UNIVERSITY OF MIAMI
MILLER SCHOOL OF MEDICINE
INSTITUTE FOR BIOETHICS

Florida Ethics: Debates, Decisions, Solutions

29
THREE DECADES OF EDUCATION & RESEARCH
SINCE 1991

Featuring Sessions on

- Climate Change, Ethics, and Racism
- Pandemic Resource Allocation: Ventilators, Therapeutics, and Vaccines
- Pandemic, Politics, Policy: Can We Please Try to Get this Right?

28TH ANNUAL CONFERENCE
FALL 2020

VIRTUAL CONFERENCE
NOVEMBER 13, 2020

FBN Florida Bioethics Network

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Acknowledgments

The University of Miami Institute for Bioethics and Health Policy and the Florida Bioethics Network gratefully acknowledge the following organizations for their generous support of this conference. *The conference would not be possible without this support*. Organizations and individuals interested in supporting bioethics education should contact UM Bioethics Institute at ethics@miami.edu or FBN@med.miami.edu for opportunities to support ethics education in Florida.

- **Arsht Ethics Initiatives**
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- **Herbert Wertheim College of Medicine, Florida International University**
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Contents

Program

10:30 a.m.-11:00 a.m. | Registration, Sign-in, and Debugging

11:00 a.m.-11:15 a.m. | Welcome and Introduction

Kenneth W. Goodman, PhD, FACMI, FACE
Director, Florida Bioethics Network; Director, University of Miami Miller School of Medicine Institute for Bioethics and Health Policy, Miami

Session I

11:15 a.m.-12:15 p.m. | Climate Change, Ethics, and Racism

Cheryl L. Holder, MD
Interim Associate Dean for Diversity, Equity, Inclusivity, and Community Initiatives; and Associate Professor; Herbert Wertheim College of Medicine, Florida International University; and Co-Chair, Florida Clinicians for Climate Action; Miami

Session II

12:15 p.m.-1:15 p.m. | Pandemic Resource Allocation: Ventilators, Therapeutics, and Vaccines

Ray Moseley, PhD (Moderator)
FBN Founder; Associate Professor of Community Health and Family Medicine, Program in Bioethics, Law and Medical Professionalism, Grace H.Osborn Professorship in Bioethics, University of Florida College of Medicine, Gainesville

Luciana Garbayo, MD, PhD
Assistant Professor, Departments of Philosophy and Medical Education; Director, Ethics and Medical Humanities LCT College of Medicine

Dennis Saver, MD, FAAFP
Chair, Cleveland Clinic Indian River Hospital Ethics Committee and Regional Medical Director for Bioethics, Cleveland Clinic, Florida

Alissa Hurwitz Swota, PhD
Bioethicist, Wolfson Children's Hospital/Baptist Health System, Jacksonville

Session III

1:15 p.m.-2:15 p.m. | Pandemic, Politics, Policy: Can We Please Try to Get this Right?

Jeffrey P. Brosco, MD, PhD
Professor of Clinical Pediatrics, University of Miami Miller School of Medicine; Director, Population Health Ethics, UM Institute for Bioethics and Health Policy; Chair, Pediatric Bioethics Committee, Holtz Children's Hospital, Jackson Health System

Kenneth W. Goodman, PhD, FACMI, FACE

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1.1 About FBN

The Florida Bioethics Network (FBN) is dedicated to the understanding and resolution of ethical and legal problems arising in health care and research in Florida's hospices, nursing homes, managed care organizations and teaching institutions. The FBN can help with a variety of health care organization ethics education needs.

FBN Assistance

The FBN can assist you with an educational activity tailored to your institution's particular needs. These activities may include lectures for your staff or the community, workshops for your ethics committee, CME and CNE programs, and conferences.

- Some of the more popular topics include:
- Developing and Running a Hospital Ethics Committee
- Taking Patient Rights Seriously: The Value of a Comprehensive Patient's Rights Program
- Effective Clinical Committee Consultations: Avoiding the Common Mistakes
- Reviving the Non-Functioning Ethics Committee
- Advance Directives: Avoiding the Problems
- Privacy and Confidentiality – Making Practical Sense of HIPAA
- Using Social Worker Proxies for Medical Decisions
- The Recurring Ethical Problems Surrounding Withdrawal of Life-sustaining Treatment
- Effectively Addressing Gender and Ethnicity Issues in the Healthcare Setting
- Medical Futility: When Patients and Families insist on Medical Procedures that Do Not Work
- Stem Cell Research
- Lessons from the Schiavo Case

For assistance with conferences, workshops or presentations and for more information about possible topics, advice on developing an educational program, speaker availability and costs of educational activities please call or e-mail:

In South Florida, Ken Goodman at 305-243-5723 or FBN@med.miami.edu

In North Florida (Orlando and north), Ray Moseley at 352-258-6945 or rmoseley@ufl.edu

FBN Florida Bioethics Network

The Florida Bioethics Network is dedicated to the understanding and resolution of ethical and legal problems arising in health care and medical research in Florida's hospitals, hospices, nursing homes, managed care organizations and teaching institutions.

JOIN OR RENEW at http://fbn.med.miami.edu/become-a-member

Individual Memberships

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Annual Dues (*Note:* Memberships run 12 months from the date of your payment.)	$10	$55	$100
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Bound, hard-copy of the FBN Guidelines for Ethics Committees			1 Copy
FBN Listserv access			

For further information please contact Ken Goodman at 305-243-5723 or FBN@med.miami.edu.

FBN Florida Bioethics Network

Mission:

The Florida Bioethics Network is dedicated to the understanding and resolution of ethical and legal problems arising in health care and medical research in Florida's hospitals, hospices, nursing homes, managed care organizations and teaching institutions.

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How to join:

To purchase an Institutional Membership, please contact FBN@med.miami.edu.

For further information please contact Ken Goodman at 305-243-5723 or FBN@med.miami.edu.

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Complimentary Bound Copies of the FBN Guidelines for Ethics Committees	1 Copy	3 Copies	5 Copies	10 Copies
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Access to the "Members Only" section of the FBN website	✔	✔	✔	✔
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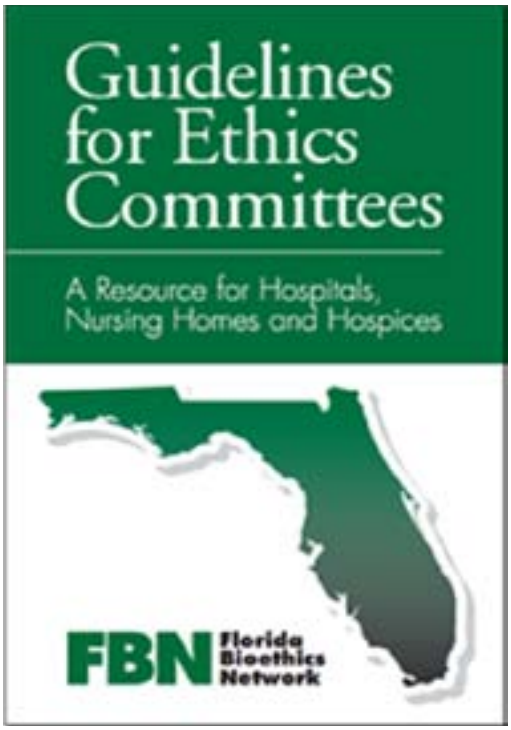
An essential resource for ethics committees.



FBN ETHICS GUIDELINES

The Florida Bioethics Network's Guidelines for Ethics Committees is a must-have resource for institutions and individuals with a serious commitment to bioethics. The current edition includes a glossary and a section on bioethics and the law.

FBN institutional and indivdual professional members already receive this important resource. The book is now available publicly for $65 (including tax, handling and postage charges if applicable).

Regular FBN members, who enjoy online access to the Guidelines, can upgrade their membership for $45 and receive a hard copy of the volume.

Visit http://fbn.med.miami.edu to obtain your copy, or email fbn@med.miami.edu.

FBN Florida Bioethics Network

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- Raul E. de Velasco, MD, UM Institute for Bioethics and Health Policy

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1.2 About the UM Bioethics Institute

The University of Miami Miller School of Medicine's Institute for Bioethics and Health Policy is an interdisciplinary entity dedicated to education, research and community service in bioethics and related fields. The Bioethics Institute seeks to foster links between and among university faculty members, researchers, students and community leaders in medicine, nursing, philosophy, law, health care administration, religion, international studies and other disciplines. The UM Bioethics Institute has been designated a World Health Organization Collaborating Center in Ethics and Global Health Policy.

Contributions to the Institute support its educational, research and service projects. A partial listing of these projects follows.

- *Clinical and Research Ethics.* Projects address end-of-life care; privacy and confidentiality; genetics; clinical research; evidence-based practice; health law; disability; etc.

- *Ethics and Computing in Health Care*. The increasing use of diagnostic expert systems, computerized outcome predictions, patient monitoring and other kinds of medical computing raises interesting and difficult ethical questions for clinicians and researchers.

- *International Initiatives.* This Program promotes educational exchanges, supports research on hemispheric and global issues, and undertakes other activities and projects.

- *Ethics in Epidemiology and Public Health*. Institute faculty and associates have developed the first courses in the nation to address ethical issues in epidemiology, epidemiological research and international health policy. This remains an area of research emphasis.

- *Community Ethics Consulting Services*. The Institute, in conjunction with the Florida Bioethics Network, has developed a program to provide training and consulting services in bioethics (including to institutional ethics committees and IRBs) and professional ethics. More information about these educational and consulting services is available on request.

