



MEDICAL ETHICS ADVISOR®

FOR OVER 25 YEARS, YOUR PRACTICAL GUIDE TO ETHICS DECISION MAKING

MARCH 2017

Vol. 33, No. 3; p. 25-36

➔ INSIDE

Clinicians' reactions to legalized physician-assisted dying 29

Ethical concerns if adverse events in clinical trials go unpublished 31

New data on reasons for lack of diverse enrollment in clinical trials 33

Why growing burnout among physicians is an ethical issue 34

Surprising effect of palliative care meetings on families 35



A RELIAS LEARNING COMPANY

Physician-assisted Dying: It's 'Perhaps the Central Question In Medical Ethics Today'

Bioethicists need thoughtful approach to conscientious objectors

Physician-assisted dying raises multiple ethical questions in the hospital setting, including how to respond to requests and assess decision-making capacity.

"You also have to consider whether the people assisting can live with this," says **Timothy E. Quill**, MD, professor of medicine, psychiatry, and medical humanities at University of Rochester (NY)'s Palliative Care Program.

Physician-assisted dying is now legal in six states: Oregon, Washington, Montana, Vermont, California, and Colorado. "Most have laws saying you, as a clinician, can be a conscientious objector," says Quill. "[Clinicians] still have the ethical right, in some sense, to say no — although if you live in a rural place and it's the only game in town, that's a little tougher."

Some physicians who have assisted in

EXECUTIVE SUMMARY

With physician-assisted dying currently legal in six states, hospitals are facing ethical questions on responding to requests and addressing conscientious objectors.

Ethicists can do the following:

- Inform clinicians who express discomfort with the practice that conscientious objection is an option.
- Offer to find an alternative person to assist to replace a conscientious objector.
- Develop policies on responding to requests.
- Suggest the ethics committee develop a policy for offering patients the alternative option of stopping eating and drinking.

NOW AVAILABLE ONLINE! VISIT AHCMedia.com or **CALL** (800) 688-2421

Financial Disclosure: Physician Editor **Arthur R. Derse**, MD, JD, Nurse Planner **Susan Solverson**, BSN, RN, CMSRN, Editor **Jill Drachenberg**, Editor **Dana Spector**, and Author **Stacey Kusterbeck** report no consultant, stockholder, speakers' bureau, research, or other financial relationships with companies having ties to this field of study.

Medical Ethics Advisor®

ISSN 0886-0653, is published monthly by AHC Media, LLC, a Relias Learning company
111 Coming Road, Suite 250
Cary, NC 27518

Periodicals Postage Paid at Atlanta, GA 30304 and at additional mailing offices.
GST Registration Number: R128870672.

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

SUBSCRIBER INFORMATION:
Customer Service: (800) 688-2421.
Customer.Service@AHCMedia.com.
AHCMedia.com
Hours of operation: 8:30 a.m.-6 p.m. Monday-Thursday;
8:30 a.m.-4:30 p.m. Friday.

SUBSCRIPTION PRICES:
U.S.A., Print: 1 year (12 issues) with free CE nursing contact hours, \$519. Add \$19.99 for shipping & handling. Online only, single user: 1 year with free CE nursing contact hours, \$469. Outside U.S., add \$30 per year, total prepaid in U.S. funds.

MULTIPLE COPIES: Discounts are available for group subscriptions, multiple copies, site licenses, or electronic distribution. For pricing information, please contact our Group Account Managers at Groups@AHCMedia.com or (866) 213-0844.

ACCREDITATION: 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.

Relias Learning, LLC, is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation. Contact hours [1.5] will be awarded to participants who meet the criteria for successful completion. California Board of Registered Nursing, Provider CEP#13791.

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.

AUTHOR: Stacey Kusterbeck
EDITOR: Jill Drachenberg
EDITOR: Dana Spector
AHC MEDIA EDITORIAL GROUP MANAGER: Terrey L. Hatcher
SENIOR ACCREDITATIONS OFFICER: Lee Landenberger

PHOTOCOPYING: No part of this newsletter may be reproduced in any form or incorporated into any information retrieval system without the written permission of the copyright owner. For reprint permission, please contact AHC Media, LLC. Address: P.O. Box 550669, Atlanta, GA 30355. Telephone: (800) 688-2421. Web: AHCMedia.com.

Copyright © 2017 by AHC Media, LLC, a Relias Learning company. *Medical Ethics Advisor®* is a registered trademark of AHC Media, LLC. The trademark *Medical Ethics Advisor®* is used herein under license. All rights reserved.

EDITORIAL QUESTIONS

Questions or comments?
Call **Jill Drachenberg** at
(404) 262-5508

a patient's death find it very difficult, and others find it very meaningful. "It's always a big deal to do this," says Quill. "Yet you do it because it's what you feel obligated to do, and it doesn't make sense not to do it, in some cases."

Striking the right balance between meeting the patient's needs and supporting clinical staff who are uncomfortable is challenging. "In my view, we still need to put a little heat on people who are conscientious objectors," says Quill. While clinicians need to respect their own ethical boundaries, it's important not to reinforce abandoning the patient. Quill sees the following possible roles for the ethicist:

- If a clinician is uncomfortable with physician-assisted dying in a state where it's legally permitted, the ethicist can suggest the option of conscientious objection.
- The ethicist might also suggest to the clinician that he or she has an obligation to help find, or at least allow, another person to assist.
- If the clinician is uncomfortable finding another person to assist, the ethicist might take on this responsibility.

