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## Ethical Issues Related to COVID-19 Treatments

Incorporating ethical principles of healthcare when resources are strained is a daily challenge; healthcare workers across the U.S. had to manage extraordinary patient loads and issues associated with treatment and vaccine distribution throughout the COVID-19 pandemic. ASPR TRACIE met with the following subject matter experts (listed alphabetically) to learn more about how they managed ethical challenges during the COVID-19 pandemic in their states (Minnesota, Washington, and Pennsylvania) and their thoughts on adjusting expectations for the future:

- **Debra DeBruin**, PhD, Interim Director and Director of Graduate Studies, Associate Professor, Center for Bioethics, University of Minnesota
- **JP Leider**, PhD, Senior Fellow, Division of Health Policy and Management, Affiliate Faculty, Center for Bioethics; Director, Center for Public Health Systems, University of Minnesota
- **Vicki Sakata**, MD, Senior Medical Advisor, Northwest Healthcare Response Network; and University of Washington, Mary Bridge in Tacoma
- **Douglas B. White**, MD, MAS, Vice Chair and Professor of Critical Care Medicine; UPMC Endowed Chair for Ethics in Critical Care Medicine; Director, Program on Ethics and Decision Making in Critical Illness; University of Pittsburgh School of Medicine

### ■ John Hick (JH)

**There was a lot of variability in how states allocated vaccines and treatments. What are some promising practices you would like to share? And what lessons did you learn about allocating treatment during a pandemic?**

### ■ Debra DeBruin (DD)

Overall, there is a balance that needs to be struck between allowing a tailoring of approaches to contexts, ensuring that plans are responsive to the needs of a particular area, and carrying out a consistent response to help avoid unfairness. From an ethics point of view, this balance is a key issue.

### ■ JP Leider (JPL)

I agree but I also approach the question from a different vantage point. You can set up frameworks and expectations ahead of time so when you approach scarcity you aren't scrambling to make the hard decisions on top of other hard decisions. In Minnesota, we have tried to be proactive over the last 15 years by, for example, engaging the public in our process. When we came together to discuss allocation in early 2020, we already had agreed-upon goals which were built upon fairness and equity. It is also worth noting the different classes of resources. One framework does not apply across the board; you should have different frameworks for different countermeasures.

■ JH

**Did you sense that there was disappointment about the guidelines or lack of guidance coming from the federal government?**

■ DD

It depends on the resource. In some cases – for example, with new therapies such as monoclonal antibodies made available through Emergency Use Authorizations – the lack of guidance reflected, at least in part, an initial lack of data to ground clinical priorities. As more data became available, it was possible to create better guidance. On the other hand, the level of inconsistency with access to vaccines across the country was troubling from an ethics point of view, as it undermined equity. It seems undeniable that fairness and equity ought to be one of the driving commitments in resource allocation.

As JP mentioned, in MN, our foundational ethics framework was clearly established before the pandemic. That has made the work much more manageable in response to COVID-19. One of the driving priorities is protection of the public's health. There is convincing analysis, however, that if you focus solely on a utilitarian concern with outcomes such as saving the most lives or getting as many people vaccinated as quickly as possible, you will perpetuate inequities. Groups that are disadvantaged during “normal” times invariably fare worse than more privileged groups during crises, unless our response specifically commits to addressing equity. We've seen that play out during COVID-19.

■ JH

**To complicate matters, when vaccination efforts were targeted in areas of Minnesota where social vulnerability indexes were high, people came into those areas from elsewhere; our most well-intentioned frameworks may get tripped up in a crisis like this.**

■ JPL

That's a fair assessment. For example, there were significant disadvantages where people from more well-off communities were coming into more socially vulnerable communities to access vaccines. Everyone wants access and everyone has some claim. It's up to the government to manage that.

The Trump and Biden administrations had different philosophies when it came to vaccines. The previous administration pushed speed over equity. Dr. DeBruin and I have both highlighted the early advantage people who were white and more privileged had over communities of color; it took months for these communities to get access to vaccines. This failing of vaccine policy exacerbated inequity. Age is easier to operationalize—and early on it even made sense from a risk perspective. People 80 and older disproportionately died from COVID-19—but when we had to decide who got priority for vaccines next and settled on just going to the “younger” groups, we could and should have done better. We ended up witnessing an equity gap in disaster resource allocation on perhaps the largest scale in history.

