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INSIDE

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Some Older, Chronically Ill Patients Don't Realize They Have a Choice in Deciding Surgery

Patients, surgeons sometimes fail to focus on quality of life

When researchers created a Patient and Family Advisory Council to identify preoperative decision needs, they were surprised at the feedback that touched on autonomy and informed consent.[1]

"Many of the patients in our qualitative study felt they had no choice about having major surgery," says **Margaret L. (Gretchen) Schwarze**, MD, the study's lead author. Schwarze is associate professor of surgery at University of Wisconsin School of Medicine and Public Health in Madison.

Patients and family members were also surprised that postoperative recovery was so difficult. Many lacked knowledge about the use of advance directives.

"We believe that informed consent should cover all of the important questions," says Schwarze. "Yet it really doesn't, when you look at the decisional and informational needs identified in our study."

EXECUTIVE SUMMARY

Patients and family members were surprised that postoperative recovery was so difficult, and lacked knowledge on advance directives and the fact that they could decline major surgery.

- Simply discussing risks, benefits, and alternatives doesn't fully inform the patient.
- The informed consent process doesn't always address whether surgery will improve quality of life for the patient.
- A checklist approach is one way to integrate patients' goals into decision-making.

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The researchers came up with 11 questions for patients to ask, such as, "What are my options?" "What should I expect if everything goes well?" and "What happens if things go wrong?"

"I believe the requirements of informed consent fall very short of patients' decisional and informational needs," says Schwarze. "Just discussing risks, alternatives, and benefits misses the mark."

As a vascular surgeon caring for older patients with multiple comorbidities, **William Doscher**, MD, says surgical decision-making is "an issue we face absolutely all the time. For many older patients, surgery doesn't do anything for them."

It could be that surgery will give the patient another month or two of life, but reduce the quality of life. "But how do you talk to them about having the procedure? What's the decision-making?" asks Doscher.

Autonomy and informed consent are two central ethical issues. "Most informed consents are really not informed. That's something that is never really discussed," says Doscher. "In my experience, we don't do a very god job of this."

Patients don't always fully understand the risks and benefits of a procedure even after a lengthy discussion. Sometimes this is because their quality of life isn't explained in plain talk.

"I think a lot of patients, if it was explained to them that, 'You're not going to get much out of this — maybe a month or two, but you are going to be miserable' — would say, 'Maybe I don't want to do the surgery,'" says Doscher.

Doscher is associate professor at Hofstra-Northwell School of Medicine and chair of ethics in the Department of Surgery. Recently, he called an ethics consult regarding one of his own patients: A woman with vascular disease had surgery scheduled for a below-the-knee amputation, but shortly before the procedure, changed her mind.

"Her children got very upset, and wanted to prolong life at any cost. I said, 'She's declined the surgical procedure, I'm not doing it,'" says Doscher. The surgery was finally done at the request of the surrogate, as the patient at that point in time had no capacity — even though that did not respect the patient's wishes when she had capacity several days prior. "I went ahead to relieve the patient's pain, which might reflect a certain degree of paternalism, but not everything is black and white," says Doscher. The patient died from a massive GI bleed a few days later.

"So what was the value of this?" he asks. "It probably sped up her demise, if anything. This is an example of what goes on."

To make an informed decision, patients need to understand the benefit of the surgical procedure, compared with not having the procedure. "We can do an operation, but is it of any value to the patient?" says Doscher.

Withholding a therapeutic modality the physician believes isn't in the patient's best interest is ethically acceptable, he emphasizes. "No physician has to give a therapy, surgical or otherwise, if they feels it's not appropriate. A patient can ask for it, but you do not have to give it," says Doscher. "And guess what: You can also withhold care if you don't think it's of any value."

If a patient is on dialysis but the physician believes it's of no value to the patient, the physician doesn't have to continue it, adds Doscher. "Lots of people are more comfortable with not giving a therapeutic

modality, than to withdraw. However, they are ethically exactly the same," he says.

