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## Challenges still persist in advance care planning billing

*Goal is for difficult conversations to become routine*

Ethics consults in the hospital setting are frequently called due to conflicts stemming, in one way or another, from the patient’s lack of advance care planning. Now, an oft-cited barrier to these important — but time-consuming — discussions has been eliminated: That of reimbursement.

Providers can now bill Medicare for advance care planning, according to finalized regulations from the Centers for Medicare & Medicaid services (CMS).<sup>1</sup> “This is an important barrier to have overcome,” says **Jane Jankowski**, DPS, LMSW, director of the clinical ethics consultation service at Albany (NY)

Medical Center’s Alden March Bioethics Institute.

Individuals are less likely to prefer life-sustaining treatment when there is no reasonable hope of recovery, notes Jankowski. “Yet it can be distressing to implement such preferences when there has not been discussion about these matters before a serious health crisis arises,” she says.

Having advance planning conversations before an episode of acute illness facilitates respect for individual autonomy — even if the patient later becomes too ill to participate in the discussion. “These discussions will become less frightening if

### EXECUTIVE SUMMARY

Providers can now bill Medicare for advance care planning, eliminating one important barrier to end-of-life conversations.

- It is unclear whether other health insurance carriers will follow suit.
- The CPT code includes advanced practice nurses.
- Many providers still lack tools and training.

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end-of-life topics are raised routinely  
in the course of general care planning,”  
adds Jankowski.

## Full effect is unknown

**Thomas D. Harter**, PhD, an  
associate clinical ethicist at La Crosse,  
WI-based Gundersen Health System,  
says, “The full implications of CMS’s  
ruling to pay for advance care planning  
are unknown at this point.” He didn’t  
expect the change to happen this  
quickly, or as a result of a CMS rule.

“We had some indications from  
different contacts in Washington, DC  
that there was significant movement  
over the past few years toward paying  
for advance care planning,” says Harter.  
However, he expected reimbursement  
to come about as a legislative action by  
Washington lawmakers.

“In the long term, this ruling is  
likely going to be a positive impact for  
advance care planning,” says Harter.  
If other insurance companies follow  
Medicare’s lead, it would strongly signal  
to providers that advance care planning  
is considered to be part of good patient  
care.

“The move toward paying for  
advance care planning will help  
cover the cost of resources needed  
to adequately provide this service to  
patients — namely, the time needed  
to have in-depth conversations,” says  
Harter.

In the short term, however, the  
ruling could place providers accepting  
a variety of healthcare insurances  
in a precarious position, financially  
speaking. Some organizations,  
including Gundersen Health System,  
have a single billing system.

“That is, we either bill for a service  
or not — regardless of insurance  
coverage,” says Harter. Thus, some  
patients with insurance that doesn’t  
reimburse for advance care planning

could be surprised by an unexpected  
out-of-pocket charge.

“This could become a barrier to the  
practice of advance care planning,” says  
Harter. Fearing dissatisfied patients,  
some healthcare providers may feel  
it’s in their best business interest to  
continue providing the service free of  
charge — until coverage for advance  
care planning becomes the norm.

On a positive note, Harter sees  
the rule as an indication that CMS “is  
recognizing the importance of advance  
care planning in providing high-quality  
patient care to all persons, not just those  
near the end of life.”

## Quantity, not quality?

While reimbursement is important,  
it’s no guarantee that providers have  
the tools or skills to engage in advance  
planning conversations, says Jankowski.

**Joan M. Teno**, MD, MS, a  
professor of medicine at University  
of Washington’s Cambia Palliative  
Care Center of Excellence, says a  
payment for service doesn’t mean that  
advance planning conversations will be  
examined in the context of quality. “I  
fear that this is only going to result in  
billing, but without knowing whether  
these are quality conversations,” she  
says. “I am doubtful that this will have  
an impact on end-of-life care.”

**John You**, MD, MSc, FRCPC,  
associate professor in the Departments  
of Medicine and Clinical Epidemiology  
& Biostatistics at McMaster University  
in Hamilton, Ontario, acknowledges  
that reimbursement “might possibly  
increase the quantity — but not  
necessarily the quality — of advance  
care planning. But maybe that’s still  
better than nothing.”

