

Access to Therapeutic and Palliative Drugs in the Context of Covid-19: *Justice and the Relief of Suffering*

Nancy Berlinger, PhD; Jean Abbott, MD, MH, HEC-C; Aimee Milliken, RN, PhD, HEC-C; Felicia Cohn, PhD, HEC-C; Matthew Wynia, MD, MPH; Grace Oei, MD, HEC-C; Nneka Sederstrom, PhD; Adira Hulkower, JD, MS, HEC-C; Hannah I. Lipman, MD, MS; Laura K. Guidry-Grimes, PhD; Lori Bruce, MA, MBE, HEC-C; Nancy Piper Jenks, MS, CFNP; D. Micah Hester, PhD

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SUPPLEMENT TO

Ethical Framework for Health Care Institutions Responding to Novel Coronavirus SARS-CoV-2 (Covid-19) with Guidelines for Institutional Ethics Services Responding to Covid-19: Managing Uncertainty, Safeguarding Communities, Guiding Practice

Nancy Berlinger, PhD; Matthew Wynia, MD, MPH; Tia Powell, MD; D. Micah Hester, PhD; Aimee Milliken, RN, PhD, HEC-C; Rachel Fabi, PhD; Felicia Cohn, PhD, HEC-C; Laura K. Guidry-Grimes, PhD; Jamie Carlin Watson, PhD; Lori Bruce, MA, MBE; Elizabeth J. Chuang, MD, MPH; Grace Oei, MD, HEC-C; Jean Abbott, MD, HEC-C; Nancy Piper Jenks, MS, CFNP, FAANP
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Summary

This supplement to The Hastings Center's *Ethical Framework* aims to help structure discussion of significant, foreseeable ethical concerns in responding to Covid-19 and to support collaboration across institutions throughout pandemic response and recovery. It is designed for use by hospitals and other health care organizations (such as community hospice and palliative care programs, nursing homes and other residential care facilities, and home health agencies) responsible for the care of patients with serious illness. These patients include those with Covid-19 and those whose treatment and care is affected by Covid-19. This document aims to support formal and informal con-

vening and policy work within the same geographic region, such as a municipality, county, metropolitan area, state, or multistate area, whether led by health care institutions, state and regional hospital associations, state medical societies, or public health authorities. Its method is to

- summarize how ethical duties apply across institutions serving the same communities and populations, drawing on the duties outlined in the *Ethical Framework*;
- describe ethical considerations arising in access to therapeutic and palliative drugs in the context of Covid-19, drawing on critical analysis of initial pandemic response;

- demonstrate how to discuss these considerations in terms of ethical duties, to support the development of ethically sound policies and processes; and
- share resources supporting discussion and policy and process development.

This document is not intended to be, and should not be considered, a substitute for clinical ethics consultation or other medical, legal, or other professional advice on individual cases or for particular institutions. It reflects an evolving public health emergency and the rapid development and updating of public health and clinical practice guidance and institutional protocols; references are current as of July 8, 2020. This rapid-response work is made possible by The Hastings Center Impact Fund.

Summary of Ethical Framework: Ethical Duties of Health Care Leaders Responding to Covid-19 across Institutions

(April 2020; updated July 2020)

Effective response to Covid-19 acknowledges the tension between the patient-focused duty of care familiar to clinicians and new or urgent public health duties to the community and the health care workforce. These public health duties include and are not limited to responsible stewardship and fair allocation of limited or scarce resources (staff, stuff, space).

Health care leaders have a duty to plan for the management of foreseeable ethical challenges during a public health emergency.

- Ethical challenges arise when there is uncertainty about how to “do the right thing” when duties or values conflict. These challenges affect the health care workforce, health care operations, and a health care institution’s communication with the public.
- Planning to meet the needs of patients with severe Covid-19 illness includes explicit attention to critical care, palliative care, and institutional ethics services and resources.
- Planning for the possibility of crisis standards of care (CSC) includes the development of triage protocols to allocate scarce resources, such as critical care beds and ventilators, and ensur-

ing adequate palliative care for patients opting for or triaged to receive comfort care.

- Understanding where drug shortages can occur, acting to prevent shortages, managing unavoidable shortages, developing appropriate allocation protocols for scarce drugs, and ensuring that health care workers are trained in safe and effective medication delivery are part of the duty to plan.

