MEDICAL ETHICS ADVISOR®

YOUR PRACTICAL GUIDE TO ETHICS DECISION-MAKING

JANUARY 2021 Vol. 37, No. 1; p. 1-12

INSIDE

Relias Media

From Relias

Consults Alone Do Not Give Full Ethics Picture: Much Work Goes Unacknowledged

Ethics services are finding that the number of consults requested does not tell the full story of their workload.

"The ability to clearly demonstrate an ethics program's value has been a persistent challenge for our field for some time," says **Jordan Potter**, PhD, HEC-C, supervisor of the Wellstar Fellowship in Clinical Ethics and a clinical ethicist at Wellstar Health System.

Wellstar's ethics service recently started to track its activities outside of consultations.[1]

"Our research examines the impact of systematically tracking other vital functions of ethics programs," Potter explains.

This includes internal education, orientation presentations, external education (conferences, seminars, and invited talks), publications, grants, committee work, rounding, policy development, and medical resident/fellow rotations with the ethics consultation service. "The quantitative criteria for each non-consult ethics activity that we track varies," Potter reports.

The three main quantitative criteria are number of sessions, number of attendees, and time spent. For example, internal education, orientation presentations, and external education are tracked in two ways: by the number of sessions and the attendees for each session. "For activities like committee work and rounding, we track both the number of sessions and the time spent," Potter says.

Quantifying all these "non-consultation ethics activities" gave hospital administration a better picture of an ethics program's value, enough to devote more resources to it. Currently, Wellstar's ethics program includes five clinical ethicists and two postdoctoral clinical ethics fellows. They recently used the data to justify adding a sixth full-time clinical ethicist.

Data on internal education and interdisciplinary rounding in particular offer "tremendous value" for the organization, says **Susannah Lee**, JD, MPH, a former clinical ethics fellow

Financial Disclosure: Physician Editor **Arthur R. Derse**, MD, JD, Nurse Planner **Susan Solverson**, RN, BSN, CMSRN, Editor **Jonathan Springston**, Editor **Jill Drachenberg**, Editorial Group Manager **Leslie Coplin**, Accreditations Director **Amy M. Johnson**, MSN, RN, CPN, and Author **Stacey Kusterbeck** report no consultant, stockholder, speakers' bureau, research, or other financial relationships with companies having ties to this field of study.

MEDICAL ETHICS ADVISOR®

***Medical Ethics Advisor®*, ISSN 0886-0653, is published monthly by Relias LLC, 1010 Sync St., Ste. 100, Morrisville, NC 27560-5468. Periodicals postage paid at Morrisville, NC, and additional mailing offices. POSTMASTER: Send address changes to *Medical Ethics Advisor*, Relias LLC, 1010 Sync St., Ste. 100, Morrisville, NC 27560-5468.**

GST Registration Number: R128870672.

SUBSCRIBER INFORMATION
(800) 688-2421
customerservice@reliasmedia.com
ReliasMedia.com

JOINTLY ACCREDITED PROVIDER™
INTERPROFESSIONAL CONTINUING EDUCATION

In support of improving patient care, Relias LLC is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC), to provide continuing education for the healthcare team.

The Relias LLC designates this enduring material for a maximum of 1.5 *AMA PRA Category 1 Credits*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

1.5 ANCC contact hours will be awarded to participants who meet the criteria for successful completion.

This activity is intended for acute care physicians, chiefs of medicine, hospital administrators, nurse managers, physician assistants, nurse practitioners, social workers, and chaplains.

This activity is in effect for 36 months from the date of publication.

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

AUTHOR: Stacey Kusterbeck
EDITOR: Jonathan Springston
EDITOR: Jill Drachenberg
EDITORIAL GROUP MANAGER: Leslie Coplin
ACCREDITATIONS DIRECTOR: Amy M. Johnson, MSN, RN, CPN

at Wellstar Health System. "These activities are a way to potentially increase ethics consult volume, as well as ensure earlier identification of cases in need of an ethics consult," Lee says.

Earlier ethics involvement can positively affect important metrics such as length of stay. There also are some intangible benefits. "More ethical awareness among caregivers leads to a better overall ethical culture within the institution, which benefits everyone," Lee notes.

When ethicists set out to quantify their work, they find there really is no standard method. "The distinction between a formal and informal consultation varies across different institutions," says **Trevor M. Bibler**, PhD, assistant professor of Medicine at the Center for Medical Ethics and Health Policy at Baylor College of Medicine in Houston.

This matters because formal consults usually are tracked, while informal conversations are not recorded in any way.

"It gets back to the question of value," Bibler says.

The value of a formal consult is clear, because ethicists can point to something concrete — a patient, a clinician, or unit received help. It is harder to pinpoint the value of a 20-minute presentation during a nursing steering committee meeting. "There is not a close connection between the ethicist's action and quantifiable outcomes," Bibler explains.

