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Developing an Ethics Framework for Allocating Remdesivir in the COVID-19 Pandemic

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Abstract

On May 1, 2020, the US Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) to allow use of the antiviral drug remdesivir to treat patients with severe coronavirus disease-2019 (COVID-19). Remdesivir is an investigational drug studied in clinical trials for COVID-19 and is available to children and pregnant women through compassionate-use access but is not yet FDA approved. In early May, the US Department of Health and Human Services began to distribute remdesivir, donated by Gilead Sciences, Inc., to hospitals and state health departments for emergency use; multiple shipments have since been distributed. This process has raised questions of how remdesivir should be allocated. The Minnesota Department of Health has collaborated with the Minnesota COVID Ethics Collaborative and multiple clinical experts to issue an Ethical Framework for May 2020 Allocation of Remdesivir in the COVID-19 Pandemic. The framework builds on extensive ethical guidance developed for public health emergencies in Minnesota before the COVID-19 crisis. The Minnesota remdesivir allocation framework specifies an ethical approach to distributing the drug to facilities across the state and then among COVID-19 patients within each facility. This article describes the process of developing the framework and adjustments in the framework over time with emergence of new data, analyzes key issues addressed, and suggests next steps. Sharing this framework and the development process can encourage transparency and may be useful to other states formulating and refining their approach to remdesivir EUA allocation.

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On May 1, 2020, the US Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) to allow use of the antiviral drug remdesivir to treat patients with severe coronavirus disease-2019 (COVID-19).¹ That EUA was based on FDA “review of topline data” from 2 trials: 1 conducted by the National Institute of Allergy and Infectious Diseases (NIAID)² and the other sponsored by Gilead Sciences, Inc., the drug’s manufacturer.³ At the time the EUA was issued, neither trial’s data had been

published, although both have since been published in a peer-reviewed journal.

Remdesivir is an investigational drug being studied in clinical trials for COVID-19⁴ and is available to children and pregnant women through compassionate-use access⁵ but is not yet FDA approved. In early May 2020, the US Department of Health & Human Services (HHS) began shipping supplies of remdesivir donated by Gilead to hospitals and state health departments for EUA distribution.⁶ These shipments have raised urgent questions of how remdesivir should be allocated ethically.^{7,8}

This article describes the process by which an ethics allocation framework was rapidly developed for the state of Minnesota to guide allocation. To develop this approach, the Minnesota Department of Health (MDH) collaborated with the Minnesota COVID Ethics Collaborative (MCEC)⁹ and multiple clinical experts. The resulting Ethical Framework for May 2020 Allocation of Remdesivir in the COVID-19 Pandemic was first approved by the state's Commissioner of Health and subsequently amended in response to emerging data.² The amended framework dated May 24 appears in the [Appendix](#). The document hosted on the MDH website will incorporate any subsequent amendments.¹⁰

The remdesivir allocation framework presented here specifies an ethical approach to distributing the drug to facilities across the state, and then among COVID-19 patients within each facility. This article presents our approach to developing the guidance, identifies key issues and how we approached them, and suggests next steps.

METHODS

The remdesivir framework is built on ethical guidance developed for public health emergencies in two previous projects: the Minnesota Pandemic Ethics Project (2007 to 2010)¹¹ and Ethical Considerations for Crisis Standards of Care (2016)¹² and additionally draws on previous work by MCEC.¹³ The previous guidance recommended that, in a public health emergency, an ethics support mechanism be deployed at the state level to share expertise rapidly and support ethical crisis response.^{12,14} In line with this guidance, the Minnesota COVID Ethics Collaborative (MCEC) was convened in March 2020 as a partnership among MDH, the State Health Care Coordination Center (SHCCC), Minnesota Hospital Association, and University of Minnesota (UMN). MCEC rapidly grew to more than 60 participants, including ethics and clinical experts from health systems across the state. To encourage open discussion, people

participate not as representatives of their organizations but as individuals with subject-matter expertise.

