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Updates from 2014 to 2020 Ethics Framework draft

The draft in 2014 was undertaken to specifically address highly lethal emerging infectious diseases during the Ebola outbreak. With this updated draft, we have addressed potentially lethal emerging infectious diseases and the possibility that an infectious outbreak (or catastrophic event) could result in large numbers of patients who might outnumber the available resources. We have designated an appendix for situations that result in scarce resource allocation in catastrophic conditions, an appendix designated to treatment considerations with potentially lethal emerging infectious diseases and one for research during times of global health emergencies.

Ethics Framework for Health Care Decision-Making for Potentially Lethal Emerging Infectious Diseases

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Note that this is a draft and will be changed and added to as the discussions and comments continue!!

I: Introduction:

The Colorado healthcare community is committed to providing the highest level of healthcare to all patients. In the setting of a potentially lethal emerging infectious disease (PLEID) which may also increase demand on health care resources, ethical principles and frameworks for decision making cannot provide definitive answers to value conflicts and dilemmas presented during such situations. However, they can enable policy-makers and individuals to make good decisions during a crisis by highlighting the need to balance rights and obligations, and commitment to fairness. Such an approach mandates transparency and accountability in order to support making difficult choices that could cause some individual harms. Additionally, recognition of shared values can provide a platform to facilitate coordination and cooperation when navigating such emergencies.

In such emergencies, the needs of patients, the healthcare workers (HCW), the community, and the healthcare system must be taken into account in order to provide the best possible care in a fair and transparent manner. Similarly, each of these parties also have responsibilities to each other. An altered treatment standard may be utilized in the setting of a PLEID, and the primary goals of duty of care and duty to fairness may be in tension. This list outlines the moral underpinnings of medical and public health commitments:

- Duty of care for all patients, those with PLEID and those with other medical needs
- Safety of staff
- Safety of other patients requiring health care
- Safety of the community
- Continuation as a functioning healthcare system
- Consistency and fairness for healthcare workers (HCW) and patients in making treatment decisions
- Consistency and fairness to patients taking into account vulnerable populations such as those at the extremes of age, those experiencing homelessness, those with disabilities and those who are incarcerated. Updated contact points and standard operating procedures (SOPs) for notifying the appropriate early warning response systems (EWRS)
- Support for a coordinated community response with other healthcare entities, governmental agencies, media, community representatives, and elected officials.
- Transparency and dialogue with the community so that everyone is aware of protocols and the rationale behind them, especially as these may change in a crisis situation.

II: Responsibilities during PLEID involving higher than average risk to patients and healthcare providers and/or increased demand on resources:

1. Institutional responsibilities:
    a. Support prompt implementation of a leadership team (as described below in III) to lead crisis decision making in the institution
    b. Treat patients fairly and to their maximum skill level
    c. Provide resources for competent and safe care of patients with PLEID
    d. Provide competent and safe care of patients without PLEID but who need medical care
    e. Use the best scientific information and recommendations in their protection of patients and employees and update regularly as information evolves.
    f. Ensure that all staff including nonmedical providers who may be exposed by cleaning rooms, serving food, greeting patients are trained and supplied properly to be able to perform their jobs safely.
    g. Ensure that all staff is protected financially to be able to self triage and self isolate and support their families as much as possible.
    h. Provide a path for anonymous communication within the workplace from workers to the leadership for reporting concerns.
    i. Advance safer mechanisms to deliver healthcare such as telemedicine
    j. Communicate clearly and often
        i. To HCWs as new information emerges in a quick fashion
        ii. To the public to teach about the disease and decision-making and encourage calm and proportionate responses to a healthcare threat
        iii. To appropriate state and national agencies for coordination

        iv. To designate a trained spokesperson who can effectively communicate the risks, strategies and procedures as well as monitor and dispel rumors and misinformation in such emergencies.
    k. Distribute risks fairly and help define “reasonable risk” for employees and professionals
    l. Assure proportionate restrictions on staff and patients with fair distribution of burdens and benefits
    m. Participate with community response efforts

2. Healthcare worker responsibilities:
    a. Provide the best possible medical care to all patients under the circumstances
    b. Follow recommendations as set forth by experts
    c. Respect patients and their healthcare decisions within the framework of the treatment standards at the time.
    d. Communicate information to patients and to experts in a real time fashion.
    e. Commit to assuming reasonable risk in their professional role and area of expertise.