Quill says that in states where physician-assisted dying is legal, the ethical issues "are somewhat similar to questions that might come up with palliative sedation or stopping life support." Some important considerations include assessment of the patient's decision-making capacity, access to palliative care, and general agreement on the ethical and legal permissibility.

Once physician-assisted dying becomes legal in a state, hospitals should not hesitate to develop a policy on how requests will be handled. "Don't wait until the first case comes in, because then you are flying by the seat of your pants,"

says Quill. "It's incumbent on an institution to handle it in an ethically sound way, given that it's legal."

Some hospitals, reluctant to offer physician-assisted dying, might instead offer palliative sedation. Quill doesn't see this as a viable alternative for these cases. "The indications are quite different. Usually people getting sedated are in immediate extremis right now," he explains. "Patients asking about physician-assisted dying are more worried about what's going to happen down the road."

Highly Contentious Issue

In a recent paper, the authors identified the following central ethical issues involving physician-assisted suicide and euthanasia in medical practice:¹

- the benefit or harm of death itself,
- the relationship between physician-assisted suicide and euthanasia and withholding or withdrawing life support,
- the morality of a physician deliberately causing death, and
- the management of conscientious objection related to physician-assisted suicide and euthanasia in the critical care setting.

"Our findings emphasize that one's view of physician-assisted suicide and euthanasia derive from one's most basic beliefs about morality and the source of ethical value," says **Ewan C. Goligher**, MD, PhD, the study's lead author. Goligher is an intensivist at Mount Sinai Hospital in Toronto and a member of the Interdepartmental Division of Critical Care Medicine at the University of Toronto.

The project began as a dialogue among concerned intensivists from

different countries and different points of view. The group realized they needed input from ethicists. **Daniel P. Sulmasy**, MD, PhD, MACP, was one of the ethicists invited to present arguments on both sides of the issue. “Good ethicists should know the arguments on both sides well enough to do this,” says Sulmasy, André Hellegers professor of biomedical ethics at Georgetown University Medical Center’s Edmund D. Pellegrino Center for Clinical Bioethics in Washington, DC.

None of the authors changed their minds as a result of working on the paper. “The most wonderful result, however, was a mutually respectful dialogue on a highly contentious issue,” Sulmasy says. “Bioethics, as a field, needs more of that.”

The debate centered on the question of whether the patient’s moral significance derives from their exercise of autonomy, or simply from their ontology — who they are as a person. Goligher explains, “Failure to resolve this issue makes the disagreement over assisted death an intractable issue.”

Despite this disagreement, the group arrived at a consensus on how requests for physician-assisted dying can be reasonably accommodated.

“Several of us insisted that there was no obligation to make an effective referral,” says Goligher. “We all agreed that a transfer of care to another intensivist does not count as a case of effective referral.”

The researchers’ hope is that physicians will carefully consider how they would respond to the questions raised in the paper. “Physicians, departments, and hospital systems need to be prepared to handle conscientious objection in a respectful and accommodating manner, in order to ensure that the patient’s well-being remains the highest priority for all,” says Goligher.

Sulmasy says that clinicians should “not merely react to opinion polls” and instead, think seriously about the following questions:

- Is it ethically good and right for clinicians to kill patients or to help them to kill themselves?
- Is such killing justified fully by the patient’s autonomous authorization? Or is the ethics of medicine broader and deeper than that?
- Is the killing of patients by physicians only wrong if it is involuntary? Or do concerns about the implications for the patient-physician relationship, about killing

and the meaning of medicine, and the social implications of legalizing such practices, outweigh the preferences of a few patients?

“These are weighty issues, making this perhaps the central question in medical ethics today,” says Sulmasy.

Consider Alternative Options

Quill is sometimes asked to provide ethical input by other physicians who are considering physician-assisted dying in the home setting, in a state where it’s not legal.

“What’s legal is not always what’s ethical, depending on your point of view,” says Quill. If physicians are thinking about secretly assisting someone, Quill encourages them to try to find a way to help that is legal. Physicians don’t always realize the full implications of helping someone illegally. “Both the clinician and the patient and family have to keep a big secret,” he notes. “And if it does get discovered, you might become a test case and bad things can potentially happen to you.”

Most physicians are aware that if suffering becomes very severe, they can legally and ethically sedate

New Data on Physician-assisted Suicide in U.S.

A recent review of available data on attitudes and practices of euthanasia or physician-assisted suicide from 1947 to 2016 found that euthanasia and physician-assisted suicide are:

- increasingly being legalized,
- remain relatively rare, and
- primarily involve patients with cancer.¹

The study also found that in the U.S., less than 20% of physicians report having received requests for euthanasia or physician-assisted suicide, and 5% or less have complied. ■

REFERENCE

1. Emanuel EJ, Onwuteaka-Philipsen BD, Urwin JW, et al. Attitudes and practices of euthanasia and physician-assisted suicide in the United States, Canada, and Europe. *JAMA* 2016; 316(1):79-90.

patients as a last resort. “But the option that’s most relevant in this circumstance is stopping of eating and drinking,” says Quill. The concept has never been legally tested in the courts, so the legality is unclear, “but the physician’s assistance is more indirect, so it’s much safer legally for physicians,” says Quill. “It’s hard to do for patients, but it does put the option completely in their hands.” It’s not that clinicians are withholding food and drink — it’s that the patient is choosing not to have it.