Shortly after receiving notification from HHS that Minnesota would be receiving shipments of remdesivir pursuant to the FDA's EUA, MDH reached out to MCEC on May 6, 2020, for ethics guidance on allocation. Because the first shipment was due imminently, MCEC quickly convened a multidisciplinary subgroup, including the co-leads, to work with MDH and clinical colleagues to develop an initial allocation framework. Those clinical colleagues included researchers leading clinical trials of remdesivir in Minnesota (J.V.B., S. Kline, S.R.).

The initial framework document was developed within days, before being reviewed by MDH and the Chair of its Science Advisory Team (SAT), approved by the Commissioner of Health, and disseminated across the state. After allocation of the initial shipment and clinical feedback, the full MCEC group met by videoconference to refine the framework. With publication of preliminary data from the NIAID trial on May 22, 2020,² the framework was amended. The [Appendix](#) presents the May 24th version of the framework. As of May 25, 2020, 4 shipments have been allocated using the remdesivir allocation framework, which is subject to further revision as new evidence emerges and the situation evolves.

ALLOCATION FRAMEWORK: KEY ISSUES

Formulating an ethical framework for remdesivir allocation in May of 2020 posed significant challenges, including the scientific uncertainty surrounding the best use of remdesivir.⁷ When the FDA issued its EUA on May 1, based on unpublished data from the NIAID and Gilead trials, the agency stated that remdesivir was associated with a reduction in median time to recovery from 15 to 11 days in hospitalized patients with severe COVID-19, and there was potential for a reduction in mortality from 11.6% to 8% that did not reach

statistical significance.¹⁵ However, preliminary results from the NIAID trial were not published until May 22, 2020,² more than 2 weeks after MDH had to make the first allocation, and results from the Gilead trial were not published until May 27, 2020.³ This paucity of evidence when the initial ethical framework for EUA allocation was needed created uncertainty about which patient populations would benefit from remdesivir.

Moreover, although the EUA stated that eligible patients should have “severe” disease, the stated eligibility criteria were broad enough to encompass almost the entire clinical spectrum of inpatient respiratory disease. The EUA also stated that patients with “both suspected or laboratory confirmed COVID-19” may be considered for treatment, potentially broadening the pool of eligible patients even more.¹ The Minnesota allocation framework thus had to specify eligibility and prioritize patients for a limited resource in the face of uncertainty and an inadequate, although evolving, evidence base.

Faced with these uncertainties, we needed to develop “real-time” guidance that could be updated when new evidence and logistical realities emerged. The timeline from notice that Minnesota would receive an allocation to receipt of the first shipment was 4 days. We had to formulate guidance quickly that could be implemented across health care systems and facilities in Minnesota and then be updated based on feedback concerning implementation, any new evidence that emerged, and the evolving shipment situation.

The Minnesota ethical framework for remdesivir allocation addresses 4 major issues: guiding ethical values; how to allocate remdesivir across facilities; how to allocate remdesivir among patients within a facility; and what processes facilities should use for allocation, documentation, and review. We present our approach here, with a text box highlighting key issues addressed more fully in the framework document reproduced in the [Appendix](#).

What Ethical Values Should Guide Allocation?

TEXT BOX 1. Ethical Values Guiding Remdesivir Allocation

- Responsibly allocate the scarce resource to reduce risk while providing benefit.
- Save the most lives possible while respecting rights and fairness.
- Promote the common good through transparency, accountability, and trustworthiness.
- Use the best available evidence while addressing uncertainty.

The remdesivir allocation framework is grounded in foundational ethical values identified in the previous ethics projects,^{11,12,14,16} expressed as commitments to trustworthiness, public accountability, transparency, solidarity and mutual responsibility, respect for individuals and groups, fairness, and effectiveness and efficiency of response. To honor these fundamental commitments, crisis response must promote the public’s health while respecting rights and ensuring fairness.

To achieve these objectives, Minnesota’s remdesivir guidance prioritized those at greatest risk of mortality and serious morbidity as well as those who stood to benefit from access to the drug. At each stage in developing the framework, we used the best available evidence and advice from clinical experts.