Doscher uses this aphorism with residents: "Some of the best operations I have done are the ones I haven't done."

"You can do all sorts of operations. But if you are in the ICU for the next couple of months, what good is it?" he asks.

It doesn't make sense for a patient to have surgery for colon cancer if he or she won't survive more than a month due to a heart problem, for instance. "Everything is on case-by-case basis, and it all comes down to informed consent," says Doscher. He gives the example of a patient with cancer diagnosis and a life expectancy of one or two years, and an aneurysm which will likely kill the patient in the next week or two, which can be surgically repaired. "Maybe we should do that, to give the patient a year or two of decent life," he says. "That's a gamble that I think I would take."

The key question that patients should be asking is, "What am I getting out of this? Am I just getting an operation? Or will this get me back with my family or give me some quality of life?" says Doscher. Similarly, surgeons should be asking, "Am I doing something to give the patient a better quality of life?"

Doscher discusses the possibility of doing an amputation with a patient's family, and says words to the effect of: "I can remove the leg, but what are we doing it for? Let's just make her comfortable."

"I can very often see that the weight is lifted from their shoulders," he says

Andrew Courtwright, MD, PhD, a physician at Massachusetts General Hospital's Institute for Patient Care, says providing high-quality, appropriate surgical care to elderly patients with serious illness requires determining which interventions are aligned with patients' core goals.

"Surgeon, patient, surrogate, and systemic factors contribute to communication challenges and non-beneficial surgery at the end of life," says Courtwright. These factors include time constraints, inadequate provider communication skills and training, uncertainty about prognosis, patient and surrogate anxiety and fear of inaction, and limitations in advance care planning.

> "YOU CAN DO ALL SORTS OF OPERATIONS. BUT IF YOU ARE IN THE ICU FOR THE NEXT COUPLE OF MONTHS, WHAT GOOD IS IT?"

"Surgeons could accomplish more effective communication with seriously ill elderly patients if they had a structured, standardized approach," says Courtwright. A "checklist" approach to exploring patients' preferences and integrating those preferences into surgical decisions might include the following:

- clarifying the patient's prognostic understanding and expectations for recovery,
- identifying the patient's priorities and goals for treatment,
- determining health states that the patient would find unacceptable,
- recommending palliative treatment alongside life-prolonging treatment, as best aligned with the individual patient's goals and wishes, and
- affirming the clinician's commitment to the patient's well-being.

Rather than expecting clinical ethics to be involved in a day-to-day basis in these conversations, Courtwright suggests ethicists partner with senior surgeons in developing and modeling structured conversational guides. These can be used to train surgical residents in how to communicate with seriously ill patients.

Courtwright envisions an intensive one-day course, followed by personal coaching for a designated period of time. "Such training could include handling intense emotions from patients and their families, discussing prognosis, and delivering basic palliative care interventions," he says. ■

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Surprising Conflicts of Advisory Committee Speakers

Even patients have industry ties

Much attention has been paid to clinicians with financial ties to industry and resulting conflicts of interest, but patients who speak at public meetings also have financial ties, found a recent analysis.[1]

Researchers analyzed speakers at all 49 meetings of the FDA's Oncologic Drugs Advisory Committee from 2009 to 2014. Some key findings include the following:

• More than 90% of the 103 public speakers who were cancer patients supported approval of the drug. About 30% reported financial ties to the drugmaker.

• In two instances, speakers failed to disclose their financial ties. The researchers discovered through online searches that the speakers represented organizations that had received money from the drug company.

• Only six speakers — none of whom reported financial ties — presented negative opinions. These speakers generally called for better safety and efficacy data.

Genevieve Pham-Kanter, PhD, assistant professor in the department of health management and policy at Drexel University School of Public Health in Philadelphia, didn't find it particularly surprising that some of the public speakers had ties to industry — either as individuals or through organizations.

