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The Edge-of-the-Field of Clinical Ethics Now, After 30 Years: Does Research Ethics Show Us the Way?

Edmund D. Howe

ABSTRACT

There have been many advances in clinical ethics over the last three decades, since *The Journal of Clinical Ethics* first came about. This issue of *JCE* notes some of them. Fortuitously for this goal, new requirements for doing research just have been published, and the leading United States research ethics meeting has just concluded. The conference offered edge-of-the-field presentations in research ethics, and indicates where we should go beyond this edge: what we still have to do. In this article I build upon foundations to explore what they imply for what we should do now in our clinics.

This issue marks 30 years of publication of *The Journal of Clinical Ethics*. Mark Siegler is the guest editor of this issue of the journal. He and the authors he invited write about how clinical ethics has evolved over this time.

When I think of the origin of the journal, I think first of Norman Quist, who founded *JCE* and is its executive editor and publisher. In these

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roles, Norman provides singular insight to every aspect of *JCE*. I think too of Leslie LeBlanc, who has been the managing editor since its start. She has orchestrated the journal and does it seamlessly. Further, she does this with a warmth and graciousness that is unparalleled.

I think also of John Fletcher, whose spirit, perhaps, most underlies *JCE*. John was, when *JCE* came about, the chief ethicist at the National Institutes of Health (NIH). Norman and I met regularly there with John and others to discuss ethics. One of the others was Fitzhugh (Hugh) Mullan, a psychiatrist whose view was that, to help patients, psychotherapists must themselves change.¹ His book, *White Coat, Clenched Fist*, provides a background to the past that underlies the 30-year reviews provided here.²

The discussions that Norman and I had at NIH with John Fletcher and Hugh Mullan influenced Norman and me greatly. Therefore, I would like to say a bit more about John before proceeding to discuss this issue of the journal.

I recall a visit I had with him about 30 years ago at his office at the University of Virginia Center for Biomedical Ethics and Humanities. He had moved from NIH to be near his son Page, who was attending medical school at UVA. I watched John as he called some parents who were upset after a meeting with the ethics committee. These parents had a toddler whose heart often stopped, and had had someone available to them around the clock to resuscitate him.

During its first meeting to discuss the services provided to the boy, the ethics committee decided this around-the-clock support would end. The parents protested, and the committee, in response, met again and changed its decision. Now it was a few weeks after this meeting, and John was calling the parents to ask them to come back and meet with the committee again, to give feedback as to how the meeting could have gone better. The parents initially said they wanted no part of it. John then said, “*We need you.*” This sufficed. They came. I was at the meeting, and it allowed healing. A commitment to caring as expressed by this healing is the legacy John left us and *JCE*. He sought to establish and maintain a maximally caring relationship with all parties, regardless of how a consult may have come out.³

After Norman discussed his desire to start a journal of clinical ethics with John Fletcher, Norman asked me to be editor in chief. I asked Edmund (Ed) Pellegrino if he would join us, and Norman asked Mark Siegler.⁴ Other luminaries soon followed suit. (I can’t name some without naming them all, so I won’t try.) Ed, Mark, and Peter A. Singer from Canada wrote several foundational articles for the first issue of *JCE*, as Mark mentions in his article in this issue of *JCE*.⁵

The authors in this issue of the journal comment on some key changes over the past 30 years. I will highlight some areas where we still have a way to go. I will describe new understandings that have contributed to our being where we are now, including how we are more able to see our limitations, what we most need, and how we can provide better treatment. I will describe how our capacity to make decisions may crumble under stress, how our views may become fixed without our knowing it, how we need to offer palliative care that is more holistic and to offer it earlier, how we may work with our patients to gain their insights, and how to prioritize treatments that may seem to be idiosyncratic in order to do what is morally right.

RECOGNIZING OUR LIMITS IN DECISION MAKING

There has been a marked division between research ethics and clinical ethics. Research ethics has primarily intended to do good for others by achieving medical advances while protecting research participants reasonably.⁶ Clinical ethics has sought primarily to put patients first, unless there are mass casualties, as after a natu-

ral disaster. The United States recently revised its requirements for the ethical conduct of research with human participants for the first time since 1991.⁷ Those who revised the policies sought to enact the highest ethical standards, including, for instance, assigning greater priority to participants’ individual interests. Throughout this article I will refer to these new research policies and consider what we, as care providers, can do better. As implied in the title of this article, I will look to new advances in U.S. research policy to show us how to do so.

The new regulations came into effect 21 January 2019. The major annual research ethics conference in the U.S., the PRIM&R (Public Responsibility in Medicine and Research) Advancing Ethical Research (AER) 2018 conference, was held last fall.⁸ Sessions at AER 2018 addressed not only the state of the art, but where we should be going. I will refer to them in this article.

I will begin by addressing patients’ capacity for autonomy and its limits, highlighting the work of Jodi Halpern. She is a psychiatrist and a philosopher who spoke at AER 2018, in a special session devoted to research with participants who have incurable illness.⁹ Some of the views she presented at the conference she expressed previously in her book *From Detached Concern to Empathy*.¹⁰ I will often refer to it here, to expand on her thoughts offered at AER 2018.

I will highlight the views of Timothy Caulfield, another speaker at AER 2018.¹¹ He spoke on how we may acquire fixed views, even when they do not accord well with evidence or reason. This proclivity, and the resulting vulnerability, may be extraordinarily harmful to ourselves and others. Caulfield uses the example of people who refuse vaccination, which may result in the re-emergence of diseases like measles, and lead to serious illness in some people.¹²

How we as a society should confront this is challenging. Caulfield raises the question, for example, of whether we should “fight fire with fire,” that is, whether we should use the same means by which people acquire fixed views to try to change them. It seems important in some cases to try. If we do try to intervene, though, we should be as respectful as possible.

Do We Have Less Decision-Making Capacity than We Imagine?

The new U.S. requirements for research with human participants significantly change how

researchers must obtain participants' informed consent. In the past, researchers focused primarily on giving participants all of the information they might need to know, particularly the risks they could encounter. This information was usually extensive, so extensive that participants sometimes chose not to read it, or at least did not read it carefully. This was seen as a problem. One factor was that participants did not see the information as relevant as they made decisions to participate in research. They saw their trust in study investigators to be sufficient as they made decisions. I don't believe that the complexity of the information was a factor, as institutional review boards (IRBs) screen informed-consent documents scrupulously to insure they are in nonscientific language that is understandable to all.

The new policies on informed consent require researchers to better meet participants' needs. These needs vary greatly from study to study. Researchers now are tasked specifically with providing participants with the information that a hypothetical "reasonable person" would want to know, and they must do this up front. They must provide information on why potential participants *would* want to be in the study, and then information on why they *would not*.¹³

There was push back at AER 2018 regarding this: "Don't we want to encourage research?" The answer to this question was that the interests of individuals always prevail over research gains for the public. An example best illustrating this is that individuals cannot participate in research without their (or their surrogate's) consent.