A recent pay-for-performance  
initiative to promote cancer screening  
by Ontario’s primary care physicians  
resulted in little improvement despite

significant expenditure.<sup>2</sup> “It turned out that providers who were already doing the screening did it more frequently, but providers who weren’t doing the screening still didn’t do it,” says You. “The same could be true of advance care planning.”

If providers are uncomfortable with advance care planning discussions, they will likely remain so even with financial incentives. “These conversations are not easy for patients, and they are not easy for clinicians either,” says You, adding that the greatest need is for clinicians to have more confidence in having these conversations.

Still, says You, “symbolically, it is super-important that a huge payer in the U.S. system is making a statement, that they needed to make this change, because advance care planning is so important.”

What matters with advance care planning is the quality of the conversations — not the quantity, or the speed at which those conversations happen, says Harter. He recommends the following approaches to facilitate high-quality advance care planning conversations:

- **The development and implementation of a full advance care planning program unique to the needs of the individual health system.** “Such programs often require systems redesign,” says Harter. “Advance care planning does not typically fit well within the standard workflows of medical providers.”

- **Training ethicists, social workers, chaplains, and other healthcare providers to provide advance care planning conversations that are as objective and as value-neutral as possible.** “While there are lots of different training programs, the one we developed and use in the La Crosse, WI, region has been shown in multiple research studies to be an effective system,” says Harter.<sup>3,4</sup> The approach has

generated large numbers of completed advance care plans and high-quality conversations. “When needed, these lead to treatment decisions that accurately align with patients’ treatment preferences,” says Harter.

## Part of regular nursing care

**Cheryl Peterson, MSN, RN,** senior director for the American Nurses Association (ANA), a role which includes oversight of the ANA’s Center for Ethics and Human Rights, was particularly happy to see that advanced practice nurses are covered by the CPT code. “One of the big obstacles has been that time is money,” she says. “Being able to have some reimbursement to support this service is important.”

Nurses have been routinely engaging in these conversations without reimbursement, however. “Nurses were often doing it regardless, because it is such an important component of nursing care,” says Peterson. “Now, it will become so ubiquitous to be almost unremarkable — just a regular part of nursing care.”

Peterson hopes reimbursement will encourage earlier conversations so patients are able to advocate for themselves. “This timing of when this dialogue occurs is important,” she says. “It has to occur early enough to allow the time for the care team to all be on board as they think of the plan of care moving forward.”

Peterson says such conversations are particularly difficult in cases where providers can’t really predict what the patient’s outcome is going to be, and it’s necessary to plan for a variety of possible outcomes. “But that’s exactly the time where we need to be having these crucial and critical discussions,” she says.

The goal is for patients, providers, and family to all be “in the same space — so if need be, we can act accordingly,” says Peterson.

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# Ethical approaches to disclose errors made by other clinicians

*Many physicians are reluctant to disclose*

There is a clear consensus that error disclosure is an ethical obligation of physicians — but what if the mistake was made by another clinician, or at another institution?

“Assuming that both the physician who made a harmful error and another physician who discovered it are the patient’s treating physicians, they both have an ethical obligation to ensure that it is disclosed to the patient,” says **Charity Scott**, JD, MSCM, Catherine C. Henson professor of law at Georgia State University College of Law in Atlanta.

In reality, many physicians are reluctant to fully disclose their own errors, let alone a colleague’s. “A number of personal, psychological, and institutional ramifications of disclosing someone else’s error can make such disclosures very challenging as a practical matter,” says Scott. She gives the following examples:

- A physician may find confronting a colleague about an error to be an uncomfortable and embarrassing conversation that risks damaging their collegial relationship.

- A physician may be concerned about jeopardizing the colleague’s reputation, or even his or her own reputation if he or she becomes viewed by other physicians as breaking collegial trust.

- A physician may be concerned about prompting an investigation or adverse disciplinary action by the colleague’s institution, or about opening up the potential for a malpractice claim by the patient.

“Professional bonds continue to make many physicians reluctant to ‘call

out’ a colleague for a mistake, either to the patient or to others in the colleague’s practice or institution,” says Scott.