To ensure the framework protected the rights and interests of all, we adopted an approach that rejected allocation based on race, ethnicity, gender or gender identity, citizenship or immigration status, socioeconomic status, or ability to pay for treatment. The framework also disallowed allocation based on age, disability status, or comorbidities as criteria in and of themselves, unless directly relevant to clinical prognosis and likelihood of survival to hospital discharge.

In striving to meet the objective of protecting those at greatest risk while maximizing benefit of the resource, the framework allocates to patients based on need as well as likely benefit through survival to hospital discharge. In addition, the patient should not be imminently and

irreversibly dying or terminally ill with life expectancy less than 6 months (eg, eligible for hospice). The framework focuses on short-term instead of longer-term prognosis (eg, 1-year or 5-year survival) to avoid disadvantaging patients on the basis of age, comorbidities, and disabilities that are not germane to short-term survival. Focusing on short-term survival also avoids disadvantaging patients for systemic health inequities that may place them at risk for comorbidities and lower life expectancy.

Grounding remdesivir allocation in an explicit consideration of ethics contrasts with approaches that leave allocation to clinical discretion^{17,18} without addressing the ethical values that should guide allocation. In Minnesota, the previous projects made it clear that allocation raises ethical questions that must be addressed.^{11,12} Those projects involved extensive consultation with experts and the public.

How Should Remdesivir be Allocated Across the State Among Health Care Facilities?

TEXT BOX 2. Allocation Among Facilities

- Allocate among facilities in proportion to the total number of COVID-positive patients currently admitted per facility (or health care system) who are not already on remdesivir (eg, through compassionate use or clinical trials).
- Allocate based on 10-day course per patient.
- Patients allocated remdesivir who are later transferred may take the remainder of their course with them.
- All courses should be allocated without holding supply in reserve.
- Facilities with surplus drug after 72 hours should contact MDH for reallocation.

Equitable allocation among health care facilities in Minnesota required determining how best to distribute the medication to reach eligible patients. This posed practical challenges.

First, obtaining granular data on the number of clinically eligible patients per facility proved excessively burdensome, so we developed the closest practical proxy: the total number of COVID-positive patients in each facility, a number each facility was already reporting to MDH on a daily basis. For each

remdesivir distribution, MDH asked the facility to subtract the number of patients in this group already on remdesivir (through compassionate use, clinical trials, or previous EUA allocations). Health care systems that included facilities outside of Minnesota were allocated remdesivir based on the patient census in their Minnesota facilities. However, the framework expressly allowed patients who transferred out of Minnesota facilities to take the remainder of their course with them, an important provision for rural patients who might need to transfer across a state border for more intensive care.

The framework's approach to allocation among facilities can be contrasted with reported approaches in other states, including those based on physician request¹⁹; random selection²⁰ among hospitals with COVID-positive patients; number of COVID patients and those "under investigation" in each hospital system¹⁷; communities' COVID death rates²¹; hospitalized COVID patients by county, and then distribute to acute care facilities within each county randomly or by a range of other methods²²; COVID patients in each facility's intensive care unit over the past 14 days²³; hospitals reporting at least 10 COVID-positive patients on ventilators or extracorporeal membrane oxygenation (ECMO)²⁴; percentage of mechanically ventilated patients¹⁸; or total COVID patients and total COVID patients on ventilators in the past 7 days.²⁵ Allocating in Minnesota based on the number of COVID-positive patients minus those already on remdesivir offers more precision in approximating the number of eligible patients than many of these alternatives.

Allocation across facilities also required determining whether remdesivir would be distributed by assuming a 10-day course for each patient or a 5-day course. The FDA's EUA Fact Sheet for Healthcare Providers stated, "The optimal duration of treatment for COVID-19 is unknown."¹⁵ It suggested that patients on invasive mechanical ventilation or ECMO receive a 10-day course, but other patients receive a 5-day course that could be extended to 10 days if they were not improving, based in part on

data from Gilead's open-label trial, which has now been published.³ To allocate each shipment upon arrival and avoid a patient needing more medication after 5 days but being unable to get it, a 10-day course of medication was allocated for each patient. The framework instructed facilities to consider stopping remdesivir at 5 days in patients not on mechanical ventilation or ECMO, depending on the patient's clinical course, and then reallocating the available remdesivir to other patients.