An example of the new focus on the interests of individuals was offered in a session at AER 2018, on potential participants who have incurable illness. A grandfather who had cancer was expected to live for no more than a few months. A Phase 1 research trial offered him a chance at a cure, or at least the possibility of living longer. The likelihood of benefit from the trial was small, as Phase 1 trials primarily are intended to detect serious risks and side-effects. To participate in the trial, the grandfather would have to travel to a research facility far from home. He would be away from family for several months, during what might be the last days of his life. When first told of the opportunity to participate in the Phase 1 trial, he might jump at the chance. This might occur because his first thought was that he wanted to live longer.

Halpern, one of the presenters of the case, pointed out that if researchers challenged him more than they usually would in obtaining his informed consent, he might have changed his mind. He might have decided, after reflection, that he would rather be with his family. While it seems to be paternalistic for researchers to challenge a participant's decision in this way, Halpern emphasized that patients may feel they have no choice but to enroll, because they want to live longer. They may believe they have no choice. The optimal intervention with patients like this, then, might be to collaborate with them as they make a decision, rather than primarily to give them information.

In her book *From Detached Concern to Empathy*, Halpern discusses the work of John Deigh, who describes the response of "immediate acceptance" as being a sort of reflex. He suggests that immediate acceptance of a potentially life-saving intervention may be like the fear some people feel at the edge of a cliff: they may know they are safe, but they feel fear nonetheless. This fear may occur as though they are on "autopilot."¹⁴ As potential participants decide whether to enroll in a study that could be lifesaving, they may know that the chance of living longer is remote, but, regardless, experience their feelings as overwhelming, like people looking over a cliff. Responding to this feeling, they may decide that they must enroll in the research study.

Although Halpern includes a description of Deigh's work in her book, she says she does not see potential research participants as cognitively uninformed or misled. Due to their illness, potential participants have been viewed as being exceptionally vulnerable to the so-called therapeutic misconception, meaning that they believe they will do better in a protocol than may be justified. Halpern says it is accurate to regard them not as being misinformed, but as being exceptionally optimistic. She urges researchers to treat participants with increased paternalism, by encouraging them to engage in additional discussion, as in the case of the grandfather, above. This may make it more likely that participants will choose what they truly want. Researchers can do this in a wholly respectful and noncoercive way by pointing out the risks of making decisions too quickly and then asking potential participants whether they would like to discuss their decision further.

We can help our patients make better decisions by being paternalistic in this same way.

That is, we can try to soften the possible negative effect of questioning their decision by first saying why they might want to ask more questions. Patients may view additional questions as attempts to impose our own views. But, instead, it is an invitation to engage in additional reflection, and may actually result in patients not choosing to participate in a research study. This approach can be used any time patients may be offended when we urge them to reflect more deeply as they make a decision. We can explain ahead of time why we are doing this and ask whether it's okay. With potential participants in research, the goal is to reflect as deeply as possible with them about what they really want before they decide whether to enroll in a study. This may require additional skills. The main skill is to listen in a way that conveys our genuine interest. Halpern goes further. In her book, she relates how we should respond when our patients feel no hope, as I will now discuss.

The Importance of Hope

Halpern describes Mrs. G, a patient who felt hopeless. She had diabetes and had had both of her lower legs amputated. Her husband told her that he no longer found her sexually attractive due to the amputations, and left her. She felt she had nothing left to live for, and wanted to stop receiving life-preserving treatments and die. Her doctors thought they should respect her decision and urged Halpern to follow suit. "They warned me against my apparent emotional desire to rescue her," Halpern writes. They said, "You can't take her with you, so leave her alone." Halpern wasn't the patient's primary doctor; she complied, and Mrs. G died. Halpern now believes she didn't see what Mrs. G may have needed the most: hope. New hope. It might have been better to ask the patient "about her ambivalence."¹⁵ This might, Halpern writes, have opened up more discussion, and possibly revealed new hope and more options. Mrs. G may have been able to find a reason to live.

If, in discussing patients' futures with them to a greater extent than we do now, we are able to evoke hope, this may provide hope for an outcome that may not happen. Some patients may not want to hope for something that may not happen. But others may want to have a light at the end of the tunnel, even though they know that the hope may end with their death.

As I would state it, Halpern's point is that, for most patients to fare well, they must be able

to have at least some hope. Halpern says that we may have hope when patients, due to reasons such as fear or loss, can't. We should not merely accept what patients see with such limited vision, but should try to impart what we see. We should seek to try to engage patients in a way that may help them acquire new hope. Halpern writes, "The conception of autonomy as involving deliberative freedom is relevant to medicine only insofar as it points to a patient's capacity to imagine her own goals for the future."¹⁶ She says she now sees her approach to Mrs. G as wrong. She still feels regret.

This is how we are. We err. We see what we wish we had done, but too late. Halpern models what may be optimal when this occurs. We can learn. She elaborates on what we can do to enhance discussions with patients. "An empathic physician" will ask several questions. Among these is, "What do you hope for?"¹⁷ This may be effective, yet it may risk connoting a negative effect. Patients may reply, "Nothing." It may be therefore preferable to ask, "Can you imagine sometime in your future that you will have any source of hope?" If patients say they cannot, we can ask, "What is it like for you now to feel that you have no hope?" Such interaction and witnessing may of itself represent a source of hope. Patients may glean, consciously or unconsciously, that this kind of intimate interaction is itself a remaining value in their life.

Helping patients to feel a ray of hope is, in any case, critically important. An absence of hope leaves many patients feeling suicidal. This poses a difficult question: What should we do if patients call us, telling us they feel imminently suicidal? Currently, there are two views. One is to simply and invariably say, "Go to the emergency room," and repeat it, as needed, and say little more. The other is to embrace patients' ambivalence, especially as it may evoke new hope. Those who believe in the first approach may be right: it may result in patients relying more on themselves. Patients may go to the ER (emergency room) on their own when feeling any risk of suicide. Whether or not they take their life does not depend on what we say on the phone. This removes profound pressure on careproviders.

Yet when we direct patients to the ER, we lose an opportunity to respond in a way that might deter them from committing suicide, and it may be our last chance to help by evoking greater hope, when this is still possible. We

might be able to provide just enough of the hope that patients need. Halpern's regret that she didn't try this with the Mrs. G triggers a regret of my own. A patient I saw had had a leg amputated due to diabetes. She needed to have the other leg amputated to survive. The patient refused the second amputation. I saw her as sufficiently competent to make this decision, and she died. Like Halpern, I could have explored more why my patient felt she had nothing to live for. This example supports one of Halpern's key insights, that when we see hope that our patients don't, we can act on it in some way, rather than let it be. But Halpern also presents an equally powerful caveat to this in a second case.