Health care leaders have a duty to safeguard the health care workforce and vulnerable populations in the community.

- The health care workforce includes clinicians caring for Covid-19 patients, such as physicians, nurses, and respiratory technicians, and other essential workers, such as janitors and housekeeping staff, who are at increased risk of occupational harms during an infectious illness outbreak. A community’s health care workforce is not limited to the employees of a single institution or system, nor to those working in hospitals and clinics. The health care workforce includes those providing hospice and home health services, caring for residents of long-term care facilities, and responding to emergency medical needs in the field as first responders. This workforce often also includes family members, friends, and volunteers, when these individuals provide direct care to patients at home or in residential care facilities.
- Vulnerable populations include people at risk of severe Covid-19 illness due to factors such as age or underlying health conditions, people facing barriers to health care access, and those at increased risk of infection due to living conditions or workforce roles and conditions, such as inability to perform work remotely or reliance on public transportation.
- Persons who live in the same household as a member of the health care workforce may also make up a vulnerable population due to increased risk of infection or because health care workers’ obligations require alternative housing or create a need for childcare and/or eldercare.
- Clinical and epidemiological data from mi-

nority populations indicate that social inequalities derived from racism are associated with higher risk of severe Covid-19 illness and mortality in these groups, creating vulnerability independent from age and comorbidity-associated risk factors.

Health care leaders have a duty to guide health care workers experiencing demanding work conditions, ethical uncertainty, and moral distress during a public health emergency.

- The devastating nature of severe Covid-19 illness and the operational demands of caring for large numbers of Covid-19 patients add tremendous stress to clinical work.
- Further sources of workforce stress include shortages of personal protective equipment (PPE) during this particular infectious disease outbreak, staff redeployment to unfamiliar areas to compensate for staff shortages amid surge conditions, and restructured staff-to-patient ratios in critical-care nursing and other areas.
- Moral distress—the feeling of being unable to “do the right thing” or being helpless to avoid wrongdoing or harm—is foreseeable during a prolonged public emergency featuring high numbers of deaths among critically ill patients, visitor restrictions and limited or no family support for dying patients, resource limitations affecting patient care and health care workforce safety, and the potential need for triage decisions.
- Guidance for health care workers should reflect findings on how social inequalities affect patient and population-level outcomes (health inequities), recognize that observation of

health inequities affecting one’s patients contributes to professional distress and frustration, and connect bedside-level guidance with system-level efforts to mitigate inequity as a public health problem.

These duties apply *across* health care institutions as well as within institutions.

- **Regional collaboration can support the duty to plan** by clarifying regional challenges, sharing resources, identifying consensus, and reducing duplication and unilateral approaches in the development of policies and processes, including triage protocols and drug allocation protocols.
- **Regional collaboration can support the duty to safeguard workers and vulnerable populations** by facilitating PPE allocation and access to therapeutic and palliative care drugs across institutions and care settings (including home hospice, home health, and residential care facilities) and identifying trustworthy ways to communicate with vulnerable populations within a region.
- **Regional collaboration can support the duty to guide** through joint workforce training reflecting regional public health priorities; processes for consultation and referrals across institutions, including among ethics committee leaders and palliative care professionals based in hospitals and in hospice programs; identification of behavioral health services available to Covid-19 health care workers and other caregivers, such as family members and volunteers, and focused work on mitigating social inequalities reflected in regional data on health inequities.

Ethical Considerations in Access to Therapeutic and Palliative Drugs in the Context of Covid-19

Access to drugs used in the treatment and care of patients with Covid-19 is affected by factors that include:

- shortages of relatively common drugs, including palliative care drugs;
- current or projected scarcity of new or experimental therapeutic drugs;
- uncertainty concerning the value of new or experimental drugs;
- changing guidance concerning which patients are most likely to benefit from new or experimental drugs;
- drug pricing; and
- social inequalities affecting population health and use of health care.

How best to allocate different types of medication given institutional and regional conditions during a public health emergency requires discussion of different approaches to resource allocation and the ethical justification for selecting an approach.

