MODULE 6: Medical Ethics in Relation to COVID-19

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In Module 6 of this curriculum, students will begin to consider the ethical discussion surrounding the COVID-19 pandemic, both locally and globally. The first section will give an overview of U.S. ethics and principles of allocation. The second section will focus on the ethics of resource distribution, particularly when supplies are limited. The third section will delve into the ethics regarding treatment and care of vulnerable populations, such as homeless individuals or children. The fourth section will center on the commitments and obligations of medical providers and trainees during public health crises. The fifth section will discuss the ethics of clinical trials, research, and treatment, especially when time is of the essence. The final section will analyze the ethics of public health interventions, particularly those that restrict individual liberties. As you work through this section, we encourage you to think critically about how these ethical debates affect your life, and how these conversations may change based on the context you are in. Please note that this module is not meant to be a comprehensive review of all ethical issues related to COVID-19, but rather provide a framework and highlight several salient topics. In addition, this module has a centrality of post-Scottish enlightenment thinking, which is the dominant framework in U.S. biomedical ethics. We recognize this bias and are working on subsequent sections that will include alternative models used throughout the world.

We expect that this module will take **5 hours** to complete.

OVERARCHING LEARNING GOAL:

Discuss various ethical controversies related to COVID-19 and apply ethical frameworks to examine the impacts of personal, medical, and governmental decisions related to the pandemic.

LEARNING OBJECTIVES:

At the end of this module, medical students of all years should be able to:

- Compare the rudimentary schools, frameworks, and principles to approach ethical issues in healthcare.
- Apply ethical frameworks to debate how healthcare resources should be distributed during a pandemic.
- Describe how COVID-19 differentially impacts populations that are already vulnerable.
- Debate the boundaries of obligation for healthcare workers and medical students during a pandemic.
- Discuss the ethical principles of clinical research design and vaccine development during times of crises.
- Discuss the tension between autonomy and collectivism in relation to public health measures.

Overview of U.S. Medical Ethics

Overview:

This section provides an overview of the major schools of thought in Western ethics: consequentialism, deontology, virtue ethics, natural law, and moral relativism. It then highlights principlism, a useful approach to medical ethics that breaks down issues into four major principles: respect for autonomy, beneficence, nonmaleficence, and justice. Moreover, it mentions the themes of negligence and reasonable care, which are often discussed in conjunction with beneficence and nonmaleficence. Finally, this section discusses the ethical principles of allocation of resources.

SCHOOLS OF ETHICS FROM WESTERN PHILOSOPHY

Centuries of scholarship have resulted in a variety of frameworks making ethical decisions. Selected frameworks are introduced briefly below, notably biased toward Western ethical approaches from the Scottish and English enlightenment. Please refer to linked resources for more details.
Sources: Dobrin 2012, Internet Encyclopedia of Philosophy, Barnhill 2010, Page Center

Consequentialism

Consequentialism is the idea that the morality of an act depends on its consequences. To decide whether an act would be right or wrong, one should examine the possible results of the act and ask whether the good effects would outweigh the bad effects. As consequentialist ethics is focused on the ends rather than the means, it is also known as teleological ethics (from the Greek word *telos*, which means "end"). Two forms of consequentialism are utilitarianism and prioritarianism.
Notable proponents: see below
Sources: Stanford Encyclopedia of Philosophy, Dobrin 2012, Internet Encyclopedia of Philosophy, The Ethics Centre, Internet Encyclopedia of Philosophy

Utilitarianism

Utilitarianism is the most well-known theory of ethics within consequentialism. Utilitarianism states that one should choose the act that results in the most good - the act that maximizes the good of all parties involved. In other words, the most ethical action is the one that leads to "the greatest amount of good for the greatest number of people" (quoted in Stanford Encyclopedia of Philosophy).
Notable proponents: Jeremy Bentham, John Stuart Mill, Henry Sidgwick, Peter Singer
Sources: Stanford Encyclopedia of Philosophy, Dobrin 2012, Internet Encyclopedia of Philosophy, The Ethics Centre, Barnhill 2010, Stanford Encyclopedia of Philosophy