Physicians have a duty to put a patient’s welfare and need for information above their own discomfort or potential repercussions from an error disclosure. This is true regardless of whether the error was made by him- or herself or another clinician, says Scott. She says that a consulting ethicist can help in the following ways:

- Suggest to the physician who suspects that another physician has erred in a patient’s diagnosis or treatment that he or she discuss the case with his or her colleague.

This gives each physician a chance to gain a more complete understanding of the situation. “It may be that, with a fuller knowledge of the medical case, they can conclude that either there was no error or that it’s simply a professional disagreement among alternative approaches, all of which are still within the standard of care,” says Scott.

- If the physician still suspects that the colleague made a mistake, the ethicist might next suggest that they request a consultation with appropriate specialists.

If the specialist consultation confirms the error, then the ethicist should recommend that the physicians discuss who should make the disclosure and how, advises Scott.

- Identify appropriate resources within the institution, such as patient safety, quality assurance, or risk management, to help physicians make the disclosure appropriately.

“Some institutions have specially trained personnel who can help to

coach the physicians on having the conversation,” says Scott.

- If the physician denies committing an error, or refuses to cooperate in the error disclosure, ethicists can recommend that the physician who discovered the error seek institutional support for making the disclosure.

“While that may appear to ‘up the ante’ from the perspective of the other physician, it seems a necessary step from an institutional perspective to report all adverse events causing harm to patients,” says Scott. It can also provide some institutional assistance and support to the discovering physician who makes the disclosure to the patient.

Ideally, the provider who made the error would be notified, allowing him or her the opportunity to disclose to the patient, says **Bryn Esplin**, JD, a bioethics fellow at the Cleveland Clinic. “If this is not possible, a disclosure that identifies the error and provides the patient with all pertinent information but does not speculate or ascribe unnecessary blame should still be made,” she says.

Bioethicists can provide experiential training so clinicians can practice these difficult conversations, Esplin suggests.

**Sandra Petronio**, PhD, senior affiliate faculty at Indiana University Health’s Charles Warren Fairbanks Center for Medical Ethics in Indianapolis, says, “In order for disclosure of mistakes made by others to occur, there are a number of difficult issues that need to be taken into account.”

First, says Petronio, the culture of the healthcare delivery system must address clinicians’ reticence to disclose someone

else's mistake, and also what constitutes a medical error. "Many attempts have been made to isolate the parameters of what constitutes a mistake, without a clear consensus except in the most obvious and egregious cases," she notes.

One clinician may define something as a medical mistake, while another would not agree. Also, many errors involve a team of clinicians.

"There needs to be a conceptual

shift from not wanting to jeopardize reputation of self or others, to making the whole system stronger by learning the best way to indicate the possibility that a medical mistake has occurred," says Petronio.

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# Many oncologists being asked to solicit donations from patients

*Docs concerned it could interfere with physician-patient relationship*

About one-third of oncologists (32%) had been asked to directly solicit a donation from their patients for their institutions, according to a recent study.<sup>1</sup> Half declined to do so.

Researchers surveyed 405 medical oncologists affiliated with the 40 National Cancer Institute-designated comprehensive cancer centers about participation in philanthropy at their institutions. Other key findings include the following:

- The majority of oncologists (71%) reported that they had been exposed to their institution's fundraising/development staff. Of those, 48% reported being taught how to identify patients who might be good donors, but only 26% received information about ethical guidelines for soliciting donations from their patients.
- About half (52%) of oncologists believed that soliciting donations could interfere with the physician-patient relationship.

"Our hope in doing this study was to stimulate a broad discussion about how to encourage the vital activity of philanthropy while also respecting important ethical principles," says lead author **Reshma Jagsi**, MD, DPhil.

Jagsi is deputy chair of the Department of Radiation Oncology and a research investigator at the Center for Bioethics and Social Sciences in Medicine at University of Michigan Health System in Ann Arbor.

Jagsi acknowledges the "tremendous potential" for philanthropy to help cancer centers pursue clinical, educational, and research missions, and the benefits such philanthropy can have for individual patients. "We often hear how empowering it can be to have the chance to become partners in the fight against a disease that has afflicted them or their loved ones," she says.