How Should Remdesivir be Allocated Within a Facility Among Patients?

TEXT BOX 3. Allocation Among Patients Within a Facility

- Clinical criteria for allocation are based on patient need (risk of serious morbidity or mortality without the medication) and likelihood of benefit defined as recovery to hospital discharge.
- Highest priority: patients on advanced respiratory support (high-flow nasal cannula, continuous positive airway pressure [CPAP] therapy, bilevel positive airway pressure [BiPAP] therapy) or patients with 3 out of 4 characteristics: < 94% oxygen saturation on room air; respiratory rate > 30; lung infiltrates on imaging; using supplemental oxygen.
- Second priority: patients who have been mechanically ventilated for ≤ 5 days or on ECMO for ≤ 5 days.
- When patients are otherwise of equal priority within a group and there is not sufficient drug for all patients in this group, a random process should be used to allocate.
- Patients who are imminently dying or terminally ill with life expectancy < 6 months should not be prioritized for access.
- Children and pregnant women are not included because of availability of remdesivir through the FDA's compassionate-use program.

Developing recommendations for allocation of remdesivir among patients within a facility required determining how to meet the ethical objective of reducing risk of morbidity and mortality while maximizing likelihood that patients could benefit from the drug. However, the supply of medication was insufficient to treat all patients who fulfilled the broad eligibility criteria listed in the EUA, and clinical trial data on which

subgroups of patients might benefit most was not yet available. The Minnesota framework thus initially sought to meet the acute need of those patients who were the most severely ill—on mechanical ventilation, ECMO, or advanced respiratory support—and then sought to provide benefit to patients who were not yet as acutely ill but had significant respiratory insufficiency.

This ethical prioritization led to the creation of a 2-tier approach for allocation of remdesivir. The guidance framework initially placed patients with COVID-19 pneumonia who were critically ill and receiving mechanical ventilation for ≤ 5 days, or on ECMO, or receiving advanced noninvasive respiratory support in the first-priority tier. A 5-day cutoff for ventilation was chosen based on expert opinion from clinicians and remdesivir researchers that patients with more prolonged critical illness would be less likely to benefit from an antiviral drug. Patients were also required to meet the EUA inclusion criteria based on kidney and liver function (glomerular filtration rate [GFR] ≥ 30 mL/min, alanine aminotransferase [ALT] < 5 times upper limit of normal).¹⁵ The second-priority tier included patients who did not meet tier-1 criteria but had severe disease and met 3 of 4 additional criteria for hypoxia and respiratory distress.

In drafting the initial framework, we debated whether the highest priority should be to treat patients earlier in their clinical course rather than patients already on mechanical ventilation or ECMO. However, without published data to resolve the question of which patients benefit from remdesivir, we relied on analysis of available sources²⁶⁻²⁸ and clinical input to determine provisionally which patients were most in need of remdesivir—based on risk of serious morbidity and mortality without the medication—and which patients were likely to benefit from access to remdesivir through recovery to hospital discharge.

After publication of preliminary data from the NIAID-funded trial of remdesivir on May 22, 2020,² we revised the framework's priorities. These data showed clearest benefit for hospitalized patients requiring

supplemental oxygen but not yet on advanced respiratory support and possible benefit for those on advanced respiratory support. The preliminary data did not show benefit for those on mechanical ventilation or ECMO, although the sample size was small and the authors cautioned that “the follow-up time may have been too short to evaluate this subgroup.”² Accordingly, we moved patients formerly in tier 2 to the highest-priority tier and moved patients on mechanical ventilation and ECMO down to the second-priority tier. As the NIAID data suggested that there may be benefit to patients on advanced respiratory support, these patients remained in tier 1.