Prioritarianism

Prioritarianism is a theory that, along with utilitarianism, falls under consequentialism. Prioritarianism proposes that priority should be given to those who are worse off because benefits have greater moral weight when given to those who are worse off. In contrast to the utilitarian perspective of maximizing good for all parties involved, prioritarianism favors assisting those who are worse off, even if this

results in a diminished maximal overall good. Prioritarianism can also be distinguished from egalitarianism. Whereas egalitarianism proposes *equality* (i.e. treating all equally because all humans are equal in worth and moral status), prioritarianism suggests an approach more similar to *equity* (i.e. providing a good unequally to those who are worse off rather than those who are better off so that there is greater equality in the end). This is an important distinction to make, and instances may arise where this may be the case. For example, suppose that a government could choose to fund a cure for canker sores (i.e. aphthous ulcers) for everyone versus a cure for an orphan disease that kills a very small number of people. An egalitarian approach would suggest that funding a cure for canker sores as the correct choice as this may benefit everyone equally, while prioritarianism would favor curing the rare deadly disease instead to help the few who suffer from it.
Notable Proponents: Larry Temkin
Sources: Oxford Research Encyclopedia, Stanford Encyclopedia of Philosophy

Deontology
The word "deontology" comes from the Greek word *deon*, which means "duty." Thus, deontological ethics is also known as duty-based ethics. In deontological ethics, one uses reason to arrive at a foundational ethical standard or standards, and one has a duty to act according to those principles. Deontological ethics is also called non-consequentialist ethics because one judges the morality of an act based on how that act conforms to ethical principles, not based on the result of the act. In one version of deontological ethics established by Kant, the basic ethical principle ("categorical imperative") to which all right acts should conform is to "treat people as an end, and never as a means to an end" (Internet Encyclopedia of Philosophy). In another statement of the categorical imperative, Kant explains that we should always act according to principles which we, as rational agents, would want to be a universal law for all people. The essence of morality is in these principles, not in the results of the acts themselves.
Notable proponents: Immanuel Kant, John Locke
Sources: Internet Encyclopedia of Philosophy, Dobrin 2012, Stanford Encyclopedia of Philosophy, Stanford Encyclopedia of Philosophy

Virtue Ethics
This is one of the oldest schools of ethics, as it is founded on the ideas of Plato and Aristotle. A virtue is "an excellent trait of character," a fundamental principle that is deeply held within a person and causes that person to act habitually in a certain way (Stanford Encyclopedia of Philosophy). According to Plato, examples of virtues are wisdom, courage, temperance, and justice (Internet Encyclopedia of Philosophy). Virtue ethics is concerned with forming the good character of a person, that is, becoming a person who embodies the virtues. If one acquires these fundamental dispositions, then making ethical decisions will naturally follow from them. In other words, in virtue ethics, the primary emphasis is on *what kind of people we are*, not on *what decisions we make*. The decisions that we make are a result of the virtuous character we have developed.
Notable proponents: Plato, Aristotle, G.E.M. Anscombe, Alasdair MacIntyre
Sources: Stanford Encyclopedia of Philosophy, Page Center, Internet Encyclopedia of Philosophy, Dobrin 2012

ONE LEVEL HIGHER: META-ETHICS

As discussed above, consequentialism, deontology, and virtue ethics are three methods that we can use to decide how to act ethically. But how do we decide which framework to use? Where do ethical standards come from? Although these questions, which fall under the purview of **meta-ethics**, are largely beyond the scope of this module, two important answers are highlighted below.