Conflicts of interest are a central ethical concern if physicians solicit donations from their own patients, however. "Little research has evaluated the ways physicians are being asked to participate in development activities or how they feel about it," says Jagsi. "That motivated us to conduct our survey."

Many respondents expressed concerns about conflicts of interest and how this could interfere with patient relationships. Jagsi says the study's findings signal a need to address existing guidelines on this practice.

**Ira Byock**, MD, executive director/

chief medical officer at the Torrance, CA-based Institute for Human Caring, Providence Health and Services, is concerned about academic health systems asking practicing physicians to not merely be on the lookout for grateful patients, but also to approach them for philanthropic contributions. "While it may seem like an attractive approach, this increasingly common practice clearly violates some ethical boundaries," he says.

Underpinning this is the unequal power relationship between physicians and patients. "There's really no way for a physician to request financial support from a patient while avoiding the potential for that patient to feel somehow manipulated or beholden to the physician," says Byock.

The American Medical Association's Council on Ethical and Judicial Affairs recommends that "physicians should avoid directly soliciting their own patients, especially at the time of a clinical encounter."<sup>2</sup>

Clearly, institutions welcome financial support from individuals who are grateful for the care they or a loved one has received. "However, the practice of providing care and solicitation of

philanthropic donations need to be separated,” says Byock. “In fact, that’s one of the reasons institutions created development departments.” Hospital fundraising staff can act as “buffers,” he explains, allowing patients to express their gratitude without compromising the physician/patient relationship.

Byock urges bioethicists to “step up” to protect patients from inappropriate philanthropic practices at their institutions. “Philanthropy belongs in the realm of the development offices and their staff, not in the clinical realm,”

he says. “We are here to serve patients and their families. They are not here to serve us.”

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# Access to mental healthcare is “question of social justice”

*Stigma is a reason for underutilization*

Access to equal benefits and qualified providers remains difficult for many insured Americans, despite the Mental Health Parity and Addiction Equity Act of 2008, according to a recent health policy brief.<sup>1</sup>

Access to mental healthcare is “a question of social justice,” according to **Brendan Saloner**, PhD, an assistant professor at Johns Hopkins Bloomberg School of Public Health in Baltimore. “There is some evidence that the law has eliminated discriminatory practices in insurance plans,” he adds.

Stigmatization is one reason for underutilization of mental health treatment. The perception that people who disclose being treated for a mental health problem will be perceived as an outcast or dangerous persists, says Saloner. “There is a lot of rhetoric out there connecting people with mental health problems as violent, and this rhetoric is not based in reality,” he adds.

Access to mental healthcare is a multifaceted problem which remains difficult to solve. “There are some promising developments in the mix. But

there are also some big challenges that have not been addressed,” Saloner says.

Only 41% of adults in the U.S. with a mental health condition received mental health services in 2014, according to the Substance Abuse and Mental Health Services Administration.<sup>2</sup> “We have a huge evidence-based mental health access problem,” says **John T. Walkup**, MD, director of the Division of Child and Adolescent Psychiatry, Weill Cornell Medical College and New York-Presbyterian Hospital, both in New York City. Insufficient provider expertise and availability, stigmatization of mental health problems, and insurance barriers such as pre-authorization requirements all contribute to the problem, he says.

In the process of ensuring that mental health services are appropriate and necessary, “insurers willingly or unwillingly create access barriers,” says Walkup. “Accessing mental healthcare is difficult for people anyway. When they make it harder, it’s a problem.”

Insurers have the responsibility to pay for needed services, but the lack

of evidence-based standards makes it difficult to determine what services to reimburse for, explains Walkup. Also, many mental health providers do not accept insurance coverage, due to most insurers’ low fee structure.

“Preauthorization requirements for medications and ongoing review of treatment, while perhaps necessary, becomes limiting, restrictive or disruptive to necessary care,” adds Walkup.

There is a need to ensure clinicians are consistently trained in evidence-based behavioral health practices, and to decrease the variability in the training provided by graduate programs, says **Patricia A. Arean**, PhD, professor of psychiatry at Seattle-based University of Washington.

