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INSIDE

RELIAS MEDIA

All Eyes on Ethics: Pandemic Means 'Shift from Status Quo'

The diverse backgrounds of clinical ethicists have strengthened COVID-19 responses at many hospitals. Patients and family, clinicians, and administrators are turning to ethics for help.

"One of the major early lessons in shepherding the ethical response to COVID-19 as a large institution is having a team with a deep bench," says **Andrew G. Shuman**, MD, FACS, co-chief of the clinical ethics service at University of Michigan Medical School Center for Bioethics and Social Sciences in Medicine (CBSSM).

At Michigan Medicine, ethicists' expertise encompasses scarce resource allocation, palliative care, neonatology, public policy, surgical ethics, research ethics, and learning health systems. Ethics has been an integral part of organizationwide disaster preparedness for the past decade.

"Our ethics team has contributed to local, state, and national discourse around disaster preparedness ethics, and how to allocate scare resources in times just like these," says **Christian Vercler**, MD, co-chief of the CBSSM's clinical ethics service. When dealing with a global pandemic, "a shift from the status quo must occur," Vercler stresses. Scarcity of resources is no longer an abstract or hypothetical issue that can be debated without a deadline. This is an acute, tangible problem that limits individuals from getting whatever they want.

"That requires thinking much more seriously about public health ethics than the individual-centered, autonomy-focused ethic that pervades Western medical practice," Vercler offers.

For patients and families who are denied certain treatments, it means emotional upheaval. It also is hard on physicians who are not used to saying no. "This is why we have developed a strategy for times like this," Vercler notes.

On the clinical side, the team that decides on allocation of scarce resources is completely separate from the clinical care team. Ethics uses the same approach.

"We have separated the clinical ethics consultation team from the ethicists who are members of the review committee

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that makes rationing decisions," Vercler explains. In some ways, it is business as usual for ethics. Regular consults are happening at the rate of about 10 per week.

"The process for requesting a consult, involving stakeholders, and addressing the ethical question remains much the same," says **Janice Firn**, PhD, MSW, a clinical assistant professor of learning health sciences at the University of Michigan.

The main difference is that consults are handled remotely now. Also, many consults are affected in some way by COVID-19, even if indirectly. There are a few ways the pandemic has affected the work of ethics:

• Ethicists are closely involved in preparations for a surge of patients. Policies are needed urgently for when the hospital is filled to capacity with COVID-19 patients.

"We are actively involved in development of those policies, and ensuring that they are applied fairly across our different healthcare settings," Firn reports.

• Clinicians are expediting the release of those who can be discharged safely to make room for anticipated COVID-19 patients. This affects ethics because the group of patients who remain hospitalized are more complex, both in terms of medical care and psychosocial care. Those patients are more likely to have more complex ethics needs, too.

"Continued hospital admission, treatment, and discharge planning have become more complicated," Firn observes. "The proportionality of risks and benefits have changed in light of COVID."

• Medical teams struggle to make clear recommendations because of known and unknown COVID-19 risks. "Patients and families are struggling with the burden of decision-making," Firn says.

Before COVID-19, discharge to a skilled care facility was viewed as a safer and less risky option for many patients. Therefore, the clinical team was confident about such a recommendation.

"This is no longer the case," Firn says. Many patients and families are choosing home over another setting because they are worried about contracting COVID-19.

For the clinical team, the goal is the same. They facilitate informed decisions about the various options available. Once a decision has been made, they mitigate risk wherever possible.

"However, the calculation of risk is challenging with so little COVID-related data available," Firn adds.

EDITOR'S NOTE

This is a special issue of *Medical Ethics Advisor* focusing on how COVID-19 has changed the work of clinical ethicists. Our cover story reports on how ethics is simultaneously handling consults and policy development. Inside, we cover policies for worst-case scenarios of ventilator shortages; a switch to remote ethics consults; and efforts to promote trust in public health, protect healthcare workers, and enlist the help of chaplains. We also report on ethical controversies over possible shortcuts in developing vaccines and treatments. Future issues of *Medical Ethics Advisor* will examine what the pandemic means for ethics in the long-term.

• **Ethicists and clinicians are suffering from physical and emotional exhaustion.** "Cases can, understandably, start to run together," Firn acknowledges. "It becomes more difficult to address the novel features of an individual case."

• **Ethicists help medical teams apply the skills they have built over years of caring for patients while also considering whether COVID-19 issues are a factor.** Is COVID-19 really something entirely different than ethicists have ever faced before? "It is, and it isn't," Firn says. In the midst of so much uncertainty, it seems as though ethical decision-making is covering entirely new territory. This mindset is not particularly helpful.