Natural Law

Natural law moral theory holds that humans can use reason to find basic moral principles that are central to human nature and that orient us toward the flourishing of all human beings. In other words, human nature tells us something about morality. Using human nature (the way humans are) as a starting point, we can reason toward moral standards. Because moral norms are grounded in human nature, they are objectively right or wrong, and all human beings can have a basic understanding of them. Thomas Aquinas and many other natural law proponents operate from a theistic perspective; the natural law is given by God who created human nature, and humans can use reason to decide whether acts are in accord with the natural law.
Notable proponents: St. Thomas Aquinas, Thomas Hobbes, John Finnis, Germain Grisez, Robert George
Sources: International Encyclopedia of the Social & Behavioral Sciences, Stanford Encyclopedia of Philosophy, Barnhill 2010, Internet Encyclopedia of Philosophy, Britannica, Soper 1992, Queensborough Community College

Moral Relativism

Moral relativism states that moral norms are not universal; rather, they are relative to a particular time, place, or culture. Because moral norms are relative, it is not possible to prove that one moral stance is generally better or more true than another. Unlike moral objectivists, moral relativists do not believe that any ethical standard is universally or absolutely true in all cases. Different societies have different standards in evaluating a moral judgment (that an act is right or wrong), and these standards may be true for one society but false for another society. Because the truth of moral standards between societies cannot be rationally debated, moral judgments cannot be absolutely true for all people. All prior theories that have been discussed in this section would be considered moral objectivist theories, as a right answer can be discerned based on certain principles.
Notable proponents: William Sumner, Gilbert Harman, Jesse J. Prinz, J. David Velleman, David B. Wong
Sources: Stanford Encyclopedia of Philosophy, Internet Encyclopedia of Philosophy

NON-WESTERN SCHOOLS OF ETHICS

Noting our Western bias in this discussion, we briefly highlight a select few of the many schools of ethical thought and philosophy that did not originate in Europe. Please see the linked resources for further details.

Confucianism

Confucianism, founded by the Chinese philosopher Confucius ca. 500 B.C., can be described as a virtue ethic, in the sense that a virtue is an ideal character trait that people should strive to attain. (However, there are important differences between Western virtue ethics described above and Confucianism; see Stanford

Encyclopedia of Philosophy - Chinese Ethics for details.) In classic Confucianism, the *junzi* ("ethical nobility" who represent the moral ideal) have certain ideal characteristics, such as filiality (respectful, loving, supportive way of relating to one's parents), respect for ritual or traditional ways of acting towards others, and good judgment of right or wrong actions. These "virtues" orient the *junzi* toward following the *dao*, or the way people should live. The source of the virtues is *ren*, which is difficult to translate, but which may be defined as the "co-humanity" or "humaneness" between human individuals. Confucianism emphasizes the performance of ritual behaviors or customs (*li*) in the attainment of, or as a reflection of the inner presence of, *ren*.
Notable proponents: Confucius, Zhu Xi (neo-Confucianism)
Sources: Stanford Encyclopedia of Philosophy - Comparative Philosophy, Stanford Encyclopedia of Philosophy - Chinese Ethics, Asia Society, Duke Center for Comparative Philosophy, Internet Encyclopedia of Philosophy - Confucius, Internet Encyclopedia of Philosophy - Neo-Confucian Philosophy

Daoism

Daoism has been an alternative or complement to Confucianism throughout Chinese history, and its formulations have varied over time. The *dao*, or "way," is the center of this philosophical framework. *Dao* can be imperfectly described as the central force in nature that is behind the way things change and function. The *dao* of nature is a road, a path, or a guide for people; it acts as a normative guide for people's behavior. People should live in accordance with the *dao* by practicing *wu'wei* - acting in a way that conforms to nature's ebbs and flows.
Notable proponents: Laozi, Zhuangzi
Sources: Stanford Encyclopedia of Philosophy - Comparative Philosophy, Stanford Encyclopedia of Philosophy - Daoism, Asia Society, Internet Encyclopedia of Philosophy