■ DD

What JP said is a clear concrete example of what I was talking about, balancing a utilitarian concern with protecting population health in the most efficient way while also living up to your commitment to equity. JP is right that focusing on age as a proxy for risk in vaccine allocation created inequities. The same is true of the strong emphasis placed on speed in vaccine allocation. On the one hand, we wanted to get as many people vaccinated as quickly as possible to improve outcomes overall. That said, privileged people have better access to care, for complex reasons (for example, ability to pay, ability to take time off work, access to information, trust in healthcare). It really was quite predictable that when emphasizing speed, groups experiencing inequities would (and did) have worse results.

## Related Resources

### ***MNRAP***

[COVID-19 Medication Options](#)

[New System Connects Patients with COVID-19 Outpatient Treatments](#)

### ***MASS***

[Clinical Prioritization of Antispike Monoclonal Antibody Treatment of Mild to Moderate COVID-19](#)

[Monoclonal Antibodies for COVID-19: Mayo Clinic Process and Outcomes](#)

■ JH

Can you tell us about MNRAP, how it was used, and its strengths and limitations?

■ JPL

When outpatient-based monoclonal antibody cocktails became available in late 2020, we were concerned about the equity of access in our state. That is where the idea for the “Minnesota Resource Allocation Platform” ([MNRAP](#)) was born. The web-based screening tool was developed by the University of Minnesota and the Minnesota Department of Health (MDH).<sup>1</sup> Users could fill out a brief questionnaire to determine their eligibility for monoclonal antibody (mAb) therapy; if they qualified, they would be connected to convenient site to receive infusions, whether they were already affiliated with a health system or not. We wanted to make sure anyone in the state could have access to these effective medications.

During surges associated with the Delta and Omicron variants, we were at our most active, with well over 75,000 referrals. An important function of MNRAP was to equitably allocate mAbs when supplies of the therapy, or appointment availability, were insufficient to meet patient needs. MNRAP was set up to implement clinical prioritization, or a lottery, if needed. Patients with a higher monoclonal antibody selection “score” (MASS) got prioritized access to the treatment (e.g., [Razonable, et al. 2021](#), [Bierle, et al., 2022](#)) during periods of scarcity.

One challenge was that MNRAP was only available online and in English, though we did work with interpreters to help patients in near real-time, but it wasn’t an ideal situation. Nonprofit organizations also stepped up to help with access. Now because resources are less scarce, everyone who meets FDA criteria gets access to treatment; the website will be sunsetted in the coming months, we think.

■ JH

You were fortunate that you didn’t have use a lottery before the scores were validated; that would have been a more challenging scenario.

■ JPL

Extremely! A faculty member at the University of Minnesota was working on risk predictors for COVID-19 at the same time the MASS system was being developed. This faculty member had some idea of risk conditions and decided to align the FDA EUA criteria against Mayo Clinic patient data. He validated their study with 40,000 of his patients, making clinicians very comfortable with this kind of statistically sound scoring system. The federal government had not provided that kind of criteria for hospitals or states to use. Information from the National Institutes of Health was somewhat useful, but the Mayo Clinic and University of Minnesota data were very important. The system proved to be very helpful for clinicians, particularly when resources were scarce.

Anytime we were in scarcity if there were appointments left over—with enough doses but not enough appointments for everyone—we used up any appointments even if there was a MASS score of 0. But then we ran out of doses, we started being more cognizant of how many people would need to receive mAbs to prevent hospitalizations (sometimes referred to as “number needed to treat” or NNT). Those who were eligible but with lower MASS had an NNT in the dozens or even hundreds, but above our threshold of 4 points, the average NNT to prevent a hospitalization was 4 patients or fewer per Mayo’s analysis. To get 4 points, you had to be immunocompromised, being 65 or older was 2 points, diabetes was 2 points, obesity was 2 points.

*The MASS system was developed by the Mayo Clinic and is based on the [FDA Emergency Use Authorization \(EUA\) eligibility criteria issued in November 2020](#). Risk factors include (but are not limited to): age, coronary artery disease, chronic kidney disease, diabetes, hypertension, and pulmonary disease.*

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<sup>1</sup>[MN DOH](#) states, “As of April 4, 2022, the public or their caregivers are not able to submit their information directly to MNRAP. As new COVID-19 treatments have become available, and as the pandemic has evolved, there is now a need for providers to do a more detailed assessment before choosing a treatment option, such as reviewing medications or lab work. Talk to your health care provider if you have questions about COVID-19 treatments.”