“Some train very well in evidence-based practices, while others do not,” she explains. “It’s an ethical obligation of our education and licensing systems to make sure clinicians are prepared.”

Poor access to evidence-based mental healthcare “comes up a lot, but it never comes up in the ethical context. It

usually comes up as a training issue,” says Walkup. Professional schools do not necessarily train to evidence-based standards, he explains, and licensing bodies do not require demonstration of capacity to implement evidence-based interventions.

“We have evidence-based standards, but we don’t consistently train people to those standards,” says Walkup. “We don’t have systems that require providers to practice consistent with the evidence base.”

There is a need to determine if people are getting the high-quality behavioral health interventions, according to Arean. “We really don’t have an oversight body that says, ‘These are the things you need to train your clinicians,’ or where a patient can get advice on what evidence-based treatments are available,” she says.

A recent report from the National Academies of Sciences, Engineering, and Medicine presents a framework to establish efficacy standards for psychosocial interventions used to treat individuals with mental disorders, including addictive disorders.<sup>3</sup>

“The report has many excellent recommendations for how to improve the quality of psychotherapy delivered in the U.S.,” says Arean. “But it will only have a positive impact if those recommendations are put into action.”

Arean points to the U.K.’s significant investment in increasing access to

mental health services and training the workforce in evidence-based practices. “We don’t need to reinvent the wheel,” she says. “We know how to improve the quality of care. It’s being done in other countries.”

With behavioral health interventions, says Arean, “it’s very hard to measure what we do. We need pragmatic ways to measure quality of care.”

Bioethicists can play a role in ensuring ethical mental healthcare in the following ways, Saloner suggests:

- **Ensuring their own institutions have policies in place that are inclusive of patients with mental health needs.** This includes ensuring that health systems’ own insurance plans include comprehensive coverage for mental health services, and that workplaces have policies that allow individuals to seek mental health treatment without jeopardizing their employment.

- **Publicly voicing ethical concerns about access to mental healthcare.** “Provide a vision of what a humane, equitable, and inclusive system would look like,” he advises.

- **Sharing anecdotal stories of patients who were helped by access to quality mental healthcare.** “The public responds to hopeful narratives which help them to understand how particular people can benefit from mental health treatment,” says Saloner.

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# Surprising data on nursing homes and “culture change”

*Medicaid-reliant facilities implemented new practices*

Some nursing homes that rely heavily on Medicaid funding have implemented “culture change” or palliative care, a recent study found.<sup>1</sup> This finding surprised researchers.

“Resource-poor nursing homes, whose residents rely primarily on Medicaid for their long-term care needs, are known to be of lower quality than facilities that do not

rely primarily on Medicaid,” says lead author **Denise Tyler**, PhD. Tyler is assistant professor of health services, policy, and practice at Brown University’s Center for Gerontology

and Healthcare Research in Providence, RI.

Resource-poor facilities often have lower staffing, lower quality of care, and are less innovative than facilities that are not resource-poor. “They often lag behind other facilities in terms of implementing best practices or new programs,” says Tyler.

When researchers previously surveyed over 2,600 nursing homes in 2009 and 2010, they were surprised to find that some resource-poor facilities were implementing two newer practices: culture change, also known as resident-centered care, and palliative care.<sup>2</sup> “This study aimed to determine how they were able to do that, considering the financial constraints they were operating under,” says Tyler.

The researchers expected that some facilities would be ahead on both culture change and palliative care. “Our hypothesis had been that if facility leaders had figured out how to implement and sustain one innovative practice, that they would apply what they had learned to other innovative practices,” says Tyler.

Most facilities had increased their resident-centered care practices. None

had increased implementation of palliative care practices, however.

“The differences weren’t so much between the facilities and their leaders, but between these two types of practices themselves,” says Tyler.

This was especially related to the intentional diffusion of culture change by multiple stakeholder groups. “Culture change and resident-centered care was being pushed by so many groups, and so many more resources such as information and training were available to nursing home administrators, that it was simply impossible not to get on board,” says Tyler.

