A survey of US hospitals' criteria for the allocation of remdesivir to treat COVID-19

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Purpose. To determine how hospitals across the United States determined allocation criteria for remdesivir, approved in May 2020 for treatment of coronavirus disease 2019 (COVID-19) through an emergency use authorization, while maintaining fair and ethical distribution when patient needs exceeded supply.

Methods. A electronic survey inquiring as to how institutions determined remdesivir allocation was developed. On June 17, 2020, an invitation with a link to the survey was posted on the Vizient Pharmacy Network Community pages and via email to the American College of Clinical Pharmacy's Infectious Disease Practice and Research Network listserver.

Results. 66 institutions representing 28 states responded to the survey. The results showed that 98% of surveyed institutions used a multidisciplinary team to develop remdesivir allocation criteria. A majority of those teams included clinical pharmacists (indicated by 97% of respondents), adult infectious diseases physicians (94%), and/or adult intensivists (69%). Many teams included adult hospitalists (49.2%) and/or ethicists (35.4%). Of the surveyed institutions, 59% indicated that all patients with COVID-19 were evaluated for treatment, and 50% delegated initial patient identification for potential remdesivir use to treating physicians. Prioritization of remdesivir allocation was often determined on a "first come, first served" basis (47% of respondents), according to a patient's respiratory status (28.8%) and/or clinical course (24.2%), and/or by random lottery (22.7%). Laboratory parameters (10.6%), comorbidities (4.5%), and essential worker status (4.5%) were rarely included in allocation criteria; no respondents reported consideration of socioeconomic disadvantage or use of a validated scoring system.

Conclusion. The COVID-19 pandemic has exposed the inconsistencies of US medical centers' methods for allocating a limited pharmacotherapy resource that required rapid, fair, ethical and equitable distribution. The medical community, with citizen participation, needs to develop systems to continuously reevaluate criteria for treatment allocation as additional guidance and data emerge.

Keywords: COVID-19, EUA, health care rationing/ethics, pandemics, remdesivir, resource allocation

Am J Health-Syst Pharm. 2020;77:xxx-xxx

Am J Health-Syst Pharm. 2020; XX:0-0

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DOI 10.1093/ajhp/zxaa391

In February 2020, the secretary of the US Department of Health and Human Services (HHS) declared a public health emergency due to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), and in March HHS authorized the emergency use of unapproved drug and biologic treatments for coronavirus disease 2019 (COVID-19). In May, the National Institute of Allergy and Infectious Diseases reported preliminary clinical trial findings showing that in adults hospitalized with COVID-19 and respiratory symptoms, remdesivir was superior to placebo in shortening the time to recovery.[1] On May 1, 2020,

after HHS determined justification for emergency use, the US Food and Drug Administration (FDA) granted emergency use authorization (EUA) for Veklury (remdesivir, Gilead Sciences) to treat hospitalized adults and children with severe COVID-19.[2] The Office of the Assistant Secretary for Preparedness and Response at HHS collaborated with Gilead Sciences and AmerisourceBergen to distribute remdesivir to states based on the number of recent COVID-19 cases. The state public health departments identified which local hospitals would receive remdesivir and how much the hospitals would receive.[3] With only EUA criteria available to them, hospitals were tasked with rapidly developing ethical criteria for allocation of a limited supply of medicine. Subsequently, in late May, a few states drafted widely varying recommendations.[4] The objective of the study described here was to determine how hospitals across the United States determined criteria to ensure that remdesivir use was consistent with the EUA while maintaining fair and ethical allocation when patient needs exceeded supply.

KEY POINTS

- The COVID-19 pandemic has exposed the inconsistencies of US medical centers' methods for allocating a limited pharmacotherapy resource.
- Methods for allocating a limited healthcare resource require rapid, fair, ethical, and equitable distribution.
- The medical community, with citizen participation, needs to develop systems to continuously reevaluate criteria for treatment allocation as additional guidance and data emerge.

Methods

The study was reviewed by an institutional review board and received an exempt determination. The multicenter, cross-sectional study was conducted using a 12-item electronic research survey distributed to academic and community medical centers within the Vizient Pharmacy Network Community and the American College of Clinical Pharmacy (ACCP) Infectious Disease Practice and Research Network (IDPRN) listserver. As of May 2020, the Vizient Pharmacy Network Community had 4,892 independent users in the Academic Medical Center Pharmacy Network Community and 432 users in the Academic Medical Center Antimicrobial Stewardship Community, who collectively represented 367 different hospitals and other organizations. As of May 2020, there were also 1,991 independent members in the ACCP IDPRN listserver. Approximately 90% of the 125 US academic medical centers were represented in these listservers. The listserver and community forums have significant membership overlap.