Questions such as "Did it change anyone's practices?" or "Did it affect patient care in any direct way, or even an indirect way?" usually are impossible to answer. Still, quantifying all the work ethics does is important for many reasons.

"The institution might look at the data for quality improvement efforts and comparisons with other consultation services," Bibler says.

The main reason ethics consults are tracked is because electronic health records are set up to capture those data.

"Unless they create one, ethics services do not have a similar system for collecting real-time data on other work they do," says **Laura Guidry-Grimes**, PhD, an assistant professor of medical humanities and bioethics and a clinical ethicist at University of Arkansas for Medical Sciences.

Creating a database to do that requires expertise and resources. "The time that ethics services have is often constrained due to high consult volume, not enough staff, and limited FTEs," Guidry-Grimes observes.

The concern is that without good data, it can falsely appear the ethics service carries little value.

"This misperception can directly translate into diminished support from leadership," Guidry-Grimes says.

That could mean less funding or no invitations to work on important initiatives (e.g., COVID-19 pandemic response). In reality, many ethicists spend most of their time performing all kinds of tasks that benefit the institution: educating staff and trainees, debriefing after difficult cases to prevent burnout, and developing policy.

"Any one of these could actually take up more time than consults in any given week," Guidry-Grimes notes.

The solution? "Ethics services need protected time to collect these data into a reliable system," Guidry-Grimes offers.

Spreadsheets in a cloud computing system (if protected health information is not involved) are one possibility. "REDCap is another system that has a mobile

option that can help collect data from ethicists at the time of an activity," Guidry-Grimes suggests.

For instance, ethicists could log in immediately after giving a grand rounds talk to record the topic and estimated number of attendees. The same could happen if night staff ask for a moral distress debrief. Ethicists could log how many people were part of the discussion and what general themes emerged.

The challenge is to make all these data meaningful. "That requires even more time — for interpretation, organization, and presentation of the data," Guidry-Grimes explains.

Once "what ethics does" data are obtained, there are many potential uses. Guidry-Grimes offers these examples:

• **Internal quality improvement of the ethics service.** Ethicists might learn some consultants hold family meetings all the time, but others hardly ever do. Similarly, ethicists could find out which units or providers never request consults. "This may indicate the need for increased visibility, or investigation of consult barriers," Guidry-Grimes notes.

• **Shed light on issues related to organizational ethics.** For example, the ethics service may discover an increase in moral distress debriefs and consult requests related to partial code status. "This discovery could prompt a bigger discussion," Guidry-Grimes says. Such a discussion could reveal a problematic hospital policy, or the need to alter the medical record system to clarify medically and ethically reasonable code status options.

• **Demonstrate the true range of ethicists' work.** "Administration can view these data as evidence of how the ethicists are serving the institution, and the need for expanded support for their work," Guidry-Grimes says.

Ethicists at University of Rochester (NY) Medical Center are engaging in ongoing discussions about how to document all their work. "This is a topic that some of us on my team, and in the world of bioethics in general, recognize as something that needs more attention," says **Marianne C. Chiafery**, DNP, PNP-BC, a nurse practitioner and clinical ethicist.

Part of the reason is the ethics field is evolving. "We are figuring this out as the field grows. It's not a bad problem to have, since the growth of the field of bioethics is a positive development in healthcare," Chiafery observes.

Many hospitals work with few ethicists, most if not all of whom work in other full-time roles. "It is rare to find anyone who does solely ethics consultation work," Chiafery reports.

Informal "curbside" consults and nursing ethics huddles are not documented; only formal consults are. "Recently, our medical director had the opportunity to see a list of all that is done in the division, and he was surprised. We do not 'toot our horn' enough," Chiafery recalls.

The information came up in an unexpected way, when the clinical director of ethics retired. For the job posting, he listed all the activities the role encompassed.

"That's when the depth and extent of his work was made known to others outside of our group," Chiafery notes.

Noon conferences, spontaneous education provided to bedside staff, presentations during staff orientations, phone calls from affiliate hospitals, debriefings, and in-services all happen on the ethicist's own time. "Not everyone is aware of these efforts," Chiafery laments.

This makes it hard to justify hiring more staff to join the ethics service.

"Until we quantitively demonstrate the amount of work being done, and what is not being done due to time and resource limitations, we will not be able to expand services within a care setting," Chiafery acknowledges. ■

REFERENCE

1. Lee SW, Potter J, Matsler JS, Shields S. Demonstrating value through tracking ethics program activities beyond ethics consultations. *J Clin Ethics* 2020;31:268-276.

Price Transparency: Ethicists Can Play a Role

Hospitals are devoting plenty of resources to the logistics of how they are going to comply with new federal price transparency requirements.[1] There also are important ethical implications.

"Several types of billing practices raise ethical issues," says **Katherine Drabiak**, JD, an associate professor at USF Health's College of Public Health and College of Medicine in Tampa.

Surprise billing probably is the most-publicized example. This usually happens when a patient visits an in-network hospital but an out-of-network physician handles treatment. "When visiting a physician, patients also expect billing to correspond to the level of care provided," Drabiak says.