The physician is involved in assessment of the patient and management of symptoms, but the patient is the one opting to decline food and drink. “Unlike physician-assisted dying, this is a process that can be done completely out in the open,” says Quill.

Quill believes stopping eating and drinking is an important option to be able to offer patients. “I have had patients who would never do a physician-assisted dying — it would have been completely out of their moral realm — but did this,” he says. A nun told Quill she viewed it as a “fast for God.”

“If somebody is in a bad situation and asks you, couldn’t I have physician-assisted dying, and is talking about wanting an escape, having them have to discover stopping and eating and drinking on their own is not fair,” says Quill. Clinicians could instead respond by stating, “Here’s something some people have chosen to do...”

Quill has seen some patients who clearly wanted physician-assisted dying and would have qualified for it, and would have been given it if the practice were not illegal in their state. Stopping food and drink is another option for this group of patients. “This practice is starting to get a little more play in the ethics and clinical

literature. But some pretty powerful forces are likely to push back,” says Quill.

If done in the hospital setting, Quill recommends getting an ethical consult. “You want people to know others are weighing in on this, and that it’s a choice that patients can ethically make,” he explains.

While developing a policy on the practice is time-consuming, it allows ethicists to carefully consider all of

“IF SOMEBODY CALLS THE NEWSPAPER AND SAYS YOU ARE STARVING PEOPLE TO DEATH IN YOUR PALLIATIVE CARE UNIT, YOU DON’T WANT THE ETHICS COMMITTEE THINKING THIS THROUGH THE FIRST TIME IN THE MIDDLE OF A CONTROVERSY.”

the issues involved. “This is good meaty stuff for ethics committees,” says Quill. “It’s a good thing for them to think through in advance of a real case.” With a policy in place, clinicians would likely feel more ethically grounded in offering the option of stopping food and drink.

“For example, when we are talking about taking somebody off life support, or giving somebody a lot of medicine to manage terminal short-

ness of breath, we almost always put our policy on ventilator withdrawal on the top of the chart,” says Quill. If a team member expresses concerns about the ethics of withdrawing life support, the clinician and the ethicist can point to the policy.

A policy with a strong informed consent process, and support of hospital administrators, is important. “If somebody calls the newspaper and says you are starving people to death in your palliative care unit, you don’t want the ethics committee thinking this through the first time in the middle of a controversy,” says Quill. ■

REFERENCES

1. Goligher EC, Ely EW, Sulmasy DP, et al. Physician-assisted suicide and euthanasia in the ICU: A dialogue on core ethical issues. *Crit Care Med* 2017; 45(2):149-155.

SOURCES

- Ewan C. Goligher, MD, PhD, Intensivist, Mount Sinai Hospital, Interdepartmental Division of Critical Care Medicine, University of Toronto, Ontario, Canada. Phone: (416) 586-8449. Email: ewan.goligher@mail.utoronto.ca.
- Daniel P. Sulmasy, MD, PhD, MACP, André Hellegers Professor of Biomedical Ethics, Edmund D. Pellegrino Center for Clinical Bioethics, Georgetown University Medical Center, Washington, DC. Phone: (202) 687-1122. Fax: (202) 687-8955. Email: sulmasyd@georgetown.edu.
- Timothy E. Quill, MD, Professor of Medicine, Psychiatry and Medical Humanities, Center for Ethics, Humanities and Palliative Care, University of Rochester (NY) School of Medicine. Phone: (585) 273-1154. Fax: (585) 275-7403. Email: timothy_quill@urmc.rochester.edu.

Medical Assistance In Dying Now Legal In Canada: Ethicists Are Providing Education

Legislation spurred “deep moral reflection”

As of June 2016, physician-assisted dying can be legally practiced in Canada. Recently passed legislation allowing the practice of “medical assistance in dying” (MAID), “has engendered spirited dialogue and deep moral reflection across the nation,” says **Ruby Rajendra Shanker**, MBBS, MHSc (Bioethics), the bioethicist for Toronto General Hospital & Women’s College Hospital.

At Ontario hospitals where MAID services are available, there is wide consensus that all staff and clinicians need a “high-level understanding” of the process, says Shanker, in order to respond to patient requests for information.

“Ethicists have been involved with providing education sessions for interprofessional teams, as well as sessions with a disciplinary focus,” adds Shanker. These sessions cover logistical and procedural information, but also tend to elicit emotional responses or reflective silence. “These reactions speak to the varying levels of comfort that healthcare providers feel in the context of MAID,” says Shanker.

University of Toronto’s Joint

Centre for Bioethics convened a task force in 2015, including ethicists, clinicians, lawyers, health policy analysts, and representatives from professional colleges and the Ontario Health Association. “The goal has been to operationalize the ethical principles of accountability, collaboration, dignity, equity, respect, transparency, fidelity, and compassion in the context of MAID,” says Shanker, a member of the task force.

The group has produced a MAID policy template for healthcare organizations, an algorithm to map out the MAID process, and FAQs for patients and families, and staff and physicians. “Interprofessionally focused educational modules have been developed,” adds Shanker.

Bob Parke, BA, BSW, MSW, MHSc (Bioethics), bioethicist at Humber River Hospital in Toronto, says, “The ethical issues which I have had in my experience of working in a secular hospital which permits MAID are several.” The following are some ethical issues encountered by Canadian ethicists since the legislation:

• **Many physicians expressed that**

the issue is morally challenging for them.