"To overexceptionalize COVID can paralyze medical teams, patients, and families from using pre-COVID decision-making skills that are transferable to this situation," Firn explains.

In important ways, the work of ethics really has not changed at all. "Ethics consult work these days includes elucidating any unique features of the case within an ethically sound triage process, creating space for reflection and creative thinking, and attending to the emotional well-being of the stakeholders involved," Firn says.

There was not always a single best medical option, and decisions could not always be made based solely on patients' values, even before COVID-19. "This reality remains true today," Firn adds. ■

Ethical Policies if Critical Care Resources Become Scarce

If and when there are not enough ventilators for all the COVID-19 patients who need them, hospitals can expect lots of public scrutiny. Clear, consistent, and transparent policies can make the ethical rationale behind decisions obvious to everyone.

"Consistency across hospitals and health systems promotes public trust, fairness, and social justice," says **Douglas B. White**, MD, MAS, director of the program on ethics and decision-making in critical illness at University of Pittsburgh School of Medicine.

White developed a model hospital policy for allocating scarce clinical care resources that has been adopted by hundreds of U.S. hospitals.[1] The policy was created after several years of intensive engagement with citizens' groups, ethicists, and disaster medicine experts. "A major strength of this allocation framework is that it avoids categorically excluding large groups of citizens while still allowing priority to go to those most likely to benefit," White explains.

Physicians also benefit from relying on this kind of policy. "It can promote clinician morale in not feeling like you are the only one having to make these tragic choices," White offers.

Ethicists are challenged to develop new contingency triage plans to cover the COVID-19 crisis. "However, much of the background for these plans comes from earlier influenza epidemics. For example, the H1N1 pandemic of 2009," says **Dennis M. Sullivan**, MD, MA (Ethics), professor emeritus of pharmacy practice at Cedarville (OH) University.

When limited resources (such as mechanical ventilators) become scarce, "autonomy must give way to utilitarian considerations, with the goal of protecting the most lives in the at-risk population," Sullivan says.

Ideally, clinicians in this situation turn to guidance from previously established allocation protocols. "Their objectivity helps to ensure fairness and justice in the midst of difficult decisions," Sullivan adds.

The normal principles of medical ethics still apply, Sullivan stresses. Healthcare providers still must consider beneficence, nonmaleficence, distributive justice, and autonomy. They must do so up until the point where resource scarcity triggers a policy shift. "Therefore, it is imperative that the circumstances that invoke a resource allocation policy be well understood beforehand," Sullivan underscores.

A definite "trigger" should signal when to shift clinical decision-making from the traditional model (based on medical principlism) to a resource-allocation model (focused on saving the most lives). "Individual hospitals within a city or region should mutually coordinate their efforts to decide when an allocation crisis is at hand," Sullivan adds.

Clear demarcation also is necessary when the resource allocation model no longer applies. The hospital's triage committee should look at this daily to determine whether it is time to revert to the standard ethical framework. "It is important that providers understand when there is an 'all-clear' moment, when normal rules of medical ethics become operative once more," Sullivan says.

If they are faced with allocating scarce resources, ethicists might need to "decide the most ethical framework for making 'unethical' decisions," says

Pamela J. Grace, RN, PhD, FAAN, associate professor of nursing and ethics at Boston College.

The conflict between what is best for the individual and what is best for the larger community is the issue. "The poorest and most disadvantaged groups are likely to be disproportionately among the sickest patients, bearing the brunt of the decisions," Grace laments.

Typically, ethicists encourage clinicians to respect patients' autonomy. Now, utilitarian principles are coming into play. "This perspective essentially allows some individuals to be harmed if it will result in a benefit to a larger number," Grace says.

Those with chronic illness are more susceptible to COVID-19, and chronic illnesses are disproportionately present among the poor and other disadvantaged groups. Thus, rationing decisions are more likely to negatively affect these patients. "Theories of social justice recognize that the least well-off should receive the most help," Grace notes.

However, in a time of scarce medical and personnel resources, the focus will be on saving those most likely to survive.

"Ethicists can help by reminding people to consider nuances when making allocation decisions, and keeping their biases about who or which groups are worthy in check," Grace offers.

One argument is that allocation decisions should be made by groups instead of one individual clinician. On the other hand, a group decision could conflict with a provider's clinical judgment. "This is one reason why ethics committees are, for the most part, advisory rather than directive," Grace observes.