Some patients receive astronomical bills for minor items or services, such as bandages, tetanus shots, or aspirin. "This not only induces patient anxiety, it also raises questions about fair and transparent billing standards," Drabiak notes.

The price transparency requirements, which took effect Jan. 1, 2021, are an opportunity for hospitals to demonstrate their financial practices are ethical. "Taking this step will increase the hospital's goodwill in the community," Drabiak predicts.

Generally, hospital-based physicians are focused on direct patient care as opposed to pricing and billing issues. Facilities really could use staff with insurance expertise to ensure patients are billed in an ethical manner. "Case managers could work in tandem with hospital administrators to assess billing practices and to ensure indigent patients are aware of their rights and payment resources," Drabiak suggests.

Surprise billing is a major economic burden for some patients. "Such bills often revolve around surgery," says **Peter Angelos**, MD, PhD, FACS, the professor of surgery and surgical ethics and associate director of the MacLean Center for Clinical Medical Ethics at The University of Chicago.

Perhaps a patient undergoes emergency surgery at an in-network hospital, but the on-call surgeon is out of network. The patient winds up with an expensive medical bill for the surgeon's services. In other cases, both the surgeon and the hospital are in network, but not the anesthesiology group.

"The ethical implications of surprise billing are that patients face economic burdens that they had no way of knowing that they would be subject to," Angelos explains.

Angelos worries surprise billing episodes may be more likely during the COVID-19 pandemic. When physicians are required to stay home because of COVID-19 exposure, hospitals are forced to bring in outside physicians for surgical care and anesthesiology services. Many might be outside patients' insurance networks.

"Although surprise billing is not a new problem, with COVID, we believe that it will increasingly be an issue, given the need for medical centers to get outside physicians to cover services," says Angelos, who recently co-authored a paper on this subject.[2]

Since patients have no idea of the surprise bill that is coming, they cannot make an informed decision on where to seek their medical care. "They are deprived of the ability to make a choice. In other words, their autonomy is not respected," Angelos laments.

Anger over unexpected bills also can interfere with the patient/physician relationship. "Bringing the ethical issues to greater awareness within hospitals may serve to encourage a greater effort at developing policy solutions for the problem," Angelos offers.

The first step in addressing any ethical problem is to verify it exists. "I would suggest that medical ethicists determine whether there are physicians rendering care at their hospitals who are not contracted as in network," Angelos says.

If those arrangements are common, it is safe to assume patients are receiving surprise bills from those providers. "Pursuing policies to make such arrangements transparent to patients would be a big step in the right direction," Angelos adds. ■

COMING IN FUTURE MONTHS

- How to evaluate satisfaction with ethics consults
- Hospital policies on inappropriate treatment
- When citizen scientists use big data
- What happens if clinical trial results go unreported?

REFERENCES

1. CMS.gov. CMS completes historic price transparency initiative. Oct. 29, 2020. https://go.cms.gov/33yAIRd
2. Sheckter CC, Singh P, Angelos P, Offodile AC 2nd. Surprise billing in surgical care episodes: Overview, ethical concerns, and policy solutions in light of COVID-19. *Ann Surg* 2020;272:e264-e265.

Decisions on Family Observing Resuscitation Efforts Center on Autonomy, Beneficence

Family presence during resuscitation efforts remains controversial, leaving clinicians to wonder whether it is helpful or harmful. A group of researchers decided to study this situation in the ED.[1]

"We started with the question of whether witnessing resuscitations is beneficial or deleterious for family members," says **Mert Erogul**, MD, the study's lead author. "Even while you're doing your best to resuscitate a critically ill patient, your mind travels to the person who will be left behind. What words will you use? And would they derive any benefit from seeing what takes place?"

Physicians have wondered whether family presence during resuscitation permits some sort of psychological closure. There have been numerous studies on family presence over the years, with inconsistent findings. "It turns out this is a relatively difficult question to approach," says Erogul, an emergency physician at Maimonides Medical Center in Brooklyn.

One consideration is whom to study. Most previous studies included cardiac arrest victims. The authors focused on family members of patients whose circulation had failed and were receiving CPR.[2-5]

Erogul and colleagues thought it would be more valuable to study all critically ill patients, regardless of the resuscitation outcome. The researchers wanted to help physicians decide how to proceed at the moment when a seriously ill patient arrives with his or her family at the ED.

Erogul and colleagues contacted 423 family members of critically ill patients, identified by the ED's EHR, and administered a validated scale that measures post-traumatic distress symptoms. Family members were divided into two groups: those who had witnessed resuscitation efforts, and those who had not.

Those who witnessed the resuscitations exhibited more PTSD symptoms one month after the event. That does not necessarily mean family presence is harmful. It is possible transient PTSD symptoms could lead to long-term psychological benefits. "There is some evidence to that end in the post-traumatic growth literature," Erogul notes.[6,7]

Another ethical question: Who makes the decision? "Does autonomy trump all in this case, as it does for many other matters of gravity in bioethics?" Erogul asks.