The Importance of Understanding

Halpern was seeing a man who was bereft of hope. He had just become quadriplegic, paralyzed in all of his limbs. She initially felt sympathy for him, and expressed this, something I expect we all might do. The patient hardly responded. She then sought to try to imagine what he was feeling. She imagined "what it would be like to be a powerful older man, suddenly enfeebled, handled by one young doctor after the next." She felt rage as she imagined "being trapped in a body that no one knew how to heal." She re-entered the patient's room, this time determined to not "patronize" him by seeking "to exhort him to have hope." He seemed to sense her effort and responded differently. He spoke "with tears in his eyes." They were able to speak together deeply and genuinely.¹⁸

Halpern believes that all of us can try to imagine what patients may feel and in this way be better able to empathize. It may be particularly important when patients evoke different and strong emotions in us. Under these circumstances we must attempt to escape or at least work alongside our emotions and, to the degree possible, try to see how patients' lives and futures look through their eyes. If we can do this, we may be better able to respond in a different way. We should not assume, much less say, that we know how patients feel. It is possible that we may, but this is always a guess.

I recall a time I was able to do this successfully. I had spent hours trying to track down a researcher in another country, to discuss with him an off-label treatment he had written about that might help a patient. I succeeded in contacting the expert, and told my patient that we could proceed with the off-label treatment. But

the patient turned it down: "I no longer want this. I no longer care." At first I felt angry, but I tried to see his point of view. I said, "I can imagine how I might feel like you do now—that I'd no longer care, after going through what you have. You've been through so much." I did not say what I felt. I did not try to evoke hope. I just sought to try to understand. The patient later said, "I'm sorry. I was bummed. Let's try it."

Should We Fight Fire with Fire When Patients Have a Fixed View that May Cause Harm?

In his keynote address at AER 2018, Timothy Caulfield described how we are most likely to acquire fixed views, regardless of the evidence refuting them. They may be destructive to others, such as members of the public, and to ourselves. He used the example of people who do not vaccinate themselves or their children.

How do we acquire fixed views, regardless of whether they are sound or false? How, too, when these views are false but fixed within another person, might we best seek to offset these views—assuming that we should?

How Do Views Become Fixed?

Caulfield provided answers to the first question. He asserted that we most often acquire fixed views from three sources: fear, visual images, and stories. I will look more closely at each.

Fear can immediately and deeply affect us. Just one frightening event can effect within us paralyzing fear that can linger and limit us profoundly throughout our life.¹⁹ This occurs not uncommonly when people have acquired a post-traumatic stress disorder (PTSD). This is referred to as "onetime learning." A fixed response to fear may endure in us because, in our evolutionary past, it was adaptive. It may have helped our ancestors survive. For instance, if they escaped the bite of a yellow poisonous snake, their memory of that particular yellow might become fixed, and enable them to spot the snake earlier. This evolutionary reductionism may be close to a cliché, but may still be effective, as it conveys how and why just one frightening experience may affect us so powerfully and indelibly.

A case that illustrates a fixed response to a visual image is that of a surgeon who was treating a young boy whose leg was injured during a natural disaster. It had become badly infected. The leg needed to be amputated for the boy to survive, but his mother refused to consent to the

surgery. To shake her fixed view, the surgeon removed the bandages and showed her how bad the infection was. Seeing it, she consented to surgery. (The smell may have contributed as well.) The boy had the surgery and survived.

The impact of story telling, the third major source of fixed thinking, may be less intuitively obvious. There is evidence that stories can affect us in ways that are singularly powerful.²⁰ All of us can be affected profoundly by the stories we hear. For example, patients often hear medical “horror stories” from family members and friends. Many find such stories on the internet. Hearing just one such story may determine what patients decide to do. They may decide to go against medical advice. So it may be with vaccines. Patients and parents may refuse vaccines even though doing so endangers the public and themselves. They may feel a sense of loyalty to their friends and decide similarly. Further, the specific harms from vaccines and how the harms should be weighed is complex.

Currently, parents who oppose vaccination may experience difficulty finding a pediatrician. One couple couldn’t locate a doctor to treat their unvaccinated child when they moved to another state to find employment. Some pediatricians will treat unvaccinated children, but only if they enter the clinic through a back door and wait in a room separate from other children.

Trying to Change Fixed Views

How might we best seek to offset such fixed views (if we should)? We may believe that we can do this by directly confronting patients with fact-based reasoning, but this is likely to fail, and it may make matters worse. That rational argumentation won’t work and instead backfires and makes matters worse goes against common logic. But this is well known, especially to careproviders who treat patients with psychiatric illness. For example, when they treat patients with paranoid delusions, they know that if they confront patients, the delusions may become more entrenched. In addition, patients may incorporate their careproviders, newly, into their delusions. Patients may then see their careproviders as among those who are conspiring against them. They may believe that this is why their careproviders confronted them in the first place.

Mental health careproviders, therefore, do not confront patients’ fixed beliefs directly. Rather, they seek to find some aspect of these

beliefs that can be validated. Glen Gabbard is a leading expert on psychotherapy, who states it this way: “When confronted about the false beliefs, the person reacts with anger, as though the confronter is attacking the fragile rampart on which the person’s self-esteem is resting.” He writes that any action resembling direct confrontation elicits “swift protest and rejection.” A better strategy is not to “mindlessly agree with the patient’s contention” but to discern and validate “what needles of truth may lie hidden in the haystack of the patient’s misperceptions.”²¹

How can we best help reduce patients’ fixed views when we do not want to directly confront them? Specifically: How should public health authorities move people who are opposed to vaccination? At AER 2018, Caulfield said that one response is to “fight fire with fire.” An example of this might be that of the surgeon who showed his patient’s mother the boy’s infected leg. The surgeon used fear and the visual effect of the infected leg to try to move the mother to change her mind about amputation, and he succeeded. In the same way, policy makers could use fear, visual images, and stories to encourage vaccination. They could, for example, broadcast television commercials that depict parents and children in great distress because the children experienced extremely bad outcomes as a result of not being vaccinated. This would evoke fear. It is also visual and tells a story.²² I have been told that such advertisements already exist.

There are many other ways we may try to change fixed views. One is to tell patients what other patients do. Some patients may resent this and respond, “Why should I care? I’m not them,” or even, “Why are you telling me this? Are you trying to change what I think?” To reduce the risk of such resentment, we can say why patients might find this additional information helpful, and why it may spare them potential harm. That is, knowing what others do may help them decide to be vaccinated. A possible downside is that if patients are informed, decide against vaccination, and then have a bad outcome, they may feel greater regret than if they had not been informed. After we share the pros and cons with patients, we can ask them whether they want additional information.