This is because individuals who are sufficiently motivated to expend the effort, time, and money to participate as public speakers in these hearings are typically those who feel very strongly about advocating for access to a particular drug.

"Their interests, and those of the sponsor of the drug, are aligned," she explains. Pham-Kanter is also a senior fellow at the University of Pennsylvania's Leonard Davis Institute of Health Economics.

What was somewhat surprising to Pham-Kanter was the relatively small proportion of public speakers who highlight potential safety issues and oppose approval.

"Consumer safety advocates are strongly motivated to keep drugs they perceive to be unsafe off the market," she notes. "We would have expected to have seen greater representation of these types of advocates."

Some Patients Do Vote

Joseph Golec, PhD, a professor of finance at the University of Connecticut, co-authored a 2015 report examining FDA advisory committees and conflicts of interest.[2] The report analyzed only individuals on the advisory committee who vote, not those who simply speak at the meetings. The authors concluded that conflicts of interest don't unduly influence voting patterns on FDA advisory committees.

"Many, but not all, committees have a patient representative who votes. So the sample of these members is relatively small," notes Golec. That subset of members voted to recommend drug approval more frequently than other members. "Because of the small sample, the statistical significance of the difference in voting between conflicted and unconflicted members is weak," says Golec.

Golec believes the effects of conflicts on voting are not significant. The report found that members with conflicts have more expertise. This is possibly because they are sought out by drug companies to run clinical trials. "To get the top specialists, one may have to accept that they will have ties to drug companies," says Golec.

Patient representatives who serve on advisory committees as voting members are required to disclose their ties and abide by conflict-of-interest rules. Pham-Kanter says, "Because many patients are interested in increasing access to therapies, they are natural allies with drug companies, who also want more drugs on the market."

As long as patients' financial ties are being disclosed and managed

EXECUTIVE SUMMARY

About a third of 103 cancer patients who spoke at advisory committee meetings in a 15-year period reported financial ties to industry, found a recent analysis.

• In two instances, speakers failed to disclose their financial ties.

• Only six speakers — none with financial ties — presented negative opinions.

• Some advisory committees have patient representatives who vote.

appropriately, Pham-Kanter doesn't see these as particularly problematic.

Other public speakers don't have a formal voting role on committees, but present as independent commentators. These speakers do not have to abide by conflict-of-interest rules.

It's possible that public speakers from patient advocacy organizations are substantially supported by industry. "But because the industry financial ties of these organizations do not have to be disclosed, advisory committees could be presented with a misleading picture of the role the public speakers are playing," says Pham-Kanter. She sees the following three ethical concerns:

• if the advisory committee doesn't know about the full scope of the speaker's — or his or her organization's — financial ties,

• if the roster of public speakers is dominated by those who are funded by industry and representing industry interests, and

• if the roster doesn't sufficiently represent consumer groups concerned about safety, which are generally less well-funded.

Currently, advisory committees incorporate public speakers' concerns in different ways. "My understanding is that the FDA has been seeking to formalize and standardize the process for including patient concerns in its decision-making," says Pham-Kanter. "Standardization would represent progress." ■

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Baby Born With Third Genetic Parent Raises Ethical Concerns

Ethical concerns continue to surround a controversial reproductive technique, further stirred by the recent birth of a baby with three genetic parents.[1] The baby is the product of genetic material from three individuals: one male who contributed nuclear DNA (nDNA), one female who contributed nDNA, and one female who contributed mitochondrial DNA (mtDNA).

Lisa Campo-Engelstein, PhD, assistant professor at the Alden March Bioethics Institute and Department of OBGYN at Albany (NY) Medical College, says the birth of the "three-parent" baby shows how quickly technology moves forward — sometimes before there is significant ethical consideration.

"Ethically speaking, this baby provides further evidence that there are multiple ways to understand what it means to be a parent, and that genetics alone does not equate to parenthood," says Campo-Engelstein. Most would not consider the mitochondrial donor the social or intended mother. "At the same time, however, this baby also shows how important it is to many people to be genetically related to their children," says Campo-Engelstein.