A survey was created to examine how institutions determined remdesivir allocation. REDCap (Research Electronic Data Capture) tools (Vanderbilt University, Nashville, TN) were used to construct the survey and collect responses. A mix of multiple-choice and short-answer questions and a "matrix/rating scale" were used. For certain questions, respondents were able to select multiple responses. Skip logic was used, so the exact number of required questions depended on previous responses.

Prior to distribution, the survey was thoroughly tested by the authors, an infectious diseases clinical pharmacist, and a subset of adult hospitalists and medical students to ensure accuracy. Feedback from these trials was incorporated into the final survey.

Questions pertaining to team composition and EUA remdesivir eligibility are described in Table 1. Questions pertaining to criteria for use and allocation are described in Table 2.

A survey invitation letter with the appropriate informed consent information was uploaded electronically to the Vizient Pharmacy Network Community and emailed to the ACCP IDPRN listserver. Submission of the survey indicated the respondents' consent to participate. The electronic survey was distributed on June 17, 2020. A follow-up was posted 2 weeks after the initial submission. The survey was closed on July 8, 2020. Duplicate responses were identified if the same institution name was entered for more than 1 survey response. Only the most recent response was used for data analysis, and earlier responses were discarded. All institutions were then deidentified during analysis. Responses were analyzed with descriptive statistics, and free-text responses were summarized categorically. Responses were consolidated with existing responses when appropriate. For example, if a respondent identified "infectious diseases pharmacist" as a member of the allocation team, this was counted in the "pharmacist" category.

Results

Overall, 74 survey responses were received. After removing duplicates, 66 unique institutions representing 28 states remained, with representation from all 4 major regions of the United States (Midwest, Northeast, South, and West). We received responses from 45 academic health centers and 21 community hospitals. The exact survey response rate could not be calculated due to significant overlap between the members of the Vizient Pharmacy Network Community pages and the ACCP IDPRN listserver, as well as an inability to retrieve a reliably up-to-date member affiliation list. Furthermore, not all hospitals surveyed received remdesivir and were therefore able to participate. Using the 367 institutions represented in the Vizient communities as the denominator, we approximated an 18% response rate, which included 36% of the 125 US academic medical centers.

Table 1. Survey Results Regarding EUA Remdesivir Eligibility Decisions at US Hospitals

Survey Questions	No. (%) Responses
1. Who was responsible for developing criteria for use and a patient-level allocation plan? (*n* = 66)	
Multidisciplinary team	65 (98)
Authorized individual	1 (1)
1a. If a multidisciplinary team was created, select all members included. (*n* = 65)	
Clinical pharmacist	63 (97)
Adult infectious diseases physician	61 (94)
Adult intensivist	45 (69)
Adult hospitalist	32 (49)
Ethics committee member	23 (35)
Pediatric infectious diseases physician	12 (18)
Pediatric intensivist	4 (6)
Pediatric hospitalist	1 (1)
Other (administration, other physician and/or pharmacy representation, or epidemiologist)	20 (31)
2. How are patients eligible for EUA remdesivir identified? (*n* = 66)	
All inpatients with suspected/confirmed COVID-19 are evaluated.	39 (59)
Treating physicians assess and request evaluation for EUA remdesivir.	33 (50)
Only patients with an infectious disease consult are evaluated.	9 (14)
3. Who makes the daily decision to allocate and/or approve use of EUA remdesivir? (*n* = 66)	
Treating physician and multidisciplinary team	25 (38)
Multidisciplinary team separate from treating physician	24 (36)
Infectious diseases consultant only	6 (9)
Treating physician with or without pharmacist oversight	6 (9)
Antimicrobial stewardship program only	4 (6)
Pharmacist only	1 (1)
3a. If the treating physician and multidisciplinary team make the daily decision to allocate and/or approve EUA remdesivir, who are the team members? (*n* = 25)	
Infectious diseases consultant	23 (92)
Pharmacist	21 (84)
Antimicrobial stewardship program	4 (16)
Not specified	2 (8)
3b. If the multidisciplinary team that makes the daily decision to allocate and/or approve EUA remdesivir is separate from the treating physician, who are the team members? (*n* = 24)	
Pharmacist	9 (37)
Infectious diseases consultant	8 (33)
Antimicrobial stewardship program	6 (25)
Intensivist or pulmonary specialist	2 (8)
Hospital command center	1 (4)
State department of health	1 (4)
Hospitalist	1 (4)
Not specified	11 (46)

Abbreviations: COVID-19, coronavirus disease 2019; EUA, emergency use authorization.