■ JH

**And Minnesota never ended up implementing points for public facing essential workers, is that correct?**

■ JPL

We were getting to a point where nonclinical factors were about to be implemented, but then the wave crashed. So, it never ended up being employed. High-risk workers and skilled nursing facility residents would have gotten a bonus to their lottery chances.

■ JH

**Can you talk about reciprocity and instrumentality and how those two factors may or may not be used in weighting allocation?**

■ DD

First, I'd like to say that MNRAP is a striking example of the way response relies on partnership between clinicians, public health staff, and ethics professionals who provided data, clinical expertise, and the ethical foundations upon which to allocate monoclonals. One thing I really appreciate about response efforts in the state of MN is the collaboration across professional groups.

About workers: from an ethics point of view, we have duties of reciprocity to essential workers, meaning that since they take on risk to provide essential services to us, we owe them protection in return. Instrumentality means we need to keep essential workers healthy – or help them to recover as soon as possible if they get sick – so they can continue to provide the services that we rely upon. These considerations may affect response plans differently at different times in the crisis. For example, early in the pandemic when there was no vaccine available and personal protective equipment (PPE) was scarce, reciprocity considerations were strong. As PPE became more plentiful and vaccines became available, duties of reciprocity weighed less heavily in our response efforts. So, it is important to think about these considerations in context, to determine how they should affect our response efforts. If it is justifiable to give some groups of workers priority in allocation of resources based on the nature of the services they provide and the level of risk they face, you then need to devise a way to operationalize that priority. For example, how many points should be associated with worker status in a scoring system to determine allocation priority?

■ JH

**As you mentioned, MN had those dialogues established based on ethics projects in the state that produced guidance in 2010, and 2016. Many states weren't prepared in that way; some chose to use a lottery. How can states and we as a country come up with a more consistent system in the future, and what does that system look like?**

■ JPL

We need to describe it in a different way and we need flexibility. When you centralize the allocation system you hear about all kinds of issues with the systems, such as appeals by people who want access. If you decentralize it, you cannot be sure how deep the issues are. In Minnesota, we have multiple after-action reviews on how the system worked and lessons we need to incorporate for future events. It seems to me for scarce resources in the future, a centralized apparatus needs the ability to go from rationing to not rationing and be flexible. We also need to address weakness in the system where it can be shown that patients have taken advantage of their privilege. It doesn't make sense to blame that patient for playing by the rules, but that doesn't mean the rules were fair to begin with.

■ JH

**How can we ensure providers will abide by a suggested framework? If we leave it to the provider level, it will be still used inconsistently and equity will remain an issue.**

■ JPL

There's something to be said for making sure every provider has to do the same thing. Are you going to audit them? Is this a situation where I should use the process, will I be in scarcity? There's a lot of fungibility even with the best crafted systems. Even in our well-functioning system, inconsistency was an issue.



■ DD

It does become complicated here. You want to allow a certain degree of professional judgement when a provider is faced with individual patients. You want to give them leeway when faced with a patient who doesn't meet a certain criterion, but appears high-risk, nonetheless. That's different from getting access based on personal relationships, which disadvantages folks who are already disadvantaged. It might not make sense to use MNRAP for all resources. In fact, we elected not to use it to allocate the oral antivirals. And there needs to be a feedback loop—such as data reporting, and after-action reports—to ensure accountability and the opportunity to adjust when it becomes clear that problems are arising.

■ JH

**To what level should our state and interstate processes intersect?**

■ DD

I think it is really important for states to learn from one another. There were a number of forums during this pandemic to facilitate that sort of dialogue. For example, ASPR did a great job providing opportunities for us to explore these issues nationally. After-action reviews should identify areas where it is important to plan together with other states for future response efforts.

■ JPL

In Minnesota we are fortunate to work with MDH, and while our state's ideas may not “fly” ideologically in other states, we could come to an agreement about other issues. For example, you could you come to an agreement for reimbursement for people who live in Minnesota being treated in a neighboring state. Those conversations you could have.