In making these changes, we demonstrated the flexibility of the Minnesota approach. The now-published NIAID trial data suggesting that earlier therapy is more beneficial are preliminary; further data may require further updates. The Minnesota framework was developed with a clear understanding of its provisional nature, and the project team assumed that the evidence would continue to evolve.

In developing this allocation framework in the face of uncertainty, we debated using randomization more broadly. Instead of creating priority tiers, one could randomize all hospitalized patients with COVID-19 regardless of severity of illness. Alternatively, one could randomize across both the framework tiers combined. However, the Minnesota framework is guided by the ethical objective to minimize risk and maximize benefit insofar as it is possible to determine how to do so. The framework does recommend that when there is not enough remdesivir for patients within a given prioritization category, eligible patients should be randomized to ensure fairness.

The framework recognizes the importance of patient consent, given that remdesivir is an unapproved medication with the potential for serious adverse events.^{2,3,15,29}

The framework recommends that patients be asked on admission whether they would be interested in receiving medications not yet approved but potentially available under an EUA. Broaching this issue early and distinguishing EUA access from compassionate use and clinical trials can facilitate decision

making later in the patient’s course. If a patient lacks decisional capacity and no substitute decision maker is available, the framework recommends that clinicians allocate the remdesivir in keeping with the patient’s best interests, unless the patient had previously declined EUA access. This avoids excluding patients simply because they are unbefriended (ie, lacking a surrogate).

Ethical guidance developed in Minnesota’s previous projects calls for prioritization of key workers to receive antiviral treatments.^{16,p28-34} However, including priority for key workers would have been impossible to operationalize on the short timeline required for development and implementation of this framework, given complexities in defining the categories of key workers to be prioritized, identifying the relevant individuals within those categories, and ensuring the availability of this information to clinical teams for allocation decisions. In keeping with the evolving nature of the guidance and the flexibility of our approach, MCEC has begun discussions about how to incorporate appropriate priority for key workers in allocation frameworks moving forward.

What Processes Should Facilities Use for Allocation, Documentation, and Review?

TEXT BOX 4. Processes for Allocation Within a Facility

- Use a triage officer or team (not bedside team) for randomization: facilities that have not yet deployed triage personnel may establish *ad hoc* triage processes.
- Remdesivir allocation should be documented at 2 levels: patients who receive EUA remdesivir under this framework should have that documented in their electronic health record (EHR), and facilities should maintain a log of allocation decisions (including randomization) to ensure transparency, accountability, and retrospective review.

The remdesivir framework envisions that the bedside clinical care team will determine whether a patient meets the drug eligibility criteria specified in the guidance. However, if randomization is needed in either tier of patients because there are more eligible people than available courses, the framework

calls for a separation of roles. A triage officer or team should perform randomization instead of the clinicians providing care at the bedside. This separation preserves the integrity of the patient-provider relationship and so reduces potential moral distress and protects the fairness of the randomization process by minimizing bias. Indeed, the framework recommends that, insofar as possible, the triage officer or team should not be provided with patient characteristics that are impermissible to consider in allocation such as race, ethnicity, and socioeconomic status.

The framework stresses the importance of documentation in addition to that required by the FDA.¹⁵ Patients who receive EUA remdesivir need the medication order and length of course documented in their EHR to ensure continuity of care across shifts and in case of transfer. At the institutional level, allocation decisions, including randomization, should be documented to permit review and allow transparency. Retrospective review and subgroup analysis will be important to surface problems and inequities. This would ideally be undertaken at both the institutional and state levels, examining how scarce resources are being allocated in the pandemic.^{12,14}

The remdesivir allocation framework does not provide a mechanism for secondary review (“appeal”) of triage decisions. Such mechanisms are crucial when allocation decisions involve complex comparative judgments among patients, as when allocating ventilators under conditions of scarcity. However, implementing the remdesivir framework simply requires that facilities offer the drug to all eligible patients, starting with those in the first tier and moving to the second tier. If the number of eligible patients within a tier exceeds supply of the drug, randomization is used to allocate rather than comparative judgments among patients. Allocation on these bases is less vulnerable to bias or error.