Inevitably, clinicians are going to face cases in which they disagree with what their institution's guidance says they should do.

"When clinicians cannot do what they think is the right thing, they suffer moral distress," Grace notes. ■

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Ethicists Explain Worst-Case Scenario Policies While Exercising Caution

Clinicians nationwide suddenly have multiple urgent concerns on hypothetical COVID-19 scenarios. They are turning to ethicists for answers.

At Columbia, MO-based University of Missouri Health Care (MU Health), clinicians' concerns revolve around mostly these three scenarios, says **Lea Brandt**, PhD, OTD, MA, OTR/L:

- Patients who are positive (or presumptive positive) for COVID-19, but want to leave the hospital against medical advice;
- Moral distress stemming from limited visitation for patients on a comfort care pathway;
- How to answer questions about critical care resource allocation policies that could become necessary.

"Our faculty and consultation service is focused on developing ethics-related policies surrounding the COVID-19 response," says Brandt, director of the MU Center for Health Ethics.

Their efforts have targeted the exact same issues with which clinicians are struggling. Ethicists are working on policies regarding balancing the public good with patients' right to leave against medical advice, critical care allocation, and modified visitation. Concurrently, they are determining the best way to make all these new policies available to the public once they are vetted and finalized.

"We want to promote transparency around the preparedness process," Brandt reports.

Institutions need to be fully prepared to make ethical decisions on allocations of scarce resources, although it may never reach that point. "It is important to note that many of the policies with which we are involved focus on preparing for worst-case scenarios," Brandt notes. In terms of conveying information on the policies, it is a balancing act. Transparency is important. "We are also wanting to limit fears that will inevitably accompany policies that offer alternative standards of care based on different ethical guidelines than those typically applied in healthcare decision-making," Brandt says.

The MU Center for Health Ethics is participating in a videoconferencing COVID-19 program, fielding questions from frontline providers. "Through this medium, we are able to communicate the ethical rationale behind various policies and recommended practices," Brandt explains.

One question in particular keeps arising. Some providers question the ethical justification for social distancing. They posited that it would have been more ethical to isolate at-risk groups and allow a rapid spread to

promote herd immunity, with the intent to restart the economy. "They are asking questions of benefit and burden. It is important that we don't completely discount these questions, but rather engage in thoughtful dialogue," Brandt says.

Ethicists explain why constraints on individual liberties are ethically justified. "The short answer is that in a pandemic, the ethical analysis shifts to focus on the public good over individual liberty," Brandt says.

This approach differs markedly from the typical ethical reasoning that is employed in the United States. However, says Brandt, "if the approach of allowing the virus to spread uncontrolled is employed to rescue the economy, there would be a significant increase in lives lost. Thus, social distancing is the ethically supported course of action."

Institutional policies related to the COVID-19 response drew in part on the organization's own 2009 white paper, which focused on pandemic flu.[1]

"In short, we have communicated that in times of pandemic, ethical responses should focus on the goal of having an objective and fair allocation framework that maximizes benefit to populations of patients," Brandt offers.

There is an immense amount of public support and appreciation for healthcare providers right now.

"But in order for the public to continue trusting, we need to be transparent on the possibility of what might happen in the future," 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.

Some hospitals are including COVID-19 pamphlets as part of the admission package, specifically addressing supply shortages. Some communication on this point is better than none, according to Bibler. "People are able to get some sense of what the institution is thinking at that moment," he says.

If there are not enough ventilators for all the patients needing them, a policy response from the organization "is going to be crucial to maintain trust," Bibler stresses. Concerns in this regard are entirely legitimate. "The public would be very right to say distribution can be unfair and unequal if it's based on a clinical decision at the bedside rather than policy-level guidance," Bibler says.

Lack of policy guidance "usually means a lack of equity in these decisions," Bibler says. "That is where the public should fight back very hard to say, 'I don't trust you to make these sort of bedside, ad-hoc decisions.'"

The downside is that openness on policies to ration care risks needless panic. "Such documents are easy to misinterpret," Bibler says. Information given to patients might cover these specific issues:

- The ethical basis for allocation and triage decisions, and that these are necessary to improve the survival and long-term health for as many patients as possible;
- Some patients may not receive the machines and medicines they would during non-pandemic times;
- A promise to allocate resources as fairly as possible.

"The right of patients to receive interventions, not just say no to interventions, but to receive interventions, is kind of foundational in American medicine," Bibler says.