■ JH

**In Minnesota we were lucky not to have interference in the dialogue and conclusions that ethics, public health, and clinicians forged. Dr. DeBruin, you mentioned the importance, when considering several disabilities, age-advocacy groups, and so on, of parsing the implications, the science, and the mechanisms we had to distribute assets. Our meetings were more than once a week and we iterated this so many times based on the changing evidence and changing pandemic. Can you expound on this being a responsive process?**

■ DD

I agree that it is critical for guidance to be developed in a process that is responsive and iterative. For example, we would create a framework for a new therapeutic and then change that framework as needed—as the availability of resources changed, or new data became available that could guide clinical prioritization, or we learned about operational challenges that required adjustments to plans. You are right, you cannot set frameworks in stone in advance at the level of detail that is needed to operationalize them. That may seem to conflict with what we said earlier about the importance of having frameworks already established prior to the start of a crisis, but those foundational frameworks are still critical. They are needed to guide development of specific response plans in a crisis. You're never going to create a framework that is tailored to a particular crisis and all its nuances until you are in the moment. For example, who counts as a critical worker may vary crisis to crisis, and the risks that workers face depend on particular circumstances such as the availability of PPE. The issues are predictable, and harder to sort through in the midst of crisis.

*A foundational framework established prior to the start of a crisis should guide whether and when some workers should get priority in allocation of resources, or in principle what the limits to their duties to provide services might be, but we can't work out details until the realities of the crisis become clear. This does not mean that foundational frameworks can only address high-level philosophical issues and not operational ones. For example, since we know that people cross state borders to access care even during “normal” times, we should develop pre-existing agreements among bordering states about how to meet the needs of all patients when states are allocated resources by the federal government based on data from their particular state (for example, state population or case incidence).*

*- Deb DeBruin*

■ JH

Candid dialogue in these situations relies on having the right people at the table who are engaged. We also need to ensure providers aren't held responsible for things that are decided systematically. For example, with monoclonal allocations going through MNRAP, if a provider was sued for not giving the treatment, the individual clinician should be protected.

■ DD

While we developed guidance in Minnesota, providers were included as experts, but were not there to formally represent their organizations. Individuals provided critical input but their views were not attributed to them personally. It would undermine the ability to engage people in good faith in developing guidance if individuals were held liable for the guidance. Ultimately, it is the responsibility of the state to decide whether it will accept and implement guidance developed by advisory groups or not.

On the implementation side, if there is guidance from the state, there must be related liability protections, since crisis response is not business as usual. How a clinician will provide care during a response will be different than in non-urgent times.

■ JH

**Do you have any other thoughts on this topic you'd like us to capture?**

■ JPL

Throughout all this I've been very motivated by my chagrin that what we knew would happen, happened. Disadvantaged communities going into the pandemic were disadvantaged coming out. The BIPOC-white mortality gap was worsened. Maybe with the advantage of retrospect, we might be able to depoliticize this next time. Whether we have 10 years or 40 until the next pandemic, we can't have this again.

And when I examine the death data in our state, it shows that COVID-19 mortality and excess mortality in general increased in 2021 compared with 2020, even though we had vaccines. How can we get people to listen to science? How do we depoliticize social justice? We will be dealing with the impacts of that forced tradeoff for quite some time.

■ DD

We need better communications about science. We also need discussions of individualism versus the pursuit of common good; we need better understanding about when it is justifiable to limit individual liberty to promote the common good. Finally, I agree with JP that equity issues have been among the most haunting of this pandemic; we need to address them when we are not in crisis mode to ensure they are not exacerbated during a crisis. Disparities are a crisis in themselves; they constitute inequities even during normal times, we need to address them for their own sake.

■ JH

Fair to say, the best time to work on those trust issues is between pandemics; in the middle of a pandemic is the worst time. Thank you so much, operationalizing ethical resource allocation is something we have learned much about but we have so much more to do.

**A note from Dr. Vicki Sakata, Senior Medical Advisor, Northwest Healthcare Response Network; and University of Washington, Mary Bridge in Tacoma**

Some of the difficulties I've seen in other states are related to the complete inability for smaller communities with fewer resources to undertake the huge efforts needed to address many of these complexities. Allocating and operationalizing ethical constructs can be overwhelming and a difficult personal burden for many to undertake. Although there were definitely strong efforts made at the federal level, "one size does not fit all." And when it comes to resource allocation, every health official wants to address the decisions/concerns of their own communities (as they should).