“What has been important, in legislation and in practice, is that conscientious objection rights of physicians are protected,” says Parke.

In Parke’s experience, the majority of doctors do not wish to participate in physician-assisted dying. “What I have found is that physicians’ willingness to participate falls along a continuum from being opponents to proponents of physician-assisted death,” he says.

Few fall at either extreme of the continuum. “Most are willing to explore why a person is making a request — but can’t cross the moral divide into causing a person’s death,” says Parke. This stance often stems from faith-based values, or in the physician’s interpretation of “doing no harm.”

“Not uncommonly I have heard, ‘I did not get into medicine for this’ — to cause someone to die,” says Parke. This point of view typically comes from physicians who do not espouse a religious tradition, whereas physicians coming from a religious perspective usually place their conscientious objection within the context of their faith.

Some physicians wanted reassurance that they had the right to conscientious objection, since they’d concluded that their personal and professional values cannot be reconciled with MAID. Shanker notes, “The rights of professionals, however, come with obligations to not abandon their patients.” There is a concomitant duty to ensure continuity of

EXECUTIVE SUMMARY

Physician-assisted dying is legal in Canada, due to legislation passed in June 2016. Ethicists are among those providing multidisciplinary education in the hospital setting. Ethicists are seeing the following issues:

- Many physicians and other team members are uncomfortable with physician-assisted dying.
- It is unclear as to the clinical meaning of some of the terminology in the legislation.
- Conscientious objectors are required to make a referral, but some are uncomfortable doing so.

care by making an effective referral to another provider who can address the patient's request.

Ethicists themselves may be conscientious objectors. "While the thought of an ethicist conscientiously objecting to discussing MAID may be seen as perplexing for some, it is important to remind ourselves that ethicists come with varied experiences, values, and cultural backgrounds," says Shanker.

Thus, ethical challenges can arise for ethicists both in institutions that permit MAID, and in those that prohibit it. "An ethicist may feel that they are unable to act in alignment with their values if they are barred from even engaging in the subject," Shanker explains.

- **A few physicians questioned whether their safety would be at risk if they participated.**

"There were concerns that there might be threats to their lives and well-being, as was experienced by some physicians who are known for doing abortions," explains Parke. In both policy and practice, ethicists keep the names of participants as private as possible. "We want to avoid participating staff being negatively labelled for participating in physician-assisted deaths," says Parke.

- **Conscientious objectors still have to provide care to a patient, while the process for assisted dying works through the assessment stages through to its completion.**

"It is hoped that a physician can transfer care," says Parke. "But this might not be possible contingent on their specialty, role, and relationship to the patient."

In Ontario, the College of Physicians and Surgeons requires that a physician who conscientiously objects make an "effective referral." "The challenge is: What does it mean for a physician to make an 'effective'

referral?" asks Parke.

For most conscientious objectors, directly referring to another physician who is willing to assist a patient in their death would make them complicit in an immoral act. "What needs to be done is to find ways to distance the objecting physician from a direct referral," says Parke. A possible solution: Having a third party, such as a chief of the department or a coordinating group, take on the various roles related to physician-assisted death, including facilitating referrals.

- **There is a concern that some people will request MAID due to lack of regularly available palliative care.**

Insufficient palliative care remains an ethical challenge, says Parke. "Across Canada, there is a patchwork quilt of excellent to non-existent palliative care."

- **Some non-clinical team members feel morally uncomfortable with physician-assisted death, yet are asked to participate.**

This includes nurses, pharmacists, social workers, chaplains, and even bioethicists. "For the most part, the law and hospital policies permit staff to identify their conscientious objection and have their values respected," says Parke.

"Behind-the-scenes" healthcare providers, such as professional interpreters or the IT team, aren't typically included in discussions when a person is moving forward with physician-assisted death, though. Professional interpreters may be called in to translate, for instance.

"Informing them ahead of time allows them the choice of whether they will participate or not — and to find an alternative person if they are morally uncomfortable in providing their services," says Parke.

At Humber River Hospital, the IT team designed the EMR screens used

to document the process of physician-assisted dying. "When a case is proceeding, IT staff can be called in to ensure that the EMR is properly completed for each component of the physician-assisted death," Parke explains. The IT team is asked to be available during cases to ensure clinicians document appropriately.

"Our experience in Canada is that all staff want to make sure that they have done all steps of the process very well," says Parke. This is important, since physician-assisted deaths do not occur frequently. "We want this assurance, as MAID is an exemption from a criminal act, and we know that the EMR will be reviewed by our coroners," Parke explains. Not all IT team members are comfortable participating, however. "We had a situation when members of our IT team did not want to be involved, which I understood and supported," says Parke. "Fortunately, they had an alternative person available."

- **Some families have asked for MAID on behalf of incapable persons with dementia.**

"In all cases, I have empathized with their request — but informed them that the law does not permit a substitute decision-maker to request MAID on behalf of an incapable person," says Parke.

- **The language of the legislation is open to interpretation.**

The legislation sets out eligibility criteria and additional safeguards. "Yet translating these into standards for clinical practice has been, at times, challenging. The language of the law and that of healthcare are often not shared," explains Shanker.

The legislation includes terms such as "death is reasonably foreseeable." "This has created problems when trying to assess if a person is eligible for MAID," says Parke.