It is only in this type of public health emergency where the shift from the individual to the community seems justified to people. "In other less-resourced communities and countries, that shift happens often," Bibler notes. "It doesn't take an emergency. It's daily care."

As if it was not enough of a challenge to create a policy in alignment with the current professional consensus — and to navigate public scrutiny — ethics also has to do so on short notice. That is different from how ethics usually operates. "The role of ethics is typically to slow down the process. A lot of that process is being short-circuited," Bibler observes. "There's going to be ethical nuances and complexity that's lost."

This could result in policies that are less helpful at the bedside than intended. "The policy should be specific enough that if you hand it to a healthcare professional, they could read it, understand it, and implement it," Bibler says.

The policy also needs some wiggle room so it is not instantly outdated if some aspect of medical care changes. "What institutions are thinking right now is: It's better to err on the side of having a policy that isn't perfect, rather than having no policy guidance at all," Bibler says. ■

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COMING IN FUTURE MONTHS

- Ethicists speed response times for consult requests
- During crises, facility leaders listen to ethics
- What to say to families still hoping for a miracle
- What to do when families threaten litigation

With Remote Ethics Consults, Nonverbal Communication Is Lost

Face-to-face communication is a cornerstone of ethics consults. Today, because of the ongoing COVID-19 crisis, consults are handled remotely.

"This requires new techniques for communicating with all stakeholders," says **D. Micah Hester**, PhD, a clinical ethicist at Arkansas Children's Hospital and chair of the University of Arkansas for Medical Sciences' Department of Medical Humanities and Bioethics.

Usually, ethicists gather input from many people affected by a patient's care situation. Now, they have to carry out these tasks by phone or through a screen.

"Remote consults are being done by phone, FaceTime, or any other legitimate communication medium — the more secure, of course, the better," Hester explains.

The same is true if ethicists are meeting with hospital leaders, which is happening much more often. "Clinical ethicists have refocused priorities somewhat away from bedside consultation," Hester reports.

They are more involved in the development of ethically grounded guidelines of care during a pandemic and educational materials. "Work with hospital leadership is typically done through an online meeting platform like Zoom or WebEx," Hester notes.

The need to avoid in-person communication is a particular challenge for ethicists.

"All consultants must change their practices, especially minimizing face-to-face encounters, because of the risk of transmission and the need to preserve PPE [personal protective equipment] in the hospital," Hester says.

Ethicists conduct "teleconsults" either at home or in office with doors closed and physical distance from co-workers.

"Sometimes, access to records and policies can only happen through institutional computers on the local area network," Hester explains.

Ethicists at Houston Methodist Hospital are handling almost all consults remotely. "It's definitely been a shift," says **Janet Malek**, PhD, director of the biomedical ethics program for the Houston Methodist System.

Normally, ethics consults include plenty of talking, mostly in-person, with patients, families, and clinicians. The remote consults miss all the communication that happens through facial expressions and body language. "Phone-based communication loses that. It is harder to be effective. We find it is really important to actually be in the same room," says Malek, associate professor at Baylor College of Medicine's Center for Medical Ethics and Health Policy.

For example, a family member's body language, or nurse's facial expression, can signal he or she disagrees with others. "This can lead to further discussions," Hester observes. "Without those cues, it is difficult to dig deeper sometimes."

For now, ethicists conduct in-person consults only when it is absolutely necessary.

"We are only going into the hospital for extraordinary situations," Malek reports.

If it is a large, multidisciplinary meeting with family members present, "it's hard to imagine being effective in that role if conversations are being held via WebEx," Malek offers.

In-person consults also might happen if a high-stakes decision is made.

"We agreed that we will only go into the hospital if the issue is important enough, and if we can't effectively help remotely," Malek adds. ■

Transparency Is Central Ethical Concern During COVID-19 Pandemic

Controversies over rationing of ventilators, vulnerability of healthcare workers, and resource scarcity are just some of the ethical topics hotly debated and discussed during the COVID-19 crisis. "These open public conversations are a welcome side effect in an unfolding tragedy," says **Margaret R. McLean**, PhD, director of bioethics at Santa Clara (CA) University Markkula Center for Applied Ethics.

The severe acute respiratory syndrome (SARS) outbreak in the early 2000s spotlighted the importance of developing an ethical framework for medical decision-making well ahead of needing it, McLean says. "The response to SARS was a public health success, stamping out the illness with rigorous infection

control," she reports. Although medically successful, the response to SARS spotlighted ethical concerns over a lack of transparency regarding necessary physical restrictions and inevitable rationing. "Perhaps most damaging was the loss of public trust," McLean laments.