3. Responsibility of Patients:
    a. Adhere to restrictions (e.g. masks, quarantine, etc.) placed in setting of PLEID
    b. Communicate honestly with their health care system about potential risk factors and symptoms, so as not to impede diagnosis and treatment
    c. Use resources that may become scare responsibly
    d. Use healthcare options that pose less risk to healthcare providers when able, such as telemedicine, phone calls rather than presenting to Emergency departments
    e. Participate in health care decisions within the framework of the decision-making and treatment standards for a particular PLEID situation.

4. Responsibility of Community:
    a. Participate in the development of evolving standards of care to be used during a PLEID crisis situation
    b. Adhere to restrictions placed by hospitals such as visitation or triage location
    c. Adhere to restrictions set by the CDPHE and other officials such as restrictions to community gatherings and quarantine recommendations
    d. Help advance and use healthcare options that pose less risk to healthcare providers and other people in the community, such as telemedicine and phone calls.
    e. Actively educate the public and help with communication and expectations
        i. Prior to emergence of a PLEID so that rationale and expectations are known up front
        ii. During an EID crisis situation so that the public is aware that evolving PLEID standards of treatment have been initiated

III: Management of patients with suspected or confirmed PLEID:

A leadership team with input from all affected disciplines (such as nursing, EMS, ED, Hospitalist, ID, MICU, surgical specialties, etc.) should convene with the goal of understanding resource needs and gaps and establishing standards of care for infected patients given the specific context of the PLEID crisis at hand, and applying the ethical principles from Appendix 3:

1. Evaluate benefits and risks of specific treatments to achieve the best possible outcomes for the most people, while mitigating risks to HCW, other patients and to the community. This should be done with expert opinion and consistent with the degree of threat, to determine appropriate care for patients as circumstances evolve.
2. Develop strategies to extend institutional capabilities to delay need to invoke crisis standards (e.g. discharge of well patients, cancellation of elective surgery)
3. Assure fair and equal treatment standards for all patients in similar categories
4. Assure a fair and consistent approach for potentially lethal emerging infectious diseases
5. Assure a fair approach if need for medical resources exceeds availability (see appendix 1).
6. Assure a fair and consistent approach if emerging infectious disease is potentially lethal (see appendix 2)
7. Evaluate treatment standards frequently and adjust as more information is known about the specific PLEID outbreak to assure that the decisions and limitations are proportionate to the situation as it unfolds.
8. Communicate with HCWs and with community about treatment standards in a bidirectional fashion as more is known about PLEID.
9. Collaborate with neighboring institutions with the goal of having similar treatment standards
10. Work with the CDPHE on treatment standards

IV: Emergency Medical Services during PLEID

The public has an understanding that when they are in need of emergency medical help, that they can call 911 and expediently receive emergency medical services (EMS) care. Further, they often also expect that they will receive care during transport, typically to a hospital of their choice.

When there are overwhelming demands on the EMS system, such as those that may present during an EID, certain expectations may have to change. These include, but are not limited to:

1. Extended wait times to receive EMS arrival and treatment

2. Paramedic initiated refusal to transport some patients (likely those who are not in need of a hospital) and referral for alternate solutions for their the their health care needs
3. Transport to ambulance destinations that are not hospitals, but other receiving locations readied to manage PLEID patients
4. Transport to destinations that are not the patient's desired destination, but are available or appropriate
5. Deferral of pre-hospital treatments such as nebulized bronchodilators, or use of alternative treatments, until patient can be safely managed by hospital providers

V: Vulnerable Populations:

Special attention should be paid to certain vulnerable populations because of particular risks/burdens that these groups may incur during a PLEID event. This does not necessarily mean that they deserve special or different treatment, but that additional thought should be given to how these groups may be affected. The lists below is not intended to be exhaustive, nor are the concerns listed, but is meant more to be a reminder of common vulnerable groups and the possible particular considerations.