Bioethics Institute Personnel

Jeffrey P. Brosco, MD, PhD, Professor of Clinical Pediatrics, is the Director of Population Health Ethics for the UM Institute for Bioethics and Health Policy and the Chair of Pediatric Bioethics Committee at Holtz Children's Hospital, Jackson Health System. His research includes an analysis of the history of health care for children and the history of U.S. disability policy.

Thomas Champney, PhD, Professor of Cell Biology and Anatomy, teaches gross anatomy, histology and neuroanatomy and coordinates the South Florida Willed Body Program for the State Anatomical Board. He writes about ethical use of human tissues, especially the use of willed bodies for medical education.

Raul de Velasco, MD, Clinical Ethics Director, is Voluntary Associate Professor of Medicine at UM’s Miller School of Medicine.

Robin N. Fiore, PhD, Voluntary Assistant Professor of Medicine, is the Institute’s Director of Special Ethics Initiatives.

Kenneth W. Goodman, PhD, is professor of Medicine and jointly of Philosophy, and the Institute's director.

Sergio Litewka, MD, MPH, a surgeon by training, is Director of International Initiatives and works on a variety of projects in international research ethics and humanitarian medicine.

Steve Olvey, MD, is an associate professor of clinical Neurology and Neurosurgery. He served as the Director of the Neuroscience Intensive Care Unit at Jackson Memorial Hospital for 25 years.

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2. Content, Goals, Syllabus, Continuing Education and Faculty

2.1 Content and Goals

Bioethics education is now an essential component of professional development. This program addresses these themes and topics: climate change, ethics and racism, Covid-19 resource allocation, and the health and social challenges of the pandemic. Bioethics education must be assigned the greatest possible role in the daily lives of health professionals and their institutions.

Upon completion of this program participants will be able to:

- Increase awareness of climate change as a clinical ethical issue
- Increase knowledge about triage and rationing
- Improve ability to contribute to institutional guidelines
- Improve recognition of ethics in institutional policy
- Improve ability to address needs of special populations

2.2 The Syllabus

This syllabus contains abstracts, presenters' biographical sketches, suggestions for further reading, and resources associated with each of the presentations.

2.3 Continuing Education Credits

"Florida Ethics: Debates, Decisions, Solutions" is available for continuing education credits in a variety of professional disciplines.

ACCREDITATION

This activity has been planned and implemented in accordance with the accreditation requirements and policies of the Accreditation Council for Continuing Medical Education (ACCME). The University of Miami Leonard M. Miller School of Medicine is accredited by the ACCME to provide continuing education for physicians.

CREDIT DESIGNATION

CME: The University of Miami Leonard M. Miller School of Medicine designates this live activity for a maximum of 3.0 ***AMA PRA Category 1 Credits***. Physicians should only claim credit commensurate with the extent of their participation in the activity.

DISCLOSURE AND CONFLICT OF INTEREST RESOLUTION: All conflicts of interest of any individual(s) in a position to control the content of this CME activity will be identified and resolved prior to this educational activity being provided. Disclosure about provider and faculty relationships, or the lack thereof, will be provided to learners.

EVALUATIONS/DOCUMENTATION OF ATTENDANCE FOR CME: The link to the electronic course evaluation will be e-mailed to all participants at the end of the meeting. Please make sure to complete the electronic survey on-line in order to claim your CME certificate. Upon completion of the evaluation, you will receive the certificate via email within 5-7 business days.

CLAIMING EDUCATION CREDIT: Upon completion of the evaluation, you will receive a direct link to enter your attendance hours. Upon submission of the completed evaluation, a CME Certificate will automatically be generated for you to print/save.

LAW: This program has been approved by the Florida Bar for Continuing Legal Education for a maximum of 3.5 General CLE Credits including 3.5 Health Law Certification Credits (Reference # 2001233N)

NURSING: This program has been planned and implemented in accordance with the Essential Areas and Policies of the Florida Board of Nursing for Continuing Education. Provider #50-2105. Credit Designation: The University of Miami School of Nursing and Health Studies designates this seminar series for a maximum of 3 CEU credits.

SOCIAL WORK: This program is approved for 3 CEU's by Jackson Health System. CE Broker Tracking #: 20-771104.

CHAPLAINS: This activity may be used for continuing education credit for chaplains certified with the Board of Chaplaincy Certification Inc.

2.4 Disclosure and Conflict of Interest Resolution

SUMMARY OF DISCLOSURE OF RELEVANT FINANCIAL RELATIONSHIPS
In accordance with the 2004 Updated ACCME Standards for Commercial Support the University of Miami Leonard M. Miller School of Medicine requires everyone in a position to control the content of a Continuing Medical Education activity – the Course Director(s), Planning Committee Members and all individuals participating as speakers, moderators or authors - to disclose all relevant financial relationships with any commercial interest. All potential conflicts of interest are identified and resolved prior to the education activity being provided to learners. Disclosure of relevant financial relationship(s) will be provided to learners prior to the beginning of the educational activity.

The following speakers have indicated that they do not have relevant financial relationship(s) with commercial interests:

Jeffrey P. Brosco, MD, PhD

Luciana Garbayo, MD, PhD

Kenneth W. Goodman, PhD, FACMI, FACE (Course Director)

Cheryl L. Holder, MD

Ray Moseley, PhD

Dennis Saver, MD, FAAFP

Alissa Hurwitz Swota, PhD

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3. Climate Change, Ethics, and Racism

Cheryl L. Holder, MD
Interim Associate Dean for Diversity, Equity, Inclusivity, and Community Initiatives; and Associate Professor; Herbert Wertheim College of Medicine, Florida International University; and Co-Chair, Florida Clinicians for Climate Action

Dr. Cheryl L. Holder, Fellow in the American College of Physicians, has dedicated her medical career to serving underserved populations. She completed her undergraduate education at Princeton University, medical school at The George Washington University School of Medicine and Internal Medicine training at Harlem Hospital. She also board certified HIV Specialist.Through her career she has served as a National Health Service Corp Scholar, Medical Director of one of Miami's largest community health centers, and participated in NIH and CDC health advisory and programmatic review panels. Since 2009, as faculty at Herbert Wertheim College of Medicine 1987, she focuses on teaching the impact of social determinants of health on health outcomes, addressing diversity in health professions through pipeline programs, increasing awareness of HIV prevention and health impact of climate change. Dr. Holder is Director of Green Family Foundation NeighborhoodHELP™ Education and Pipeline Program, President of the Florida State Medical Association –the state affiliate of the National Medical Association and Co-Chair of Florida Clinicians for Climate Action. She has received many awards including the FIU Medallion Cal Kovens Distinguished Community Service Award, the Faculty Convocation Award in Service and Tow Humanism in Medicine Award. Most recently, she was a featured TEDMED2020/ TED Talk -"Clinicians for Climate Action".

❖ **ABSTRACT**

For the poor and vulnerable, the health effects of climate change have already arrived. Unseasonably hot temperatures, disease-carrying mosquitoes and climate gentrification threaten those with existing health conditions, while people who can afford to move to higher ground. As a warmer planet makes people sicker, the role of bioethics needs to expand its role and scope accordingly. This has been true for some time – and now, as our country comes to terms with systematic racism, the stakes are higher than ever. If disparities are wrong, if injustice is wrong, if social justice requires eliminating disparities and injustice – then bioethics needs to put its shoulder to the wheel. People of color are doubly burdened by climate change and racism. Fortunately, clinicians can protect their patients from climate-related health challenges and at least some aspects of racism by joining with others to build a healthcare system that incorporates economic and social justice.

📖 **SELECTED READING**

The link between climate change, health and poverty
https://www.ted.com/talks/cheryl_holder_the_link_between_climate_change_health_and_poverty?language=en

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4. Pandemic Resource Allocation: Ventilators, Therapeutics, and Vaccines

Ray Moseley, PhD
FBN Founder; Associate Professor of Community Health and Family Medicine, Program in Bioethics, Law and Medical Professionalism, Grace H. Osborn Professorship in Bioethics, University of Florida College of Medicine, Gainesville

Dr. Moseley is the founder and was the first President of the Florida Bioethics Network (FBN), and has played a key role in the development of the FBN as a significant statewide resource and as a model for other bioethics networks around the country. His research includes publications on 'Withdrawal of Life-Sustaining Medical Treatment,' 'Advance Medical Directives,' 'Genetic Testing,' 'New Medical Technologies,' and 'Prenatal Testing.'

Luciana Garbayo, MD, PhD
Assistant Professor, Departments of Philosophy and Medical Education; Director, Ethics and Medical Humanities LCT College of Medicine

Dr. Garbayo received her MD from the Federal University of Rio de Janeiro and holds a PhD and MA in Philosophy. She was previously an Assistant Professor in the Department of Philosophy at the University of Texas El Paso. Dr. Garbayo then transitioned to teaching at the Federal University of Rio de Janeiro in the Doctoral Bioethics Program. Her subject matter included Applied Ethics and Public Health. She later went on to work as faculty in Medical Education Reform. Dr. Garbayo joined the University of Central Florida in 2015. She is jointly appointed as an Assistant Professor in the College of Arts & Humanities, Department of Philosophy and the College of Medicine in the Department of Medical Education. Dr. Garbayo is the Longitudinal Curriculum Theme Director for Medical Ethics and Humanities in the M.D. program and is responsible for implementing ethical topics throughout the four-year curriculum. Dr. Garbayo has taught ethics and philosophy-based courses in both undergraduate and graduate level programs. Dr. Garbayo was previously awarded the esteemed Teaching Distinction Award from the Federal University of Rio de Janeiro for her work on curriculum development and delivery of the course. Dr. Garbayo is currently involved in multiple Philosophy-based research projects, some topics include: ethics in the medical practice, prescriptive and descriptive philosophy of medical decision-making medical simulation and future studies and measurement and metrics in epidemiology. She is actively involved in numerous organizations, and has been an elected member of the American Philosophical Association Committee for Hispanics/Latinos and previously held the role of President of the New Mexico Texas Philosophical Society from 2011-2014.