This question of vaccination for children is paradigmatic of other fears. I think of parents who do not want genetic testing for their child after the birth. A general question this raises is: What should a society do when some people see

their needs as outweighing the needs of others? There may be a benefit in allowing dissenting individuals to follow their discrepant beliefs.

A clear starting point would be to take the time to share the facts, as we see them, with patients. In time, a new subgroup of professions could be especially trained to carry out such discussions, as now is the case with genetic counselors and counselors who are trained to inform patients and families about the benefits of donating organs after the patient's death.

In some cases, it would seem appropriate to try to change patients' and parents' fixed views. There may be an additional concern: We have personal relationships with patients that public health authorities don't have. We must therefore consider how pushing our own views on patients in the privacy of our offices may adversely affect our relationships with them. We should, in general, respect our patients' autonomy and not use our implicit power as care-providers to try to persuade them.

In a recent article, Caulfield addressed the effect of celebrities who speak out on vaccination: "I am fully aware of the paradox that writing about the need to forcefully debunk the pseudoscience [brings about]. . . . It is, no doubt, a tough balancing act. But, in the long run, it seems essential to set the record straight."²³ If he is right, it may be that we, as a society, should sometimes exert extra effort to present the facts to people. We may do this now, but there may be better ways to do this. For example, doing this by one-on-one personal discussion, or the creation of a new cadre of professionals to do this, or by means that are successful in other contexts, such as promoting such discussions in smaller community groups.

ENHANCING HOLISTIC AND PALLIATIVE CARE

At the AER 2018 presentation on participants with incurable illness, speakers strongly recommended that two kinds of existing interventions be expanded: holistic care and palliative care. I will discuss how we can adopt their recommendations in clinical settings.

Holistic Care

Holistic care takes into account not just the body, but the mind, body, and soul—all aspects of patients. The notion that all research partici-

pants should receive holistic care when they need and want it goes well beyond what we now provide in research settings and in our clinics. Empirically, we know that holistic approaches may have greater medical benefits than previously thought.²⁴ If we have the resources to provide holistic care to patients, we can begin in two steps. First we can ask patients how, outside of their medical needs, they are hurting. Second, we can try with them to find ways to address their needs. Even just inquiring about this may seem paternalistic. To soften this potentially offensive effect, we can do what I suggested above: (1) Explain to patients why we want to ask questions about how they are hurting that may go further than our usual questions. (2) Explain why we are doing this: that reducing stress can produce health benefits. (3) Ask patients whether they want us to ask these additional questions. Here are two examples of how additional questions can help patients.

Finances and Employment

Some mental health careproviders believe it is more important for some patients to be employed than it is to have psychotherapy, because being having a job and maintaining it may enable immeasurable gains in self-esteem.²⁵ Employed or not, patients may suffer greatly from financial insecurity.²⁶

One patient of mine was unable to sleep due to his financial fears. He acquired a thought disorder, a rare result, and had to be hospitalized. Once home, his ongoing bills kept him from getting better. This is an instance of the onetime learning and fear discussed above. The patient's paralyzing fear re-emerged whenever he saw a new bill. His treatment was to pay his bills gradually, spacing them out, and to approach them incrementally. To do this, he had to monitor his anxiety, stop when it got too great, and relax before going on. This was roughly equivalent to desensitizing a patient to ever-more threatening visual images.

Asking patients questions about their employment and feelings of stress about finances may be ways that we can holistically work to enhance their health. These inquiries may help us to discern and then help to effect optimal treatment. But reducing the sources of patients' stress with the resources available now may be far from enough. Being able to do this may require significant changes within our medical systems.

Discerning Patients' Emotional Needs

Treating patients holistically includes finding out what they need emotionally, for example, what may feel overwhelming to them. A less common holistic intervention is the presence of a pet.²⁷ Asking patients about a pet is beneficial in itself and may even be lifesaving. Some patients will not agree to medical treatment that requires an overnight stay such as a sleep study, because they will not leave their pet alone overnight. If they have sleep apnea, a diagnosis based on an overnight sleep study may be lifesaving. This should not be surprising. Some people choose to stay in their home with their pet during a natural disaster such as a hurricane, even though there may be life-threatening flooding. They stay in their home to try to protect their pet from dying, or to some what is worse, their pet dying alone. They therefore refuse to be rescued.

We can ask patients who have a pet whether they need assistance. Some hospitals have services staffed by volunteers who are skilled and trained in caring for pets. Thus, this, too, is a holistic initiative we can take.

Palliative Care

In the past, large numbers of patients may have been harmed because palliative care was offered only after efforts to cure failed. As a result, many patients conclude that when a palliative careprovider comes to their door, it's a death knell. Speakers at the AER 2018 session on incurable illness emphasized that palliative care should be offered and possibly given from the first moment participants enroll in a research protocol. This might be understood to include all care that may help to relieve participants' suffering.²⁸ There are many ways to do this in research settings and in our clinics.

The best known example of palliative care is pain relief. We all know how important relieving pain is, but we can strive to do better. Attempts to treat pain may not be successful in emergency room care. Careproviders in the ER may fear that patients are addicted and are merely seeking drugs. Careproviders also may fear, and fear more than they have in the past, that if they give too much pain medication, it may result in a patient's death.²⁹ In addition, whether we do it intentionally or not, we must not treat patients who are in pain differently due to their race or ethnicity.³⁰

Some palliative interventions are less widely recognized, but, when appropriate, can be provided as palliative care. The best example is patients who can't sleep. Those who suffer from insomnia may hurt more during the day than at night, because during the day they dread an upcoming night without sleep. There are sound reasons to remain cautious; for example, sleep meds may increase the risk that older patients will fall and break a hip. Still, we may underestimate the degree to which patients suffer from not being able to sleep. We can't not treat it because we fear its cause does not justify medication, or because we overly fear we may support patients' addiction or endanger their life.

Undervaluing the degree of patients' suffering is only one of the reasons that careproviders do not offer adequate palliative care, much less give palliative care earlier. Thus, I will discuss two additional, positive initiatives that we can take to enhance patients' well-being.

Inquiring Regarding Patients' Sexual Needs

The case of the patient Halpern described, whose husband said he was not sexually attracted to her after she had both legs amputated, is arresting. As noted above, the patient chose to die. This is not uncommon. It is a frequent source of grief for breast cancer patients. The number of breast cancer survivors in the U.S. currently is 3.5 million.³¹ Survivors can experience decreased sex drive and arousal, body image concerns, and depression. As with Halpern's patient, these effects may wreak havoc with their relationships. Couple's counseling may be immensely beneficial.³² Unfortunately, careproviders who treat survivors often fail to suggest counseling early on, much less try to prepare survivors for the negative effects that treatment may have on sexual response.³³ We can imagine that part of the difficulty in discussing the effects of treatment on sexual response is that this is extraordinarily painful for patients and careproviders to consider, much less to openly discuss. Yet we should.