After the crisis passed, a University of Toronto study highlighted that developing an ethical framework before disasters helps leaders make better-informed, values-based decisions.[1] "It also engenders public trust, easing fear and reducing misinformation," McLean adds.

Transparency — from government leaders, medical experts, and news outlets — is crucial, McLean stresses. "An ethical response to COVID-19 demands our better selves, relying on hard data, telling the truth with conviction, and rebuilding trust," she underscores.

Some ethical decisions are heartbreaking to make, but clearly are necessary. "COVID-19 confronts us with a different kind of decision, the tragic choice, in which every available option is simply unacceptable," says **Samuel Gorovitz**, PhD, professor of philosophy and former dean of arts and sciences at Syracuse (NY) University. Gorovitz was a member of a 2015 New York state task force that updated voluntary guidelines on how to triage patients in the event of an influenza pandemic.[2]

Clinicians unlucky enough to be such decision-makers deserve the utmost empathy, Gorovitz says. "They are in such positions only because they are courageously striving to minimize harm, even as they face harm themselves," he notes.

To minimize fear that decisions might be made unfairly, people must know what guidelines or mandates have informed them. "We confidently assume that a patient's politics are irrelevant. We hope that a patient's wealth or political connections are irrelevant. We wonder whether a patient's age is relevant, and if so, how," Gorovitz observes.

People hope disability is irrelevant. "Only if there is transparency about how such parameters matter can we have confidence that fairness pervades the process," Gorovitz adds.

There are long-term ethical implications at stake, too. "If we do not have that confidence now about COVID-19, it will be difficult at best to secure it in the future for other public health crises," Gorovitz cautions.

Transparency and truth-telling are foundational ethical values in medicine and in public health, says **Craig M. Klugman**, PhD, a professor in the department of health sciences at DePaul University in Chicago. Klugman has been involved in writing crisis and pandemic plans for states, cities, and health centers, with transparency always a key focus. "People can deal with adversity and disappointment," Klugman says. "What they can't deal with is what they don't know about."

Efforts to hide or soften information may make people feel more secure in the short term. "But when the reality comes out — and it always does — they will feel betrayed and lied to," Klugman observes.

Once people stop believing healthcare providers and public health officials, they no longer heed important messages. Changing COVID-19 recommendations already have presented a challenge. Initially, people were told they should not wear masks, based on the fact that a limited supply needed to be saved for healthcare providers, and also that masks would not fully protect people. "What we did not know at that time was the likely large numbers of asymptomatic carriers," Klugman notes.

Since wearing masks can prevent spreading the virus, updated recommendations now call for wearing homemade masks. "Some very knowledgeable people are expressing hurt that they should have worn masks weeks ago, and they feel 'stupid' for having heeded the original recommendations," Klugman explains.

The first recommendations were based on the best available information at the time, but this may have been lost on some people. "Trust is essential for getting through this time with the least injury," Klugman stresses. "The basis of trust is transparency."

When there is a public health emergency, "the tendency is for people in charge of the response is to sort of go into a bunker mentality," says **Alison Thompson**, PhD, associate professor at the University of Toronto Leslie Dan Faculty of Pharmacy. In fact, the exact opposite is needed. "This is a strategic issue, but is also an ethical one," Thompson offers.

For public health, the "default" setting is to be transparent, unless there is an excellent reason not to be, Thompson explains. Some exceptions: If the information could affect national security or police investigations, violate privacy laws, or stigmatize certain ethnic groups. If people feel they are not hearing the whole story, or that data are fudged, it becomes an ethical concern. "Then, we're going to see problems with compliance with public health measures," Thompson warns.

Still, the natural reaction is to control messaging tightly in this kind of situation. "We've seen this in places like China, where they very much had a politically governed response rather

than a public health-driven response," Thompson notes.

Public health officials are now walking a tightrope between convincing people to act and not causing panic. If officials are seen as overreacting, it could mean long-term adverse consequences in terms of trust when the next outbreak hits.

"It's an age-old problem for public health," Thompson laments. "The absence of an event is usually a sign of success. But then people scratch their heads and say, 'What was that about?'"

Unlike in previous public health emergencies, there is the added issue of massive amounts of information shared via social media — sometimes prematurely.

"We still have a long way to go to figure out how to make data transparent in a way that isn't confusing to people," Thompson reports.