Buddhism

Buddhists believe that people must strip away the contrived perception of reality created by thoughts and emotions in order to see the world as it is. Buddhist ethics is perhaps most well-known for the rule of karma, the foundational principle that a good action leads to a good result, and a bad action leads to a bad result, either in this life or in reincarnated lives. However, Buddhism is not focused only on the consequences of actions; it also places a heavy emphasis on good intention or internal motivation as a necessary condition for a good action. Early Buddhism includes three parts of ethical training (right speech, right action, and right livelihood) as part of the core principles known as the eightfold noble path. Practical guides for Buddhist ethics include the Five Precepts (do not kill other living beings, do not steal, do not perform sexual misdeeds, do not speak untruthfully, and do not become intoxicated) and the Ten Good Courses of Action (seven actions - do not kill, steal, commit sexual misdeeds, lie, speak divisively, speak harshly, or make idle talk - and three mental states - do not be greedy, spiteful, or ignorant).
Notable proponents: Buddha (Siddhartha Gautama)
Sources: Stanford Encyclopedia of Philosophy, Internet Encyclopedia of Philosophy, The Buddhist Centre, The Buddhist Society

Other schools of ethics

Due to space limitations, we have omitted the rich traditions of Islamic ethics, Hindu ethics, Jain ethics, Jewish ethics, African ethics, Latin American ethics, and many others.

Thought questions:

- How would you describe, in your own words, the difference between consequentialism and deontology?
- What potential objections can be raised against moral relativism? Against natural law theory?
- In a recent article, Emanuel et al. argue that, in a situation of scarce resources, such as a limited number of ventilators during the COVID-19 pandemic, the limited resources should be allocated first to healthcare workers and other workers who maintain and operate critical infrastructure (see "Recommendation 2"). Which ethical framework(s) do they use in arriving at this recommendation?

BASIC PRINCIPLES OF MEDICAL ETHICS

The four basic principles outlined by Beauchamp and Childress in *Principles of Biomedical Ethics* provide the foundation for modern American biomedical ethics. These principles are 1) respect for autonomy, 2) justice, 3) beneficence, and 4) nonmaleficence. These principles provide a practical but reductionist framework to approach biomedical ethics and draw on elements of each of the above schools of ethics. For example, deontologists could argue that the morality of an act in medicine could be based on how that act conforms to these principles, rather than on the result of the act. Consequentialists could instead argue that these principles are heuristic ways to have the best likelihood of maximizing the good effects of an act.

Each of these four principles are considered and may be weighed against one another in the process of ethical decision-making in a given scenario.

- **Respect for Autonomy:** The principle of respect for autonomy originated in the Belmont Report - which summarized ethical principles for research involving human subjects - as "respect for persons." Under this principle, patients must be given the opportunity to think, decide, and act independently and without coercion. One key way that this principle is seen in everyday medical practice is through the process of informed consent, in which patients must be informed of the relevant information and given the opportunity to evaluate, consider, and agree to a treatment modality prior to initiating a treatment.
- **Justice:** The principle of justice is founded upon the idea of fairness. As such, the concept of *equality* - that all should be treated the same - plays an important role in justice. However, equality can also lead to unfairness because giving the same thing to those who are already better off may not promote justice. Some have argued that justice should actually be based on *equity*, which is the idea of providing a good un-equally between those who are better and worse off so that there is greater equality in the end. In medicine, the principle of justice has been used to argue that the burdens and benefits of advances in medical treatment and technology should be distributed fairly across all groups of people. Key areas of medical ethics in which justice is often considered are: fair distribution of scarce resources, balancing competing needs, and fulfilling obligations to different communities.
- **Beneficence:** The principle of beneficence describes the duty to do good for patients. It requires that all interactions, treatments, and decisions have the goal of increasing the well-being of the patient involved.

This principle asks that providers develop and maintain their knowledge and skill-sets, consider the individual circumstances of their patients, and strive for net benefit. It requires providers to take active steps to help their patients, as opposed to merely avoiding harm. Typically, when patient autonomy is compromised (e.g., incapacity), beneficence is the guiding ethic for decision-making on behalf of the patient's best interests.

