

Ethical and Legal Aspects of Pandemics During COVID-19 and Beyond for the Hepatology Community

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KEY POINTS

- Pandemics are associated with major human suffering, including ethical and legal challenges that impact daily practice profoundly.
- Safety concerns impact all parties concerned, from personal fears of health care workers to infect their beloved to profound economic disasters for health care systems and society.
- A transparent ethical and legal framework is mandatory and should include policies toward the powerless and disadvantaged.
- The hepatology community needs to revisit their approach to medicine, turning a medical and societal disaster into opportunities to improve the way we deliver care in an equitable and fair way with improved outcomes.

Implementing new concepts and policies in clinical hepatology during and after the coronavirus disease 2019 (COVID-19) pandemic requires awareness of ethical and legal issues. Prior pandemics highlight common events that can help guide preparedness for the future. 1,2 Descriptions of prior health catastrophes, such as the bubonic plague, include exhausted health care workers, inability to keep up with the dead, government restrictions, medical professionals under scrutiny, firing of those who brought bad news, overreach by governments, censorship, public anger, and violence. They illustrate the challenges to translate medical advice into workable policies. In 2007, 194 countries, including the United States, signed updated binding international law and with a leading World Health Organization (WHO) role "to prevent, protect, control and provide a public

Abbreviations: AASLD, American Association for the Study of Liver Diseases; CLD, chronic liver disease; COVID-19, coronavirus disease 2019; DM, diabetes mellitus; HTN, hypertension; ICU, intensive care unit; PPE, personal protective equipment; WHO, World Health Organization.

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health response to the international spread of disease and which avoids unnecessary interference with international traffic and trade."3 Extensive federal law is applicable in disaster/emergency situations. US states and governors have increasingly uniform regulations in place, in part enacted after 9/11 and the anthrax attacks.4,5 Yet without coordinated national direction, little was uniform across states during the COVID-19 outbreak. The literature on ethical and legal implications surrounding the COVID-19 pandemic is rapidly evolving and accessible on multiple websites (Centers for Disease Control and Prevention, WHO, Bioethics.net, etc.). The COVID-19 pandemic has highlighted and enlarged the socioeconomic divide between the poor and the wealthy. 6,7

ETHICAL AND LEGAL FRAMEWORK **DURING A PANDEMIC**

A comprehensive multidisciplinary input may be required with leadership shared with civil and/or military disaster authorities and community leaders^{2,8} (Fig. 1). Ethical and legal standards need to be refocused from the individual toward the best outcome for all (Fig. 2).

Any restrictions imposed may provoke strong opposition in society and should be limited to the minimum to accomplish a specific goal. Transparency is critically important and should include the scientific basis of guidelines and modifiers, such as shortages of resources, and with updates on the evolving role of testing, vaccines, and treatments.^{8,9} One-voice communication is key in attaining

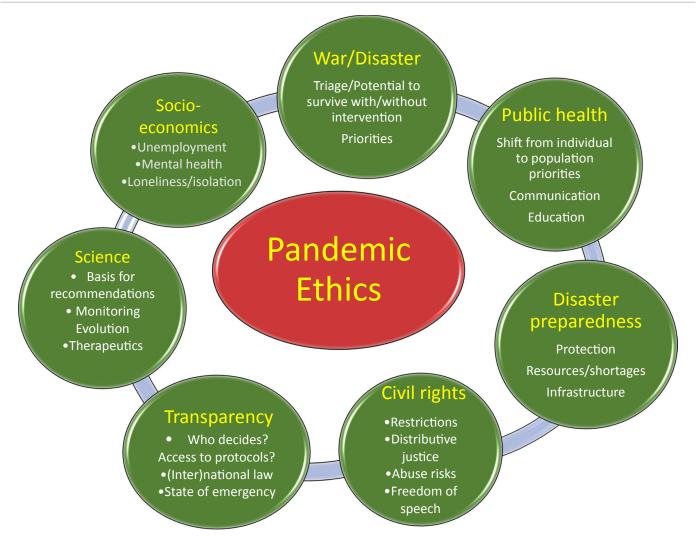


FIG 1 Pandemic ethics evolve from multiple perspectives that require ethical and legal input.