Transparency does not just mean the indiscriminate release of information. It needs to be interpreted in a way that is useful. "When you've got all these data streams coming at you from all these different media information sources, you can't figure out what's going on," Thompson says.

It is far from easy to build trust during a pandemic, "but it's certainly possible to make it worse," Thompson concludes. ■

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Shortcuts in Clinical Trials May Cause More Harm Than Good

All clinical trials raise certain ethical issues. "But trials conducted during epidemics are especially difficult, both ethically and practically," says **Charles Weijer**, MD, PhD, professor of philosophy and medicine at Western University in London, Ontario, Canada.

Dozens of potential treatments for COVID-19 are under investigation: existing antiretrovirals, anti-malaria drugs, monoclonal antibodies, and Chinese traditional medicines among them. Additionally, companies are rapidly developing new drugs.

"It is critical that any new treatment for COVID-19 be rigorously evaluated in one or more randomized, controlled trials," Weijer stresses.

Uncontrolled trials that yield no conclusions "are themselves inherently unethical," according to **Gerald T. Keusch**, MD, professor of medicine and international health at Boston University School of Medicine. Keusch co-chaired a committee for the National Academy of Medicine on the clinical research response during the West Africa Ebola epidemic in 2014-2015.[1]

Poorly designed studies subject patients to the risks of adverse events without learning if the intervention works. That is ethically problematic.

"There is an ethical obligation to employ rigorous trial design that can provide answers about efficacy and safety," Keusch says.

Investigators are testing drugs in Phase III randomized, controlled trials with hundreds of patients on the basis of "very minimal evidence" indicating these are likely to work, Weijer notes. There are several key ethical issues to consider:

• It is unclear whether investigators are adequately protecting the welfare interests of patients in COVID-19 clinical trials.

• Failure to conduct prior research in animal models and Phase II trials with smaller groups of patients generally is thought to violate equipoise. This requires that at the start of a trial there be a state of honest disagreement as to the preferred treatment.

"But if there is no evidence in animals or humans that a drug has an effect against COVID-19, how can we say equipoise exists?" Weijer asks.

• Proceeding directly to Phase III trials may not be a responsible use of resources.

"The worry is that we may be exposing patients with COVID-19 to ineffective or possibly harmful treatments that could have been weeded out with smaller preliminary trials," Weijer observes.

• The sheer number of treatments under evaluation is affecting ongoing and planned clinical trials for other diseases. An increasing number of clinical trials globally are putting recruitment on hold. This slows the pace of other medical research.

"Should some of these trials be postponed or canceled, this would undermine the social value that was

key in the ethical justification for enrolling human volunteers," Weijer warns.

• The use of unproven interventions for COVID-19 outside of ongoing clinical trials is ethically worrisome.

"It seems as though every modern epidemic starts with unwarranted enthusiasm about untested treatment, only to be corrected by time, experience, and evidence," Weijer notes.

Thus, clear public health messaging is critical. "Plainly irresponsible messages about some unproven treatments, including malaria drugs, have already cost lives," Weijer laments.

Off-label uses of drugs for COVID-19 treatment, "based on hype and weak data, is one of my biggest ethical concerns right now," says **Holly Fernandez Lynch**, JD, MBe, assistant professor of medical ethics and health policy at University of Pennsylvania Perelman School of Medicine. Such practices may backfire, says Fernandez Lynch, because they likely will inhibit rigorous investigation.

That is the case not only for off-label use of approved drugs, but also for drugs that are not yet approved for any use.

"We're taking a big gamble that these off-label uses are going to be safe and effective, and that they're going to be better than some of the other options under investigation," Fernandez Lynch cautions. Another concern is that patients will favor certain investigational options over others, based solely on the amount of media attention they receive. "Patients will likely have a preference for what they can actually get their hands on," Fernandez Lynch predicts.

This favors off-label prescribing over unapproved drugs, but not for strong scientific reasons. This speaks to a need to make clinical investigations more accessible.

"That can be a challenge in emergency circumstances," Fernandez Lynch admits. "But it is even more critical because of them."

Poorly designed trials could lead patients and providers to form treatment preferences that are not supported by actual evidence of efficacy.

"This can lead to the widespread use of ineffective or harmful interventions, and delay recruitment into studies that would tell us what actually works," says **Alex John London**, PhD, director of the Center for Ethics and Policy at Carnegie Mellon University in Pittsburgh.

In reality, the vast majority of medical interventions fail in clinical testing; about half of those fail in Phase II testing.