1. **Incarcerated persons** - Prisoners may be at higher risk for spread of infectious diseases because of their housing situation and difficulty in separating from the general population.

2. **Unrepresented patients -** Patients without social supports, proxy decision makers and who cannot participate in their own goals of treatment decisions are at risk in the setting of PLEID.

3. **Elderly –** The elderly are often at higher risk of severe disease in times of PLEID. Advance Directives should be explored in this group to ensure patients are participating in decision-making with respect to goals of treatment within the confines of PLEID.

4. **Persons experiencing homelessness** - Those experiencing homelessness may face discharge difficulties ranging from keeping medications from being stolen to difficulties maintaining appropriate social distancing during a PLEID event. Coordination with other community resources would be highly valuable for these patients.

5. **Pregnant persons** – Pregnant women may be at risk for higher risk for severe maternal disease, and may have adverse pregnancy outcomes. Considerations may need to be taken for newborns.
6. **Persons with disabilities** – Because this is a diverse group comprised of a variety of differences categorized as disabilities, it is difficult to point out specific recurring themes to consider. Engaging the community itself may be the most fruitful path to understanding their concerns and needs in a PLEID situation
7. **Persons with mental Illness** - Those with mental illness may have increased barriers to receiving mental health care during PLEID in addition to stressors of PLEID
8. **Persons with Limited English proficiency** - Because of the fluid nature of these situations, and the importance of clear communication, proper interpretation services and engaging trained interpreters to communicate with the community are critical.

Appendix 1: Scarce resource allocation in catastrophic conditions

In a public health or catastrophic emergency, there is the possibility that the number of people requiring care outnumber the resources that we have available. Resources might include equipment, staff, physical space or medications. Within our framework, the leadership team should be called upon to make decisions about how limited resources are allocated and possibly reallocated. These decisions should not be made at the point of care by the bedside clinician. The goal is to provide the best quality care available given the situation and to be transparent and fair about the approach to this situation. It is important to note that in a public health emergency, there is a significant shift in the priority of values away from patient autonomy and towards societal good via a maximization of benefit and protection of healthcare workers.

Our approach focuses on implementing a public health emergency information policy with the following principles:

- Justice – ensure compassion, care, respect for the individual's autonomy and dignity, as well as the fair distribution of the benefits and burdens while maintaining the public and patient trust.
- Transparency – transparent and ongoing communication of accurate information to foster public trust
- Active collaboration – between stakeholders and the public through direct engagement, education and communication, ideally before, during and after such an event.

Multiple frameworks for this complex ethical decision making have been proposed and there are variations in these themes from hospital to hospital and in different public health emergencies. Additionally, there are studies suggesting that communities differ from HCWs in opinions about the importance of different resource allocation schemes. It is important that a framework is set up and that the community is aware of our process and participates when possible during times of resource scarcity.

There are no easy answers to these complex ethical decisions. With input from multiple departments and ethics colleagues, we have suggested a framework that would help make difficult but fair decisions about, for instance, balancing the needs of the sickest patients with the needs of those who may have better chances of survival in a time of limited resources. In terms of accountability and duty to care, the institutional responsibility to our HCWs and staff requires training and proper protection. We suggest that details of operational issues by the Leadership Team should include input by a wider group that should be convened as an Advisory Committee (including experts knowledgeable about affected resources such as respiratory therapy, critical care specialists, Palliative Care if treatments may be reallocated or withheld, spiritual care, etc.). Ideally this would include community representatives. Some of these difficult decisions may have significant limitations to individual liberty and access to the "best" care, and would represent a significant shift in the way medical institutions and patients proceed with decision-making. In some situations, the coercive force of the state may be utilized.