One of the criteria for eligibility is that a person must have a “grievous and irremediable” condition.

“This terminology is unfamiliar to clinicians,” says Shanker. “While the legislation elaborates on it to some degree, its meaning and application are not obvious to non-lawyers.”

The legislation seems to have been written in a manner which invites a range of interpretations, so as to leave room for clinical judgment. “However, in clinical practice, this introduces additional layers of complexities,” says Shanker.

• **There is no consensus on a standardized clinical tool to assess**

capacity for MAID.

“Capacity assessments in the context of MAID give one pause for ethical reflection,” says Shanker.

In Canada, the test for capacity to consent to MAID follows the same legal standard as those for other healthcare decisions. Shanker recently conducted a review of capacity assessment tools within mental health, and concluded there is no consensus on the best tool for evaluating the capacity to make complex treatment decisions.

“Capacity assessments for MAID thus represent one aspect of the evolving landscape of practice,” says

Shanker. “Clinicians must learn from experience and support others as they continue to build skills and enhance competency.” ■

SOURCES

- **Bob Parke**, BA, BSW, MSW, MHSc (Bioethics), Bioethicist, Humber River Hospital, Toronto, Ontario, Canada. Phone: (416) 242-1000 ext. 82808. Email: BParke@hrh.ca.
- **Ruby Rajendra Shanker**, MBBS, MHSc (Bioethics), Bioethicist, Toronto General Hospital/Women’s College Hospital, Toronto, Ontario, Canada. Phone: (416) 340-4800 ext. 8750. Email: Ruby.Shanker@uhn.ca.

‘Very Serious Ethical Problem:’ Adverse Events Often Unpublished

Patients want information on potential harm

Much information on adverse events in clinical trials remains unpublished — and the number of adverse events is higher in unpublished than published versions of the same study, according to a recent review.¹

“We have been studying adverse effects for many years,” says study author **Yoon K. Loke**, MD, professor of medicine and pharmacology at Norwich Medical School at United Kingdom’s University of East Anglia. The researchers conducted the study because they noticed it was very difficult to find information on adverse effects in scientific journals.

“We wanted to find out if we were the only people having this difficulty, or if there were other people who had uncovered similar problems of missing or hidden data,” says Loke. “The scale of the problem was surprising.” The researchers found reports of similar

issues occurring in the U.S., Canada, Germany, and the U.K. The median percentage of published documents with adverse events information was 46%, compared to 95% in the corresponding unpublished documents. “This is a very serious ethical problem that I would like to see institutional review boards and ethics committees take action on,” says Loke.

Efforts campaigning for full disclosure and full transparency of research data include the international AllTrials initiative. “I fervently believe that ethics committees should bite the bullet and lend their voice to these calls,” says Loke. “After all, their role is to protect research participants.”

Individuals participate in research in good faith, usually for altruistic reasons, notes Loke. Often, participants face significant risk of harm from the research and no clear prospect of personal gain. “If you were a patient,

would you give up your time to volunteer for an experimental research study, if you knew that the results would never be made publicly available?” asks Loke.

Loke argues it’s clearly unethical to have human beings volunteering to be experimented on, with results never released. “What could be worse than for someone to let their body be used for research, yet the information or findings are never made available?” he asks.

Sunita Vohra, MD, MSc, FRCPC, FCAHS, professor at University of Alberta’s Faculty of Medicine and School of Public Health, says, “Research confirms that clinical trials do an inadequate job of reporting adverse events.” This creates the false impression that the therapy being studied is safe. “The problem is compounded when systematic reviews of clinical trials fail to identify or report adverse

events,” says Vohra.

Franklin G. Miller, PhD, professor of medical ethics in medicine at Weill Cornell Medical College in New York City, sees two problematic scenarios:

- investigators fail to publish the results of a clinical trial for various reasons, such as disappointing outcomes for the drug under investigation, and
- the results are published, but adverse events are not reported accurately.

In either case, if the drug under investigation produces adverse events and these are not published or described accurately, the same problem exists: Clinicians can't get information on adverse events that could be important for patient care.

“There are potential problems here of harm to patients from withholding clinically valuable information — and deficiencies in informed consent if patients are not told about side effects or complications that might be important for them,” says Miller.

Patients, healthcare providers, and health policymakers require accurate knowledge of both potential benefits and potential harms for informed decision-making. “If harms are not measured or not reported, patient safety is put at risk. To knowingly suppress reporting of adverse events is not ethical,” Vohra says.

Kay Dickersin, PhD, director of the Center for Clinical Trials and Evidence Synthesis at Johns Hopkins Bloomberg School of Public Health in Baltimore, says lack of publication of adverse events is getting more attention because researchers are paying more attention to patients' views.

“Ten years ago, there was emphasis on the patient view. But committees were made up of doctors who said what the patient view was,” says Dickersin.

Now, patients are consulted di-

rectly by investigators. In some cases, they're even part of the research team. As a result, the lens of investigators' focus has shifted somewhat.

“What we've found is that patients really want to know not just whether there is a beneficial effect, but about adverse events,” says Dickersin.

In particular, patients want enough specific information to allow them to make a decision as to whether the benefits versus risks are worth the trade-off to them in particular. The fact that a painkiller is known to cause dizziness might be of great importance to a 90-year-old patient with a fall history, for instance. “Information about adverse events can be lost in several ways,” says Dickersin.