Personally, all the tools, concepts, scores, and frameworks are important. But the bottom line in scarce resource allocation is someone is not going to get the resource or is going to get the resource later than others. There are two main pillars in making those decisions: 1) the right science and 2) operationalizing the ethical constructs **while maintaining scientific rigor (bold print intended) (i.e., we can't change science just because it doesn't meet ethical scrutiny).**

I have also found that if you get 20 ethicists in a room together you will get 20 different opinions. I feel clinicians often waver as to their clinical decisions when faced with an ethicist. I've found that operationalizing ethical constructs depends largely on relationships within your community, especially those marginalized or specialty population advocates. Everyone wants to and deserves to be heard. This task **MUST** start happening now. And this must be a priority **especially** in smaller communities with few resources. In the future I can see these smaller communities feeling more comfortable using federal/state resources and assistance **as long as they have these relationships built first**. These relationships cannot be built in the heat of the moment especially in an environment of stress and mistrust.

I would also like to point out (hopefully) the obvious: much of the inequity and ethical dilemmas we have faced over the past two years are not due to the pandemic or even due to the allocation decisions made during the pandemic. It's the sad fact that decades of healthcare inequality have **produced** marginalized and at-risk groups. If we lose sight of this bigger problem, we will have lost the forest for the trees. And if we don't address the root cause, the next pandemic will be equally—if not more—heartbreaking.

**A note from Douglas B. White, MD, MAS, Vice Chair and Professor of Critical Care Medicine; UPMC Endowed Chair for Ethics in Critical Care Medicine; Director, Program on Ethics and Decision Making in Critical Illness; University of Pittsburgh School of Medicine**

A valuable case study of one way to center equity considerations when allocating scarce COVID therapeutics is the efforts that have been undertaken by the Commonwealth of Pennsylvania. Building on prior community engagement—and prompted by the authorization of remdesivir in the spring of 2020—the Commonwealth convened a diverse task force to provide recommendations to guide allocation of scarce COVID treatments. This task force was comprised of experts in ethics, healthcare delivery, disability rights, health disparities, and health law. What I found particularly important about the process is that, when developing recommendations, the task force explicitly considered the disproportionate burden experienced to date in the pandemic by disadvantaged communities. Consequently, the task force articulated two main ethical goals for allocation: promoting population-level benefit and mitigating disparities in COVID-19 outcomes among disadvantaged groups ([Pennsylvania Department of Public Health, n.d.](#)).

In essence, the Commonwealth expressed a view that it's not enough for the allocation strategy to not exacerbate existing disparities in outcomes; instead, it should actively lessen those disparities. This is an ambitious goal, because in order to mitigate disparities, one needs to find a way to direct a larger share of treatment to the disadvantaged groups experiencing the disproportionate burden, while also ensuring that the treatment is being allocated in a way that promotes population-level benefit.

In parallel, a working group of scholars convened at the University of Pittsburgh to develop [a weighted lottery to allocate scarce COVID treatments](#), which the Commonwealth endorsed as one reasonable strategy to achieve its ethical goals. A weighted lottery is an attractive allocation strategy when multiple ethical goals need to be achieved simultaneously, such as efficiency and equity ([Jansen and Wall, 2021](#)). The weighted lottery was designed to give all eligible patients a chance to receive the scarce treatment, while giving higher chances to disadvantaged groups who were experiencing the greatest harm from the COVID pandemic. We deployed this lottery across 20 hospitals in Pennsylvania and found that it was effective in achieving the ethical goal of allocating more treatment to disadvantaged populations.

One thing that I wish the Commonwealth would have done is to create a centralized treatment allocation process for the entire Commonwealth ([White and Angus, 2020](#)). This would have promoted equity across the entire population of Pennsylvania AND promoted operational efficiency—the latter of which is a critically important, but neglected consideration. Because this did not occur, in order for health systems to accomplish Pennsylvania’s ethical goals, they needed to build their own allocation systems on the fly. The problem is that this is very hard to do; it is both time-consuming and requires a great deal of expertise that individual hospitals may not have. This operational burden on hospitals was especially problematic because at the time hospitals were badly strained due to caring for huge numbers of patients with COVID.

Even if individual hospitals had the expertise to do this well, it’s quite inefficient to have hundreds of hospitals each essentially reinvent the wheel regarding allocation strategies. I very much admire the work that Debra DeBruin and JP Leider led in Minnesota to create a centralized allocation process for the entire state. It’s an elegant example of a public-private partnership that promoted both equity and population health, which should serve as a model for the other 49 states.