Françoise Baylis, PhD, professor and Canada research chair in bioethics and philosophy at Dalhousie Medical School in Halifax, Nova Scotia, outlined ethical issues involving creating children with three genetic parents in a recent paper.[2]

These include harms to egg providers, potential offspring and future generations, harms to specific interest groups, and harms to society. In Baylis' view, the biggest ethical issue is prioritizing individual reproductive choice over important matters of social justice.

"If our limited resources — time, talent, money, and human eggs — are invested in this technology for the benefit of a very few, then other more important needs will go unmet," says Baylis.

Some have suggested that the mtDNA donated by one of the two women is somehow not important, and so the person who provided this is not important. "But this is clearly false," says Baylis. "The donated mtDNA can make the difference between an offspring with a serious illness and an offspring without that

illness."

In addition, if the offspring born is female, her mtDNA will be passed on to all of her children. "So how is it that the mtDNA is not significant?" asks Baylis.

The technology involved in creating children with three genetic parents is only potentially effective for avoiding the births of children with mitochondrial disease when the disease is caused by defective mtDNA. Most mitochondrial disease in children is caused by defective nDNA.

Recent calculations suggest that the maximum potential direct benefit of this technology is 778 healthy births per year in the U.S.[3]

This number is inconsequential in a country of just over 300 million people. This fact "should raise questions about the value of investing in the science of manipulating human embryos to avoid mitochondrial disease caused by dysfunctional mtDNA," says Baylis.

Further, Baylis believes this number is a significant overestimate. This number assumes that all women with dysfunctional mtDNA who are at risk of having children with mitochondrial disease will choose to reproduce using egg providers, IVF, and human nuclear genome transfer.

"For a number of reasons, this assumption is very likely incorrect," says Baylis. Not all women with dysfunctional mtDNA want to become pregnant, not all will choose IVF followed by human nuclear genome transfer, and of those that do, not all will be successful. Baylis recalculated by taking these facts into consideration and came up with her own estimate of a maximum benefit of fewer than 113 births per year in the U.S.

Some clinicians and scientists are arguing the technology should be used to treat older infertile women.[4] This might expand the customer base for the technology, says Baylis.

R. Alta Charo, JD, Warren P. Knowles professor of law and bioethics at University of Wisconsin Law School in Madison, believes the technique is unlikely to become commonplace due to the relatively small number of people for whom it is the only, or even the best, option for minimizing the risk of serious disease in their children. "While we are learning more about mitochondrial disorders, only a portion of them are due to problems in mitochondrial DNA," she explains.

Charo notes the technique, at present, cannot be performed in the U.S. because it is a form of cell therapy that requires an Investigational New Drug (IND) application from the FDA. Congress passed a provision that prevents FDA from considering an application for an IND to begin clinical trials of this technique. "That provision may not be renewed, but is in effect at the moment," says Charo.

The technique will continue to be developed, however. Charo says this will occur "in the U.K. under strict regulatory oversight, or in other countries that have fewer protections for the research participants and less vigorous oversight to ensure the technical quality of the effort." ■

EXECUTIVE SUMMARY

A controversial reproductive technique recently resulted in the birth of a baby with three genetic parents. Some ethical concerns include the following:

- If limited resources are invested in this technology, other important needs may go unmet.
- The technology would be of benefit to very few individuals.
- The technique could be utilized in countries with fewer protections for the research participants and less vigorous oversight than the U.S.

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Ethical Concerns if Cancer Drugs, and Science in General, are Overhyped

It's not just the media — scientists are also guilty

Half of the cancer drugs described with superlatives such as "breakthrough," "groundbreaking" and "game-changer" were not yet approved as safe and effective, found a recent study.[1] Fourteen percent had never been given to a human being.

