The Ethical Allocation of Remdesivir Within Hospitals

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Recent evidence has shown that remdesivir may shorten length of hospital stay and recovery in COVID-19 patients.1-3 Many hospitals are experiencing shortages of remdesivir and are being forced to determine systems for the ethical allocation of this drug. Ethical allocation of remdesivir is imperative for upholding principles of justice during public health crisis.2 Currently, there is no consensus on the ethical distribution of remdesivir to patients within hospitals. This article discusses places of consensus, variance, and limitations of hospital level remdesivir allocation policies throughout the US during the COVID-19 pandemic.

Consensus in Allocating Remdesivir

Hospital policies and ethics literature has reached consensus that remdesivir requires allocation criteria as the potential for drug shortage could create a public health crisis.4 The overarching structure of these policies includes ethical guiding principles, drug eligibility sion and criteria, and an allocation process. Guiding principles of ethical allocation has found consensus in not excluding patients based on characteristics such as age, disability, gender, race, and immigration status. Allocation criteria have reached consensus on inclusion criteria for patients

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This is the author's manuscript of the work published in final edited form as:

Comer, A. R. (2021). The Ethical Allocation of Remdesivir Within Hospitals. *The Journal of Hospital Ethics*, *7*(2), 82–84.

who should be considered for remdesivir which is derived from the FDA Emergency Use Authorization (EUA) guidelines and includes clinical data such as laboratory confirmed COVID-19 test and oxygen saturation (SpO2) <94% on room air, requiring supplemental oxygen.5

Consensus in regard to an allocation process is that a first-come-first-serve process of allocation should not to be utilized and that some form of lottery should be used when the number of eligible patients exceeds remdesivir supply.

Variance in Allocating Remdesivir

The greatest variance in ethics policies allocating remdesivir is found in the exclusion criteria for the drug. Some policies did not outright exclude patients, while other policies excluded or reduced the priority of patients who are imminently and irreversibly dying or who are terminally ill with life expectancy under six months.6-10 Other policies excluded pregnant patients and children as they could receive remdesivir through the compassionate use program.7 An important variation in allocation policies was the way in which the lottery was structured. Some polices chose to use a weighted lottery, while other polices, such as the Veterans Affairs Hospitals chose to use a random lottery.6-10 Within weighted lottery policies, variations were found in which patients received greater priority with some lotteries giving patients such as essential workers and disadvantaged populations priority.7 Most policies chose to implement a random lottery as weighted lotteries which give patients priority based on life

style may not be easily implemented and have the propensity to create complex ethical dilemmas which may result in judgements that some people have greater societal value.6-10

Limitations in Allocation of Remdesivir Policies

There are several major limitations in remdesivir allocation policies that need to be addressed. First, the EUA guidelines have created a sort of purgatory for pregnant patients.11 Several hospitals use pregnancy in their exclusion criteria because these women were able to use the compassionate use program; however, under the EUA guidelines, patients are not eligible for compassionate use if their hospital has remdesivir. This issue should be corrected in current hospital policy exclusion criteria. Another limitation is that many of these policies do not include an appeals policy in the event that a patient believes they have had remdesivir withheld unfairly. This may be because many policies have developed binomial exclusion and inclusion criteria which does not lend itself to exceptions. Although this may be the case, patients should have the right to appeal the decision to ensure just treatment.

The fact that each individual hospital is creating their own allocation policy is a limitation in-and-ofitself. Without a community standard for the allocation of remdesivir several problems may arise: 1) patients may qualify for remdesivir at one hospital and be excluded at the hospital across the street; 2) hospitals have varying supplies of remdesivir and hospitals who more conservatively allocate the drug may not be open to sharing their supply with hospitals who run out due to a more liberal allocation policy.