These are cases in which researchers have had time to pick the best candidates for an indication and to conduct carefully planned studies before introducing the intervention into humans.

"Just because a treatment is urgently needed doesn't mean that it is going to be easier to discover," London notes.

Well-designed clinical trials play an important role in epidemic response, according to a National Academy of Medicine report.[1] "When there are no established effective treatments for a disease, new interventions should be tested as early as possible in well-designed, randomized clinical trials," says London, one of the committee members who wrote the report.

The goal is to quickly generate reliable medical evidence so physicians know whether an intervention is likely to help or harm a patient. This also helps policymakers know that scarce resources are not squandered on interventions that are ineffective or even harmful.

Clinicians have the discretion to prescribe drugs already approved to treat one condition on an off-label basis.

"But in an outbreak of this size, that practice risks creating the perception that a drug works for a new indication when that has yet to be established," London cautions.

It also can make it more difficult for patients to access those drugs for the indications where they have been proven to be effective. Additionally,

if trial administrators cannot recruit enough participants, the information they produce can be misleading. Likewise, if trials are not coordinated with similar endpoints and measures, it is going to be difficult to compare their results.

"This makes research less efficient, and that raises questions of justice," London says.[2] Protocols that establish a single approach for testing multiple interventions across different clinical centers is a way of conducting trials quickly. "This ensures that the many different stakeholders who rely on that information can make better decisions," London says. ■

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The COVID-19 Vaccine: Usual Ethical Questions in Unusual Times

Informed consent, protection of human subjects, fairness of testing, and eventual distribution: These all are important ethical questions and considerations surrounding the development of a COVID-19 vaccine.

"One of the questions I keep hearing is whether we are going to see a short-circuiting of decision-making, and shifting of ethical goalposts," says **Marian W. Wentworth**, president and chief executive officer at Management Sciences for Health, an Arlington, VA-based nongovernmental organization providing healthcare development support in low-income countries.

The underlying ethical principles are the same as with vaccine development in general. Researchers always want to ensure they are conducting a study with scientific merit. They always need the ability to create reasonable informed consent for study subjects.

"What's changing now is external circumstances and the lack of normative data to answer ethical questions," Wentworth notes.

People have come to understand that masks are necessary to protect others from virus exposure as opposed to protecting the person wearing the mask. **Shira Shafir**, PhD, says a similar mindset is needed when it comes to participation in vaccine trials. "It needs to be made very clear to participants that they are participating in the vaccine trial as a service to society, and not the potential protection of self," says Shafir, faculty assistant vice chancellor for research ethics at the UCLA Fielding School of Public Health. Researchers must ensure individuals realize they are likely susceptible until the vaccine is approved and brought to market, Shafir adds.

Trial participants are taking on more risk than they would if they were trialing an approved licensed product that is used for its designated purpose. With COVID-19 vaccine research in particular, says Wentworth, "the difference is, you can't find somebody who is not at risk of the disease. It will be difficult to ensure that they understand that they are unlikely to benefit."

This contrasts with other vaccine trials, where the first patients studied have no reason to believe that they can benefit from the vaccine. For example, a healthy adult receiving the first dose of a vaccine for a childhood disease is unlikely to expect any direct benefit. "The work that ethicists still have to do is to figure out where there's sufficient scientific merit and sufficient informed consent," Wentworth offers.

The prospect of paying participants to test a COVID-19 vaccine is ethically controversial.[1] "There is always lots of concern about paying healthy volunteers," Wentworth notes. The central question is whether financial compensation is appropriate due to subjects taking on additional risks, or whether it is exploitative to vulnerable populations. This issue is not unique to COVID-19; it has been debated previously in other research contexts. "The questions are the same," Wentworth explains. "But the environment is causing us to think about them from a different angle."

Significant animal safety work should occur before human subject testing. "Whether or not you get regulatory approval, you are still trialing in massive amounts of patients," Wentworth says. "You are going from tiny numbers of human beings to massive numbers of human beings."

Ultimately, any kind of preventive vaccine is going to be trialed in "huge numbers," Wentworth predicts. This reveals side effects that occur more rarely. "If you really want to do the kind of risk-benefit analysis you

usually do, you will want to study it longer," Wentworth says. "But with so many people sick and dying, how long does a placebo stay relevant?"

The main ethical concern is the push to forgo usual restrictions in how vaccines are tested.