"The most surprising aspect of our findings was the several articles that used superlatives to describe drugs that had not even been tested in humans," says **Matthew Abola**, a student at Case Western Reserve University's School of Medicine, and one of the study's authors. The researchers see the following ethical concerns:

• **Overhyping unproven drugs can mislead patients into thinking these drugs are their shot at a cure.** "I know if I was a patient with an advanced cancer, I might want to try the new 'game-changer' instead of arrange for more palliative-focused care," says Abola.

• **In reality, the drug may offer marginal benefits, if any, and have severe side effects.**

• **While patients can try experimental drugs, the researchers say this should start in a healthcare setting, with the involvement of a physician.**

"Using these superlatives is purely about generating hype — not about a levelheaded discussion of the risks and benefits of a new drug," says Abola.

Zubin Master, PhD, assistant professor at Albany (NY) Medical College's Alden March Bioethics Institute, says hype isn't unique to cancer drugs, and to some extent, is to be expected.

"When every novel technique is first discovered, there's a fair bit of hype around it," he says. "Only later do we see the potential development of a product and its ability to be taken into the marketplace."

Since the late 1990s, people have been predicting that stem cell therapies will be widely available in just a few years. "And all these years later, there are no stem cell therapies," says Master, adding that overly optimistic timeframes were also predicted for gene therapy and neurotechnologies.

Hype can also cause a rush from research trials to clinical practice. In the late 1990s, gene therapy trials led to the death of an adolescent, and other serious adverse events. "We didn't know enough about how genes worked. Not until the death of Jesse Gelsinger did the NIH and other authorities say, 'We need to slow down instead of prematurely rushing translation of the technology,'" says Master.

Another ethical issue involves justice. "We have a limited pot of money," says Master. "If we hype stem cell research or genetic technologies, we may put all our financial resources into it. We don't know if some of these technologies will work, at the end of the day."

In reality, research may be of little practical value for years to come, or might contribute to the overall body of scientific knowledge but never have a direct clinical application. "Even if we don't get a drug or a novel diagnostic, these are still valuable things to invest in," says Master.

Master notes that the public's understanding of science doesn't typically come from a textbook or taking a biology course. "It comes from the media," he says. "Hyping science raises people's expectations and hopes."[3]

It's not just the media that hypes science, however. Scientists are also guilty of the practice. "It's also scientists who are making these predictions. In the context of stem cell research, many feel scientists are making exaggerated claims in the public press," says Master. "It's kind of like lying."[2]

EXECUTIVE SUMMARY

Half of the cancer drugs described with superlative language were not yet approved as safe and effective, and 14% had never been tested in humans, found a recent study.

- Overhyping unproven drugs can mislead patients into thinking these drugs provide a cure.
- Patients might try an unproven drug instead of arranging for needed palliative care.
- In reality, drugs may offer marginal benefits, if any, and have severe side effects.

Scientists might simply want to showcase their research and stir up interest in what they're studying, and possibly attract more funding. The marketing of unproven stem cell treatments can be traced back to hype, however.

"Providers are playing on the hype to recruit patients who are suffering from some serious disorders to get these fake therapies that can potentially hurt them and are expensive," says Master.

During a recent presentation on stem cell tourism, Master raised the issue that hype contributed to development of the industry. A physician commented, "The problem is, when we are asking benefactors to donate millions of dollars, they want to hear some of that hype. If you give it to them 100% straight, you won't get anything."

When simplifying things for a lay audience, scientists may wind up saying things that are inaccurate, without realizing the ramifications. "We want scientists to realize that hype may be indirectly contributing to something that is bad for society," says Master.

In a recent paper, Master argued that communication of science to the lay public should be part and parcel of ethics education.[4]

"The media is hungry for science," he says. "Scientists can still talk about the potential of discoveries and predict timelines and the future development of drugs without being over the top." ■

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Ethical Responses if Patient is Offended by a Healthcare Provider's Tattoos

If a healthcare provider's visible tattoos offend a patient or family member, does this supersede the clinician's rights to self-expression?