There may be no formal way of collecting data on adverse events. To address this, researchers can ask participants specific questions such as, “Have you experienced dizziness?” instead of open-ended questions such as, “Have you experienced anything you'd consider an adverse event since we last talked?”

“It may not be reported by the patient if the patient doesn't know it's important,” says Dickersin. If the percentage of people experiencing an adverse event doesn't meet a specified threshold, such as 5%, it may never become known to the public.

“That's not necessarily the way we should be doing things. We had space constraints with paper journals, so I can see how that evolved,” says Dickerson. “But now with online supplements, we may not need to use thresholds.”

Information on adverse events can be lost if a clinical trial goes unpublished. Dickersin co-authored a paper arguing that “invisible” and abandoned trials should be restored, with findings including adverse events made publicly available.²

Patients typically get information

on adverse events from labels. However, these lack enough specificity for a truly informed decision. “The label needs to be made better,” Dickersin says. Patients might want to know more about a particular adverse event, such as whether dizziness reported by participants was severe or mild.

“Ethically, I think we should be paying attention to adverse events because it matters to patients,” says Dickersin. “It's part of the whole picture of the intervention.” ■

REFERENCES

1. Golder S, Loke YK, Wright K, et al. Reporting of adverse events in published and unpublished studies of health care interventions: A systematic review. *PLoS Med* 2016; 13(9):e1002127.
2. Doshi P, Dickersin K, Healy D, et al. Restoring invisible and abandoned trials: a call for people to publish the findings. *BMJ* 2013; 346:f2865.

SOURCES

- **Kay Dickersin**, PhD, Director, Center for Clinical Trials and Evidence Synthesis, Johns Hopkins Bloomberg School of Public Health, Baltimore. Phone: (410) 502-4421. Email: kdicker3@jhu.edu.
- **Yoon K. Loke**, MD, Professor of Medicine and Pharmacology, Norwich Medical School, University of East Anglia, United Kingdom. Email: Y.Loche@uea.ac.uk.
- **Franklin G. Miller**, PhD, Professor of Medical Ethics in Medicine, Weill Cornell Medical College, New York City. Phone: (301) 656-8757. Email: FMiller@cc.nih.gov.
- **Sunita Vohra**, MD, MSc, FRCPC, FCAHS, Professor, Faculty of Medicine and School of Public Health, University of Alberta, Canada. Phone: (780) 492-6445. Fax: (780) 492-5883. Email: svohra@ualberta.ca.

Data Reveal Reasons for Under-enrollment of Minorities In Clinical Trials

Reasons are complex and multilevel

Barriers to enrolling a diverse population of patients in clinical trials are complex and multilevel, concluded a recent study.¹

“The problem of severe under-enrollment of racial and ethnic minorities into clinical trials persists,” says lead author **Lauren M. Hamel**, PhD, an assistant professor in the department of oncology at Wayne State University School of Medicine and the Karmanos Cancer Institute in Detroit. This is true despite a National Institutes of Health requirement that members of minority populations be represented in clinical research.

“Our research team has extensive experience studying racial healthcare disparities, especially in cancer treatment and cancer clinical trials,” notes Hamel. “So we were in a great position to take this on.” To increase enrollment of racial and ethnic minorities in clinical trials, future interventions should address barriers at multiple levels, the researchers concluded.

“My colleagues and I have studied what prevents and facilitates enrollment into clinical trials for many years,” says Hamel. Thus, it came as no surprise that barriers to diverse enrollment exist on multiple levels.

“What this paper provides is a summary of the barriers at each level, how they influence one another, and also some ideas for solutions to the problem,” Hamel says. Ideally, interventions should address as many levels as possible — system, individual, and interpersonal.

“This increases the likelihood of an intervention achieving substantial and sustained change and to produce additive, and possibly multiplicative, effects,” says Hamel. Scarce resources are an obstacle. “A multilevel intervention is not always possible,” acknowledges Hamel. “However, it’s important to recognize that

“WHAT THIS PAPER PROVIDES IS A SUMMARY OF THE BARRIERS AT EACH LEVEL, HOW THEY INFLUENCE ONE ANOTHER, AND ALSO SOME IDEAS FOR SOLUTIONS TO THE PROBLEM.”

discussions about clinical trials do not exist in a vacuum.” Some key findings include the following:

- **Barriers at the system level can create barriers at the individual level.**

For instance, physicians might not mention a clinical trial to a patient if they don’t believe it’s adequately supported by the hospital.

- **Individual attitudes are a factor.**

Negative attitudes toward minority patients could lead physicians to believe these patients will be poor candidates for clinical

trials, for example.

Sarah L. Goff, MD, associate professor of medicine at University of Massachusetts Medical School—Baystate Medical Center in Springfield, notes that studies often are designed without input from patients. Thus, patients don’t have any say as to the pertinence of the study question, the design of the study, and how results will be communicated to participants.

Goff views this as one underlying cause of lack of diverse enrollment. “The movement toward funders encouraging various levels of patient and stakeholder engagement in research holds promise for addressing ethical issues related to enrollment of racial and ethnic minorities in clinical trials,” says Goff.

REFERENCE

1. Hamel LM, Penner LA, Albrecht TL, et al. Barriers to clinical trial enrollment in racial and ethnic minority patients with cancer. *Cancer Control* 2016; 23(4):327-337.