- **Nonmaleficence:** This requires that providers do not inflict harm on other persons, and that harm is to be avoided or minimized in pursuit of the greater good. This principle is the underlying tenet of the Hippocratic Oath ("*Primum non nocere*" - "First, do no harm"). Avoiding harm can sometimes be difficult because many beneficial therapies also have serious risks; the pertinent ethical issue is whether the benefits outweigh the burdens. In contrast to beneficence, the core of this principle is avoiding avoidable or unacceptable risks/harm. For instance, nonmaleficence describes not causing unnecessary pain related to a surgery even if the benefits of having the surgery still outweigh the unnecessary pain (i.e., making sure to give good rather than minimal post-surgical pain control). Alternatively, perhaps a procedure should not be done even if the benefits would be substantial (this principle is often evoked in the debate on the ethics of physician-assisted suicide).

So far we have discussed the rightness of acts, but these principles are also relevant to failures to act, as is illustrated by negligence and reasonable care - legal principles with ethical implications. **Negligence** is when an unintentional injury results from actions that were not intended to do harm. It requires that a provider have a duty, that he or she breach that duty, and that an injury results that was caused by the breach of duty. **Reasonable care** describes the degree of care that a reasonable person in a similar situation would use, and it depends on the standard of care for the procedure being performed.

- Negligence occurs in situations in which a duty to use reasonable care is owed to another person. An injury results from a failure to use reasonable care.
- Reasonable care may be determined by the applicable standards of care, by statute, or by previous judicial decisions known as precedents. If a duty is not performed with reasonable care, a physician may be held responsible.

Thought Questions:

- How can physicians and health care providers balance respect for the autonomy of patients while simultaneously providing their own medical opinions/recommendations? For example, how can we balance a patient's refusal to quarantine after a positive test for COVID-19 versus a public health requirement to quarantine?
- Should the fundamental principle of justice be based upon equality or equity? For example, should everyone with COVID-19 be given equal access to ventilators, no matter how sick, or should those who are sickest be favored?

References:

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Miles SH. The Hippocratic Oath and the ethics of medicine. 2004. Oxford; New York: Oxford University Press.

PRINCIPLES OF ALLOCATION:

Our modern societies have chosen to develop medical systems in which only a limited amount of resources - such as nurses and physicians, treatment, equipment, and money - are available. Even in seemingly normal times, patients are triaged in the emergency room based on the urgency of their complaint and the availability of clinicians to see them. In the current COVID-19 pandemic, the limitations in our medical resources as a nation and globally have become increasingly apparent, as we hear in the news daily about shortages of essential equipment for patients and providers such as surgical and N95 masks, beds, and ventilators. As such, determining the allocation of medical resources has become a pressing and important topic for all. Below, we provide a simple framework that incorporates the above basic principles of medical ethics (autonomy, justice, beneficence, and nonmaleficence) and guides decision-making regarding who receives a finite medical resource (i.e. “rationing”).

Based on the principles of autonomy, justice, beneficence, and nonmaleficence, Persad et al. propose four categories of ethical values to guide the allocation of scarce medical resources: 1) treating people equally, 2) giving priority to the worst off, 3) maximizing benefits, and 4) promoting and rewarding social usefulness. (Persad et al. Lancet 2009 Principles for allocation of scarce medical interventions). Within each category of ethical value, there are two competing ethical principles (for a total of 8 sub-principles) that are competing specifications of the higher-order ethical value.

- **Treating people equally:** Allowing people to have equal opportunity to receive a medical intervention underlies this ethical value. The following two principles are based off of this ethical value, though reach different conclusions:
    - **Lottery (Random Selection):** This ethical principle uses a lottery in order to provide people with an equal probability of obtaining a given medical resource, regardless of other circumstances.
    - **First-come, first-served:** Under this ethical principle, people who require a limited resource first receive it, without regard to differences between people. For example, during non-pandemic times, patients are allotted a hospital bed on a first-come, first-served basis.
- **Giving priority to the worst off:** This ethical value embodies prioritarianism (see above), in which individuals who are worse off are given priority access to needed medical resources. Below, two ethical principles that incorporate this ethical value are discussed, though they differ in their definition of who is considered worst off. While these two are among the most discussed, they are not the only ones - there are multiple other ways of defining who is “worse off.”
    - **Sickest first:** In this ethical principle, those with the worst chance of survival without a given scarce medical intervention are prioritized as they are considered to be “worst off.”