Typically, autonomy concerns the patient who has a direct relationship with the physician. If the patient is too sick to participate in decision-making, clinicians are left with a secondary relationship (between the physician and the family member).

"It seems reasonable that family members be permitted autonomy to make a decision in this case. The outcome of the decision has bearing on real consequences in their lives," Erogul says.

At the Maimonides Medical Center ED, clinicians typically give family members the choice to be present. "We still do not know for certain if this will harm or help the person who is left behind," Erogul says.

While it is not realistic for an ethicist to be at the bedside when that decision is made, ethicists can discuss underlying ethical issues with clinicians proactively.

"Given the considerable burden of keeping up with the medical literature, most doctors never have an opportunity to reflect on these kinds of things," Erogul observes.

Ethicists also can help develop clear, consistent policies on family-witnessed resuscitation. Based on all the evidence to date, says Erogul, "it's reasonable to give family members the choice to be present — and to support them should they choose not to watch." ■

REFERENCES

1. Erogul M, Likourezos A, Meddy J, et al. Post-traumatic stress disorder in family-witnessed resuscitation of emergency department patients. *West J Emerg Med* 2020;21:1182-1187.
2. Robinson SM, Mackenzie-Ross S, Campbell Hewson GL, et al. Psychological effect of witnessed resuscitation on bereaved relatives. *Lancet* 1998;352:614-617.
3. Compton S, Grace H, Madgy A, Swor RA. Post-traumatic stress disorder symptomology associated with witnessing unsuccessful out-of-hospital cardiopulmonary resuscitation. *Acad Emerg Med* 2009;16:226-229.
4. Compton S, Levy P, Griffin M, et al. Family-witnessed resuscitation: Bereavement outcomes in an urban environment. *J Palliat Med* 2011;14:715-721.
5. Jabre P, Belpomme V, Azoulay E, et al. Family presence during cardiopulmonary resuscitation. *N Engl J Med* 2013;368:1008-1018.
6. Kleim B, Ehlers A. Evidence for a curvilinear relationship between posttraumatic growth and posttrauma depression and PTSD in assault survivors. *J Traum Stress* 2009;22:45-52.
7. Dekel S, Ein-Dor T, Zahava S. Posttraumatic growth and posttraumatic distress: A longitudinal study. *Psychological Trauma: Theory, Research, Practice, and Policy* 2012;4:94-101.

Ethical Concerns About Surge of Involuntary Psychiatric Detention, Lack of Data

The number of involuntary psychiatric detentions has risen sharply over the past decade, according to the authors of a recent study.[1]

Researchers struggled to find these data. "Anyone can easily look up information about how many people in the U.S. are arrested for what types of criminal offenses ... No one can look this up for people taken by the police to a facility to be examined involuntarily and detained," says **David Cohen**, PhD, one of the study's authors and a professor of social welfare at UCLA Luskin School of Public Affairs in Los Angeles.

Cohen and a colleague analyzed state health and court websites in the 38 states for which data were available. In the 22 states with available continuous data from 2012 to 2016, the average rate per 100,000 people rose from 273 to 309.

Only 25 states are included in the study because they had what the researchers judged to be usable data. "The other 13 states had some data, but labeled them simply using the words 'mental health,' with zero other definition or description, or mixed civil and criminal commitments, [which] were excluded," Cohen says.

There is no national database on involuntary detentions. States and jurisdictions inconsistently report rates. States differ as to what label they use for detentions; whether they count events or unique persons; whether they report the age group (adult or child), sex, or ethnicity; whether the detention is short- or long-term; how long people are held; whether all eligible counties or institutions are reporting; who prepares the data; and time frames to release data.

"Except for about five states, which still have important but not terrible data shortcomings, it's a mess," Cohen laments.

It is difficult to explain why states vary widely in duration and rates of commitments, or to find out what happens to people who are involuntary committed. Only one of the 25 states included in Cohen's study provided any data on how long people were held.

"Without any national numbers in 40 years, the lowest-inference work — how many, where, and how long — had not been done," Cohen explains. "Commitment is our main response to people's breakdowns, but it is acknowledged to be traumatizing and stigmatizing — and might lead to suicide because it accentuates powerlessness."

Central ethical concerns with involuntary psychiatric hospitalizations include autonomy of the detained person, stigma of psychiatric populations, and the desire to prevent harm (to the person or others), says **William R. Smith**, MD, PhD, a psychiatry resident in the Scattergood Program for Applied Ethics of Behavioral Health Care in the Penn Department of Medical Ethics and Health Policy.

These all are important ethical principles that sometimes conflict, making decision-making difficult. "In my experience, many psychiatrists do struggle with decisions that they have had to make on these fronts, often keeping them awake at night," Smith says.