1. Leadership team responsibilities
    a. Team members
        i. Consult experts in affected disciplines (e.g. nursing, ED, Hospitalist, ID, MICU, RT, surgical specialties, etc.)
        ii. Include Ethics, Palliative care and chaplain services if resources may be withheld or reallocated
        iii. Balance rights, interests and values to ensure equitable, proportional, legal and non-discriminatory decisions.
        iv. Use of best available evidence while remaining flexible to evaluate the effectiveness and benefits.
    b. Knowledge about what resources we have and when possible, where other resources might be accessible to the institution
    c. Attention to increasing resources such as stopping elective surgeries, discharging patients whose medical acuity that can be seen to elsewhere such in order to free up usable beds in the setting of a surge capacity.
    d. Ensure all scarce resources are being used if needed
    e. Reassess the situation frequently
    f. Ensure our process is available to HCW, patients, families and the community
    g. Ensure communication is occurring with HCW, patients and families and the community.
    h. Recognize that there will be moral distress among HCW,and have a forum for discussion and mental health resources available.
    i. Address the emotional toll on patients and their loved ones with help from Palliative Care and Psychiatry services.
    j. Have a process for those who are conscientious objectors or those with competing interests who may not want to participate in providing care.
    k. Seek input from the Advisory Committee early and as the situation unfolds (including experts knowledgeable about affected resources such as respiratory therapy, critical care specialists, Palliative Care if treatments may be reallocated or withheld, spiritual care, etc.).
    l. Collaborate with CDPHE so that they are informed of our reasoning and process as they may make final decisions.
2. Various ethical processes for distributing and reallocating scarce resources fairly and transparently have been proposed (in no order of preference). Of note, some of these themes are being used during Covid-19 in Italy where patient need for ventilators exceeds the number of ventilators that are available.
    a. First come, first serve – not typically embraced, though some community members preferred this method when interviewed.
    b. Lottery – though fair, would ignore patients' severity of illness and ability to improve as well as patient years after recovery, reciprocity and value.

    c. Sickest patient first – though such patients may need a source that is scarce, they may have indicators that they would not survive and take the resource from a sick patient who has a better chance at survival
    d. A life-cycle allocation principle – gives priority to people between adolescence and middle age on the basis of the amount the person has invested in his or her life balanced by the amount left to live.
    e. Better chance at survival – based on various clinical scoring systems
    f. Reciprocity – As health care providers are showing up for the event and possibly putting themselves at risk, resources should be given to health care providers and their families
    g. Social value – some members of society may be needed either to take care of sick patients and/or needed to rebuild a society and thus should be given preferential access to resources.
3. Community participation – lay persons may have differing perspectives and priorities than healthcare experts; thus non-medical members of the community should participate in discussion of allocation schemes for scarce resources.
4. Persons included in process
    a. Leadership team
    b. Ethics
    c. Palliative care
    d. Community members, including faith leaders/clergy, who are not healthcare workers
    e. Elected officials
5. Those making decisions will be informed by:
    a. Scientific knowledge as it evolves
    b. Review of prediction tools that consider epidemiology, severity of illness, and clinical factors to predict efficacy of interventions
    c. Ethical principles ensuring the values articulated in Appendix 3
    d. Cultural and faith-based considerations
6. Such a process should strive for transparency and on-going open communication with the community

Appendix 2: Potentially lethal emerging infectious diseases(PLEID)

At times, infectious diseases carry significant mortality risks to those infected or large portions of the population affected (such as Ebola in 2014, SARS in 2003 and Covid-19 currently). The management of such patients requires the weighing of risks and benefits of potential treatments to infected patients with PLEID, healthcare providers and other non-PLEID patients. Additional training and protection of HCWs and non-PLEID patients is warranted as priorities shift from maximizing individual clinician-patient benefit to working to achieve the best outcomes for patients while preserving the safety of HCWs and patients without PLEID.