Ranjana Srivastava, an oncologist, points out in her article in this issue of *JCE*, "Reflection of a Physician-Writer: On Why I Write," that careproviders are affected by their patients and their situations, and that this may extract "a toll" on careproviders.³⁴ The challenges posed to careproviders are minuscule, relative to those faced by patients. Keeping this profound difference in mind may help us muster the courage we need

to discuss these painful issues with patients, to give them the optimal care that they need. Feeling this pain may help us benefit patients. It may enable us to appreciate more what patients feel, as Halpern notes, so that we can better know and respond. Srivastava emphasizes the importance of being there, even when we can't help. "Despite all the trapping of modern medicine," she says, "a young woman was dying, and all I could do was bear witness to her suffering."

Srivastava stresses the importance of acting: "An early morning consult found me in front of a patient who looked like he was dying, yet he was scheduled for the surgical theatre. Instead of sticking my neck out and urging palliation, I assumed that the surgeon knew better. But when the patient died, I was seized by regret, which was multiplied when the surgeon lamented that he would have heeded my warning." She goes further, even advocating political action: "A patient's inability to purchase insulin moves us to advocate for fairer prescription coverage. A patient's frequent no-shows turns our mind to absent public transport."

People to Care and to Trust

The most effective palliative intervention of all is to provide patients access to people they love and trust. This is best expressed by Lawrence C. Gostin, who writes about the need for what he call a "bottom-up culture of palliation."³⁵ "What kind of a culture," he asks, "nourishes genuine caring?" He answers, "It requires a cadre of compassionate staff—food-servers, counselors, social workers, and clergy tending to every emotional, social, and spiritual need."

Gostin's list combines the holistic care described above with palliative care that is provided by loved ones and others. Provision of this kind of care requires structural change as well as cultural change. For example, for the grandfather who would have had to travel to participate in a Phase 1 trial, it may have been possible to train careproviders, such as nurses, to assist him so that he could have participated in a research study from his home. Clearly this would require greater funding and would require a change in the medical risks that we would deem acceptable. Yet for this grandfather, the net benefit might have been far better.

There are other research interventions that would be ethically preferable that have never been widely brought about. Pediatric protocols could include, from the start, funds to pay for

parents' travel and childcare, when otherwise parents would not have sufficient funds to allow their child to participate in research. The grandfather might similarly need funded assistance to participate in research from home, if the increased risk of home treatment had been acceptable.

We might take the unusual initiative of helping patients to reconnect with a loved one. For example, we may glean that patients miss a loved one as they reminisce. Or we might ask patients directly if there is anyone they wish they could see. We might then try to bring about the wanted contact, or ask another to attempt it. I have had success contacting loved ones for patients. Sometimes patients haven't seen loved ones for decades because one or both chose to be estranged. When I ask patients whether they want me to try to arrange a meeting, they are sometimes initially reluctant, but then they say yes.

This intervention might seem to be too paternalistic, but it may not be. Rather, it may enable patients to see newly and more clearly, especially later in life, what they really want most of all. Without such intervention patients may not be able to see what it is they want most.

NEW VISTAS

AER 2018 produced two additional new, over-arching perspectives. The first is that, in research and in finding what patients most need, we should look to the public and to patients and hone our expertise by working with them. This is a departure from seeing ourselves as experts working alone, as has sometimes been the case.

A second new perspective is that we must value each individual's needs to a greater extent than we have in the past. This is exemplified in a new research provision that assigns unprecedented status to participants' culture. It affirms the principle that an individual participant's interests should never be sacrificed for the good of the many, and extends this principle, as seen in new considerations of the requirements for obtaining informed consent. In this last section I will consider how these two directions may affect us when we care for patients.

Working with Patients to a Greater Extent

Speakers at AER 2018 offered two ways that we can work more with patients, rather than work, for the most part, on our own. The first

way is to consult patients on how to resolve emerging unanswered questions involving “big data,” the information researchers may obtain about us from ordinary sources such as credit cards, social media, the internet, email, phone calls, and even interaction with Alexa, Amazon’s virtual assistant. Another way to work more with patients is to ask them why they don’t accept some treatments that are now available. I will provide examples and indicate how we may be able to incorporate them into our own practices.

Big Data

Speakers at AER 2018 identified emerging risks posed by big data.³⁶ Use of these huge data sets may produce benefits that are unprecedented and not obtainable by other means.³⁷ Using big data in the medical context, for example, we may be better able to predict emerging epidemics such as Ebola and pandemics such as the H1N1 virus. The use of big data may save extremely large numbers of lives. But researchers who “mine” big data may also do great harm.³⁸ They may violate the privacy of individuals in ways that are unprecedented. Researchers can now access reams of data that are publicly available on the internet. There are no research regulations that limit or prevent it. Present research rules exempt researchers using these public data sets from review due to the assumption that the “public-ness” of the data sets renders them to be inherently low risk.³⁹ The means for doing this kind of research are also readily available. Thus, researchers can mine data sets while working out of their basement.⁴⁰

A published study illustrates the risk. Investigators carried out the study for the paradoxical purpose of showing that it is the kind of study that shouldn’t be done.⁴¹ The study was presented at AER 2018 to raise the question of what we should do, in light of these risks.⁴² Researchers took pictures of the faces of gay and heterosexual persons from internet dating sites and “showed” the pictures to an artificial intelligence (AI) program and to people, to see whether the AI program or people could better discern which people were gay, based solely on the the pictures. The AI program won handily. People, by and large, failed at this task.⁴³ Their failure may be a good thing: the study indicates that people generally can’t judge persons’ sexual orientation from how they look. This finding may be helpful when people make such harmful assumptions.

By and large, though, as the researchers pointed out, using these kinds of data may greatly violate individuals’ privacy.⁴⁴ This kind of research may be conducted for worthy purposes, for example, to better understand whether a woman’s taking sex hormones during pregnancy will affect the sexual orientation of her child. But the individuals who posted their photos online, whose pictures were used in the AI prediction study, did so intending merely to seek someone to date. Internet sites could post warnings, and their users could read the warnings, foresee the risks, and, if they chose to, avoid them. But we already know how and why this may not be effective: even those interested in participating in research may not “read the fine print” when asked to provide informed consent.