Lessons from the Initial Covid-19 Surge

The initial hospital response to surges of patients with Covid-19 experiencing severe respiratory symptoms, including life-threatening complications affecting major organ systems, demonstrated system-level vulnerabilities in securing supplies of medications integral to the care of critically ill patients and dying patients. The care of patients with life-threatening Covid-19 includes symptom palliation and the use of medication to help patients tolerate interventions. Palliative drug shortages experienced by some hospitals under surge conditions included symptom-relieving medications, such as aerosol albuterol to alleviate dyspnea (breathlessness); paralytic agents such as intravenous (IV) cisatracurium, and sedatives such as IV ketamine to help patients tolerate intubation and mechanical ventilation, and opioids, such as IV morphine, to alleviate pain and symptoms in the comfort care of dying patients. Alternatives to compensate for shortages under surge condi-

tions, when many patients present with the same needs, may have contributed to adverse events. For example, alternatives to standard paralytics used in critical care settings may have increased ICU delirium, a known risk of critical care experienced by some Covid-19 patients. In some institutions, drug shortages under surge conditions deepened chronic shortages of medications and IV fluids that predated the pandemic.

Moral and ethical imperative to ensure access to palliative care for all patients

Acting to relieve suffering is ethically mandatory in health care work. Symptom palliation and other aspects of palliative care are practical expressions of this ethical mandate. The 2012 Institute of Medicine report *Crisis Standards of Care: A Systems Framework for Catastrophic Disaster Response* states that the “provision of palliative care in the context of a disaster with scarce resources can be considered a moral imperative of a humane society.” Symptom relief is a foreseeable need of all seriously ill patients, including Covid-19 patients in critical care or end-of-life care contexts. Access to palliative care must be built into all aspects of Covid-19 planning.

Ethical considerations in approaching the allocation of therapeutic drugs

The fair allocation of limited supplies of new or experimental therapeutic drugs for Covid-19 patients raises separate questions. For example, there is evidence that the antiviral drug remdesivir, a multiday IV therapy delivered in a critical care setting, is effective in shortening time to recovery of some Covid-19 patients. Since being granted an emergency use authorization by the U.S. Food and Drug Administration (FDA), this drug has been distributed as available, but it will continue to be in short supply. Proposed allocation approaches for antiviral drug allocation, and ongoing discussion and debate concerning these approaches have identified ethical considerations for hospitals and state health departments concerning remdesivir allocation

and potential future drug therapies (see Selected Resources).

The allocation of each new or existing antiviral drug in the context of a novel coronavirus must take into account how much is known about the effectiveness of a given drug, how much benefit to expect, the burdens and risks associated with a drug and whether potential benefits outweigh burdens and risk, and which patients are more likely to benefit. Careful analysis may reveal that an approach ethically justified in the allocation of a proven life-saving resource would not be appropriate for allocating a scarce resource of limited or unproven value.

For example, in the development of ventilator triage protocols, a patient's death has been presumed to be certain if mechanical ventilation is not attempted. Yet emerging data on the high mortality of intubated Covid-19 patients, especially those over age 75, and on the effectiveness of other approaches to respiratory support, suggest that ventilator triage protocols will benefit from ongoing review, and especially so in the days or weeks before surge conditions are reached, to ensure they incorporate the latest evidence.

In addition, a protocol designed to ethically allocate a life-sustaining technology among patients on the point of death—and who may die whether or not they have access to this technology—may not be well-suited to allocation questions concerning potentially beneficial drugs among patients who are stable enough to benefit from a multiday therapy. Where scarcity and uncertainty about the short- and long-term benefits and risks of potential therapies exists, clinical trial protocols may offer a framework for hospitals and state health departments to use in thinking about the allocation of experimental drugs, including how to talk with patients and families about these drugs.

Equity in access to therapeutic and palliative drugs

It is well-established that social inequalities, including racism and other forms of discrimination embedded in structures of privilege within social institutions (structural inequality) produce health inequities measurable in morbidity and mortality data. Clinical and epidemiological data from the initial phase of Covid-19 in the United States have exposed underlying social inequalities distinct from vulnerabilities associated with age and comorbidities. In particular, Black patients with Covid-19 are significantly more likely to need hospitalization compared to non-Hispanic white patients. (Hospitalization rates are highest among Native Americans.) Covid-19 mortality is significantly higher among Black patients compared to all other racial and ethnic groups.

These disparities are rooted in multiple factors, including that Black patients may delay seeking treatment even when severely ill due to longstanding clinical biases in health care, such as the under-treatment of pain in Black patients. Latinos are significantly over-represented in Covid-19 cases due to factors likely to include higher risks of occupational and environmental exposure, and they too face longstanding barriers to health care associated with immigration status and policies.