This was not at all true of palliative care. “In fact, many facility administrators had trouble even defining what that was,” says Tyler. She says the following are important take-home messages for bioethicists:

- **Providers shouldn’t assume that goals of care conversations are happening at nursing homes.**

“Take the opportunity to have these conversations with nursing home residents and their families when they are in the hospital setting,” says Tyler.

- **Providers shouldn’t assume that**

**patients’ wishes, identified during goals of care discussions in the hospital setting, are communicated with the nursing home.**

“Ensure that systems are in place so that this information is relayed back to the facility when the resident is discharged back to the nursing home,” says Tyler.

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# Growing evidence that teleconsultation can support palliative care provision

*Pilot projects test the waters*

As a primary care physician considering switching a patient to methadone, having trouble managing a patient with delirium, or in need of input on what medication is best to manage a patient’s shortness of breath? Growing evidence suggests that telepalliative care is a viable solution for this scenario.

A recent qualitative study of 18 home-based patients in the Netherlands showed that the introduction of

specialist palliative care team-patient teleconsultation led to collaboration between primary care physicians and specialist palliative care team clinicians in all 18 cases.<sup>1</sup>

“In the Netherlands, many people — 83% of the population — prefer to die at home,” says lead author **Jelle van Gorp**, Msc, a palliative home telecare researcher at the Netherlands’ Radboud University Medical Centre. “This results

in a great responsibility for Dutch family physicians, who are primarily responsible for providing palliative care at home.”

The researchers set out to investigate whether and how teleconsultation would contribute to more personalized palliative care.

“There remains a substantial group of family physicians who have only general knowledge of treatment

options, and limited knowledge and competencies when it comes to specific medical-technical treatments,” notes van Gorp. These providers could very much use specialized support and/or education, preferably delivered at the right time, he adds. “What surprised us was that although the technology is quite simple and almost everywhere available by now, human collaboration is still so multifaceted,” van Gorp says.

Multiple professionals talking to a patient at the same time ended up hindering communication. “Professionals felt they could not say everything they wanted to say in front of the patient,” explains van Gorp. The study suggested a more promising approach: several providers each talking to the patient at different points in time, then having “backstage” conversations with one another.

The University of Rochester (NY) uses teleconsultation to provide geriatrics psychiatric consults. “It seems to have wide acceptance, and people are coming up with good cases,” says **Timothy E. Quill**, MD, professor of medicine, psychiatry, and medical humanities in the University’s Palliative Care Program.

The University’s Palliative Care Program will soon start a pilot project using a similar approach for palliative care consultations. “I think a lot of them could be done by providing input to the primary treating people, which they can then implement,” Quill says. “That would have a lot of pluses if we did that.”

This increases the expertise of the treating clinicians, and the family doesn’t have to meet yet another doctor or team. “We could restrict consultations to the tough cases where the basics aren’t working,” Quill says.

Teleconsultations, on the other hand, can be used to improve symptom and pain management in the majority of cases. “If you can improve the basics,

you can improve the care of a huge number of people,” says Quill. “You can do a tremendous amount of good just by raising the floor in terms of symptom and pain management.”

Telepalliative care consults allow multiple providers to conference with one another. “If the patient is seeing a pulmonologist, a cardiologist, and a primary care doctor, the odds of them all talking to each other are low. Maybe nobody is looking at the big picture,” says Quill.

**Robert M. Arnold, MD**, director of the University of Pittsburgh’s palliative care service, says telepalliative care is especially important in rural areas. “You need to utilize technology to expand your reach,” says Arnold. “As important as that is, the telemonitoring is also important.”

This allows palliative care specialists to electronically track how the patient is doing. “Some of that is already happening in the healthcare world, but we are at a pretty early stage of it. Newer technologies allow patients to report on a regular basis,” he says. This allows providers to treat pain or other symptoms early.

“Our health system is very interested in this, and is working quite hard to roll out ways to better integrate these technologies,” reports Arnold.

Arnold says the best data comes from heart failure patients whose palliative care needs are very high. By stepping on a scale and having the data transmitted, clinicians can tell whether the patient is gaining weight. “That’s a perfect example of keeping people out of the hospitals by controlling symptoms early,” says Arnold.