The speakers presented this study at AER 2018 acknowledged that they had no answers about what should be done to reduce the risks. They did have one core notion about the process that we might use: we might conduct focus groups to explore and try to predetermine the needs and wants of those people likely to be most vulnerable to this kind of research. The presenters conducted focus groups at the conference to illustrate how this might be done.

Focus groups may be part of the best plan at present. With information from the focus groups, new research regulations might be devised that could help prevent the conduct and publication of studies that violate privacy. At present, after a period of time, brand name drugs become generic. Perhaps, in the same way, after some time, researchers would have to make their data sets publicly available. Then, if it is found that they violated regulations that protect privacy rights, sanctions could be applied retrospectively.

At present, researchers may include research participants in constructing study designs by using focus groups. As I describe in the next section, researchers may also go directly to patients to try to find out why they don’t accept treatments that researchers believe would help them.

Why Don’t Gay Adolescents Use Truvada?

Focus groups can help us learn what vulnerable people may want or reject. The practice of going to those who are most vulnerable, rather than relying on our own knowledge and experience, may help us improve how we treat our patients. Presenters at a AER 2018 session described how research was conducted to determine why gay adolescents chose not to use a

medication known as Truvada (emtricitabine and tenofovir disoproxil fumarate), a pill approved by the U.S. Food and Drug Administration that reduces the risk of acquiring HIV-1 through sexual contact. Even though this prophylactic medicine is available, many who could benefit don't take it. A group of particular concern was adolescents who are gay. No one knew why so many chose not to use Truvada.

Using focus groups, researchers asked gay adolescents why they didn't take Truvada, and they learned that many adolescents, like gay adults, feared stigma, but the stigma that adolescents feared was not what we might imagine.⁴⁵ Like adults, the adolescents said they feared that if their partners knew that they were taking Truvada, their partners might presume that they were taking it because they practiced unsafe sex. Truvada might still protect the adolescents from acquiring HIV-1, but their sexual partners might not want to have sex with them due to this inference. There was another reason: some of the adolescents lived at home and had not disclosed they were gay to their parents. They feared if they had a response to Truvada that their parents could detect, their parents might want to find out its cause, which could result in the parents finding out they were gay.⁴⁶

These two examples—researchers working with focus groups to try to reduce the risks posed by big data and to understand why gay adolescents did not take Truvada—depicts approaches that we should consider using. Patients and care-providers working together as a team seems preferable to more-paternalistic models in which we try to resolve problems by ourselves. Federal institutional review boards (IRBs) must currently require that a nonscientific member of an IRB be present for the IRB to vote. Ethics committees, likewise, often have a member who represents patients. One way that we can do better right now is to strive to have more than one non-expert member on our IRB and ethics committee. This might make it easier for such IRB and ethics committee members to speak.

Attending to Idiosyncratic Needs

The recently revised U.S. regulations on research add a new and unprecedented component. Researchers can now make some exceptions to what otherwise might be required of them to obtain participants' informed consent when the exception is warranted by the partici-

pants' cultural beliefs.⁴⁷ The regulations value the individuality of participants to a greater extent, and we may do better, likewise, by doing this with patients. An example posed at AER 2018 was that of a Buddhist patient with a terminal illness who wanted to enter a study that might benefit him, but on the condition that he not be informed of any negative effects he would risk in the study. The presenters at the conference asked whether he should be permitted to enroll in the study, but they chose not to answer this question.

An analogous question occurs in clinical practice when a patient is accompanied by family members, and they inform the patient's clinicians that decisions regarding the patient's care may be discussed only with family, not with the patient. The family members explain that this is how they do it in their culture. Predictably, some clinicians protest. They cannot make decisions involving a patient, they say, unless the patient is involved. Should we respect the cultural norms of patients and family members? In the U.S. there is a legal answer. Patients can refuse to be informed, just as they can insist that we fully inform them. We can refuse to not inform patients based on the principle of therapeutic privilege: we can argue that not informing patients may be exceedingly harmful to the them. We may have to prove this in court.

The question of whether a Buddhist research participant should be able to refuse the disclosure of negative information poses different considerations in research than it would in a clinical setting. Research requirements are, in many ways, more strict, because research participants do not join a study to benefit themselves. Clinical equipoise, a criterion that is necessary for research to proceed, requires that any anticipated gain from being in one arm or another of a research study cannot reasonably be predicted. The new regulations increase the weight that should be accorded to participants' individual needs. This suggests that we should, likewise, strive to a greater extent to meet patients' individual needs in the clinic. I will give two examples.

Treating Patients as Much as They Need

Some have questioned whether psychotherapists should be able to treat patients for an unlimited number of sessions, and this proposition has recently been raised in Canada.⁴⁸ In institutional settings in the U.S., mental health-

care providers are sometimes urged to see *more* patients for a *limited number* of sessions based on the premise that, if they do this, they will meet the needs of more patients. Some argue that careproviders should prioritize meeting the broader needs of the many rather than prioritize the deep needs of the few. No doubt this will continue to be vigorously debated. But some argue that treating patients effectively may mean never abandoning them. In this regard, I think of a colleague who has seen one patient more than 500 times. He reports that she has just now overcome her ever-present, all-else-devouring anger sufficiently to be able to “begin to work.” While others may disagree with providing care to this degree, the new research criterion may be seen as supporting meeting individuals’ needs to a greater extent, and as supporting this careprovider’s choice to treat his patient this way.

Research studies may not seek the good of the many if doing so compromises the dignity of a research participant. This new research policy underlines the importance of providing what each participant—and by extension what each patient—needs.

Going Where We Haven’t Been Before

Researchers who attend particularly to the needs of gay persons—for example, the researchers who investigated the use of Truvada—illustrate how we can take the lead in society to seek the best for all. In concluding, I will look to the clinic and introduce two new problems that may arise for patients who are transgender.⁴⁹ The first example involves charting. Patients may want to discuss their transgender concerns with us, but not have this noted in their medical record.⁵⁰ Accurate charting is a professional duty, but, following the spirit of the new research requirement to more strongly honor individuals’ needs, we may want to break new ground and not chart this information.

A second example involves genetics: parents and clinicians throughout the world agonize over what to do when genetic results show that the presumed parent of a child is not the child’s parent. This result may shatter a family. Transgender parents may pose new, unprecedented problems. A parent may have changed gender and not want a child to know this.⁵¹ As with new questions involving charting, we should consider what to do. We should ask these parents what they want before we do testing, or if it is too late, seek ways to do whatever we can to

meet parents’ requests, so that findings will not adversely affect their family and child. We should do this however we can, whether our response breaks a tradition or not.