Dennis Saver, MD, FAAFP
Chair, Cleveland Clinic Indian River Hospital Ethics Committee and Regional Medical Director for Bioethics, Cleveland Clinic, Florida

Dennis F. Saver, MD, is a family physician and founding president of Primary Care of the Treasure Coast in Vero Beach, FL. His background includes a decade of service in the rural Appalachian town of Newburg, WV, starting as a National Health Service Corps assignment. After returning to Florida, he volunteered in 1991 as chair of his county medical society's indigent task force, which developed a volunteer physician clinic using the Florida Medical Association's "We Care" model. He continues volunteer services weekly since retirement in 2019, and is also President of the We Care Foundation of Indian River (www.WeCareofIRC.org) which raises donations to operate the program. Dr. Saver spearheaded the development of a medical ethics teaching program at the Medical college of Pennsylvania as a 3rd year medical student in 1976, where he was also a Board of Directors member of the Health and Human Values Task Force in Philadelphia. In Vero Beach, he has chaired the Ethics Committee at (Cleveland Clinic) Indian River Hospital for 20 years, is a Clinical Associate Professor of Family Medicine at FSU and University of Florida medical schools, and is the Regional Bioethics Medical Director, Cleveland Clinic Florida. He was President of the Florida Academy of Family Physicians in 2004, and was recognized as the national 2001 Family Physician of the Year by the American Academy of Family Physicians.

Alissa Hurwitz Swota, PhD
Bioethicist, Wolfson Children's Hospital/Baptist Health System, Jacksonville

Dr. Swota is the bioethicist for Wolfson Children's Hospital/Baptist health System. Previously, Dr. Swota was formerly an associate professor at the University of North Florida and director of the Florida Blue Center for Ethics. She received her Ph.D. from the University at Albany and completed a post-doctoral fellowship in clinical and organizational ethics at the University of Toronto Joint Centre for Bioethics. Her research focuses on issues at the end of life, pediatric bioethics, advance care planning, and the connection between culture and ethical issues in the clinical setting. Dr. Swota's research has resulted in a book, numerous book chapters, and journal articles. Dr. Swota delivers talks and workshops across the US and Canada.

❖ ABSTRACT

The Florida Bioethics Network has expanded its mission to provide guidance on a number of pandemic-related policy issues. The first effort was a document, "Ethics Guidelines for Crisis Standards of Care in Public Health Emergencies," which has been adopted by the Florida Hospital Association. Today's panel introduces the FBN's "Managing Shortages of Therapeutics in Hospitals." Its introduction reads, in part, "The COVID-19 public health emergency has made clear that many hospitals and other institutions in Florida and elsewhere at times have insufficient drugs and other therapeutics to treat their patients. The Florida Bioethics Network (FBN) has prepared this guidance document to offer recommendations and offer points to consider for healthcare institutions trying to manage drug and therapeutics shortages."

> Note: These guidance documents are available as a service to Florida's healthcare community without charge at https://fbn.miami.edu/resources/covid-19-resources/index.html. They are offered on the honor system: If an institution finds these documents useful, it should become an FBN institutional member.

🕮 SELECTED READING

"Managing Shortages of Therapeutics in Hospitals Florida Bioethics Network Guidelines" (https://fbn.miami.edu/_assets/pdf/resources/covid-19-resources/fbn-therapeutics-111320.pdf)

Managing Shortages of Therapeutics in Hospitals
Florida Bioethics Network Guidelines
November 13, 2020

Contents

Introduction

The COVID-19 public health emergency has made clear that many hospitals and other institutions in Florida and elsewhere at times have insufficient drugs and other therapeutics to treat their patients. The Florida Bioethics Network (FBN) has prepared this guidance document to offer recommendations and offer points to consider for healthcare institutions trying to manage drug and therapeutics shortages. This document provides neither medical nor legal advice. It was approved by the FBN Board of Advisors in November 2020.

This is a companion to the FBN's "Ethics Guidelines for Crisis Standards of Care in Public Health Emergencies,"[1] which addresses ventilator allocation and related issues.

Managing supply shortages poses significant ethical challenges. Hospitals must have clear, ethically defensible, and transparent allocation plans and policies in place to meet these challenges. Indeed, such plans and policies should be in place before shortage-induced allocation problems arise. This will support decisions grounded in ethics and evidence. Although plans will differ from institution to institution, the values and ideals of each institution – we presume these to be shared, inter-institutional values – ought to be embedded in a framework to guide resource allocation. These values include nondiscrimination and inclusivity, require a commitment to dignity and respect, and signal the importance of evidence over ideology. The FBN recommends that hospitals and other healthcare institutions consider the following values, principles, and practices in developing or adopting allocation plans and policies.

[1] Available at https://fbn.miami.edu/_assets/pdf/resources/covid-19-resources/csc-fbn-6.pdf.

1. Allocation plans/policies should be based on the best available evidence.

Track scientific research. The underpinnings of allocation policies must be clear and transparent and identify areas in which there are gaps in scientific knowledge. Biomedical knowledge can be volatile; this requires regular re-evaluation. Changes in the evidence base have been shown to affect drug dosing and efficacy, the utility of additional synergistic treatments, or new treatments altogether. All must be continuously reassessed and revised.

Determine policy thresholds. Hospitals should have an explicit mechanism for identifying and selecting "triggers" to activate an allocation policy. These triggers should be based on the evidence just noted, and assessed in light of local availability and expertise, and supply chain considerations. New treatments are constantly being developed and tried; the best generally emerge from successful phase III randomized clinical studies. In the setting of a public health emergency that has overwhelmed existing medical resources, unproven therapies may receive publicity and create public demand which cannot be reined in with scientific resolve. Even clinicians may seek to use, if not insist on using, unproven therapeutics. This can divert attention from treatments which have documented benefit and from other patients receiving care for conditions unrelated to the public health emergency.

Be transparent. Hospitals should establish and implement a publicly disclosed and transparent process for determining that an emergency has necessitated a special process to fairly and justly allocate scarce resources. Some hospitals in Florida have successfully established resource allocation or crisis standards teams to ensure an apt process. Participants on such teams should when possible include clinicians with appropriate expertise, institutional leaders, lay community representatives, and ethics committee members. Such teams should have diverse membership. The teams must monitor empirical and ethical guidance from state, regional, and national experts.

2. Allocation policy should be based on clearly articulated ethical principles.[2]

Utility. When there are inadequate resources in a public health emergency, hospitals should publicly announce that they are shifting to an "emergency" ethical framework in which triage is used to maximize the greatest possible good for the greatest number of individuals.

- To effect such a maximization requires an analysis of consequences, including unintended consequences.

[2] The principles articulated here rely extensively on those put forward by the Ontario Ministry of Health and Long-Term Care's "Ethical Framework for Resource Allocation During the Drug Supply Shortage," Version 1.0, available at http://www.health.gov.on.ca/en/pro/programs/drugs/supply/docs/ethical_framework.pdf (last accessed October 23, 2020). While there are many other lists of principles that are similar in salient respects, we found the Ontario document to be superior. The passages that are direct quotes are italicized.

- The Principle of Utility must be titrated to accommodate higher values related to nondiscrimination and patient rights.
- Mere utility itself might worsen existing disparities.

Beneficence. Uphold the highest-possible standard of *safe and effective care*.

- Ensure adoption of evidence-based medical practices whenever possible.
- *Minimize pain and suffering*.
- Avoid or minimize the need to ration resources by using alternative drugs or treatments when available *evidence suggests similar clinical efficacy* [and effectiveness].

Stewardship. Utilize existing resources judiciously.

- Ensure drug use aligns with current clinical recommendations.
- *Prioritize access to scarce drugs based on urgency* and likelihood of benefit.
- Establish checks and balances to reduce waste, bias, and secrecy.

Trust and accountability. *Foster and maintain public, patient, and health-care provider confidence in the institution*.

- Communicate truthfully, clearly, in a timely fashion.
- Decision-making should be transparent and inclusive, with accountability clearly denoted.
- Establish quality improvement processes to evaluate relevant procedures.

Equity. *Promote fair access to resources*.

- Do not worsen disparities
- Actively engage those most affected by disparities in the design and implementation of allocation guidelines.
- Racism and other forms are bias are often difficult to identify. Attend to the risks of racism and other forms of discrimination.

Autonomy. Maintain respect for decision-making by patients and their representatives.

- Within the constraints of any allocation policy, provide opportunities for shared decision-making if possible.
- Communicate clearly to patients about risks and benefits of various treatment alternatives – and about the (un)availability of certain therapeutics.

3. Resource management teams should address allocation issues and manage protocols.

Such teams should be well-informed and guide difficult allocation decisions for their institutions. They should have the following traits.