Table 2. Survey Results Regarding Criteria for Allocation of EUA Remdesivir at US Hospitals

Survey Questions	No. (%) Responses
1. In addition to the minimum use criteria outlined by the FDA EUA statement identifying severe disease, what other minimum criteria were established for inclusion? (*n* = 66)	
Confirmed positive test for SARS-CoV-2	61 (92)
Requiring supplemental oxygen	49 (74)
Short symptom duration (eg, ≤10 days)	24 (36)
Abnormal chest imaging	23 (35)
Recent hospitalization (eg, <7 days ago)	23 (35)
Requiring mechanical ventilation or ECMO	19 (29)
Treated in an intensive care unit	2 (3)
Other	4 (6)
2. Which of the following were used as exclusion criteria? (*n* = 66)	
ALT >5 × upper limit of normal	56 (85)
eGFR <30 mL/min or receiving renal replacement therapy	40 (61)
Expected immediate short life expectancy such that administration of remdesivir is highly unlikely to change the clinical outcome	31 (47)
Already improving on current treatment/supportive care regimen	22 (33)
Previous receipt of remdesivir (in clinical trial or via EUA)	19 (29)
Eligible for compassionate use remdesivir (ie, pediatric or pregnant patient)	15 (23)
Duration of mechanical respiration longer than specified number of days	13 (20)
Enrolled in clinical trial	13 (20)
Life expectancy of <6 months	11 (17)
Duration of hospitalization (>*n* days)	10 (15)
DNR and/or DNI status	9 (14)
Duration of ECMO (>*n* days)	7 (11)
Significant vasopressor requirement	3 (4)
Age above a certain cutoff (eg, age >65)	1 (1)
Other	7 (11)
3. Which of the following factors were used to prioritize use of EUA remdesivir when demand exceeds supply? (*n* = 66)	
"First come, first served"	31 (47)
Patient factors: vital signs and/or oxygenation (see question 4)	19 (29)

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Survey responses indicated that 98% of participating institutions used a multidisciplinary team to develop the allocation criteria. A majority of teams included clinical pharmacists (indicated by 97% of respondents), adult infectious disease physicians (94%), and/or adult intensivists (69%). Many teams included adult hospitalists (49%) and/or ethicists (35%). Representation by pediatric intensivists and pediatric hospitalists was low, at 6% and 1.5%, respectively. The data are shown in Table 1.

The survey results indicated that 59% of institutions evaluated all inpatients with suspected and/or confirmed COVID-19 for potential use of EUA remdesivir, with 50% delegating the initial identification of potential patients to treating physicians. Close to half of survey respondents (47%) indicated that the daily decision to allocate or approve use of remdesivir involved treating physicians, often in consultation with infectious diseases physicians or a broader multidisciplinary team (see Table 1). Only 2 respondents indicated that the treating physician alone, without pharmacist oversight, made the decision to allocate remdesivir. A multidisciplinary team separate from the primary treating physician determined remdesivir allocation at 36% of respondent institutions. However, the treating physician was involved in the initial identification of potential candidates for remdesivir therapy and/or the decision to allocate remdesivir at 73% of respondent institutions. A pharmacist was identified as a member of the allocation team by 54% of respondents and as a member of the antimicrobial stewardship program by 21% of respondents.

Most institutions (92%) required a positive SARS-CoV-2 test for remdesivir eligibility. Most institutions (74%) required that patients be receiving supplemental oxygen. Despite EUA guidance recommending against use of remdesivir in patients with an estimated glomerular filtration rate (eGFR) of <30 mL/min, only 61% of respondents used this as an exclusion criterion.[5]

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Table 2. Survey Results Regarding Criteria for Allocation of EUA Remdesivir at US Hospitals