"There are many ethical issues involved when hospitals attempt to regulate the physical appearances of hospital employees," says **Bob Parke**, BA, BSW, MSW, a bioethicist at Humber River Hospital in Toronto, Canada.

Regarding hospital employees with visible tattoos, Parke takes the position that while some patients and families could take offense, "one needs to look beyond a provider's physical appearance to the quality of care that person provides to their patients."

Parke says, however, that it may be ethically acceptable for lines to be drawn in certain cases, depending on the nature of the tattoo. Many tattoos are artistic in nature, or a form of memorial — for example, a way of honoring a family member or friend who has passed away. "Conversely, some tattoos may be perceived as offensive, lewd or hateful in nature," says Parke. "In some cases, this is clear — for example, a tattoo of a swastika or a racial slur."

Lauren Notini, MBioeth, PhD, a fellow in clinical and organizational bioethics at The University of Toronto Joint Centre for Bioethics, notes that in other cases, there is a certain amount of subjectivity involved. "Some patients may be more offended by certain images than others," says Notini. For example, a very conservative patient is more likely to be more offended by a tattoo of a woman in a bikini than a less conservative patient.

"Alternatively, a very religious patient may perceive a tattoo of a devil as a sign of evil, whereas the same tattoo may not bother an atheist patient," says Notini. "Hence, the way a particular tattoo is perceived will depend to a large extent on the values and beliefs of the person perceiving it."

A particular kind of tattoo could harm the therapeutic alliance between the patient and provider, such as victims of trauma or abuse becoming upset by certain images. "It may be ethically acceptable for a different provider to take over the patient's care, if the original provider is not willing to cover up the tattoo,"

says Parke.

While visible tattoos may offend some patients and families, they may have the opposite effect on others.

"Indeed, some patients may personally identify with a hospital employee who has visible tattoos," says Notini. She is aware of a pediatric anesthetist with cartoon characters tattooed on his arm. "The children this anesthetist provides care to are typically enamored with his tattoos and more willing to engage with him," says Notini.

Similarly, tattoos can create an initial talking point between the patient and healthcare provider, strengthening the therapeutic alliance.

What if an existing hospital employee adds a highly offensive tattoo? Parke says, "As the ethicist would not be in a direct supervisory relationship with the healthcare provider, the provider may be more willing to discuss their tattoo with the ethicist, rather than with their supervisor," he explains. If the employee refuses to cover up or even discuss the offensive tattoo, says Parke, the case may move beyond the scope of ethics and become an administrative and human resources issue.

Notini sees the following two possible roles for ethicists involving regulation of hospital employees' appearances:

• Participating in developing or updating existing guidelines and policies addressing this issue to ensure these are consistent with ethical principles such as respect for persons and their rights.

"The ethicist may also be asked to comment on whether such documents inadvertently perpetuate social stigma on the basis of appearance," says Notini. For instance, it should be explored whether such policies implicitly suggest that employees with visible tattoos are less professional than their non-tattooed peers.

• Consulting on specific cases.

For example, a patient or family may complain about a healthcare provider based on that provider's tattoos or another aspect of the provider's appearance, or may request a different healthcare provider take over their care. An ethicist can mediate between patients, families, and employees.

"In consulting about such issues, the ethicist may consider various factors," says Notini. These include how the patient/family are perceiving the provider's tattoos, the reasons behind the patient's/family's dislike of the tattoos, and the quality of care provided.

The ethicist also can explore whether the provider is willing for a colleague to take over caring for the patient, and whether such a transfer of care is appropriate and possible. "It may not be feasible, for example, if there is only one occupational therapist available on the unit," says Notini. ■

SOURCES

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Cost Savings for Palliative Care in ACOs 'Astounding,' Say Researchers

Home-based palliative care within an accountable care organization (ACO) was associated with significant cost savings, fewer hospitalizations, and increased hospice use in the final months of life, found a recent study.[1]

"The motivation for our study was to evaluate the outcomes and cost of providing a specially trained team of nurses, social workers, and doctors to care for people with advanced illness in their home with 24/7 availability," says lead author **Dana Lustbader**, MD, FAAHPM. Lustbader is chair of the department of palliative medicine at ProHEALTH in Lake Success, NY, and professor of clinical medicine at Hofstra Northwell School of Medicine.