SOURCES

- **Sarah L. Goff**, MD, Assistant Professor of Medicine, University of Massachusetts Medical School—Baystate Medical Center, Springfield. Email: sarah.goff@baystatehealth.org.
- **Lauren M. Hamel**, PhD, Assistant Professor, Department of Oncology, Wayne State University School of Medicine/Karmanos Cancer Institute, Detroit. Phone: (313) 576-9672. Fax: (313) 576-8270. Email: hamell@karmanos.org.

Growing Focus On Physician Well-being: More Than Half Report Burnout

Current efforts are 'all over the map'

More than half of U.S. physicians are now experiencing professional burnout, found a recent study.¹ Of 6,880 physicians surveyed, 54% reported at least one symptom of burnout, compared to 46% to a similar study done in 2011. Satisfaction with work-life balance also declined (49% in 2011, compared to 41% in 2014). In contrast, the general U.S. working population had only minimal changes in burnout or satisfaction with work-life balance during the same time period.

Of 369 gynecologic oncologists surveyed in another recent study, 33% screened positive for depression, and 34% reported impaired quality of life.² Interventions targeted at improving quality of life, treatment of depression, or alcohol abuse may have an effect on burnout, the researchers suggest.

“More attention is being paid to physician well-being,” says **Gene Beresin**, MD, MA, professor of psychiatry at Harvard Medical School in Boston, who authored a recent paper on this topic.³ “What are our obligations in training, to optimize the growth and resilience of our providers?” he asks. Beresin notes that providers have an ethical obligation to provide care that respects the dignity and rights of their patients. Similarly, he sees an ethical obligation to consider and foster the well-being of providers themselves.

“We need to look at what enables physicians to be able to perform their duties in a way that does not promote burnout,” says Beresin. “It’s the flip side of safety training: What provides

safety for physicians?”

A Moral Obligation

Burnout is detrimental to patient care, adds Beresin, as it contributes to lack of empathy and medical errors. “We’ve realized that what’s good for the patient tends to be good for the physician,” he says. “It becomes an ethical obligation and a professional obligation. They go hand in hand.”

Beresin concludes that healthcare leaders have a moral and professional obligation to ensure providers are mentally and physically healthy. “We can only provide optimal care if we take care of ourselves. That means paying attention to all aspects of physician well-being,” he says.

Obstacles include a physician shortage, decreased reimbursement, excessive caseload, and more regulations and administrative burdens. Beresin says, “Once we accept that we have an ethical imperative to promote physician well-being, we have to look at the elements that work against it.”

Stigma against psychiatric disorders makes some physicians reluctant to seek help. “The important news is, we have data to show physicians do have a higher rate of depression and burnout than others in the population. We can talk openly about it,” says Beresin.

Beresin would like to see medical schools include well-being in the curriculum, and health systems to take steps to address well-being of practicing clinicians. As for what medical schools and residency

programs are actually doing, says Beresin, “it’s all over the map. What we have not codified are the kinds of activities that support resilience. On the other hand, we have sound research about the kinds of activities and methods that prevent burnout.”

While many accreditation organizations support well-being, they’ve stopped short of mandating specific practices.

Beresin would like to see a core requirement for a skill set promoting well-being. This could include modules on nutrition, reflective writing, group discussions, cognitive behavioral therapy, yoga, sleep, exercise, and meditation. One study found that participation in a mindful communication program was associated with short-term and sustained improvements in well-being, and attitudes associated with patient-centered care.⁴

“Given our social contract to care for other people who are entrusting their well-being to us, we have an ethical obligation to keep our providers healthy as well,” says Beresin. ■

REFERENCES

1. Shanafelt TD, Hasan O, Dyrbye LN, et al. Changes in burnout and satisfaction with work-life balance in physicians and the general US working population between 2011 and 2014. *Mayo Clin Proc* 2015; 90(12):1600-13.
2. Rath KS, Huffman LB, Phillips GS, et al. Burnout and associated factors among members of the Society of Gynecologic Oncology. *Am J Obstet*

Gynecol 2015; 213(6):824.e1-9.

3. Beresin EV, Milligan TA, Balon R, et al. Physician well-being: A critical deficiency in resilience education and training. *Academic Psychiatry* 2016; 40 (1): 9-12.

4. Krasner MS, Epstein RM, Beckman H. Association of an educational program in mindful communication with burnout, empathy and attitudes among primary care physicians. *JAMA* 2009; 302(12):1284-1293.

SOURCE

- **Gene Beresin**, MD, MA, Professor of Psychiatry, Harvard Medical School, Boston. Phone: (617) 726-8471. Fax: (617) 724-8690. Email: eberesin@partners.org.

Study: Palliative Care Meetings Did Not Reduce Anxiety, Depression

Palliative care-led informational and emotional support meetings with families of ICU patients did not reduce anxiety or depression symptoms, and may have increased post-traumatic stress disorder symptoms, found a recent study.¹

“We had hypothesized that structured meetings with families of patients in the ICU about prognosis and treatment options would reduce anxiety and depression,” says **James A. Tulsky**, MD, one of the study’s authors. Tulsky is chair of the Department of Psychosocial Oncology and Palliative Care at Dana-Farber Cancer Institute, and professor of medicine at Harvard Medical School.

Instead, the researchers found no difference between the intervention and the control group. In fact, family members receiving the intervention were more likely to experience long-term negative outcomes. Tulsky theorizes this is perhaps because families experienced the trauma of receiving bad news about potential outcomes, without ongoing emotional support.