CONCLUSION

The best way to sum up this discussion is to note the key clinical points that careproviders, whether treating patients or acting as ethics consultants, can employ right now. They are remarkably straightforward. As Halpern advises, we can try to be aware of what patients may want most, and speak up, acknowledging their needs and wants. When patients have fixed views that work against their own interests, we can try to engage them, be open, and follow their lead as best we can. We can provide patients with counter examples to their fixed views, or ask them if they would like us to tell them what other patients do. We can ask patients whether they are interested in holistic care. If palliative care would help, we can give it to patients early on.

We can ask patients how they feel about and/or would resolve a clinical problem that affects them, and we can try to treat them as much as and as long as they need, even though it may affect the care that others receive. For example, a careprovider spent two hours with a parent explaining the cellular mechanisms behind vaccination, using a white board. He was able to change the parent’s mind about vaccination.

Is this careprovider a hero who models how far a clinician should go? Or is he just practicing good medicine? Or is he acting in a way that is not clinically justifiable, because when he takes so much time with one parent, other patients may go untreated? Notwithstanding our own views, we should be willing to take unprecedented routes, as Halpern and Srivastava urge, when others won’t.

We should see ourselves, no less than our patients, as having needs that may overwhelm us. This is what Fletcher modeled when he said, “We need you.”

BLINDING OF THE CASES

Details of cases have been changed to protect the privacy patients and family members.

NOTES

I would like to thank Norman Quist for his most insightful comments on this article.

1. F. Wright, “Personal Reflections on Hugh

Mullan: Existential Group Therapist,” *International Journal of Group Psychotherapy* 62, no.1 (January 2012): 23-42.

2. F. Mullan, *White Coat, Clenched Fists* (Ann Arbor, Mich.: University of Michigan Press, 2006).

3. John was tall, and would support patients and families by putting his arm around their shoulders. Others have told me that when John would marry couples in his role as a clergyperson, he would require them to forgive others for whom they felt ill will before he would marry them.

4. I knew Ed because I asked him to speak to students at the Uniformed Services University of Health Sciences, where I teach, on medical student ethics. He taught that all patients should be able to request they be treated only by an attending, even at medical teaching centers, although such a request had never been made to him. He surmised this was because he always reassured patients he would be looking over the shoulder of the medical student or resident.

Often over the years, when I have not been sure what to do, I have asked myself what Ed would do. Ed was a former boxer. He was also a knight of the Equestrian Order of the Holy Sepulchre of Jerusalem.

5. M. Siegler, “Clinical Medical Ethics: Its History and Contributions to American Medicine,” in this issue of *The Journal of Clinical Ethics* 30, no. 1 (Spring 2019).

6. I use “participants” rather than “subjects” because I don’t like connotations connected with “subjects.” The importance of such connotations was recognized in recent research changes. The phrase “mentally disabled persons” was changed to “individuals with impaired decision making capacity.” 32 CFR 219.111(a)(8), “Federal Policy for the Protection of Human Subjects,” *Federal Register* 82, no. 12 (19 January 2017), “Rules and Regulations,” 7259-69.

7. *Ibid.* See, generally, J. Menikoff, J. Kaneshiro, and I. Pritchard, “The Common Rule, Updated,” *New England Journal of Medicine* 376, no. 3 (19 January 2017): 613-5.

8. The PRIM&R 2018 AER conference was held 14-17 November 2018 in San Diego, Calif.

9. A.M. Capron et al., “Panel II: At the Crossroads of Hope and Hype; Recruiting the Desperately Ill for Clinical Trials,” plenary presentation at the PRIM&R 2018 AER conference, 14 November 2018, San Diego, Calif.

10. J. Halpern, *From Detached Concern to Empathy* (New York: Oxford University Press), 2001.

11. T. Caulfield, “Research Ethics Discussion Luncheon: ‘Fighting Health Myths with Stories, Art, and Fun,’ ” presentation at the PRIM&R 2018 AER conference, 15 November 2018, San Diego, Calif.

12. J.K Olive et al., “The State of the Antivaccine Movement in the United States: A Focused Examination of Nonmedical Exemptions in States and Counties,” *PLoS/Medicine* 15, no. 6 (12 June 2018): e1002578.

13. Menikoff, Kaneshiro, and Pritchard, “The Common Rule, Updated,” see note 7 above, p. 614.

14. Halpern, *From Detached Concern*, see note 10 above, p. 45, citing J. Deigh, “Cognitivism in the Theory of Emotions,” *Ethics* 104 (1993): 824-54.

15. Halpern, *From Detached Concern*, see note 10 above.

16. *Ibid.*

17. *Ibid.*

18. In addition, careproviders may take no extra time to *feel* and let their patients see what they feel, as they speak. For example, when moved to, careproviders can grimace to show patients how they feel. Halpern notes, “A doctor’s apparent worry is much more likely to induce trust than cheerfulness or friendliness.” Halpern, *From Detached Concern*, see note 10 above, citing D.L. Roter et al., “Effectiveness of Interventions to Improve Patient Compliance: A Meta-analysis,” *Medical Care* 36, no. 8 (1998): 1138-61.

19. Caulfield, “Research Ethics Discussion Luncheon,” see note 11 above.

20. M.F. Dahlstrom and D.A. Scheufele, “(Escaping) the Paradox of Scientific Storytelling,” *PLoS Biology* 16, no. 10 (October 2018).

21. G.O. Gabbard, *Gabbard’s Treatments of Psychiatric Disorders*, 5th ed. (Washington, D.C.: American Psychiatric Publishing, 1014), 1001.

22. L.H. Sun and M. O’Hagan, “A Uniquely Dangerous Outbreak,” *Washington Post*, 7 February 2019.

23. T. Caulfield, “Elle Macpherson, ‘Anti-Vaxx’ Nonsense, and the Opportunity to Engage,” *BMJ* 362 (31 July 2018).

24. F.F. Aquilina and D.V. Fondacaro, “Outlining the Psychopathology behind a Case of Conversion Syndrome: Is a Holistic Approach Beneficial?” *PsyCh Journal* 5, no. 1 (March 2016): 31-5, 33.

25. H. Hoffmann et al., “Long-term Effectiveness of Supported Employment: 5-year Follow-up of a Randomized Controlled Trial,” *American Journal of Psychiatry* 117, no. 11 (1 November 2014): 1183-90. In one study, people who were “job insecure” had a likelihood of serious mental illness five times those who were not. J. Garrick, “Tending to Patients’ ‘Financial Mental Health,’ ” *Clinical Psychiatry News* 44, no.12 (December 2016): 8-9, p. 8.

26. Suicide and suicide attempts have been linked with financial and relational and legal problems. Garrick, “Tending to Patients’,” *ibid.*

27. K. Hodgson, M. Darling, D. Freeman, and A. Monavvari, “Asking About Pets Enhances Patient Communication and Care; A Pilot Study,” *Inquiry* 54 (1 January 2017).