The researchers expected that a team approach to caring for frail elderly patients, or those with advanced illness, would result in improved quality of life, fewer symptoms, and less distress.

"What surprised us most was that better care cost significantly less — $12,000 less than usual care," says Lustbader. "That was astounding."

The vast majority (87%) of patients who died did so in their homes, compared to only 24% of those receiving usual care without palliative care. "Most people want to be at home when they are at the end

of life, and not in a hospital or ICU," says Lustbader. "Palliative care is not only what most seriously ill people want, but costs significantly less."

Unfortunately, the current healthcare system financially rewards high care intensity, hospital admissions, and medical treatments, says Lustbader.

"Most people with advanced illness want access to care where they live — in their homes, when they can no longer get to the doctor's office, or when symptoms develop during off hours," says Lustbader. People with advanced illness often go to the ER or hospital when their disease progresses or they develop distressing symptoms. "This is burdensome, costly, and often dangerous, as these patients can get worse by being hospitalized," says Lustbader.

Focus On Quality Measures

Physician Quality Reporting System (PQRS) was implemented as part of healthcare's shift toward a value-based reimbursement system. Failure of providers to submit PQRS data can result in a reimbursement penalty up to 4%.

"Currently, PQRS measures do not align with palliative care services," says **Janet Bull**, MD, MBA, FAAHPM, HMDC, chief medical officer at Four Seasons Compassion for Life in Flat Rock, NC. Bull is lead author of a paper which gave palliative care providers assistance in deciding how to report and what measures to report.[2]

The quality measures focus on symptom assessment, pain improvement, and advance care planning. Bull says collecting PQRS data will enable benchmarking with other providers and help define benchmarks.

"As the country moves toward a value-based reimbursement system, it is important to show value in palliative care," she concludes.

Lustbader points to evidence that seriously ill people can live longer, with better quality of life, when offered palliative care teams who provide care at home.

"The moral imperative is that all people with advanced illness and their loved ones should have access to palliative care and health plans should pay for it — period, end of story," says Lustbader.

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570 Clinics Found Marketing Unproven Stem Cell Treatments

'The sheer size surprised me,' says researcher

Researchers recently identified 351 U.S. businesses engaged in direct-to-consumer marketing of stem cell interventions, being offered at 570 clinics.[1] The clinics advertised treatments for neurological disorders, spinal cord injuries, heart disease, lung problems, eye injury and diseases, and other conditions.

"Although I realized the stem cell clinic industry in the U.S. had been growing, the sheer size surprised me," says **Paul Knoepfler**, PhD, the study's co-author and a stem cell expert at the University of California, Davis.

Knoepfler expected to find less than half the number of clinics selling non-FDA approved stem cell interventions to patients. "The size of this industry raises many practical and bioethical concerns," he says.

The researchers found stem cell "hot spots" in California, Florida, Texas, Colorado, Arizona, and New York. They found at least one stem cell clinic operating in every state. "This is really a ubiquitous industry in the U.S.," notes Knoepfler. "Based on this new research, we have to re-think how we use the phrase 'stem

cell tourism.'"

The researchers had been tracking stem cell clinics for a number of years, and recently noticed that the number had grown substantially. "But no data had been published based on a comprehensive analysis of this industry. That was a big gap to try to fill," says Knoepfler.

Growing numbers of patients were asking the researchers for information about stem cell clinics. Most were interested in getting stem cells in the U.S. rather than abroad. "This raised concerns about patients being put at risk," says Knoepfler.