Multidisciplinary. Teams should include scientific/medical experts, social workers, nurses, members of the hospital ethics committee, pharmacists, legal advisors, and the community served by the institution. Consideration should be given to including people with disabilities and the clergy.

Nimble. Teams must have adequate administrative resources, be well-coordinated, meet as needed, and enjoy open communication channels to support inquiries from health care workers and the community.

Accountable. Decisions made by the resource management team should be reviewed or audited regularly to ensure that the allocation policy is being applied as intended and that implicit or explicit patient selection bias has been avoided. Ideally, a group separate from the team should perform the reviews. For small hospitals, it might make sense to outsource this function.

4. Therapeutics allocation policies should articulate bases or criteria for allocation.

This means, for instance, that rationing or triage decisions should be made explicit. The following are among the criteria to be addressed.

Priority. Several approaches have merit depending on drug availability, patient population, urgency in individual cases, comorbidities, etc. These include: likelihood of success; lotteries; or a combination of two or more approaches.

Decision procedure. Within allocation categories, teams should specify how decisions will be made between categories/tiers of patients. Any "tie-breakers," i.e., secondary validated prognostic information, randomization process, etc. should be specified.

5. Communication materials and channels should be established.

Patients and their families should understand how allocation decisions are made. Patients in an allocation pool should receive information about the institution's allocation process as handouts. Appropriate language translations should be obtained as best as possible under emergency circumstances .

- Handouts should be accurate and use language appropriate across education levels
- Regular and clear communication with hospital leadership, staff, affected patients, and the general public is essential. A public information phone line and website are recommended during crisis allocation periods.
- The values of veracity and transparency should guide this communication.

6. Clinicians should not make allocation decisions for their own patients.

- The clinician's primary duty of loyalty is to her/his own patients, generally without regard for other patients
- Conflicts of interest can occur if a patient's treating physician or nurse is directly involved in a specific allocation decision. Instead, resource allocation teams should determine which patients receive limited therapeutics.
- If there are not enough clinicians to separate allocation decisions from treating physicians or nurses, more robust audits and reviews should be conducted.

7. An appeal process should be established.

- Such a process should be available to patients, families, and treating clinicians.
- Appeals should assess whether the allocation protocol was properly followed, not the clinical correctness of any individual administration of a therapeutic agent. Of course, the very idea or existence of an allocation protocol or team is not open to appeal.
- All hospitals should have a functioning ethics resource or process, if not a full ethics committee. Such resource, process, or committee should be involved in any appeal.

8. Resources

Centers for Disease Control and Prevention. COVIDView: A Weekly Surveillance Summary of U.S. Covid-19 Activity. Available at https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html

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Acknowledgements

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5. POLST: End-of-Life Advocacy and Public Policy

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❖ ABSTRACT

The sadly managed COVID-19 pandemic has occurred at the same time as a national reckoning over systematic racism and a divisive election. It has been a difficult and conflicted year – so difficult, in fact, that public discourse itself has become thoroughly fraught and contentious. The bioethics community has tried to rise to the occasion. This is interesting: where our topics and issues are often the source of disagreement, there has been a concerted effort to make plan the value and virtue of respectfully managing divergent views. This exchange, a kind of fireside chat between two senior bioethics scholars, aims to increase clarity about the role of bioethics in healthcare institutions and in county and state health organizations.

🕮 SELECTED READING

"Ethics Guidelines for Crisis Standards of Care in Public Health Emergencies" (https://fbn.miami.edu/_assets/pdf/resources/covid-19-resources/csc-fbn-6.pdf); and Executive Summary (https://fbn.miami.edu/_assets/pdf/resources/covid-19-resources/csc-summary-040220.pdf)

FBN Florida Bioethics Network

ETHICS GUIDELINES FOR CRISIS STANDARDS OF CARE IN PUBLIC HEALTH EMERGENCIES

March 27 / April 8 / May 1, 2020

This document was initially approved by the FBN Advisory Board on March 27, 2020. Version 2 was approved on April 8, with authorization for the Director to correct and amend as needed. This is version 6; it was revised to better accommodate and address concerns of Florida's disability community. No FBN members are authorized to speak on behalf of any institution they might work or volunteer for, and any listing of members' institutions is for identification purposes only. This document does not provide, and should not be inferred to provide, medical or legal advice of any kind. It provides ethics guidance; it is not dispositive. For medical or legal questions, contact qualified professionals.

1. Preamble

Public health emergencies can pose extraordinary if not unprecedented challenges for health care systems, institutions and practitioners. Many of these challenges are shaped by shortages of people, equipment, medication and/or appropriate treatment venues. When systems, institutions or clinicians lack adequate resources, it is both unrealistic and inappropriate to expect or require them to conduct operations or practice their professions according to non-emergency standards. For this reason, many states have adopted "crisis standards of care" policies, guidelines or laws to govern such altered standards.

A goal here is to provide ethically optimized, evidence-based guidance on clinical management in the COVID-19 emergency. It includes a commitment to do our best to provide respect, care, and compassion to all patients without regard to race, ethnicity, citizenship status, national origin, religion, sex, disability,[1] veteran status, age, genetic information, sexual orientation, gender identity or any other such characteristic or trait. This does not mean that all patients can be guaranteed access to resources that might be limited – only that we will apportion resources based on data and evidence, and not any of these characteristics or traits as such.

Moreover, the use of such objective measures as given in this document are themselves barriers to bias and discrimination, implicit and explicit, documented in some clinical decision making. Objective, evidence-based criteria reduce human bias.

This document incorporates, is shaped by and is prepared in awareness of

- Evolving national crisis-care standards
- Guidance by the U.S. Food and Drug Administration, Centers for Disease Control and Prevention, and Department of Health and Human Services' Office of Civil Rights

[1] References available at https://bioethics.miami.edu/education/public-health-ethics/pandemic-resources/index.html. These guidelines are informed by and undergoing revision in light of the HHS Office of Civil Rights' March 28, 2020, "BULLETIN: Civil Rights, HIPAA, and the Coronavirus Disease 2019."

- Communication with critical-care physicians and ethics experts from around the country

2. History

The State of Florida has some experience in crisis standards of care. In response to the 2009 H1N1 influenza emergency,[2] the Florida Department of Health in 2010 established a Pandemic Influenza Technical Advisory Committee and commissioned "Pandemic Influenza: Triage and Scarce Resource Allocation Guidelines," which was completed in 2011.[3] The Committee's draft was not formally approved or adopted. Its "Introduction" reads, in part,

> In the event of a pandemic influenza or other public health emergency, the demand for healthcare resources and services will dramatically increase. Out of necessity, scarce resources and patient care will have to be allocated so as to generally "do the greatest good for the greatest number". Towards this end, the Florida Department of Health has prepared this guidance document to assist public and private medical and healthcare entities statewide in dealing with such events.* The Department's responsibilities in such events include: 1) development and coordination of a State Pandemic Influenza Response Plan and other health/medical emergency response annexes included in the State Comprehensive Emergency Management plan, 2) epidemiology surveillance/ situational awareness, and investigation, 3) implementation of Governor and Surgeon General directives, including, but not limited to, executive order(s), emergency declaration, or a declaration of public health emergency, 4) coordination of resource requests through Emergency Support Function (ESF) 8 at the State Emergency Operations Center (SEOC), 5) provision of guidance for healthcare facilities in a pandemic, and 6) issuance of patient triage and care recommendations.

Moreover, under "Basic Premises," it notes,

> Ethical goals informing the department's recommendation to allocate resources include: reducing harms and promoting benefits; respecting equal liberty and human rights; ensuring that the burdens imposed by allocation are shared fairly and do not fall disproportionately on some of Florida's residents. Public officials and healthcare workers should be professional and accountable, and their decision-making process should be open and transparent, culturally sensitive, and sustain public trust. The department recommends focusing on the treatment

[2] http://www.floridahealth.gov/diseases-and-conditions/disease-reporting-and-management/disease-reporting-and-surveillance/data-and-publications/_documents/2009-section5.pdf

[3] http://www.floridahealth.gov/programs-and-services/emergency-preparedness-and-response/healthcare-system-preparedness/_documents/acs-guide.pdf. Alternative link: https://bioethics.miami.edu/_assets/pdf/about-us/special-projects/ACS-GUIDE.pdf

> that would most likely be lifesaving and on those whose functional outcome would most likely improve with treatment. The ethical rationale for this recommendation is that it most likely secures the goals of public health emergency preparedness, including allocating resources, and minimizes the burdens that might result if decisions were made unfairly… In scarcity, efforts should focus on treatments most likely to be lifesaving and on patients most likely to improve with treatment. Decisions should minimize the burdens on others.

The Advisory Committee did not encounter any public opposition to its Guidelines. Then as now, there was broad state and national consensus on

- The need for such guidelines
- The medical science justifying altered care standards
- The ethical foundations of such standards

The 2011 Guidelines for altered care standards included extensive empirical evidence and featured uncontroversial statements of core public health values. Then as now, Florida's academic, medical and nursing communities enjoy significant expertise and experience on ethical and other issues arising in public health emergencies.[4]

3. Scope and Adoption/Activation

These guidelines apply to adult and pediatric patients, including those diagnosed with or strongly suspected of having contagious and life-threatening maladies. In the current context this means COVID-19. The document's principles, values and guidance can be applied to other, similar public health emergencies. These Guidelines are authorized or enacted either by order of the Governor or Surgeon General or, failing that, institutional leadership; such orders will also specify their duration. After such a declaration, the institution may accelerate or delay implementation of various provisions, as circumstances warrant. For instance, it might be that authorization of the Guidelines might never lead to activation of its individual provisions; or to the activation of some and not others. The institution will need to set triggers and duration according to local circumstances.