Ethicists can help psychiatrists become more familiar with the analysis of ethical principles that come into play. Every quarter, members of Penn's Scattergood program analyze emergency psychiatric evaluations, with a strong focus on the ethics of recent cases.

"Just about any medical trainee is going to be familiar with standard bioethical concepts," Smith says. "Being able to name terms and then being able to apply them to hard cases are two different things." ■

REFERENCE

1. Lee G, Cohen D. Incidences of involuntary psychiatric detentions in 25 U.S. states. *Psychiatr Serv* 2020; Nov 3;appips201900477. doi: 10.1176/appi.ps.201900477. [Online ahead of print].

New Guidance Outlines Ethics of Embryo Research

A new position statement offers some much-needed ethical recommendations on embryo research.[1]

"There have been some scientific and cultural changes" necessitating the guidance, says **Sean Tipton**, chief advocacy policy and development officer for the American Society for Reproductive Medicine (ASRM).

According to the statement, human embryo research is ethically acceptable if it is "likely to provide significant new knowledge that may benefit human health, well-being of the offspring, or reproduction." The ASRM Research Institute is sponsoring embryo research, with a particular focus on work that is, right now at least, ineligible for federal funds. "When you are working outside of the federal funding system, some of those protections and oversight mechanisms disappear," Tipton says. "As a funder, we needed some overarching guidelines on what we are going to fund."

Researchers applying for funding through the institute or other organizations also need to know what the rules are going to be. "The ban on federal funding of embryo research leads to a big void. We felt if we could provide more guidance, it would make other independent research institutions feel more comfortable getting into this area of investigation," Tipton reports.

The reproductive medicine field is fraught with difficult ethical issues. "It's a field of medicine where you generally are requiring tissues from two different people with the objective of creating a third," Tipton notes.

As science advances, longstanding ethical questions become more pressing. Some people previously drew a line at research on embryos in vitro as ethically acceptable only until a specific time frame, such as two weeks. At a time when longer time frames were not possible, it was easier to prohibit.

Likewise, the concept of germline gene editing was at one point merely a hypothetical argument; now, it is scientifically possible. "The concept of germline gene editing is not easy clinically and it's certainly not easy ethically. On the other hand, the potential is enormous," Tipton says. "The concept that you can essentially wipe out something like sickle cell disease is not something that should be ignored just because the current ethical framework can't handle it."

The concern is that reputable researchers will step away from the field, and leave it open only to unscrupulous or rogue researchers. The reality is, science is going to advance with or without ethical guidance. "You need to have some guidelines on how that happens, as opposed to just saying, 'Don't do it,'" Tipton argues. "We are trying to establish an informed framework under which reproductive research can move forward in a careful, ethical manner." ■

REFERENCE

1. Ethics Committee of the American Society for Reproductive Medicine. Ethics in embryo research: A position statement by the ASRM Ethics in Embryo Research Task Force and the ASRM Ethics Committee. *Fertil Steril* 2020;113:270-294.

Privacy Remains Central Problem with Genomic Data-Sharing

Genomic data-sharing is popular, but there are significant privacy concerns.

The Genetic Information Nondiscrimination Act (GINA) prevents health insurers and employers from using genetic information in discriminatory ways. There also are state laws protecting against genetic discrimination. "However, these laws are not comprehensive. Concerns about genetic privacy persist," says **Amy L. McGuire**, JD, PhD, director of the Center for Medical Ethics and Health Policy at Baylor College of Medicine in Houston.

Genetic testing performed by a healthcare provider or researcher at an academic medical center most likely will be secured as protected health information (PHI) under HIPAA. Research data also may be protected under a Certificate of Confidentiality from disclosure without consent.

"Yet there are concerns about breaches, especially given recent high-profile security breaches of other digital data platforms," McGuire says.

Unanticipated uses of genetic information are a valid worry. Law

enforcement has begun using direct-to-consumer genetic genealogy services to generate leads in criminal investigations. Agencies upload crime scene DNA and compare that information to the DNA of other database participants to identify potential genetic relatives (and, ultimately, the suspect).

"Although law enforcement is not using medical or research data for this purpose, it has raised some additional concerns about genetic privacy and unanticipated uses of shared genetic information," McGuire says.

Decisions on participation in genetic research always involve a trade-off between concerns about privacy and perceived benefits to the individual and society. It is uncertain how exactly this information could be used in the future.

"Individuals and groups need to be able to trust the systems that are in place to secure their data and protect them against future harm," McGuire says.

Making the system more trustworthy requires greater transparency, clear principles of accountability, and more comprehensive laws and regulations that protect against discriminatory uses of genetic information, according to McGuire. The results of a recent survey may reveal the work ahead. Investigators surveyed 36,268 people in 22 countries to learn about the public's understanding of genomics and preferences about who can see this information.