Pandemic: Ethical/Legal Refocusing of Values

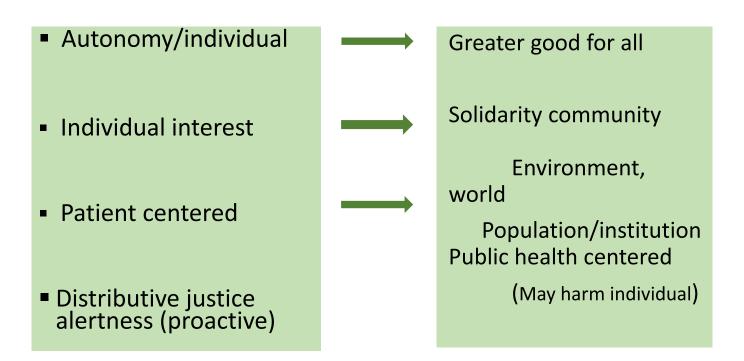


FIG 2 Refocusing of traditional ethical individual doctor–patient and legal values can be challenging.

public adherence.¹⁰ COVID-19 is highly contagious, requiring preparedness of patients, professionals, and institutions. Figure 3 summarizes ethical and legal health dilemmas from individual and institutional perspectives.

TRIAGE ISSUES AND WHAT AND WHEN TO ADDRESS

During times of scarcity of resources, medical selection criteria may be proposed for the best outcomes for most (Fig. 4). In the most severe scarcity situation, overwhelmed systems demand nonmedical choices (1 intensive care unit [ICU] bed for 10 acutely needy patients). Choices not only apply to patients with COVID-19 but to all who need and are entitled to intensive care, and dilemmas are challenging (Fig. 5 and 6). 11,12 As an example, Dutch ethicists, incorporating societal input of many groups, suggested resource allocation could be determined by factors such as the frailty index (beware of discrimination of handicapped people), selected health

care workers with patient exposure if they had lacked access to protective devices, anticipated ICU turnaround time (short is preferred), or if all fails a lottery or first come, first saved. 13 "Life innings opportunities" refers to a concept that all people should have fair and equal chances to complete various stages of life. 14 People can be divided into generational groups of ages, such as <40, 40 to 60, 60 to 80, and >80 years and somewhat less restrictive as specific age per se. Noteworthy, older people showed a considerable willingness to give up their spot for a younger person. Is predicted remaining years to live easier and also fair? Typical questions may come up, for example, if a 23-year-old "drunk driver" carpenter is more deserving than a 68-year-old hepatologist. However, personal faults/quilt tends not to be used as an ethical exclusion criterion.

Against this background, what is the best time to communicate and prepare emotionally charged issues (updated living wills?) that cause anxiety to many elderly and high-risk

Pandemics: Rationing and Preparedness "Shortages of Everything"

- Shortages
 - Manpower Medication Equipment
 - Beds, Back-up facilities
- Who will be admitted? Impact of code red/black?
- Equitable Selection of COVID and non-COVID-19 patients
- Continuum of care?
 - Telecare
 - Home <> Outpatient <> Hospital/Nursing home <> ICU
 - If dying: Access to palliative care?
- What if no Internet, no smartphone?
 - What if illiterate, homeless?

FIG 3 Limited resources: criteria for best outcomes.

patients? Again in the Netherlands, many older patients died at home after their primary care physicians guided them, before turning ill, in review of their options in case they were to contract COVID-19. Many (>50%) firmly decided that they did not want hospitalizations and weeks of ICU on their belly with uncertain rehabilitation perspectives. 13 How and which data will we present to the individual and our referring providers in the community for patients with likely a prolonged recovery period and a worsened clinical frailty score? ¹⁵ Social isolation with absence of farewell or funeral adds major grief that will have a health impact for years to come for survivors. The way potential outcomes are framed may clearly impact a patient's decisions. Will timely preparation of our patients reduce the decisive burden on care teams if new waves or comparable challenges would present?

PANDEMIC ETHICS IN HEPATOLOGY **PRACTICE**

In response to the pandemic, featured information on the American Association for the Study of Liver Diseases (AASLD) and other professional websites now includes safety aspects, telemedicine and billing, confidentiality issues, dilemmas surrounding procedures, and disease group-specific information. Yet applying this information across the COVID-19 patient spectrum is challenging. Patients with chronic liver disease (CLD) with COVID-19 are heterogeneous, from those with abnormal liver tests identified incidentally on routine bloodwork to patients with end-stage liver disease. Patients with CLD at risk for poor outcomes from COVID-19 infection also need to balance the risk for exposure to health consequences of missing surveillance testing and treatment of advanced liver disease, tumor, and/or liver transplantation.