    - **Youngest first:** This ethical principle prioritizes the distribution of resources to those who have lived fewer life years - thus defining those who are "worst off" as those who have yet to benefit from having lived longer.
- **Maximizing benefits:** This ethical value is based upon utilitarianism (see above for detailed background on utilitarianism) and, at its core, aims to maximize the possible good that can be done. There are multiple ways, however, to define a "benefit" and different ethical principles differ in the "benefit" that they promote. Two ethical principles falling under this ethical value are described below.
    - **Saving the most lives:** This ethical principle prioritizes saving the most individual lives. It treats each life as holding equal value and does not compare the individual worth of each life - for example, the lives of a 20-year old and 70-year old are weighed equally.
    - **Saving the most life-years:** In this ethical principle, saving the most life-years is preferred over saving the most lives, regardless of how this distribution is concentrated or spread. For example, this ethical principle would favor saving one person who goes on to live 21 more years rather than 20 people who each go on to live 1 more year (20 life-years). There are multiple ways in which life years are quantified (see below).
- **Promoting and rewarding social usefulness:** This ethical value prioritizes people who have previously provided or will provide, in the future, benefit to society. It is important to recognize the effect that culture and societal norms have on defining these benefits to society and thus who would be prioritized.
    - **Instrumental value:** In this ethical principle, people are prioritized who have future usefulness. For example, a system valuing instrumental value could focus on treating health care workers in the current COVID-19 pandemic because of the added value in the future that they may have for treating others.
    - **Reciprocity:** This ethical principle prioritizes and rewards people who previously were useful or had to sacrifice. For example, in this system, a person who previously volunteered to test a new COVID-19 vaccine in a clinical trial would be prioritized if they were to require treatment in the future.

An important concept to understand within the context of the allocation of scarce resources (i.e. rationing) is the "life-year," as it underlies the ethical principle of "Saving the most life-years" in order to maximize benefits. There are two general systems used to quantify life-years.

- **Quality-adjusted life-year:** Quality-adjusted life-year systems measure the gain of equivalent healthy years. In this system, a quality-adjusted life-year (QALY) is defined as one year of perfect health. A year of life with a specific illness or disability (i.e. health-related quality-of-life; HRQOL) is then normalized relative to this year of perfect health. Specific criteria for determining this normalized value vary, especially given the subjective nature of the "value" of a specific condition. For example, in the UK's National Health Service, a year of life with a moderate mobility impairment is defined as 0.85 QALYs.

QALYs formula: QALYs = additional years of life x health-related quality-of-life (HRQOL)