"In general, publics [sic] across the world do not appear to be aware of, nor familiar with, the concepts of DNA, genetics, and genomics. Willingness to donate one's DNA and health data for research is relatively low, and trust in the process of data's being shared with multiple users (e.g., doctors, researchers, governments) is also low," the authors wrote.[1] "Participants were most willing to donate DNA or health information for research when the recipient was specified as a medical doctor and least willing to donate when the recipient was a for-profit researcher. Those who were familiar with genetics and who were trusting of the users asking for data were more likely to be willing to donate. However, less than half of participants trusted more than one potential user of data, although this varied across countries."

Researchers may reassure people that data are "de-identified." It is questionable to what extent this really can be true.

"DNA is an identifier. For example, it's used to track down individuals who have committed crimes and to determine family relationships," says **Mary Anderlik Majumder**, JD, PhD, a professor of medicine at Baylor's Center for Medical Ethics and Health Policy.

It is questionable whether a DNA sequence, especially a whole exome or whole genome sequence, can be considered truly de-identified.

"Yet our whole regulatory framework for healthcare and biomedical research is built on the assumption that removing standard identifiers — names, addresses, significant dates, and so on — is sufficient to protect people's privacy," Majumder says.

A person with an elevated genetic risk of Alzheimer's disease might not want that known to the world, especially insurers or employers. But that same person might want qualified researchers to have access to their genetic sequence if the research could lead to new approaches to prevention. "With advances in sequencing technology, it is becoming possible to extract more data from biospecimens," Majumder adds. Other advances will make sense out of those data in terms of what it means for a person's future health or life course. "The pitfall to guard against is genetic determinism. A lot of what we learn will be probabilistic and contingent," Majumder explains.

Also unpredictable is what happens in the social and legal environment. "A 'Gattaca' scenario, where people find that their career and life prospects are limited based on sequence reads, is not just about technology. It's also about the response to what the technology makes possible," Majumder says.

Some informed consent form templates address the potential for things to change. "Generally, though, they describe the law in a static way," Majumder reports.

For instance, researchers explain how GINA protects privacy and its limitations, without making clear that changes could occur. This could happen in either direction, with nondiscrimination and privacy laws strengthened or weakened. "However, that is asking a lot of the informed consent process, which is already pretty overloaded just trying to convey basic information of immediate and near-term significance," Majumder observes.

People should not have to worry that the rules are going to change depending on who can access their genetic data in the future.

Still, says Majumder, "I wouldn't advocate for lengthier descriptions of all the possible future scenarios, or an informed consent process that resembles a science fiction book club meeting."

The emphasis should be on trustworthy approaches to data governance. People have a right to expect that health systems or researchers will care about their privacy, and will be

held accountable to do what they can to protect it.[2] "But there are limits," Majumder adds. "Members of the public or patients should not imagine that health systems or researchers possess crystal balls." ■

REFERENCES

1. Middleton A, Milne R, Almarri MA, et al. Global public perceptions of genomic data sharing: What shapes the willingness to donate DNA and health data? *Am J Hum Genet* 2020;107:743-752.
2. Deverka PA, Gilmore D, Richmond J, et al. Hopeful and concerned: Public input on building a trustworthy medical information commons. *J Law Med Ethics* 2019;47:70-87.

'It's a No-Man's Land': The Pitfalls of Genetic Data-Sharing and Informed Consent

The National Institutes of Health's All of Us Research Program aims to eventually capture the DNA and health data of 1 million participants.[1,2]

Investigators carefully considered how to best inform people of whether or how their information would be shared, says **Anita L. Allen**, JD, PhD, who served on the initiative's institutional review board. "Any time people give up sensitive information, or confidential or private information, without fully understanding the implications in terms of discrimination or third-party sharing for advertising or marketing, there are privacy concerns. And they are very real concerns," says Allen, professor of law and philosophy at University of Pennsylvania.

It is unclear how well participants really understand all the potential risks of sharing their DNA. "It's always tricky. How many average Americans really understand the data analytics, or how putting information in the cloud could make it vulnerable?" Allen asks.

Many future uses of DNA already are on the horizon, says **Leslie P. Francis**, PhD, JD, distinguished professor of law and philosophy at the University of Utah. These include polygenic risk-scoring for psychiatric or other traits, increasingly good prediction of life course outcomes (e.g., risks of earlier death), understanding of varying susceptibilities to infectious disease, or forensic use of DNA outside of heinous crimes. It is impossible for investigators to cover all these possibilities in informed consent discussions.

This is where effective storytelling can come in handy. Francis suggests sharing an anecdote like this on consent forms: "Our knowledge of genetics is expanding rapidly. Right now, we cannot effectively predict what we will learn in the future. However, it is likely there will be surprises. For example, we can use DNA databases to try to identify people whose DNA has been found at crime scenes. The DNA of a distant relative was used to capture the 'Golden State Killer.' If you think you might be uncomfortable about surprises from new knowledge of this kind, you should think carefully about agreeing to unlimited future uses of your DNA."

There always will be limitations to informed consent when it comes to the complexities of genetic information privacy. "What do we do about that? We don't over-rely on consent," Allen says.