The vast majority of palliative care is delivered by primary care doctors, “as well it should be,” says Arnold. “The question is, how can technology help doctors do a better job of being more centered on patient goals?”

Lack of reimbursement for

telepalliative care is one obstacle. “Most of clinical medicine is based on a doctor seeing a patient face to face and getting paid for the visit,” notes Quill.

Having primary care physicians consult with palliative care specialists is “a very efficient use of time and can improve care,” says Quill. “But that is not the economic model we are used to working on.”

Under the fee-for-service model, telepalliative care is bad for business, he explains — even though it’s good for patient care. If systems move to capitated payment, says Quill, “this model makes a tremendous amount of sense, because you want to spend money most efficiently.”

Switching to a telepalliative care model, concludes Quill, “requires a thinking through at a systems level, and investing in a completely different way of how we do things.”

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# Were study's findings misleading?

*Ethical concerns of "data slanting"*

When the data from a clinical trial supporting a drug's efficacy in treating adolescent depression was re-analyzed by independent researchers 14 years later, a different conclusion was reached: that the drug did not show efficacy.<sup>1</sup>

"The main ethical implication is that much of the scientific literature on drug efficacy is not based on a primary value of finding out the truth, as often is assumed, but rather, is based on the primary value of maximizing marketing goals," says **Nassir Ghaemi**, MD, MPH, professor of psychiatry and director of Tufts Medical Center's Mood Disorders Program in Boston.

Ghaemi says journal editors, healthcare leaders, and governmental regulatory agencies should insist pharmaceutical companies open up the process of data analysis of their clinical trials. "There needs to be a second level of confirmation of the claims made in interpretations of those data," he says.

Ghaemi would like to see major scientific journals refuse to publish clinical trials from the pharmaceutical industry without independent verification of the interpretations of the data analyses from academic statisticians. "This step already happens with the Food and Drug Administration [FDA], which legally requires that pharmaceutical companies provide their databases for analyses by internal statisticians," he says.

This data, which could reveal bias, isn't published in scientific journals. "Only the pharmaceutical industry companies' own analyses

are published, unverified, and unchecked by anyone else," says Ghaemi.

## Some findings omitted

While people outside of scientific research probably view study findings as black and white, "the process of interpreting data may depend on who is doing the interpreting," says **Erick Turner**, MD, associate professor of psychiatry at Oregon Health & Science University (OHSU)'s School of Medicine in Portland, and a senior scholar at OHSU's Center for Ethics in Health Care. Turner previously worked at the FDA as a reviewer, where he became aware that drug companies were conducting studies that were not represented in the published literature.

An investigator who believes a treatment is effective will likely report the findings more positively than an investigator who expected the treatment to be ineffective. "The first author may try and find some aspects of the data that do suggest benefit, and try to find reasons why the study came out the way it did," says **Susan S. Ellenberg**, PhD, professor of biostatistics at the University of Pennsylvania's Perelman School of Medicine in Philadelphia. "The second author may write a paper emphasizing that the treatment simply doesn't work."

Caution must prevail where one set of authors accuses another set of slanting data, however. "Deliberately presenting data in a way that masks a true finding, when that finding is not desired by the investigators, is

unethical," says Ellenberg. "But one has to allow for the fact that honest investigators will often disagree about the implications of certain results."

Investigators may fail to mention certain aspects of the study that, if known, would call the conclusions into question. "I certainly saw some of that when I was at the FDA," says Ellenberg. "We had access to all the data, and we could see when authors left out of their papers things that didn't jibe with their conclusions."

A recent study examined the efficacy of FDA-approved second-generation antidepressants for anxiety disorders and found that the existence of reporting bias depended on how a given clinical trial turned out.<sup>2</sup>

If the trial was positive according to the FDA, the journal article would agree. "By contrast, if the FDA found that the trial results were negative, the corresponding journal article would usually convey a positive conclusion, thus disagreeing with the FDA," says Turner, one of the study's authors.

Before investigators were required to register trials on ClinicalTrials.gov, it wasn't uncommon for investigators to write a paper focusing on something that appeared positive in their study, even if it didn't relate to the primary study question, adds Ellenberg. "Readers would not know that this could easily be a chance finding — a fluke result of multiple looks at the data," she says.

