumenthal-Barby. "I think that these movements are good, because they shift the focus from arguments about the greater good and 'rationing' — which are inherently controversial, and as such fail to get practical traction — to arguments about individual well-being and professional obligations," she says.

Dwyer points to international comparisons indicating the United States spends far more than any other country on health care. "Yet by any measure of health, we don't fare very well," he says. "What also

EXECUTIVE SUMMARY

The need to reduce, avoid, or not to adopt costly treatments which provide very small benefits, and the need to provide everyone with treatments that are very effective and reasonably priced, present ethical challenges. Bioethicists argue that:

- Physicians need to take into account other patients, other people, public health, and the health care system.
- Patients are becoming more aware of risks of unnecessary treatments.
- Indirect harms of unnecessary treatments include lack of access to care.

COMING IN FUTURE MONTHS

- More affordable genetic testing
- Access to emergency contraception
- Challenges when prescribing narcotics
- What to do if clinicians disagree with ethicists

stands out in my mind are small area variations — the differences in costs and outcomes across different areas within the United States."

Indirect harms of higher-cost health care are substantial, adds Dwyer, such as pricing many people out of care, and making universal health care harder to achieve. "We need to remember that the point is not to spend more money on health care, or even to develop new technologies," he says. "The point is to provide good care, and to achieve relatively healthy and long lives, at reasonable costs."

Dwyer says his chief concern is that the entire discussion about cost-effective care will be framed unfairly. "We will examine — as we should — small ethical problems that will arise in attempts to control costs," he explains. "But we will ignore huge ethical problems that exist in the current system, that arise from not including people and from using a fee-for-service payment system."

A related concern is that there will be too much focus on individual physicians or individual hospitals, while the role of social incentives, systems, and structures will be overlooked. "It will take more and better civic engagement to make deeper changes in the system," says Dwyer. "Health care debates seem to bring out extreme forms of ideology. The evidence, problems, and suffering of people tend to get ignored." ■

SOURCES

• **J.S. Blumenthal-Barby**, PhD, MA, Assistant Professor of Medicine and Medical Ethics, Center for Medical Ethics and Health Policy, Baylor College of Medicine, Houston, TX. Phone: (713) 798-3785. E-mail: Jennifer.Blumenthal-Barby@bcm.edu.
• **James Dwyer**, PhD, Associate Professor of Bioethics and Humanities, State University of New York Upstate Medical University, Syracuse. Phone: (315) 464-8455. E-mail: dwyerja@upstate.edu.
• **Michael Weber**, MD, professor of medicine at SUNY Downstate College of Medicine in Brooklyn, NY. Phone: (714) 815-7430. E-mail: michaelwebermd@cs.com.

CME OBJECTIVES

Upon completion of this educational activity, participants should be able to:

- Discuss new developments in regulation and health care system approaches to bioethical issues applicable to specific health care systems.
- Explain the implications for new developments in bioethics as it relates to all aspects of patient care and health care delivery in institutional settings.
- Discuss the effect of bioethics on patients, their families, physicians, and society.

CME INSTRUCTIONS

To earn credit for this activity, please follow these instructions.

1. Read and study the activity, using the provided references for further research.
2. Log on to www.cmecity.com to take a post-test; tests can be taken after each issue or collectively at the end of the semester. First-time users will have to register on the site using the 8-digit subscriber number printed on their mailing label, invoice, or renewal notice.
3. Pass the online tests with a score of 100%; you will be allowed to answer the questions as many times as needed to achieve a score of 100%.
4. After successfully completing the last test of the semester, your browser will be automatically directed to the activity evaluation form, which you will submit online.
5. Once the completed evaluation is received, a credit letter will be e-mailed to you instantly.