Survey Questions	No. (%) Responses		
Patient factors: clinical course and/or other factors (see question 5)	16 (24)		
Random lottery	15 (23)		
Patient factors: laboratory parameters	7 (11)		
Patient factors: comorbidities and/or demographics	3 (4)		
Essential worker status	3 (4)		
Socioeconomic disadvantage	0		
Validated scoring system	0		
Other (eg, demand has not yet exceeded supply, tiered system, pregnant women and children, or not applicable)	11 (17)		
	Higher Priority	**Lower Priority**	**Not Used**
3a. Patient factors: vital signs and/or oxygenation (*n* = 19)			
Elevated heart rate	1 (5)	5 (26)	13 (68)
Elevated respiratory rate	4 (21)	3 (16)	12 (63)
Hypotension	3 (16)	4 (21)	12 (63)
Low $PaO_2/FIO2$	10 (53)	2 (10)	7 (37)
Mechanical ventilation	14 (74)	4 (21)	1 (5)
High-flow nasal cannula	13 (68)	3 (16)	3 (16)
Nasal cannula	9 (47)	7 (37)	3 (16)
ECMO requirement	7 (37)	3 (16)	9 (47)
	Prioritized		**Not Used**
	Longer Duration	**Shorter Duration**	
3b. Patient factors: clinical course and/or other factors (*n* = 16)			
Duration of hospitalization	0	9 (56)	7 (44)
Duration of intubation	0	12 (75)	4 (25)
Duration of symptoms	1 (6.3)	9 (56)	6 (37)
Duration of ECMO	1 (6.3)	8 (50)	7 (44)
	No. (%) Responses		
4. Have you made adjustments to your original criteria? (*n* = 66)			
Yes	31 (47)		
No	35 (53)		

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When demand exceeded supply, prioritization of allocation was determined on a "first come, first served" basis (47% of respondents), according to a patient's respiratory status (29%) and/or clinical course (24%), and/or by random lottery (23%); laboratory parameters (11%), comorbidities (4%), and essential worker status (4%) were rarely considered. Close to half of institutions (47%) had adjusted their allocation criteria in the month after the original EUA recommendations, including loosening oxygenation requirements, prioritizing earlier use, and removing time limits on symptom duration. The data are shown in Table 2.

Discussion

When the COVID-19 pandemic first presented in the United States, healthcare institutions needed to rapidly develop guidelines on how to allocate scarce resources, such as personal protective equipment, intensive care access, and ventilators. Twenty-eight states developed crisis standards of care (CSCs) as alternatives to the "first come, first served" approach.[6] Nearly all state CSCs recommended that teams develop prioritization criteria and designate the allocation of scarce resources through a triage system separate from the direct care, treating physician. Prioritizing the allocation of limited medical resources needs to be fair, consistent, and transparent.[7] Decisions determined by a qualified team relieve the treating clinician from bias, moral distress, and conflicts of commitment.[8] In our survey, 97.0% of respondents indicated that the treating physician was not the sole decision maker. Yet, the treating physician was still involved in either the primary identification of patients or the decision to allocate remdesivir nearly three-quarters of the time. Therefore, the potential for unintentional bias and moral conflicts was not completely relieved in most of the institutions surveyed.

In addition to keeping the direct care physicians from deciding allocation of scarce intensive care unit (ICU) and ventilator resources, the states'

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Table 2. Survey Results Regarding Criteria for Allocation of EUA Remdesivir at US Hospitals

Survey Questions	No. (%) Responses
4a. What were the changes? (*n* = 31)	
Loosening oxygenation criteria or allowing use in less critically ill patients	10 (32)
Removal of cutoffs related to symptom duration or time since positive test	6 (19)
Prioritizing earlier use or adding a shorter cutoff from onset of symptoms and/or positive test	6 (19)
Removal of exclusion criteria related to poor renal function and/or RRT	5 (16)
Changes in process or prioritization	5 (16)
Clarifications to duration of treatment with remdesivir	3 (10)
More strict oxygenation criteria	2 (6)
Removal of exclusion for poor hepatic function	1 (3)
Other or not clearly indicated	6 (19)

Abbreviations: ALT, alanine aminotransferase; DNI, do not intubate; DNR, do not resuscitate; ECMO, extracorporeal membrane oxygenation; eGFR, estimated glomerular filtration rate; EUA, emergency use authorization; FDA, Food and Drug Administration; $Pao_2/Fio2$, ratio of arterial partial pressure of oxygen to fraction of inspired oxygen; RRT, renal replacement therapy; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2.