4. Principles and Values

The following are uncontroversial and widely accepted principles and values to guide medical and institutional decisions during a public health emergency.

[4] The Florida Bioethics Network (FBN, https://fbn.miami.edu), for instance, is a 30-year-old professional organization, the leaders and members of which have expertise in ethical issues related to public health, clinical practice and biomedical research. FBN institutional members (including state and private academic medical centers, hospitals, nursing homes and hospices) have long collaborated with the Departments of Health, Children and Families and Elder Affairs; and the U.S. Centers for Disease Control and Prevention. One Florida institution, the University of Miami, is home to a World Health Organization Collaborating Center in Ethics and Global Health Policy, the only such in the United States.

1. Clinicians have fundamental, uncontroversial and overarching duties to treat patients, including those with contagious maladies. This is known as the "duty to treat." Such a duty both assumes and implies that clinicians have the resources necessary to provide the intended treatment, and that treatment is expected to be effective. That is, one cannot be said to have a duty if one is unable to carry out the duty.
2. It follows that physicians, nurses and other health professionals have no duty to offer or provide treatments which they have determined, based on the best available evidence and within a reasonable degree of medical probability, will not benefit patients, are not effective or are contrary to standard clinical judgment.
3. In normal circumstances, it is reasonable to evaluate, treat and admit patients, and provide them with equipment and other resources on a "first-come, first-served" basis. In a public health emergency, however, that approach risks wasting resources, using resources ineffectively or depriving patients who might benefit from appropriate attention and resources.
4. All patients deserve the highest-quality care possible in the circumstances. However, offering or delivering interventions believed to be ineffective does not contribute to high-quality care.
5. As with all clinical judgments, the judgment that an intervention is non-beneficial or futile need not be infallible. These decisions are always left to appropriately trained clinicians – as they must also be under these guidelines. The standard for decision making given in Florida Statutes is "a reasonable degree of medical probability."[5]
6. Palliative care is always appropriate, and should be made available as available and as widely as possible, especially for patients for whom crisis standards of care are adopted.

4.1 Institute of Medicine (IOM) and Centers for Disease Control (CDC)

4.1.1 IOM

The IOM in 2009 defined "crisis standards of care" as

> A substantial change in usual healthcare operations and the level of care it is possible to deliver, which is made necessary by a pervasive (e.g., pandemic influenza) or catastrophic (e.g., earthquake, hurricane) disaster. This change in the level of care delivered is justified by specific circumstances and is formally declared by a state government, in recognition that crisis operations will be in

[5] FS 765.101(4) (http://www.leg.state.fl.us/Statutes/index.cfm?App_mode=Display_Statute&URL=0700-0799/0765/0765.html) uses this standard to identify (in)effectiveness of a treatment, i.e., "end-stage condition" is defined as "an irreversible condition that is caused by injury, disease, or illness which has resulted in progressively severe and permanent deterioration, and which, to a reasonable degree of medical probability, treatment of the condition would be ineffective." That probability concept is sometimes known as the "standard of medical reasonableness."

effect for a sustained period. The formal declaration that crisis standards of care are in operation enables specific legal/regulatory powers and protections for healthcare providers in the necessary tasks of allocating and using scarce medical resources and implementing alternate care facility operations. [6]

Moreover, the IOM emphasized "the need for states to develop and implement consistent crisis standards of care protocols both within the state and through work with neighboring states, in collaboration with their partners in the public and private sectors."[7] Such standards should be driven by ethical norms and process elements.[8] Norms or values include the following:

- **Fairness**. This requires that all patients be treated equally based on their diagnosis and prognosis and not their social standing, socioeconomic class, ability to pay, etc. People with mental or physical disabilities, non-citizens, prisoners or religious minorities, for instance, may not be discriminated against.
- **Professional duty to care**: As above, this is the duty one acquires by virtue of having specialized knowledge or skills.
- **Professional duty to steward resources**: Professionals enjoy great power and standing, and with this comes the responsibility to ensure that resources are used wisely and not squandered.

Ethical process elements are needed to foster and sustain clinician confidence and public trust, and include these:

- **Transparency**: Civil society requires that public health and resource-allocation decisions, as well as policies governing the behavior of professionals, be subject to public scrutiny. Community engagement is a component of transparency.
- **Consistency**: To promote fairness, similarly situated individuals and groups must be treated similarly. Consistency helps prevent discrimination against vulnerable groups.
- **Proportionality**: Measures adopted to manage emergencies should not be more restrictive or onerous than necessary. Any rationing plan, for instance, should not be more severe than needed. To be sure, there can be uncertainty about what will be needed in the near- and long-term future.
- **Accountability**: This means that individuals must be able to explain to and educate colleagues and communities about the reasons for policy and other decisions. There is an important role for state and institutional leadership in this regard. Accountability "puts a face" on institutional responsibility, and builds public and trust.

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[6] IOM (Institute of Medicine). 2009. *Guidance for establishing crisis standards of care for use in disaster situations: A letter report.* Washington, DC: The National Academies Press, p. 18.
[7] Ibid., p. 4.
[8] Ibid., pp. 18ff. Similar norms are identified by the Society of Critical Care Medicine ("Critical Care Resource Allocation Recommendations," draft, forthcoming).

These norms and values themselves are not rules; some of them might in certain circumstances conflict with others. What is required throughout emergency planning and operations is ongoing self-scrutiny to ensure that values are honored to the extent possible, and that review of the decisions and processes is ongoing and competently conducted. A review mechanism is described below.

4.1.2 CDC

The Centers for Disease Control and Prevention's Ethics Subcommittee of the Advisory Committee to the Director saw the need, also in 2011, to identify "ethical standards and principles relevant to allocation of ventilators during a severe pandemic or other public health emergency …"[9] The group made clear that

> A public health emergency creates a need to transition from individual patient-focused clinical care to a population-oriented public health approach intended to provide the best possible outcomes for a large cohort of critical care patients. The trigger for the transition from usual critical care procedures to emergency mass critical care should occur when there is a substantial extreme mismatch between patient need and available resources, that is, when the numbers of critically ill patients surpass the capability of traditional critical care capacity.[10]

In such a case, there is a need to make difficult decisions related to resource allocation: "In order to use scarce resources most efficiently, in some clinical situations where there is a severe shortage of life-saving medical resources, priority is given to those who are *most likely to recover* after receiving them."[11] Moreover,

> To achieve the public health goal of minimizing the number of preventable deaths during a severe pandemic emergency, states and hospitals need to address the issue of removing from ventilators patients with respiratory failure whose prognosis has significantly worsened in order to provide access to patients with a better prognosis. During a declared public health emergency, decisions about allocation of scarce resources must be made in accordance with transparent, accountable, and fair public health directives. Policies for withdrawal of patients from ventilators need to be the least restrictive possible – i.e., withdrawing of ventilation without requiring assent of patient or surrogate continues only as long as the shortage of ICU resources continues.[12]

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[9] https://www.cdc.gov/os/integrity/phethics/ESdocuments.htm. One Florida University contributed to this committee.
[10] Ibid., p. 7.
[11] Ibid., p. 9; original emphasis.
[12] Ibid., p. 21.

5. Shared Goals and Obligations

The following stances are uncontroversial and widely accepted. To articulate them is to signal the importance of shared goals and to make clear to Florida's institutions and and their clinicians that they enjoy and should count on the support of the people in their communities.

1. The duty to treat neither entails that all possible treatments are appropriate nor requires that they be attempted. Certain interventions – mechanical ventilation, extracorporeal membrane oxygenation (ECMO) and cardiopulmonary resuscitation (CPR) being key examples – might be non-beneficial or futile and therefore ethically may be withheld or withdrawn.
2. The overarching goal of these guidelines is to ensure institutional readiness to deliver the best care possible in the context of a public health emergency. There might arise circumstances in which it is medically contraindicated, physically impossible, or not beneficial to a patient to provide certain kinds of diagnostic or therapeutic interventions. These guidelines apply to circumstances in which such impediments require flexibility and clinical judgment in determining the appropriate level of patient care.
3. That a clinician might be at risk of infection is in itself not an over-riding consideration. However, if a clinician contracts a serious malady in the course of providing futile care and is therefore quarantined or sickened (and hence unable to treat other patients), such nonbeneficial intervention undermines the institutional mission and deprives other patients of treatment – *without any counterbalancing benefit to the initial patient*.
4. These guidelines are intended in part to support attending physicians, front-line nurses and other healthcare providers during a public health emergency. They do not require or forbid any specific intervention. They do require a decision based on ethical norms, clinical judgment, the best-available evidence and accessible resources in individual cases. This parallels non-emergency triage standards, such as organ transplantation in which a patient may receive an organ (i) if the patient is a candidate, i.e., it is believed the new organ will work; (ii) an appropriate organ is available to transplant. It would be irresponsible to transplant an organ with a low probability of a successful outcome.
5. Although informed and autonomous *refusals* of treatment by patients or legally authorized representatives should be honored, their *requests* do not enjoy the same status. That is, some patients and family members make requests that are inappropriate, are contrary to sound medical judgment, violate medical standards, are dangerous or increase risk. Whether any request should be honored must be assessed or filtered by standard medical judgment. The making of a request does not in itself impose a duty on a clinician.[13]

[13] Compare in this regard requests for (i) antibiotics for viral infections, (ii) narcotics with no correspondingly appropriate pain symptoms or (iii) treatments, interventions or surgeries for which there is

6. An alteration in standards of care must be carefully reviewed. **Table 1** gives some examples of care standards which might be temporarily altered depending on the severity of the malady and on the magnitude or scope of the emergency it has produced. A review process is recommended below.