## Attempt to curb abuses

Research suggests that when

clinical trials are funded and conducted by a pharmaceutical company, there is greater likelihood of bias in reporting of data.<sup>3,4</sup>

“This is a serious problem, affecting academic investigators as well as pharmaceutical companies,” says Ellenberg. “Over the past decade, there has been an attempt to curb these abuses.” Investigators need to report primary aims on ClinicalTrials.gov before starting the research, she says. This prevents researchers publishing a manuscript that only reports favorable secondary aims. Investigators should also report every study prior to starting the research. “This way, we can know how many studies go unpublished — which are often those with less favorable results,” says Ellenberg.

The National Institutes of Health (NIH) is considering a requirement that all NIH-funded studies have their results deposited in ClinicalTrials.gov. Currently, the NIH requires data from studies it funds to be made available to any other investigator who wishes to explore and potentially re-analyze. “Transparency helps protect against gross distortions of study findings,” says Ellenberg.

**David Hammond**, director of Kenmore, WA-based Bastyr University’s Office of Research Integrity, says the key issue is the separation of the research and the publication. When an institutional review board (IRB) reviews a study, they review the protocol and the proposed study design; the protocol usually includes a general description of the statistical methods to be run, and the types of analysis planned.

“This portion of the protocol, unless the study is sponsored by industry and has a fleet of

biostatisticians writing very detailed plans, is often a bit vague,” says Hammond. There is no additional IRB oversight of the analysis and the publication.

“The journals are often in a tough position, because they are unable to view the source data and verify the claimed results in the article,” says Hammond. This leaves the slant and potential bias in the reporting of the results solely in the hands of the investigators.

The public should not worry about these analyses and their effect on FDA approvals of products, says Hammond, since the FDA does review the source data looking for bias. “With the publication of results that do not have that FDA oversight, however, this safety check does not exist,” he says.

Hammond says ethical research can be supported with good clinical practice training for investigators, the existence of IRBs, and sound scientific and analytical principles employed in study protocols.

However, he concludes, “The only way to continue ensuring these good practices in the analysis and reporting is by continuing to re-evaluate and question the results that are published.”

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## COMING IN FUTURE MONTHS

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## CME/CE QUESTIONS

**1. Which is true regarding reimbursement for advance care planning, according to Jane Jankowski, DPS, LMSW?**

- A. Providers are reimbursed only if they demonstrate having the required tools and skill to engage in discussions.
- B. Providers will be reimbursed only for advance planning conversations occurring during an episode of acute illness.
- C. The amount of reimbursement a provider receives is linked to the quality of the discussion.
- D. Reimbursement is no guarantee that providers have the tools or skills to engage in advance planning conversations.

**2. Which is a finding of a survey of oncologists regarding philanthropic donations?**

- A. A third had been asked to identify potential donors and directly solicit donations.
- B. The majority of surveyed oncologists reported willingly taking a more active role in soliciting donations in order to support their institutions.
- C. The majority of the oncologists who were asked to identify potential donors received ethical guidelines on the practice.
- D. Few of the surveyed oncologists voiced specific concerns about harming physician-patient relationships.

**3. Which is true regarding nursing homes' implementation of culture change and palliative care, according to a recent study?**

- A. Most facilities had increased their resident-centered care practices.
- B. Resource-poor nursing homes implemented palliative care far more often than facilities that are not resource-poor.
- C. None of the resource-poor facilities were able to implement resident-centered care.
- D. All facilities increased implementation of palliative care practices to varying degrees.

**4. Which is true regarding use of teleconsultation for palliative care provision, according to Timothy E. Quill, MD, FACP, FAAHPM?**

- A. Patients are at significant risk of medical errors if providers electronically track pain and other symptoms.
- B. Telepalliative care consults are only financially feasible under fee-for-service systems.
- C. Teleconsultations are a promising approach to improve basic management of pain and other symptoms, especially in rural areas.
- D. Patients and families typically demand that palliative care be provided by specialists instead of primary care doctors.