Fortunately, we have already increasingly been acknowledging the role of palliative care when considering life-prolonging interventions. Now we have also to face the challenge of incorporating life expectancy and transplant opportunities into a COVID-19 medical and nonmedical triage system. We may need to forego transfer to an

Professional Duties vs Institutional Responsibilities?

- Healthcare workers
- Risks inherent to profession
- Non-abandonment of patients
- Solidarity with colleagues
- Are all equally at risk?
 - Location specific
 - Hospital in war time (Bombardment)
 - Covid-19 specific
 - Individual Risk related assignments?
 - Age/HTN/DM/Obese

- Institutional responsibility
 - Adequate staffing
 - Safe working environment (PPE)
 - Preventative policies towards professional risks
 - · Risk related assignments
 - Care for dying professionals and their families
 - Appropriate pay
 - Hazardous
 - Overtime
 - Death benefits

FIG 4 Responsibilities and dilemmas of health care workers versus institutions in management of the pandemic.

ICU in agreement with more general admission policies as recently proposed, and specifically in the case of multiorgan failure. ¹⁶

A call to action to address social determinants exposed by the COVID-19 pandemic was recently published in *Hepatology*. ¹⁷ The authors summarize the health care inequities in the United States and the impact of social conditions on individual health, especially disparities in liver disease prevalence, outcome, and access to care. This call to action is a natural extension of the ethical and legal considerations as a moral imperative to promote fairness, equitable access to care, compassion, and justice. Where individual and small group practices are increasingly becoming part of larger systems, the opportunities to share responsibility among all should increase considerably with multidisciplinary input, including home health care, palliative care, and social work.

SOME PRACTICAL SUGGESTIONS

- Ensure that gastroenterology/hepatology practices are transparent and current ethical and legal standards are incorporated.
- Address proactively barriers to accessing care, communication/Internet, language, transportation, and food/dietary care, specifically for disadvantaged patients and aligned with community efforts.
- Develop a modified questionnaire to optimize communication and understanding of patient issues surrounding COVID-19, like the American College of Surgeons toolkits (https://www.facs.org/).
- Create sustainable team telemedicine involving home health care and primary care.
- Incorporate more "frontline palliative care," ideally focused also on preventing unnecessary presentations at emergency departments, helping to explore end-of-life

Pandemic reaches Code Black

- ICU overwhelmed with COVID-19 and non-Covid19 patients
- Institutional, regional, national resources overloaded
- State of Emergency or equivalent (No easy routing elsewhere)
- Medical criteria no longer workable
- Shift to non-medical criteria for triage
 - Frailty index (careful not exclude certain groups with preexisting handicap)
 - Selective groups of healthcare workers (lacked access to PPE)
 - Generational groups / fair innings principle
 - Anticipated ICU turn around time
 - Anticipated years to live
 - · First come, first serve
 - Lottery

FIG 5 Challenges during Code Black ("1 bed for 10 patients").

Hepatology Care during/beyond COVID-19

- Revisit ethical and legal standards, protocols in own practice
 - Fair/equitable system (For-profit vs. not-for-profit to be continued?)
 - Protection of disadvantaged (Poverty, mental/physical impairment etc.)
 - Quality and improvement indicators
- Sustainability of innovations including telemedicine
- Redefining role of players (Social work, palliative care and others)
- Infrastructure of new health care systems
- How to implement? (locally, globally)

What are we willing to give up for the better?

FIG 6 Issues for now and after COVID-19.

REVIEW

choices, and assisting in more uniform guidance and policies at all levels.

- Expand joint ventures, focusing on optimizing care, instead of competing, and upgrading a sustainable financial infrastructure.
- Participate in and help design and implement institutional triage rules that incorporate unique features of patients with advanced liver disease or transplantation and decide how limitations in intensive care options and availability of surgical and especially transplant options are fairly and equitably prioritized.

CONCLUSION

The history of pandemics gives us insights into the nature of problems to be expected and opportunities to address them. The 2021 challenges are how hepatology could translate a disaster era into an advantage, embedded in ethical and legal principles as outlined (Fig. 6). A focus on disparities to equitable and fair access for all is a starting point that should also enhance value-based, costeffectiveness of care. It is encouraging that such topics are rapidly going to the list of priorities of the AASLD and our related hepatology and gastroenterology societies. This is a unique time to take a step back and review what we should do today and how we can shape a new future for hepatology that truly serves and inspires all.

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