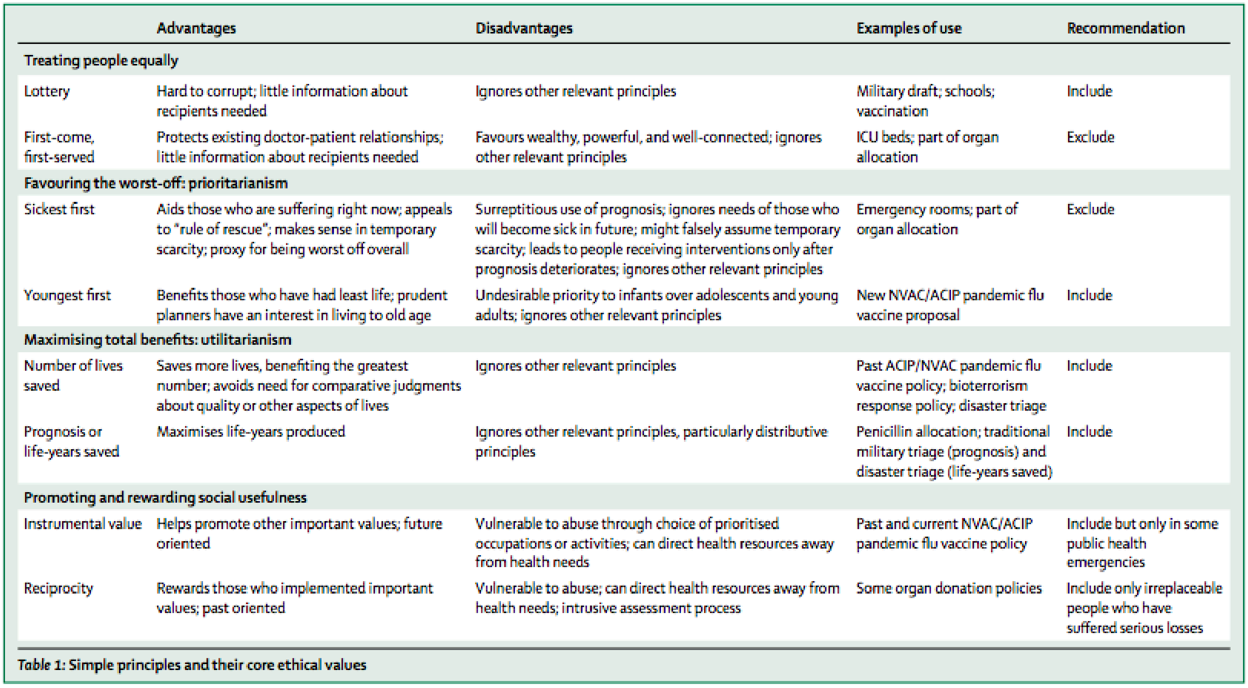
- **Disability-adjusted life-year:** Disability-adjusted life-year systems measure the loss of health. This system measures the total length of time that a specific illness is disabling to an individual over their lifetime. Similar to a QALY, it incorporates quality-of-life factors to normalize a year of living with a specific condition/illness to a year of perfect health. Prior DALY systems included an age-weighting such that a year for a younger person was weighed as more valuable than that for an older person, but these weightings have generally since been removed.

  DALYs formula: DALYs = years of life lost to premature mortality (YLL) + years lived with disability (YLD)

Each of these ethical values and principles has advantages and disadvantages (summarized in Table 1 below). Persad et al. (2009) have also developed a recommendation on whether each ethical principle should be included or excluded when developing guidelines for allocation.

When developing a framework for allocation of scarce resources, it is important to recognize that no single value or principle is sufficient in determining whether a given individual receives the resource. Ultimately, a multi-value and multi-principle framework is necessary to facilitate such decision-making (Emanuel et al. NEJM 2020 Fair Allocation of Scarce Medical Resources in the Time of Covid-19).

Table 1: Simple principles and their core ethical values (Persad et al. Lancet 2009 DOI: https://doi.org/10.1016/S0140-6736(09)60137-9)