1. Evaluate benefits and risks of specific treatments to achieve the best possible outcomes, for the greatest number of patients, while mitigating risks to HCW, other patients and to the community. This should be done with expert opinion and consistent with the degree of threat, in an ongoing fashion as new information becomes available, to assess appropriate care for patients, given circumstances:
    a. Likely benefits and acceptable risks
    b. Unacceptably high risk and low likelihood of benefit.
    c. Unacceptably high risk despite possible benefit
2. Develop specific treatment standards for the following potential scenarios:
    a. General population and screening questions
    b. Emergent high-risk presentations
    c. Suspected cases while awaiting confirmation
        i. Higher risk or symptoms
        ii. Lower risk or symptoms
    d. Confirmed cases
        i. Early in disease
        ii. Later in disease
        iii. In extremis
    e. Convalescing cases – how will convalescence alter risks and benefits?
3. Create safe spaces for patients to be treated that will not potentially expose other patients or staff depending on the threat of the infection.
4. Have a process for conscientious objectors or those with competing interests who may not want to participate in providing care.
5. Support patients who are not expected to survive through aggressive attention to symptom support and care in the dying process by appropriate specialist.

Appendix 3: Ethical Values

1. **Fairness**: Fair allocation of resources, benefits and burdens, attending particularly to vulnerable populations. Use of a fair process based on evidence, even when outcomes may be uneven.
2. **Duty to Care**: Professional commitment to treat their patients, even in the face of some risk. Commitment to deliver the best care possible given the available resources, and not to abandon patients, particularly as they may be dying. Protection of professionals and HCWs in their duty to care through adequate personal protective equipment as well as making allocation decisions by leaders, not by those caring directly for patients.
3. **Duty to Steward Resources**: Obligation to use resources intentionally to achieve the greatest good for the greatest number, recognizing and addressing the tension between the duty to care and the duty to fairly allocate resources. The commitment to assure equity in access to resources by vulnerable populations and groups affected by disparities in access.
4. **Transparency**: Consistent sharing with all affected (healthcare workers and general population) in the principles for making difficult decisions and their application. Affirmation of changing value priorities from individual to more collective distribution of resources to achieve the most benefit to the population. Inclusion of affected stakeholders in planning and response as much as possible.
5. **Consistency**: Uniform application of decisions to all affected even as those decisions may evolve over time. This consistency should span regions, even as it may limit local flexibility in utilization of their individual resources.
6. **Proportionality**: Commitment to best understanding of justification for rationing and triage, and to minimizing the limitations on interventions and restrictions to liberty commensurate with actual situation at the time.
7. **Accountability**: Defining and being transparent about lines of responsibility for decision-making and creating an open and fair process for allocation and other decisions.

Adapted from: IOM (Institute of Medicine). 2009. Guidance for establishing
crisis standards of care for use in disaster situations: A letter report. Washington,
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Appendix 4: Research conducted during global health emergencies:

Promoting ethically-conducted research plays a crucial role not only in terms of obtaining evidence but in supporting HCWs in providing the best response to current crisis, as well as learning for the future to improve emergency preparedness and response. There are recommendations to ‘duty bearers’ such as research funders, research organizations, governments, and researchers that would provide an “ethical compass”. The recommendations align with the policies and practices that observe the three core values of fairness, equal respect, and help reducing the suffering of the very wide range of people involved in research in global health emergencies. Governments and research funders are encouraged to adhere to the following recommendations in order to improve the health of people affected by emergencies that can only be achieved through robust and ethical scientific research:

- Ensure that research is not supported unless the basic health needs of research participants are being addressed through the response effort. Research funders will need to work in partnerships with humanitarian organizations and governmental health agencies to ensure this.
- Invest in putting community engagement mechanisms into emergency research to make them a reality. In the longer term, engagement must be a central part of local healthcare systems to ensure sustainability and preparedness.
- Promote fair and equitable collaborations between research organizations, particularly between external research institutions and their local partners in high- and low-income settings.
- Support emergency planning - including securing robust health and health research systems - given the vital importance of properly resourced preparedness between emergencies.

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