28. See “WHO Definition of Palliative Care,” <http://www.who.int/cancer/palliative/definition/en>; World Health Assembly, “Strengthening of palliative care as a Component of comprehensive care throughout the life course, Resolution WHA67.19,” <http://apps.who.int/medicinedocs/en/d/Js21454zh/>; H. Starks et al., “Pilot Study of an Interprofessional Palliative Care Curriculum: Course Content and Participant-Reportee Gains,” *American Journal of Hospice & Palliative Care* 35, no. 3 (March 2018): 390-7.

29. E.M. DeFilippis, “Mom Needed Pain Relief.

The ER Ignored Her,” *Washington Post*, 2 October 2018.

30. Racial and ethnic disparities in prescriptions of opioids given in emergency rooms have been shown to exist nationally. *Ibid.*

31. B. Sadick, “For Breast Cancer Survivors, Another Grief: Sexual Intimacy,” *Washington Post*, 5 February 2019.

32. A.J. Carroll, S.R. Baron, and R.A. Carroll, “Couple-based Treatment for Sexual Problems Following Breast Cancer: A Review and Synthesis of the Literature,” *Support Care Cancer* 24, no. 8 (August 2016): 3651-9; R.E.G. Dikmans et al., “Sexuality, a Topic that Surgeons Should Discuss with Women Before Risk-Reducing Mastectomy and Breast Reconstruction,” *Breast* 43 (2019): 120-2.

33. Dikmans et al., “Sexuality,” *ibid.*, 220.

34. R. Srivastava, “Reflection of a Physician-Writer: On Why I Write,” in this issue of *The Journal of Clinical Ethics*, 30, no. 1 (Spring 2019).

35. L.O. Gostin, “Living, Aging, and Dying in Healthy and Just Societies: Life Lessons From My Father,” *Milbank Quarterly* (17 January 2019).

35. *Ibid.*

36. B. Sussman, “Alexa’s ‘Big Data’ Reveals How We Behaved during the Holiday Season,” State of the Phish, 4 January 2019, <https://www.secureworldexpo.com/industry-news/amazon-alexa-stats-2018>.

37. Such traces reveal huge amounts about people. They are invaluable in tracking terrorists and criminals, even child sexual abuse rings and serial killers, earlier than would otherwise be the case. D. Hand, “Aspects of Data Ethics in a Changing World: Where are We Now?” *BigData* 6, no. 3 (17 September 2018); H. Shah, “Use Our Personal Data for the Common Good,” *Nature* 556, no. 7699 (5 April 2018): 7.

38. “Cambridge Analytica Controversy Must Spur Researchers to Update Data Ethics,” editorial, *Nature* 555, no. 7698 (29 March 2018): 559-60.

39. J. Metcalf and K. Crawford, “Where are Human Subjects in Big Data Research? The Emerging Ethics Divide,” *Big Data & Society* 1, no. 3 (1 June 2016).

40. Hand, “Aspects of Data Ethics,” see note 37 above. See, generally, E. Vayena, M. Salathé, L. Madoff, and J.S. Brownstein, “Ethical Challenges of Big Data in Public Health,” *PLoS Computational Biology* 11, no. 2 (9 February 2015); S. White, “6 Ethical Questions about Big Data,” *Financial Management* (15 June 2016).

41. Y. Wang and M. Kosinski, “Deep Neural Networks Are More Accurate than Humans at Detecting Sexual Orientation from Facial Images,” *Journal of Personality and Social Psychology* 114, No. 2 (2018): 246-57; W. Youyou, M. Kosinski, and D. Stillwell, “Computer-Based Personality Judgments Are More Accurate than Those Made by Humans,” *Proceedings of the National Academy of Sciences* 112, no. 4 (7 January 2015): 1036-40.

42. J. Metcalf, L. Odwazny, and S.J. Rosenfeld, “IRB Review of Big Data Research,” presentation at

the PRIM&R 2018 AER conference, 15 November 2018, San Diego, Calif.

43. Wang and Kosinski, “Deep Neural Networks,” see note 49 above, p. 247.

44. “We used deep neural networks to extract features from 35,326 facial images. These features were entered into a logistic regression aimed at classifying sexual orientation. Given a single facial image, a classifier could correctly distinguish between gay and heterosexual men in 81% of cases, and in 71% of cases for women. Human judges achieved much lower accuracy: 61% for men and 54% for women. . . . given that companies and governments are increasingly using computer vision algorithms to detect people’s intimate traits, our findings expose a threat to the privacy and safety of gay men and women.” *Ibid.*, 248.

45. S.K. Calabrese and K. Underhill, “How Stigma Surrounding the Use of HIV Preexposure Prophylaxis Undermines Prevention and Pleasure: A Call to Destigmatize ‘Truvada Whores,’” *American Journal of Public Health* 105, no. 10 (October 2015): 1960-4.

46. S. Hosek et al., “Preventing HIV among Adolescents with Oral PrEP: Observations and Challenges in the United States and South Africa,” *Journal of the International AIDS Society* 19, no. 7, supp. 6 (18 October 2016): 21107; C.B. Fisher et al., “Facilitators and Barriers to Participation in PrEP HIV Prevention Trials Involving Transgender Male and Female Adolescents and Emerging Adults,” *AIDS Education and Prevention* 29, no. 3 (29 June 2017): 205-17.

47. 32 *CFR* 219.116—General requirements for informed consent, <https://www.govinfo.gov/app/details/CFR-2011-title32-vol2/CFR-2011-title32-vol2-sec219-116>.

48. The government of Ontario is in the process of arbitration for a new contract with all physicians. As part of the negotiations, it proposes that psychotherapy be limited to about 24 hours per patient per year for a given psychiatrist, alleging a lack of evidence for long-term psychotherapy. “Controlled Act of Psychotherapy,” 24 November 2017, <https://www.crpo.ca/controlled-act-of-psychotherapy-2/>.

49. A. Condat et al., “Biotechnologies that Empower Transgender Persons to Self-Actualize as Individuals, Partners, Spouses, and Parents are Defining New Ways to Conceive a Child: Psychological Considerations and Ethical Issues,” *Philosophy, Ethics, and Humanities in Medicine* 13, no. 1 (17 January 2018).

50. H.M. Thompson, “Patient Perspectives on Gender Identity Data Collection in Electronic Health Records: An Analysis of Disclosure, Privacy, and Access to Care,” *Transgender Health* 1, no. 1 (1 October 2016): 205-15.

51. K.D. Cato, W. Bocking, and E. Larson. “Did I Tell You That? Ethical Issues Related to Using Computational Methods to Discover Non-Disclosed Patient Characteristics,” *Journal of Empirical Research on Human Research Ethics* 11, no. 3 (July 2016): 214-9.