Ethical considerations in access to therapeutic and palliative drugs in the context of Covid-19 include how to mitigate (or at least prevent the worsening of) health inequities during the pandemic. For instance, populations at greater risk of Covid-19 infection and severe Covid-19 illness may be further harmed by resource shortages in Covid-19 care settings and triage protocols that reduce their likelihood of receiving resources in shortage by clinical biases that are worsened under conditions of time pressure and other stressors, and through relative lack of access to experimental therapies.

Justice and the Relief of Suffering: *Using This Ethical Framework to Develop Policies and Processes for Access to Therapeutic and Palliative Drugs in the Context of Covid-19*

Covid-19 has created a prolonged public health emergency that has revealed the consequences of health system fragmentation and social inequality in the United States. Reflection on how health care institutions responded to the initial phase of the pandemic supports the *duty to plan* for future outbreaks and strengthen patient care systems. Analysis of Covid-19 clinical and epidemiological data support the *duty to safeguard* vulnerable populations through focused work on social inequalities that render minority and low-income populations more vulnerable to Covid-19 and to deficiencies in care systems for this and other conditions. Critical discussion of resource allocation approaches, including proposals aimed at advancing health equity through resource allocation, supports the *duty to guide* by clarifying the justifications for the selection of any proposed allocation approach.

The Ethical Framework summarized on pages 2-3 can support structured discussion of topics concerning access to therapeutic and palliative drugs in the care of patients with Covid-19. The following questions are offered as examples:

- **The duty to plan: How should foreseeable shortages of palliative care drugs be prevented in advance of need?**
- **The duty to safeguard: How should the health care workforce and vulnerable populations be protected from the consequences of drug shortages?**

Palliative care drugs are integral to the care of all patients with severe Covid-19 illness in all settings, given the high symptom burden associated with this condition, burdens associated with medical management, and high mortality and morbidity. Among patients expected to survive, medical control of symptoms may require large doses of opioids and sedatives. Shortages of palliative care drugs increase patient suffering,

impede the relief of patient suffering, and add to the moral distress of the health care workforce and of patients' families. Given increased morbidity and mortality of Covid-19 illness in minority patients, shortages of palliative drugs worsen health inequities by disproportionately affecting patients with higher burdens of illness. Institutional and regional shortages of symptom-relieving medications also risk harms to patients with non-Covid-related needs for palliative care and hospice care.

The duty to plan encompasses understanding operational failures that lead to shortages of palliative care drugs and taking concrete steps to prevent shortages under normal and surge conditions. The use of a planned approach to palliative care under contingency conditions and crisis standards of care is recommended; see the Selected Resources for model approaches from the National Hospice and Palliative Care Organization (NHPCO) and from several states. System-level initiatives or public policy advocacy may be needed to resolve shortages of essential medications.

The duty to safeguard encompasses learning from frontline Covid-19 health care workers, including palliative care specialists, about their experiences with palliative care drug shortages in critical care and in comfort care for dying patients. Critical reflection on lessons from frontline experiences may pinpoint training needs and ethical uncertainties of staff providing palliative care under surge conditions. Every effort should be made to adequately stock medications essential to preventing avoidable suffering. Further steps include scaling up of palliative care staffing, including telemedicine, in anticipation of increased need for consultation; training frontline staff in primary palliative care, including the safe and effective use of palliative drugs, and ensuring that regional planning and allocation includes health care workers who may provide palliative care to Covid-19 patients in nonhospital settings.

- **The duty to guide: What are ethically appropriate or problematic approaches to using allocation protocols for access to therapeutic drugs as tools to mitigate health inequities?**

During the initial phase of the Covid-19 pandemic, development of allocation criteria for access to scarce resources such as ventilators under crisis standards of care featured discussion of “equity scores.” Assuming two gravely ill patients with equivalent need, should allocation criteria aim to mitigate the health inequities of social injustice by prioritizing access for the patient from a socially disadvantaged group, even if that patient has marginally poorer health status? Or should allocation criteria be limited to medical survivability, and if so, what duration of survivability should be considered? Tension between differing views of justice in health care are at work in this ongoing debate about fairness in a distributional process.