Medical or Hospital Standard	**Alternative**
Direct or face-to-face clinician-patient interaction	Telehealth interaction
Mechanical ventilation with a particular device	Ventilation with another kind of device, e.g., use of a transport ventilator when the standard is an intensive-care ventilator. In cases of device shortages, triage might be necessary to allocate available tools.
One ventilator for each patient	Use of ventilator to support more than one patient
Each patient in a bed in a standard hospital room	Patients in beds placed in other venues
Critically ill patients in critical care units	Critical care patients in other units refitted to extent possible
Cardio-pulmonary resuscitation	No CPR
Extracorporeal membrane oxygenation	No ECMO
First-come, first-served access to treatment and resources	Triage standard of saving as many lives as possible

TABLE 1: Standards and Alternatives

It is important to note that some standards are based on considerations other than the best-available evidence, and, therefore and moreover, do not advance best practice. This is especially the case with CPR, which is often attempted with the knowledge that it will not benefit the patient. In an emergency, at the least, clinicians must be able to forgo non-beneficial interventions. There is no ethical or legal basis[14] for requiring licensed clinicians to undertake procedures they believe will not work.

inadequate evidentiary support. Authorities and experts agree it is inappropriate to comply with such illicit requests.

[14] FS 765, which addresses advance directives, includes the following: “765.205 Responsibility of the surrogate… [Surrogates must] “provide written consent using an appropriate form whenever consent is required, including a physician’s order not to resuscitate.” This is interpreted by some as requiring surrogate concurrence with the withholding of CPR and perhaps other interventions in a public health emergency. Legislative intent under 765, about advance directives, was not and, indeed, could not possibly have been to require ineffective treatments during mass-casualty events or to forbid triage decisions that are based on a “reasonable degree of medical probability.” Indeed, 765.202 seems to contradict 765.101(4) and undermines that standard.

6. Triage, Rationing and Crisis Standards of Care

The first breathing machines were negative-pressure respirators invented in the 19th Century. They found widest use in the first half of the 20th Century as “iron lungs” for polio patients. The first positive-pressure ventilators evolved from the 1950s and shaped modern critical care medicine and hospitals’ special critical- or intensive-care units. These machines push air into lungs for patients who cannot breathe, or breathe adequately. Intended as “bridge” treatments to sustain life until underlying maladies are cured or mitigated, the goal is eventually to wean patients from the machines. Some patients cannot be weaned. Some patients develop ventilator-acquired pneumonia and other complications.

Patients with respiratory disorders often require ventilator support. Reputable assessments and calculations project that there will not be enough ventilators to meet patient needs in the current Coronavirus pandemic. Therefore, not every patient who needs a ventilator will get a ventilator. Failure to plan for this at the institutional and governmental levels invites disorder, permits arbitrariness, risks introducing bias, damages public trust and increases the likelihood that patients who would have survived with ventilator support will die because ventilators were being used on patients who were more likely to die.

With a rationing plan to address this, preventable deaths will be reduced; without such a plan, preventable deaths will occur anyway, along with those that were not preventable. Put differently, institutions need to guide their clinicians’ decisions about which patients should receive ventilator support to reduce the number of deaths that would otherwise result. This is a form of triage: save those who can be saved; efforts to save those who cannot be saved are futile.

Triage entails difficult decisions. Clinicians are not used to it; they are accustomed to trying to save many patients with poor prognoses; and few if any have training in triage principles. They face great moral challenges and distress. They should be supported in fostering and acting with increased moral confidence and courage. To decrease clinicians’ moral distress, institutions should adopt protocols with thoughtful and uncontroversial ethical foundations. This can help ensure that difficult decisions are as consistent as possible across providers.

Evidence-based plans driven by widely accepted ethical principles constitute the best if not the only way to save as many patients as possible and support those making the difficult decisions needed to accomplish this.

6.1 Guidelines for Institutional Processes

Institutions should institute triage protocols. These protocols should incorporate the following elements.

6.1.1 Triage Evidence Support Teams

The institution should establish teams to meet regularly in person and/or electronically and as needed to evaluate the latest crisis information and to direct responses to that information. There is no standard composition of such teams, but there is an evolving consensus that (i) team members should not be directly involved in the care of any patient being evaluated by the team and (ii) institutions should consider the following members:

- Chief medical officer or designee
- Chief nursing officer or designee
- A critical care expert
- An ethics expert
- A social worker
- A member of the clergy
- A person with a disability

Institutions with pediatric practices should ensure pediatricians are included.

These teams must be able to act quickly, as emergency situations can evolve quickly. Teams should be on call 24/7, and should establish on-call rotations and information collection and sharing procedures. A chair may be designated.

Members of these teams would benefit from instruction regarding anti-discrimination laws and research describing the role of implicit and explicit bias in health care.

The teams will direct decision making regarding the various and challenging criteria to be used for resource allocation and reallocation. They should have access to such expertise as the institution or its neighboring institutions can provide. This is will be a fluid and nimble process as circumstances might worsen or abate during the period of the Guidelines' activation.

Triage teams will

- Shape, direct development of and determine activation of crisis standards policies or guidelines in consultation on any significant or nontrivial changes with institutional leadership
- Create and use a list or spreadsheet with salient patient information and ventilator status and other drugs and supplies that might be in short supply.

- Try to ensure appropriate principles, values and norms are incorporated in those spreadsheets and other documents, and in their application
- Oversee the review process described below
- Direct public engagement and communication
- Constitute and signal institutional accountability for crisis care management

6.1.2 Review Process

Triage, rationing and emergency resource allocation decisions should be fair, unbiased, proportional and as effective as possible. One way to accomplish this is with an ongoing review process by a Triage Evidence Support Team. This team has two primary review functions, although more can be identified as needed.

The first is to support clinicians in decisions related to resuscitation, ventilator allocation and blood, dialysis and medication use. Time permitting, i.e., not in an unexpected emergency, physicians, nurses and others should try to seek advice and second opinions when applying an alternate care standard, as during triage. Such support is generally not required. It is recommended if a clinician wants guidance.

The second is to develop and provide an ongoing review mechanism to track institutional decision making, ensure an evidence-based and ethically optimized application of crisis standard guidelines and revise those guidelines – including this one – as needed. The Triage Evidence Support Team will review both the cases submitted for bedside or on-the-spot review, as just above; and review all cases after triage decisions are made (whether reviewed at the time or not). This process should be ongoing and iterative, that is, should include regular reviews of triage decisions to inform any needed revision to guidelines and future bedside case reviews. The periodic reviews should be conducted regularly and, based on available information and resources include, but not be limited to, analysis regarding fair and appropriate treatment of people based on race, ethnicity, citizenship status, national origin, religion, sex, disability, veteran status, age, genetic information, sexual orientation, gender identity or any other such characteristic or trait.

Results of these overviews should be communicated to critical-care team members and others, as appropriate; and team members should be encouraged to comment on the reviews. This sliding-scale or interactive process ensures an ongoing cycle to solicit, receive and act on information as situations evolve. It is a day-to-day process, and should help institutions both make of-the-moment decisions and, as importantly, anticipate future challenges.

6.1.3 Role of Institutional Ethics Committees

The Joint Commission, the American Society for Bioethics and the Humanities and the Florida Bioethics Network all call for, at the very least, an ethics process to guide and advise clinicians, patients and families, administrators and others when they face a decision shaped by ethical issues, tensions or conflicts. Ethics committees are widely agreed to have three functions: education, case consultations and policy creation and review. All three functions will be needed in a public health emergency or mass casualty event.

Most generally, ethics committees should

- Help prepare and review crisis standards of care policies, guidelines and procedures
- Be available for case consultations that arise in the application of such guidance documents
- Inform leadership about ethical issues arising in all other matters arising during an emergency

The Florida Bioethics Network has published *Guidelines for Ethics Committees,* which provide comprehensive advice about their composition, structure, functions and operations. Ethics committees should strive to represent the patient population served by the institution, including race, ethnicity, citizenship status, national origin, religion, sex, disability, veteran status, age, genetic information, sexual orientation, and gender identity.

6.2 Guidelines for Visitors

In accordance with the Americans with Disabilities Act, hospitals should continue to provide reasonable accommodations in their visitor policies for people with disabilities who need additional support from known and acknowledged caregivers, including family members, direct support professionals or other designated caregivers. Lack of access to such caregivers can result in detrimental outcomes from loss of vital and person-specific information and practical physical/emotional assistance in the provision of health care, especially during a public health crisis.[15]

[15] See https://www.ada.gov/contact_drs.htm and https://www.hhs.gov/civil-rights/for-individuals/disability/index.html

7. Ventilator Allocation and Re-allocation Guidelines

This section provides a Resource Triage Protocol. It calls for decisions to be based on the best available evidence regarding patients' conditions and prognoses, available resources and anticipated resource needs and ethical values (as given above). This evidence and these values entail that:

- Triage decisions should be determined by expected incremental increase in short-term and long-term survival. Patients most likely to survive to discharge and to live longest in the community after discharge are given priority.
- If patients have similar clinical conditions and expected incremental increases in survivability, priority should generally be given to younger patients based on the principle that people should have the opportunity to live as much of the normal human life cycle as possible.[16]

Even as different institutions might adopt somewhat different technical criteria for crisis management, it is essential that all institutions adopt a crisis protocol of some kind. The protocol here is both evidence-based and flexible; it is likely to evolve as more is learned about the scope of the crisis and the changing need for resources. Specific data and thresholds will need to be decided by individual institutions (e.g., triggers for ventilator triage).