LIMITATIONS

Our approach had significant limitations, including the lack of robust data from

clinical research on which to base clinical allocation criteria. Minnesota’s previous guidance on the allocation of resources during a pandemic called for the creation of evidence-based standards to define patient subgroups with the highest need for a clinical intervention, and that would benefit the most from receiving that scarce resource.^{11,12} This is required to minimize potential bias and inequities in the distribution of scarce resources. At the time that we created our initial allocation framework, the data needed to create evidence-based allocation criteria were unavailable. Indeed, the data cited in the FDA’s EUA—“the topline data” from the NIAID trial and Gilead-sponsored trial¹—had not yet appeared in print. Although subsequent publication of the NIAID trial data was helpful, those data remain preliminary,² and Gilead’s open-label study was not a trial of efficacy.³

In addition, previous work on pandemic response in Minnesota was developed with extensive expert stakeholder and community input.^{11,12} Although MCEC’s work customarily involves substantial and iterative input from expert stakeholders in the development of guidance, the opportunity for such input was limited in developing the remdesivir framework owing to time constraints. Moreover, although MCEC work on allocation of ventilators and other scarce resources as well as remdesivir has involved dialogue and engagement on issues of inequity, structural racism, disability discrimination, and implicit bias, more systematic engagement with stakeholders and broader community input are warranted.

CONCLUSION

Unresolved Issues and Next Steps

This remdesivir allocation framework is a living document, subject to revision with the emergence of new and more definitive data to guide use of the medication. Future remdesivir availability will also affect the use of this framework, including the relative availability over time through the FDA’s EUA, compassionate use, clinical trials, and—ultimately—through sale. The

Minnesota framework addresses allocation of EUA remdesivir, distinct from compassionate use and research. However, if the availability of remdesivir is interrupted, or shifts from EUA to use in clinical trials in combination with other drugs or to sale, allocation frameworks should adapt to address the ethical issues raised.

A strength of the Minnesota process has been the collection of feedback on each successive version of the remdesivir framework to guide revision. Ethical frameworks for allocation must be evaluated to assess whether they work in practice, accomplish their stated goals, create unexpected negative consequences, and operate equitably across population subgroups, especially subgroups that are historically underserved and more vulnerable to poor health outcomes. At a national scale, we urge systematic collection of information on the range of allocation strategies being deployed—including assessment of how those frameworks are being implemented—with subgroup analysis and outcomes data to evaluate fairness. Such analyses, plus robust public input, will support development of sound allocation frameworks across the country.

In a public health crisis such as a pandemic, when knowledge is continuously evolving, a wide range of stakeholders may need to collaborate quickly to guide allocation approaches. It may be challenging to mobilize statewide support for an allocation framework on a very short timeline in the absence of longer-term engagement across health care systems, ethics professionals, academic institutions, relevant branches of government, and the community. Ethics advisory groups such as MCEC can facilitate this collaboration, acting as a “rapid-response” team to develop guidance during times of urgent need. As this pandemic evolves, additional frameworks are likely to be necessary to address the allocation of a range of possible therapies and prevention strategies, including a vaccine. Minnesota’s experience with the formulation of this framework for allocation of remdesivir may be useful to other states responding to the

rapidly emerging ethical challenges posed by COVID-19.

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SUPPLEMENTAL ONLINE MATERIAL

Supplemental material can be found online at <http://www.mayoclinicproceedings.org>. Supplemental material attached to journal articles has not been edited, and the authors take responsibility for the accuracy of all data.

Abbreviations and Acronyms: ECMO = extracorporeal membrane oxygenation; EHR = electronic health record; EUA = emergency use authorization; FDA = Food and Drug Administration; HHS = Department of Health and Human Services; MCEC = Minnesota COVID Ethics Collaborative; MDH = Minnesota Department of Health; NIAID = National Institute of Allergy and Infectious Diseases; SAT = Science Advisory Team; SHCCC = State Health Care Coordination Center; UMN = University of Minnesota

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