No Sign of Crackdown

It is not ethically permissible to sell stem cell "treatments" to patients without data providing a reasonable expectation of both safety and efficacy, says Knoepfler. "Clinic medical providers have an inherent conflict of interest, since they are profiting from selling unproven stem cells to patients," he adds. This also raises the concern over whether clinics can properly administer informed consent.

Knoepfler wonders if people paying for treatments at the clinics realize that they're being given experimental interventions. "This goes against a long historical tradition of not charging people to be experimental subjects," he explains. Some clinics also market stem cell treatments for pediatric conditions such as autism and cerebral palsy, which raises additional ethical concerns.

"I believe we will continue to see this industry grow, despite all the ethical concerns, until at some point either the FDA or the FTC crack down," says Knoepfler. The FDA recently issued a warning letter to three co-owned clinics which offer unproven stem cell therapies for a range of diseases.[2]

"I don't necessarily view the one warning letter as a clear sign of an impending FDA crackdown," says Knoepfler. The FDA has only been issuing about one or less of such warning letters per year, despite there being nearly 600 stem cell clinics operating in the U.S. without FDA approval. "It's not clear why these three clinics, out of hundreds, got warned," he says.

A surge in malpractice lawsuits is another possibility. "If agencies do not take appropriate action, it is possible that litigation against certain clinics may serve as a deterrent to the growth of this industry," says Knoepfler.

In 2015, the FDA published a draft guidance on stem cells.[3] If implemented, these would result in fat stem cells — the most common stem cells used at clinics — being defined as drugs requiring premarket approval.

"That kind of regulatory change could have a major, positive impact by requiring more oversight and data before experimental cells go into patients," says Knoepfler. ■

EXECUTIVE SUMMARY

Stem cell interventions are offered at 570 clinics, with generally unproven treatments being marketed to consumers, found a recent study. Some ethical concerns include the following:

- Patients are paying for stem cell treatments without sufficient data on safety and efficacy.
- Clinics may not be able to properly administer informed consent due to conflict of interest.
- Patients may not realize they're being given experimental interventions.

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SOURCE

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COMING IN FUTURE MONTHS

- Efforts to combat continuing stigma against palliative care
- Ethical responses if patient is possibly victim of human trafficking
- Update on efforts to make results of all clinical trials available
- Social media is affecting patients' access to investigational drugs

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CME/CE QUESTIONS

1. Which is true regarding cancer patients who spoke at advisory committee meetings, according to recent research?

A. All of the speakers with financial ties to industry disclosed these, even if they were not required to do so.
B. Speakers with financial ties were more likely to support drug approval.
C. Patient representatives are allowed only to express opinions to advisory committees but do not vote, so their financial ties are irrelevant.
D. Strong concerns were expressed by virtually all of the patient speakers regarding lack of sufficient safety data.

2. Which is true regarding cancer drugs described with superlatives, found a recent study?

A. Half were not yet approved as safe and effective.
B. All the drugs had been tested in humans, but some of the claims were somewhat exaggerated.
C. Researchers found that superlatives used in media coverage were rarely, if ever, used by scientists themselves.
D. The "hype" was proven by science in subsequent studies, as these drugs were very likely to result in good clinical outcomes.

3. Which is true regarding home-based palliative care within an accountable care organization, according to a recent study?

A. Palliative care is linked to significant cost savings, fewer hospitalizations, and increased hospice use.
B. Cost of care increased due to increased hospice use, but quality of life was somewhat better.
C. Despite receiving palliative care, most patients died in the hospital setting.
D. Problems were found with symptom assessment, pain improvement, and advance care planning.

4. Which is true regarding stem cell treatments currently being offered in the U.S., according to a recent study?

A. Clinics marketed only FDA-approved stem cell interventions, unlike similar clinics in other countries where unproven treatments are the norm.
B. There is at least one stem cell clinic in every state.
C. Clinics are relying on word of mouth due to prohibitions on direct-to-consumer marketing of unproven stem cell interventions.
D. Regulations have banned offering unproven treatments for pediatric conditions, so clinics are focusing solely on adult treatments.