7.1 Resource Triage Protocol

1. Triggers for ventilator triage
    a. Fewer than *X* ventilators on stand-by: This trigger is activated *only* after (i) leadership activates this protocol, *and* (ii) a separate trigger is activated by the Triage Evidence Support Team; or
    b. Predicted time to reach capacity < *Y* hours
2. Activation of Ventilator triage
    a. On call Triage Evidence Support Team is notified by critical care leadership.
    b. MD designated by the Chief Medical Officer is assigned the ventilator triage pager. Clinician must be free from clinical duties during period of triage service.
    c. The availability of a ventilator (due to death or terminal extubation of a ventilated patient) is communicated immediately (at any hour) to the team chair. The chair then contacts other team members. The next eligible patient is selected according to process outlined below.
3. Deactivation of ventilatory triage plan

[16] These three statements, not in any particular order, are elaborated below. They are adapted from a policy developed by the Center for Medical Ethics & Health Policy at Baylor College of Medicine.

Once it has been determined that the predicted time to reach capacity is no longer <*Y* hours (for *z* hours consistently), this plan is deactivated and norms of care and use of ventilators return to policy prior to initiation of triage. It can be reactivated again if the trigger threshold is again reached.

4. Mortality risk assessment and triage
    a. Principles
        i. Allocation is independent of reason for mechanical ventilation (influenza vs. COVID vs. CHF exacerbation vs intra-abdominal sepsis are all weighted equally)
        ii. No priority for social status, demographic characteristics or "value to society," with the exception of healthcare workers and staff who perform tasks vital to the public health response, as noted below in 4.d.vii and viii.
        iii. Priority is maximizing survival to hospital discharge
        iv. Defined triage system balances saving the most lives and the most life-years
    b. A triage system will be implemented to stratify patients for resource utilization
        i. Short term prognosis will be scored by SOFA scores or, for pediatric patients, modified SOFA scores, PELOD-2 criteria[17] or other appropriate indexes.
        ii. Long term prognosis will be scored by estimation of expected survival that is (a) less than 1 year or (b) less than 5 years[18]
        iii. Scores for both short- and long-term prognosis will be added to obtain a final score
        iv. Ties within Priorities Groups are adjudicated using individualized assessment of, first, co-morbidities associated with short-term survival; second, life cycle; third, healthcare workers and staff.
    c. Scoring via Sequential Organ Failure Assessment (SOFA) scores.[19]

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[17] Leteurtre S, Duhamel A, Salleron J, Grandbastien B, Lacroix J, Leclerc F, Groupe Francophone de Réanimation et d'Urgences Pédiatriques (GFRUP). PELOD-2: an update of the pediatric logistic organ dysfunction score. *Critical Care Medicine* 2013;41(7),1761-1773.

[18] Other possible variables for secondary triage include first-come, first-served, and a lottery. Both of these present significant ethical challenges. The former might disproportionately disfavor lower socio-economic status and those who have difficulty accessing medical care. A lottery system will be difficult to put in effect (place all patient names in a hat every time a vent becomes available?). Moreover, both options undermine the goal of triage by allowing the allocation of a scarce resource to someone who will not benefit at the expense of another who would. However, if all other criteria outlined here are the same – that is, for instance, if two clinically indistinguishable patients need a ventilator – then a lottery might be permissible.

[19] Raith EP et al. JAMA 2017;317:290-300. Other guidelines utilize only Red, Yellow, Blue and Green, with the cutoff for Blue as >11. Due to the severe nature of this illness and the anecdotal reports of improvement after prolonged and severe illness, this proposal creates an additional triage category and elevates the score for the exclusionary Blue category.

1. 1 point: SOFA <6
2. 2 points: SOFA 6 - 8
3. 3 points: SOFA 9 - 11
4. 4 points: SOFA ≥12

d. Scoring via long-term prognosis (based on underlying conditions unrelated to acute infection by COVID-19)
   i. 2 points added for individualized assessment of conditions likely to lead to death within 5 years, such as
      1. Moderate dementia[20]
      2. Malignancy <5-year survival
      3. NY Heart Association class III
      4. Moderate lung disease (COPD/ILD)
      5. End-stage renal disease
      6. Severe (inoperable) CAD
   ii. 4 points added for individualized assessment of conditions likely to lead to death within 1 year, such as
      1. Severe dementia
      2. Metastatic/stage IV cancer
      3. NY Heart Association stage IV
      4. Severe chronic lung disease (FEV1 < 25%, TLC < 60%, room air PaO_2 <55mmHg
      5. Cirrhosis with MELD > 20
      6. Traumatic brain injury with GCS best motor response = 1
      7. Severe burns where predicted survival <10%
      8. Cardiac arrest categories:
         a. Unwitnessed arrest
         b. Recurrent arrest
         c. Trauma-related arrest
      9. Severe immunocompromised states

e. Scores then dictate priority of ventilator usage by Priority Categories
   1. Priority Group 1: Scores 1 – 3
   2. Priority Group 2: Scores 4 – 5
   3. Priority Group 3: Scores 6 – 8
   4. Priority Group NA: no significant organ failure or no requirement for critical care resources

f. Tiebreakers Within a Priority Group. For individuals within the same Priority Group, preference is given as follows:

[20] Cf. the Functional Assessment Staging Test (FAST), a validated measure of the course of Alzheimer's disease: Reisberg, B. Functional Assessment Staging (FAST). 1988; 24:653-659; and https://www.mccare.com/pdf/fast.pdf.

i. Individuals with no comorbidities known to affect short-term recovery from COVID-19 will have higher priority than an individual with at least one comorbidity[21]
ii. Life-cycle considerations should be used as the next tiebreaker, with priority going to younger patients, according to these categories/ranges: ages 12-40, 41-60, 61-75 and older than 75
iii. Individuals who perform tasks that are vital to the public health response, including all those whose work directly supports the delivery of acute care to others, should be given increased priority.[22] This applies to individuals who play a critical role on treatment teams, including front-line physicians, nurses, respiratory therapists, as well as other key personnel including clinical support and maintenance staff.
iv. Raw patient prioritization score should be used as the final categorical tiebreaker, with priority going to the patient with the lower score.
v. If all these factors are identical, a lottery or other form of random allocation should be used to break the tie

5. SOFA score assignments and periodic reassessments
    a. On admission and daily, all patients are assigned a SOFA score by a designated member of the treatment team.
    b. The tracking spreadsheet is updated daily by 8 a.m. and posted.
    c. When more than one patient requires a single, available ventilator, the triage team chair assigns the ventilator to the patient requiring intubation based on ranking within priority scores.
    d. Teams are expected to update SOFA scores and need for ventilation by 8 a.m. daily. At that time, the Triage Evidence Review Team will review all scores. to determine if any intubated patients have achieved scores ≥ 12.
6. If the SOFA score equals or exceeds 12 at any point during the course of a patient's treatment with mechanical ventilation, the triage team shall make an assessment, including any likelihood of recuperation/recovery and, if appropriate, instruct the treatment team to consult palliative care as well as the patient's family and primary care physician/surgeon and withdraw mechanical ventilation within 8 hours.[23]

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[21] These conditions will be based on the most recent medical literature and will include conditions such as diabetes, coronary artery disease and hypertension. The decision whether and to what extent to include such maladies in scoring must be left to the clinical judgment of physicians.

[22] White DB, Lo B. A Framework for Rationing Ventilators and Critical Care Beds During the COVID-19 Pandemic. *JAMA* 2020 Mar 27. doi: 10.1001/jama.2020.5046. [Epub ahead of print].

[23] Limiting extubation to patients with such a poor prognosis departs from recommendations of other protocols that suggest extubating patients with mortality predications of 50%. In this protocol, limiting extubation to mortality scores >80% strikes a balance between continuing to care for sick, intubated

7. In a crisis situation, a decision to withdraw support might need to be based on a SOFA score lower than 12.
8. Re-evaluation of clinical status of all intubated patients if ventilator triage is required
    a. Ventilators currently in use on patients with high mortality are better used in times of crisis on patients with a higher likelihood of surviving.
    b. All currently ventilated patients in Priority Group 3 will be evaluated for extubation with Triage Evidence Support Team.
9. Ongoing clinical evaluation of ventilated patients for prognosis
    a. A lengthy intubation both monopolizes a ventilator and portends a worse outcome. Analysis of a patient's medical course at intervals of 48 and 120 hours after intubation will provide prognostic information to guide ventilator usage.
    b. Ventilated patients at 48 and 120 hours after intubation will be evaluated for prognosis, and a decision on continuing mechanical ventilation will be made by the Triage Evidence Support Team.
    c. For all ventilated patients
        i. Parameters at 48 hours will serve as the baseline for clinical evaluation.
        ii. Comparison of same parameters at 120-hour intervals will determine if clinical condition has improved, stagnated or deteriorated.
        iii. Patients with clear clinical deterioration based on comparison of 48- and subsequent 120-hour assessments will be removed from the ventilator if the Triage Evidence Support Team agrees. Patients who have been on the ventilator the longest without clinical improvement will be evaluated first. Removal may come earlier than 120 hours if clinical status is worsening; this decision will require the attending ICU physician to make a judgment based on clinical trajectory.
        iv. Patients with stagnant or improved clinical progress will be re-evaluated daily using same criteria to determine clinical course.
        v. Parameters for evaluation:
            1. All patients with ARDS (Berlin criteria) regardless of COVID-19 status
                a. P/F ratio using same FiO2, PEEP and positioning (prone/supine) at 48 and 120 hours (necessitates coordination of arterial blood gas analysis)

patients while recognizing that there are others with a better chance of survival. This threshold can be revised as conditions change and warrant.

   b. SOFA scores will be used as secondary analysis to further stratify prognosis in patients experiencing additional complications, such as shock.
2. All patients without ARDS (Berlin Criteria)
   a. SOFA scores at 48 hours will be compared to scores at 120 hours.
3. The clinical judgement of the attending ICU physician must also be considered in weighing decisions on terminal extubation.