Researchers are ethically obligated to be sure that what they are asking people to consent to is just, fair, appropriate, and respectful of human rights. "We need to be extremely thoughtful in how we do it, since not everybody understands the implications of data disclosure. Genetic data in the U.S. right now is very much a subject for concern," Allen says.

People may be giving up their own information too freely, especially genetic information, when they do not understand the implications. "I don't say this to wag my finger. I myself find it very fun and useful to share my DNA with other people, which would have been inconceivable to do 20 years ago," Allen says. "But there is less of a sense that generic information is exceptional and sensitive."

Not even privacy researchers know all the possible future harms to participants. "We are letting down our guard, for better or worse," Allen observes. "Until we adopt stronger laws, there will be very little we can say is pre-emptively protected when it comes to our data. It's a no-man's land out there." ■

REFERENCES

1. Denny JC, Rutter JL, Goldstein DB, et al. The "all of us" research program. *N Engl J Med* 2019;381:668-676.
2. National Institutes of Health All of Us Research Program. Protecting data and privacy. https://bit.ly/2VNP9fM

Most Parents Decide on Study Participation Before Receiving Consent Form

Efforts to improve informed consent for research usually focus on consent forms, making them shorter, less complicated, and easier to understand. A recent study revealed most parents decide whether they want their children to participate in research before they ever see a consent form.[1] "We conducted this survey to better understand when people make decisions about participating—or not—in research," says **Stephanie A. Kraft**, JD, an assistant professor at the Treuman Katz Center for Pediatric Bioethics at Seattle Children's Research Institute.

The findings upend the traditional assumption in research ethics — that the consent form plays a big role in decision-making. "Yet most efforts to improve informed consent haven't increased participant understanding to the degree that we might have hoped they would," Kraft says.

Kraft and colleagues wanted to learn more about the timing of when participation decisions are made. They surveyed 88 parents who enrolled or declined to enroll their children in a study on a weight management intervention. Sixty-seven percent made their decision before receiving the consent form. Of those who remembered receiving the consent form, only 25% said it taught them new information.

"Even though people viewed the consent document as a valuable part of the process, it played a fairly minimal role in decision-making," Kraft says.

Instead, decisions were made early. Often, parents made the decision after the first conversation with a member of the study team, or after reviewing recruitment materials. "Our findings suggest that we should be paying attention to these early interactions as places to improve how we support potential participants in making decisions about research that are right for them and their families," Kraft suggests.

Staff are the first ones to approach people about the study. "[Staff] need to be provided the tools they need to support potential participants," Kraft adds. ■

REFERENCE

1. Kraft SA, Porter KM, Duenas DM, et al. Assessing parent decisions about child participation in a behavioral health intervention study and utility of informed consent forms. *JAMA Netw Open* 2020;3:e209296.

Informed Consent Remains a Process, Not a Checkbox

The use of electronic consent (e-consent) at Weill Cornell Medical College has expanded rapidly with the sudden demands of COVID-19 research. Researchers have been experimenting with various forms of e-consent for several years.

The health system built a home-grown solution (based on the NIH-sponsored REDCap system),[1] which was more successful — at a lower cost, according to **Curtis L. Cole**, MD, chief information officer.

While working to find the single best way to implement e-consent, researchers conducted a systematic literature review. They examined 69 studies, hoping to learn from the experience of other health systems. The investigators found there was no unified approach for e-consent implementation.[2] "I personally was surprised by how little was written, and the relatively low quantity of strong studies," says Cole, one of the study's authors.

The lack of consensus on how to switch to e-consent makes it more difficult to realize its potential benefits. Not everyone has the time or patience to explain the same thing at varying educational levels, in different languages, and confirm comprehension. "While humans still outperform computers in many ways, we are not great at consistency, and we all have biases," says Cole, adding the ethical obligation is to maximize the benefits of e-consent while minimizing its harms.

E-consent can make the informed consent process better than the current paper-based format, according to another systematic review.[3] "Different organizations are showing increasing interest in electronic tools to supplement or replace traditional, paper-based informed consent forms. However, implementation in biomedical research is slow," says **Evelien De Sutter**, PhD, the study's lead author and a researcher at KU Leuven in Belgium.

De Sutter and colleagues identified several concerns with e-consent, including confusion about the ethical review process. There also

were varying views regarding the use of e-signatures, and what to do if participants lack digital literacy. "It is important to offer [participants] the choice between electronic informed consent and a paper-based informed consent form. It cannot be tolerated that participants are excluded from a research study," De Sutter says.

Problems arise if e-consent turns informed consent into a "check the box" mentality, according to **Julie M. Aultman**, PhD, director of the medical ethics and humanities program and chair of the institutional review board at Northeast Ohio Medical University in Rootstown.

Researchers should be inviting questions and, along the way, determining people's decision-making capacity. The level of risk involved in the study also should be weighed. An anonymous, minimal-risk survey that involves investigators gathering information on healthcare providers might be appropriate for e-consent.