"If we loosen the science that we allow, and we do an end run around best practices in order to try and get a vaccine to market, what we may end up doing is bringing a vaccine that's neither safe or effective," Shafir cautions. This could further deteriorate trust in public health and medical enterprise at a crucial time. "The history of vaccine development is rife with examples of unethical conduct, particularly when viewed from a modern perspective," Shafir notes. The urgency to develop a COVID-19 vaccine stems in part from the recognition that without one, there is no clear path to return to normalcy. "Science sometimes happens slowly and cautiously," Shafir says. "But that does not mean we should cut corners to make things happen faster." For COVID-19 vaccine researchers, the fundamental principles of ethics have not changed. The same question remains: Does the benefit outweigh the risk for participants? "But your ability to calculate the benefit or the risk is severely curtailed by the fact that you don't have a baseline experience," Wentworth says.

In an environment where normal patterns of accessing medical care are shifting so radically, questions are raised on what it all means for research. "How do you even interpret any data that you get from the placebo arms of early trials?" Wentworth asks. "It's a new world." ■

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Healthcare Workers' Well-Being Is Ethical Concern During Pandemic

Half of 1,257 healthcare workers caring for COVID-19 patients in 34 hospitals in China reported depression, 45% reported anxiety, 34% reported insomnia, and 71.5% reported psychological distress, according to a recent study.[1]

These findings point to significant ethical concerns regarding clinicians' well-being. "Society depends on healthcare workers who use their skills to provide for the best interests of patients," says **James G. Adams**, MD, senior vice president and chief medical officer at Northwestern Medicine in Chicago.

Clinicians always face some risk as they carry out routine duties, including acquiring infection or sustaining injury. However, the pandemic has significantly increased these risks, with healthcare providers around the world acquiring the infection at work.

"Importantly, healthcare workers have transmitted the virus to others, including family members, co-workers, and other patients who were previously uninfected," Adams notes. Many healthcare workers have recovered, but some have died. "In this context, there is an obligation to ensure that the healthcare workers are protected," Adams says. There are a few relevant ethical considerations:

- Inadequate protection could result in insufficient numbers of healthcare workers;
- Healthcare workers are not ethically obligated to assume undue, excessive risk of harm to carry out their professional duties;
- There is a duty to protect healthcare workers to prevent harm to others (family members, colleagues, and other patients for whom they provide care);
- As healthcare workers care for patients, it is reasonable for society to ensure these people are protected.

"Without a sense of reciprocal obligation, the social compact between healthcare workers and patients will weaken," Adams cautions.

People understand well healthcare workers' professional obligations to patients. The reverse is not. "The obligation of society and the hospital to healthcare workers is not clear, and is not explicitly and broadly recognized," Adams adds. ■

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CME/CE OBJECTIVES

Upon completion of this educational activity, participants should be able to:

1. Discuss new developments in regulation and healthcare system approaches to bioethical issues applicable to specific healthcare systems;
2. Explain the implications for new developments in bioethics as it relates to all aspects of patient care and healthcare delivery in institutional settings;
3. Discuss the effect of bioethics on patients, their families, physicians, and society.

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CME/CE QUESTIONS

1. **Which is true regarding hospital policies for allocating scarce clinical care resources?**
   a. Consistent policies statewide are unethical because it puts specific groups at a disadvantage.
   b. Physicians experience more moral distress if policies are in place, compared to making decisions on an individual basis.
   c. Autonomy should not give way to utilitarian considerations, regardless of how scarce resources become.
   d. A definite "trigger" should signal when to shift clinical decision-making from the traditional model based on medical principlism to a resource allocation model.

2. **Which should ethical responses focus on during the pandemic?**
   a. Maintaining an objective and fair allocation framework that maximizes benefit to populations of patients
   b. Maintaining patient autonomy over the public good
   c. Avoiding communicating worst-case scenarios to prevent needless panic
   d. Publicly discounting questions on the need for social distancing

3. **Which is true regarding transparency during a public health emergency?**
   a. Transparency is ethically required, even if privacy laws are violated.
   b. The "default" setting is to be transparent, unless there is an important overriding reason.
   c. Whether certain ethnic groups will be stigmatized should not be taken into consideration.
   d. Responses should be politically governed.

4. **Which is true regarding clinical trials during a pandemic?**
   a. Rigorous evaluation in randomized, controlled trials is no longer appropriate.
   b. There is an ethical obligation to dispense of the need for equipoise.
   c. The use of unproven interventions for COVID-19 outside of ongoing clinical trials is ethically problematic.
   d. Protocols that establish a single approach for testing multiple interventions across different clinical centers are unethical.