Conclusions

There are varying ethical approaches to the allocation of remdesivir being implemented throughout the country. A community standard for the ethical allocation of remdesivir should be devised in order to ensure just and equal access to this drug for all COVID-19 patients. As a community standard does not yet exist, hospitals should develop a policy for the ethical allocation of remdesivir in order to ensure just treatment of all patients within their institution. Policies should be developed by an interdisciplinary team. Ethical consensus among hospital policies suggests the following policy format: 1) developing patient inclusion and exclusion criteria for remdesivir eligibility that is based on clinical criteria and is blinded to patient characteristics such as age, gender, race, disability, and immigration status; 2) distributing remdesivir to all eligible patients until the number of eligible patients outnumbers the courses of treatment available; 3) at the point in which the supply of remdesivir is lower than eligible patients, entering all eligible patients into a random lottery for distribution; and 4) developing an appeals process for patients who feel they have been unfairly excluded. Once a policy is developed, it should be reevaluated as new evidence emerges.

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REFERENCES

1. Gilead. Remdesivir. https://www.remdesivir.com/us/access/?gclid=CjwKCAjw1K75BRAEEiwAd41h1O4edfM6LE3B9HaIJ62Z9OC_GxgtZA5NFJfl3fPyhyd2hYxt4vJH4R°CXLAQ AvD_BwE&gclsrc=aw.ds. Accessed August 6, 2020.

2. Beigel JH, Tomashek KM, Dodd LE, et al. Remdesivir for the Treatment of Covid-19 - Final Report. N Engl J Med. 2020;383(19):1813-1826. doi:10.1056/NEJMoa2007764, 10.1056/NEJMoa2007764

3. WHO Solidarity Trial Consortium, Pan H, Peto R, et al. Repurposed Antiviral Drugs for Covid-19 - Interim WHO Solidarity Trial Results. N Engl J Med. 2020;. doi:10.1056/ NEJMoa2023184, 10.1056/NEJMoa2023184

4. DeJong, C, Chen AH, Lo B. An Ethical Framework for Allocating Scare Inpatient Medications for COVID-19 in the US. JAMA. 2020;323(23):2267-2368.

5. U.S. Food & Drug Administration. EUA Letter of Approval. https://www.fda.gov/media/137564/download. Accessed January 13, 2021.

6. Pennsylvania Department of Health. Ethical Allocation Framework for Emerging Treatments of COVID-19. https://www.health.pa.gov/topics/disease/coronavirus/Pages/ Guidance/Ethical-Allocation-Framework.aspx. Accessed August 6, 2020.

7. Veterans Affairs Hospital. Remdesivir Emergency Use Authorization (EUA) Requirements. May 2020. https:// www. va.gov/covidtraining/docs/20200618_Dynamic_Drugs_in_the_Battle_of_COVID_ 19/Remdesivir_Emergency_Use_Authorization_Requirements.pdf. Accessed August 6, 2020.

8. Lim S, DeBruin DA, Leider JP, et al. Developing an Ethics Framework for Allocating Remdesivir in the COVID-19 Pandemic. Mayo Clin Proc. 2020;95(9):1946-1954. doi:10.1016/j.mayocp.2020.06.016, 10.1016/j.mayocp.2020.06.016 demic. Mayo Clin Proc. 2020;95(9):1946-1954. doi:10.1016/ j.mayocp.2020.06.016, 10.1016/j.mayocp.2020.06.016

9. Washington Department of Health. Washington State Remdesivir Distribution Plan. June 3, 2020. https://cdn.ymaws.com/www.wsparx.org/resource/resmgr/covid/WA_Remdesivir_Distribution-2.pdf. Accessed August 6, 2020.

10. Black H, Buhr R, Cederquist L, Dastur C, Dicker R, Doucet J. et. al. Allocation Guidelines for Remdesivir if Demand Outstrips Supply. University of California Critical Care Bioethics Working

Group. June 26, 2020. https:// committee-guidance/uc-critical-care-bioethics-working-group-report.pdf. Accessed August 6, 2020.

11. Burwick RM, S, Stephenson KE, Collier ARY, Pritha S, Blackburn BG, et. al. Compassionate use of remdesivir in pregnant women. Clinical Infectious Diseases. 2020; (ciaa 1466). https://doi.org/10.1093/cid/ciaa1466