CSCs also recommended using patients' likelihood of survival, comorbidities, and illness severity scores, such as the Sequential Organ Failure Assessment (SOFA) score, to determine priority for allocation.[6] In contrast, an illness severity score was not used by any of our survey respondents in decisions regarding allocation of limited remdesivir. These findings highlight the fundamentally different approach that must be taken in allocation of medications vs ventilators and the need to consider the difference in benefits between the 2 treatments. The preliminary results of the Adaptive COVID-19 Treatment (ACT) Trial-1 suggested that patients benefitted most from receiving remdesivir earlier in the course of illness, when they required oxygen supplementation but before requiring mechanical ventilation.[1] Additionally, patients with less severe illness often recover without use of remdesivir. Therefore, applying an illness severity score, such as the SOFA score, is unlikely to appropriately prioritize patients most likely to benefit from remdesivir, whereas it is more appropriately applied in the context of ventilator allocation.[9] It is important to note that this concept may not apply to future medication treatments that become available for treatment of COVID-19, highlighting the importance of critically assessing available clinical trial results and identifying patients most likely to benefit from use of the drug.

Recently, the COVID-19 treatment guidelines developed by the National Institutes of Health added a recommendation that in situations where remdesivir supply is limited, remdesivir use should be prioritized for hospitalized patients who require supplemental oxygen but not those who are mechanically ventilated or receiving extracorporeal membrane oxygenation (ECMO).[10] Of the 19 hospitals that used vital signs and/or oxygenation status as criteria for allocation, 73.7% placed a higher priority on those who were receiving mechanical ventilation, and 36.8% placed a higher priority on patients receiving ECMO; this was despite 47.0% of institutions surveyed having already revised their criteria, with 32.3% doing so to allow use in less critically ill patients (ie, those not yet requiring mechanical ventilation, and even those not yet on supplemental oxygenation). This highlights the need for continued reevaluation of the clinical criteria by which hospitals allocate scarce resources as new data and recommendations become available.

Four fundamental values, based on the Four Principles of Beauchamp and Childress, have been outlined for fair allocation of medical resources: maximizing benefits by saving the most life-years, treating people equally, rewarding instrumental value by giving priority to those who can save others, and prioritizing the worst off when it aligns with maximizing benefits.[11] "First come, first served" can potentially minimize community benefit and exacerbate health disparities.[7,8,11,12] Although many of the CSCs recommend not taking into account age, race, or demographics, the COVID-19 pandemic has brought the inequities of structural racism and unequal access to medical care to the forefront of discussions. COVID-19 has infected three times more majority-black counties than majority-white counties. There is also a 6 times greater mortality rate in majority black counties vs majority white counties.[13] Socioeconomic factors such as crowded housing, and essential jobs with greater risk of COVID-19 contact are more common in black and Latinx communities. Many medical professionals are now voicing the ethical concern that if race and social factors are ignored, fair allocation is not ensured and inequities are propagated, resulting in "devastating effects on disadvantaged communities."[14]

The Pennsylvania Department of Health, using guidelines developed by the University of Pittsburgh, recommended that a crisis triage team draft and implement a remdesivir allocation strategy based on a weighted

lottery system, giving higher priority to essential workers and individuals from disadvantaged communities and lower priority to individuals with an expected survival of less than 1 year. Essential workers were defined by the Commonwealth of Pennsylvania's list of essential businesses requiring physical operations during the COVID-19 pandemic. However, some critics of that approach have used distributive justice principles to argue that essential healthcare workers should not receive priority.[15] Disadvantaged communities in Pennsylvania were identified by zip code and assigned an "area deprivation index."[8,12] We found that 63.6% of responses used a "first come, first served" and/or random lottery approach. No responses accounted for socioeconomic disadvantage, and only 4.5% accounted for essential workers. It is, however, important to note that many hospitals surveyed may have changed their criteria since the June survey to account for the rapidly emerging data and guidance in the literature and from state departments of health. In our study, 47.0% of survey respondents indicated adjustments to original criteria.

The COVID-19 pandemic has exposed the ethical struggles that hospitals are faced with when rapid determination of fair and equitable allocation of limited resources is required. How scarce resources are dispensed during a pandemic can vary widely depending on the state and specific institution. The medical community, and larger community of citizens, need to continuously reevaluate their criteria for use of scarce medications as more data and guidance become available. It is necessary to advocate for public policy changes that guide the development of criteria for equitable distribution of scarce products because there will be insufficient time to address these ethical frameworks once a pandemic occurs.[16] Although remdesivir will soon become more available, these issues of fair and equitable allocation of scarce resources will continue to manifest as new medications and vaccines enter the COVID-19 pandemic arena.

Disclosures

The authors have declared no potential conflicts of interest.

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