The debate over equity in ventilator triage, plus data on the disproportionate impact of Covid-19 on communities of color, has informed the development and critical review of proposals for allocating scarce medications. For example, the University of Pittsburgh’s “Model Hospital Policy for Fair Allocation of Scarce Medications to Treat COVID-19” offers a thoughtful approach to equity scoring, informed by pandemic data: “We show equal respect for all members of society by mitigating the negative circumstances that cause disadvantaged persons to bear the greatest burden of the pandemic. Providing heightened access to treatment for patients with severe COVID-19 who are from disadvantaged groups is one way to mitigate the unequal effects of the pandemic.”

When there is limited data about the effectiveness of a drug or other therapeutic intervention—a foreseeable situation in the context of a novel corona-

virus—using heightened access alone as a tool to mitigate structural inequality is problematic. Approaches to drug allocation informed by equity considerations should be refined in light of emerging data on safety and effectiveness, to safeguard vulnerable populations from undue risks and burdens. Clinical research should aim to collect data and contribute to knowledge of the actual impact of interventions, including allocation approaches, on health equity.

Equity in the allocation of scarce, potentially beneficial drugs should be connected to larger clinical, organizational, and public policy initiatives to uproot social inequalities producing health inequities. Analysis of county-level epidemiological data suggest that structural factors broadly affecting a population better explain disproportionate Covid-19 deaths than do medical, socio-economic, or environmental conditions. Hospitals need to better understand barriers to health and health care faced by populations at high risk of severe illness. Clinician education, including ethics education, reflecting lessons from Covid-19 needs to be well informed about structural racism in health care (as well as other forms of bias, such as ableism and ageism) including how this problem may present in access to therapeutic and palliative drugs.

State health departments involved in the allocation of scarce drugs should collaborate with health systems to develop ethical frameworks for drug allocation that reflect local and regional needs and equity considerations, clarify areas of consensus, and avoid duplication of effort. These efforts, and public health and clinical communications about scarce drugs, should be informed by ongoing review of evidence concerning drug benefits, and should avoid conflating unproven therapies with proven treatments.

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Contributors

*Project Director: Nancy Berlinger, PhD
Research Scholar, The Hastings Center
Bioethics Committee, Montefiore Medical Center*

The following individuals are coauthors of this document. Their institutional affiliations are provided for purposes of identification only.

- Jean Abbott, MD, MH, HEC-C
*Professor Emerita, Emergency Medicine, University of Colorado
Ethics Committee, University of Colorado Health*
- Lori Bruce, MA, MBE, HEC-C
*Chair, Community Bioethics Forum, Yale School of Medicine
Associate Director, Interdisciplinary Center for Bioethics, Yale
University*
- Felicia Cohn, PhD, HEC-C
*Bioethics Director, Kaiser Permanente Orange County
Clinical Professor of Bioethics, University of California, Irvine,
School of Medicine*
- Laura K. Guidry-Grimes, PhD
*Clinical Ethicist and Assistant Professor of Medical Humanities
and Bioethics
University of Arkansas for Medical Sciences*
- D. Micah Hester, PhD
*Chair, Department of Medical Humanities and Bioethics, and
Professor of Medical Humanities and Professor of Pediatrics,
University of Arkansas for Medical Sciences*
- Adira Hulkower, JD, MS, HEC-C
*Chief, Clinical Ethics Consultation Service
Montefiore Medical Center*
- Nancy Piper Jenks, MS, CFNP
*Medical Site Director of Internal Medicine, HRHCare, Peekskill,
NY*
- Hannah I. Lipman, MD, MS
Director of Bioethics, Hackensack University Medical Center
- Aimee Milliken, RN, PhD, HEC-C
*Clinical Ethicist and Nurse Scientist, Brigham and Women's
Hospital*
- Grace Oei, MD, HEC-C
*Director of Clinical Ethics, Loma Linda University Health
Attending Physician, Division of Pediatric Critical Care, Loma
Linda University Children's Hospital*
- Nneka Sederstrom, PhD, MPH, MA
*Director of Ethics
Children's Minnesota*
- Matthew Wynia, MD, MPH
*Professor, Schools of Medicine and Public Health, Director, Center
for Bioethics and Humanities, University of Colorado, Anschutz
Medical Campus, Aurora, CO*

*Editors: Julie Chibbaro, Isabel Bolo
Designer: Nora Porter
Digital media: Mark Cardwell, Susan Gilbert, Julie Chibbaro*

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