10. Provision of ECMO
    a. ECMO is a highly resource-intensive intervention.
    b. There is a limited number of ECMO perfusion specialists; one is always required at the bedside of each patient, i.e., 24 hours a day.
    c. Given severe limitations in resources (hardware, expendables, staffing and additional critical care resources associated with ECMO use), ECMO should be used sparingly or not at all during periods of "ventilator triage" activation.
    d. ECMO will not be offered during the stipulated crisis period addressed by these guidelines. Appeals may be considered by the institution's Triage Evidence Support Teams and will be decided based on outcome probability (e.g. SOFA or, in pediatrics, PELOD-2 etc.; data available from the Extracorporeal Life Support Organization registry).
11. Communication and consultation
    a. When the ventilator triage protocol is activated, all patients on mechanical ventilation and their families, as well as all subsequently admitted patients, should be informed about the triage protocol and offered a copy of these guidelines.
    b. All patients admitted during periods of triage activation, or their legally authorized representative, if available, should be informed that changes in clinical status might entail withdrawal of mechanical ventilation.
    c. Any withdrawal from mechanical ventilation should be accompanied by a palliative care consultation.
12. Appeal process: A patient or family may request an appeal of the decision to withdraw a patient from a ventilator. Such a request for an appeal should be honored to the extent possible, time permitting and given the extent or magnitude of the crisis. In some cases, an appeal might not be possible. The request for an appeal should be communicated to the Triage Evidence Review Team; the unit's ethicist will respond as soon as possible, review the decision and confer with other team members and the primary care physician/surgeon if immediately available. The full triage team will then render a decision. This review is to be limited to ensuring the protocol was properly administered, i.e., in the decision to

extubate; and determine there was no discernable deviation from the ethical principles, norms and processes identified above.

13. Other interventions, including but not limited to endotracheal intubation, hemodialysis, radiologic imaging and surgery, should be assessed and decided by similar criteria. These criteria may be modified as necessary and appropriate.
14. This crisis protocol promotes the needs of the community over the preferences of individuals. This will cause moral distress in those clinicians who, despite agreeing with this stance because of a public health emergency, are still aware of the effect it will have on individual patients' lives. Doing the right thing for public health can pose difficult challenges for the traditional clinician-patient relationship. The purpose of this document is to maximize efficient use of a limited resource and to provide treating clinicians with a moral justification for life-saving actions in extraordinary circumstances. After the crisis, the institution should evaluate its use of these guidelines to learn and adopt principles to improve future crisis preparedness and response.

8. Cardiopulmonary Resuscitation

The determination whether to attempt to resuscitate a patient whose heart has stopped or malfunctioned is guided by similar values and norms. In this case, however, the step-wise detail required for ventilator allocation is not required. This section is compliant with major professional guidance.[24]

1. Patients will receive such evaluation, medication and support as determined necessary for their treatment.
2. When possible and time permitting – that is, not in an emergency – any adoption of an altered standard of care may be reviewed in advance by the Triage Evidence Support Team. Advance or pre-emptory review is permissible. All decisions to limit an intervention will be reviewed after the case by the institution's Triage Evidence Support Team.
3. In cases in which two attending physicians determine, according to a reasonable degree of medical probability, that a patient is dying and that aggressive medical treatment is or would be ineffective or of no demonstrable benefit, then the patient's, surrogate's or proxy's requests for such treatment do not impose an obligation on the health care team to offer or provide the treatment.

[24] That is, Edelson et al. Interim Guidance for Basic and Advanced Life Support in Adults, Children, and Neonates With Suspected or Confirmed COVID-19: From the Emergency Cardiovascular Care Committee and Get With the Guidelines®-Resuscitation Adult and Pediatric Task Forces of the American Heart Association in Collaboration with the American Academy of Pediatrics, American Association for Respiratory Care, American College of Emergency Physicians, The Society of Critical Care Anesthesiologists, and American Society of Anesthesiologists: Supporting Organizations: American Association of Critical Care Nurses and National EMS Physicians. *Circulation, o*riginally published 9 April 2020, https://doi.org/10.1161/CIRCULATIONAHA.120.047463.

4. Assessments of effectiveness, benefit or futility should be made on the basis of the likelihood of medical success, and not on the patient's current or projected quality of life. That is, the assessment should emphasize the physiologic status of the patient (e.g., "the patient will die despite the treatment") and not the physician's estimation regarding the quality of the life likely to follow the attempted treatment (e.g., "the patient will survive but not be restored to baseline status"). Patients and their surrogates or other authorized representatives, on the other hand, might very well want to consider quality of life in deciding whether to consent to or decline treatment.
5. In cases in which clinical judgment determines that CPR would be ineffective, clinicians need not commence CPR. A do-not-resuscitate order (DNR) may then be entered in the patient's medical record. Such a decision should be based on the likelihood of CPR's failure and/or increased harm to the patient. In case the intervention increases risk of death or disease to caregivers, this may be taken into account in addition to the treatment's ineffectiveness and insofar as it will have a detrimental effect on the institution's ability to continue care for that patient or for other patients.
6. In the event that the institution has implemented its Resource Triage Protocol, it may also be appropriate not to offer CPR for certain patients with or without COVID-19, on the grounds that if the patient had a cardiac arrest and return of spontaneous circulation were achieved, the patient would not receive a high enough priority for subsequent critical care.
7. In public health emergencies declared by appropriate government or institutional authorities, as above, such a medical determination does not require the concurrence of the patient or surrogates. Communication with the patient or surrogates is always appropriate, if possible, and reasons for forgoing any treatment should be explained. If there is not time to do this before a treatment is not provided, such an explanation should be attempted afterward.
8. Other interventions, including but not limited to endotracheal intubation, hemodialysis, radiologic imaging and surgery should be assessed and decided by similar criteria, including the availability of necessary equipment.
9. In case of disagreement (between or among team members; team and family; family members) about a clinical judgment, second opinions are strongly encouraged. The institution's Ethics Committee will often be able to provide insight on ethical issues and offer mediation or other support.

9. Blood, Dialysis, Drugs

As a general consideration, decisions regarding use and allocation of other scarce resources may be managed similarly, that is, in accord with the principles and standards articulated so far. These include but are not limited to

- Blood and blood products
- Hemodialysis

- Medications, e.g., antibiotics, vasopressors/inotropes, etc.

In case of questions related to allocation of such things, questions should be put to the Triage Evidence Support Team, which will provide guidance and, as needed, detailed instructions.

10. Other considerations

- A decision to forgo any treatment shall be documented in the patient's medical record.
- Appropriate pain management shall be provided in all cases.
- Care teams must support to the extent possible approved research during emergencies.
- The institution's Ethics Committee(s) shall be available at all times for consultations. It is understood that, as per professional standards, ethics committees do not dictate or direct patient care. All patient care decisions rest on the authority of the attending or other physicians, as available and appropriate.

1 May 2020

Executive Summary and notes on the Florida Bioethics Network's "Ethics Guidelines for Crisis Standards of Care in Public Health Emergencies"

April 2, 2020

The Florida Bioethics Network is a volunteer membership organization established 30 years ago. Members include nurses, physicians, social workers, clergy, lawyers, philosophers and others. Its missions include education programs and other professional development activities. Its advisory board is a subset of members. That board approved the "Ethics Guidelines for Crisis Standards" document. No FBN members are authorized to speak on behalf of any institution they might work or volunteer for, and any listing of members' institutions is for identification purposes only.

The document provides what are regarded as ethically optimized guidelines for ventilator rationing and triage, cardiopulmonary resuscitation and other challenges faced in an emergency. They do not provide and should not be understood to provide legal advice. The following points may help inform use of the Guidelines.

1. The document neither requires nor forbids any action by a clinician.

2. It is subject to ongoing revision.

3. *The document is not ready-to-use*. It must be customized by any institution that chooses to adopt it. For instance,

    - Though an institution might adopt the overarching Guidelines, institutional leadership must specify when any of its particular provisions take effect. Thus, one might adopt the Guidelines on a Monday but not trigger the ventilator triage provisions until Saturday. Such triggers might need to be revised regularly.

    - Each institution will need to decide on the composition of a Triage Evidence Review Team; its scope, process and workflow; and a mechanism to communicate about its availability.

    - Specific ventilator triage criteria details might be modified. Pediatric institutions in particular will need to adopt appropriate metrics and scoring systems.

4. Institutions concerned about liability should seek appropriate legal and risk management support.

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