For a study with known risks that are outside the scope of everyday practice or living, the consent process is more complex. That probably calls for a combination of e-consent and in-person communication. Research subjects might use e-consent during ongoing studies after an initial face-to-face paper consent is completed. Some studies include various stages or activities over months or years, such as a medical intervention followed by a focus group.

"E-consent can be useful to remind subjects of the multiple research activities they might be involved in over time, and of the continuous opportunity to ask questions and disclose concerns," Aultman offers.

At any point of a study, a subject has the right to withdraw. "The process of consent is an important reminder of such rights," Aultman says.

The drawback of e-consent is that if researchers cannot see the person, it is more difficult to gauge how well all this information is understood. Virtual meetings, pre-study surveys to assess capacity to consent, and follow-up phone calls are some options to ensure an ethical informed consent process.

Finally, consider whether people own the right equipment and can participate. "To deny opportunities due to inability to utilize e-consent is an injustice," Aultman adds. ■

REFERENCES

1. Chen C, Turner SP, Sholle ET, et al. Evaluation of a REDCap-based workflow for supporting federal guidance for electronic informed consent. *AMIA Jt Summits Transl Sci Proc* 2019;2019:163-172.
2. Chen C, Lee PI, Pain KJ, et al. Replacing paper informed consent with electronic informed consent for research in academic medical centers: A scoping review. *AMIA Jt Summits Transl Sci Proc* 2020; 2020:80-88.
3. De Sutter E, Zaçe D, Boccia S, et al. Implementation of electronic informed consent in biomedical research and stakeholders' perspectives: Systematic review. *J Med Internet Res* 2020;22:e19129.

Patients with HIV More Likely to Take Medication Described as 'Cure'

Those living with HIV were more willing to take a medication if clinicians described it as a "cure" as opposed to calling it "clinical remission," according to the authors of a recent study.[1]

Researchers surveyed 454 people with HIV about how willing they would be to take a hypothetical HIV treatment that causes flu-like symptoms. Respondents were more willing to take the drug that was described as a "cure."

Jennifer Blumenthal-Barby, PhD, MA, one of the study authors, says respondents were willing to take "significant risks" if it meant a drug could cure them. However, she and research colleagues could not determine clearly how respondents interpreted the word "cure."

"The concern is that 'cure' wording might offer false hope and be misleading," says Blumenthal-Barby, associate director at the Center for Medical Ethics and Health Policy at Baylor College of Medicine in Houston.

In light of these findings, Blumenthal-Barby says clinicians and researchers should improve informed consent so that people living with HIV have a realistic understanding of treatment options and possible outcomes. ■

REFERENCE

1. Fridman I, Ubel PA, Blumenthal-Barby J, et al. "Cure" versus "clinical remission": The impact of a medication description on the willingness of people living with HIV to take a medication. *AIDS Behav* 2020;24:2054-2061.

MEDICAL ETHICS ADVISOR®

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

NURSE PLANNER
Susan Solverson, BSN, RN, CMSRN
Grafton, WI

EDITORIAL ADVISORY BOARD
John D. Banja, PhD
Professor, Department
of Rehabilitation Medicine
Medical Ethicist, Center for Ethics
Emory University
Atlanta

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

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

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

CME/CE QUESTIONS

1. **Regarding family presence during resuscitation efforts, the authors of a recent study found:**

   a. only families of cardiac arrest victims benefited from being allowed to observe resuscitation efforts.
   b. families who witnessed resuscitations exhibited more PTSD symptoms one month later than family members who had not witnessed resuscitation efforts.
   c. physicians no longer allow families to witness resuscitation efforts without the patient's consent.
   d. transient PTSD symptoms led to long-term psychological harm for family members who observed resuscitation efforts.

2. **Which did the authors of a recent study find regarding involuntary psychiatric detentions?**

   a. Higher rates of violence caused by lower rates of psychiatric detentions
   b. Increases in the number of involuntary psychiatric detentions over the past decade
   c. Lower suicide rates for patients who were committed involuntarily
   d. Less stigma surrounding psychiatric commitment

3. **Which is true regarding parents' decision-making on research participation?**

   a. Most parents decided on research participation before they received a consent form.
   b. Parents identified confusing consent forms as the main barrier to participation.
   c. Parents learned no additional information from consent forms.
   d. Engaging in conversations with the study team before reviewing consent forms resulted in confusion.

4. **Which did the authors of a study find regarding sharing genomic data?**

   a. State laws protecting against genetic discrimination are enforced too strictly.
   b. Genetic testing performed at academic medical centers is not protected by patient privacy regulations.
   c. Research data rarely are protected from disclosure without consent.
   d. Most people view DNA as different from other types of information.

5. **Which did researchers find regarding e-consent?**

   a. No unified approach for implementation
   b. Better ability to confirm comprehension
   c. Improved assessment of capacity to consent
   d. Problems if a combination of e-consent and paper consent are used