“We recognize that these were not true palliative care consultations, and that many important elements of such care were missing,” notes Tulsky. The primary difference was that there was no longitudinal follow-up, and the families were not

really treated as the responsibility of the palliative care clinicians.

“The clinicians leading these meetings never had an opportunity to develop real relationships with the families, and follow up with them over time to help them process the experience,” Tulsky explains.

The study’s findings do not support routine or mandatory palliative care-led discussion of goals of care for all families of patients with chronic critical illness.

“This study and other reports remind us that information given in serious illness can be damaging, if not done under the appropriate circumstances,” Tulsky says.²

“Disclosing prognosis outside of the context of a therapeutic relationship risks creating harm.” The study left the researchers wondering which aspects of palliative care make the greatest difference.

“We need to think carefully about

palliative care or ethics interventions that don’t allow for longitudinal care,” Tulsky concludes. ■

REFERENCE

1. Carson SS, Cox CE, Wallenstein, et al. Effect of palliative care-led meetings for families of patients with chronic critical illness: A randomized clinical trial. *JAMA* 2016; 316(1):51-62.
2. Rose S, Bisson J, Churchill R, et al. Psychological debriefing for preventing post-traumatic stress disorder (PTSD). *Cochrane Database Syst Rev*. 2002; (2):CD000560.

SOURCE

- **James A. Tulsky**, MD, Chair, Department of Psychosocial Oncology and Palliative Care, Dana-Farber Cancer Institute, Boston. Phone: (617) 582-9201. Fax: (617) 632-6180. Email: jamesa_tulsky@dfci.harvard.edu.

CME/CE 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 onto AHCMedia.com and click on My Account.
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 test, 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.

EDITORIAL ADVISORY BOARD**CONSULTING EDITOR:**

Arthur R. Derse, MD, JD
Director and Professor
Center for Bioethics and Medical
Humanities
Institute for Health and Society
Medical College of Wisconsin
Milwaukee

NURSE PLANNER:

Susan Solverson, BSN, RN, CMSRN
Staff RN Educator, Nursing 4P
Froedtert and the Medical College of
Wisconsin Froedtert Hospital
Milwaukee

EDITORIAL BOARD:

John D. Banja, PhD
Associate Professor
Department of Rehabilitation
Medicine, Emory University
Atlanta

J. Vincent Guss, Jr., DMin, BCC
Clinical Ethicist/Bioethics Professor
Georgetown University School of
Medicine
Washington, DC

Marc D. Hiller, DrPH
Associate Professor
Department of Health
Management and Policy
University of New Hampshire
Durham, NH

Paul B. Hofmann, DrPH
President
Hofmann Healthcare Group
Moraga, CA

Melissa Kurtz, MSN, MA, RN
Bioethics Consultant
The Montefiore-Einstein Center for
Bioethics
Bronx, NY

Interested in reprints or posting an article to your company's site? There are numerous opportunities for you to leverage editorial recognition for the benefit of your brand. Call us: 800.688.2421 Email us: Reprints@AHCMedia.com

To reproduce any part of AHC newsletters for educational purposes, please contact The Copyright Clearance Center for permission:

Email: info@copyright.com
Website: www.copyright.com
Phone: (978) 750-8400

CME/CE QUESTIONS**1. Which is true regarding conscientious objection to physician-assisted dying, according to Timothy E. Quill, MD?**

- It is an ethical imperative that the objecting clinician find someone to assist, and that this responsibility not be delegated to someone else.
- Assessment of the patient's decision-making capacity should be done more stringently for requests to withdraw life-sustaining interventions than for physician-assisted dying.
- It is unethical for ethicists to suggest the option of conscientious objection to clinicians who express discomfort with the practice.
- Assessment of the patient's decision-making capacity, access to palliative care, and general agreement on the ethical and legal permissibility are important considerations.

2. Which is true regarding offering patients who meet criteria for physician-assisted dying, in states where this is not legal, the option of voluntarily stopping eating and drinking, according to Quill?

- It is unethical for physicians to suggest this option if what patients are really requesting is physician-assisted dying.
- Based on recent court rulings, the practice is clearly illegal because clinicians are withholding required oral nutrition and hydration from patients.
- Institutional policies can help clinicians feel more ethically grounded in offering patients this option.
- Obtaining an ethical consult is not advisable, as long as the clinician has obtained informed consent, because it sends a message to others on the clinical team that the

practice is possibly unethical.

3. Which has been encountered after physician-assisted dying was legalized in Canada, according to Bob Parke, BA, BSW, MSW, MHS?

- The vast majority of physicians have become active proponents of the practice because it reduces their patients' suffering.
- Physicians who are against the practice also object to exploring why the person made the request.
- Some non-clinical team members, such as interpreters and the IT team, were uncomfortable participating with a physician-assisted death.
- Clinicians occasionally grant the requests of families for physician-assisted death for patients with dementia who lacked decision-making capacity.

4. Which is true regarding palliative care-led meetings with families of ICU patients, according to a recent study?

- The meetings did not reduce anxiety or depression symptoms, and may have increased post-traumatic stress disorder symptoms.
- There was no short-term decrease in anxiety or depression, but families reported significantly less severe symptoms over the long term.
- Families were less traumatized by the grieving process, primarily because of the bonds developed with palliative care clinicians.
- Long-term negative outcomes occurred even when ongoing emotional support was provided in longitudinal follow-up.