	Advantages	Disadvantages	Examples of use	Recommendation
Treating people equally				
Lottery	Hard to corrupt; little information about recipients needed	Ignores other relevant principles	Military draft; schools; vaccination	Include
First-come, first-served	Protects existing doctor-patient relationships; little information about recipients needed	Favours wealthy, powerful, and well-connected; ignores other relevant principles	ICU beds; part of organ allocation	Exclude
Favouring the worst-off: prioritarianism				
Sickest first	Aids those who are suffering right now; appeals to "rule of rescue"; makes sense in temporary scarcity; proxy for being worst off overall	Surreptitious use of prognosis; ignores needs of those who will become sick in future; might falsely assume temporary scarcity; leads to people receiving interventions only after prognosis deteriorates; ignores other relevant principles	Emergency rooms; part of organ allocation	Exclude
Youngest first	Benefits those who have had least life; prudent planners have an interest in living to old age	Undesirable priority to infants over adolescents and young adults; ignores other relevant principles	New NVAC/ACIP pandemic flu vaccine proposal	Include
Maximising total benefits: utilitarianism				
Number of lives saved	Saves more lives, benefiting the greatest number; avoids need for comparative judgments about quality or other aspects of lives	Ignores other relevant principles	Past ACIP/NVAC pandemic flu vaccine policy; bioterrorism response policy; disaster triage	Include
Prognosis or life-years saved	Maximises life-years produced	Ignores other relevant principles, particularly distributive principles	Penicillin allocation; traditional military triage (prognosis) and disaster triage (life-years saved)	Include
Promoting and rewarding social usefulness				
Instrumental value	Helps promote other important values; future oriented	Vulnerable to abuse through choice of prioritised occupations or activities; can direct health resources away from health needs	Past and current NVAC/ACIP pandemic flu vaccine policy	Include but only in some public health emergencies
Reciprocity	Rewards those who implemented important values; past oriented	Vulnerable to abuse; can direct health resources away from health needs; intrusive assessment process	Some organ donation policies	Include only irreplaceable people who have suffered serious losses

Table 1: Simple principles and their core ethical values

Similar to Persad et al., White and colleagues (2009) suggest a framework for the allocation of scarce medical resources that include maximizing life-years, broad social value, instrumental value, and the life-cycle principle (i.e. providing each individual with an equal opportunity to live through various stages of life). (Who Should Receive Life Support During a Public Health Emergency? Using Ethical Principles to Improve Allocation Decisions). However, they caution against an over-reliance on the principle of maximizing life-years, as it may selectively discriminate against groups with certain conditions. For example, maximizing life-years could lead to favoring the lives of the young and able, while disadvantaging those who are old and disabled. Please see vulnerable populations below for further discussion.

Although the above ethical values and principles for medical resource allocation suggested by Persad et al. are well-known, there are others as well. Some advocate for the interrelated concepts of cost, opportunity costs, and cost effectiveness to be considered within the principles of allocation. Sheehan and Hope in *Allocating Health Care Resources in the UK* promote this approach. Because cost is a limiting factor in medical budgets, they argue that it is important to assess the opportunity costs of one approach to allocation versus another as funding one area means that another area will not receive it. As such, cost effectiveness can be an essential consideration in deciding where to direct medical resource allocation. This approach to cost effectiveness is also not solely limited to the hospital or medical center setting and applies to society more broadly - for instance, during an economic downturn, cost effectiveness is also used when deciding where stimulus money should be directed (hospital vs. industry vs. directly to families).

Thought Questions:
- If you were developing a system of allocation for your country, which principles would you weigh most heavily and/or least heavily and why?
- What role should monetary cost have in guiding decisions within an allocation system?
- What decisions (societal, governmental, personal, etc) have been made in the past that have now caused rationing to be necessary in the setting of scarcity?
- Are there solutions that can solve the scarcity of medical resources besides rationing?

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Resource Distribution

Overview:
This section will discuss the ethical arguments around scarce resource distribution with a focus on various scenarios that may arise in the COVID-19 pandemic. Briefly, we consider two broad forms of resource allocation: macroallocation and microallocation. Macroallocation decisions determine how a particular society allocates funding and issues policies across areas such as defense, education, infrastructure, public health, and health care. It focuses on the healthcare needs of a population as an aggregate with distributive justice as the underlying principle. In contrast, microallocation relies on context and individual judgment in the distribution of scarce supplies such as ventilators and face masks. It uses ethical principles such as the ones discussed above in PRINCIPLES OF ALLOCATION to make decisions among individual cases. In short, macroallocation decisions affect statistical and hypothetical lives, while microallocation decisions affect identified lives.

In this section, we first consider issues of macroallocation involving resource distribution between hospitals, states, and nations who may have differential access to resources or ability to produce them on their own. We then turn to various scenarios involving microallocation of personal protective equipment (PPE), testing for SARS-CoV-2, and ventilators, all of which may be preferentially directed to certain people over others. All of these decisions may be required in the current pandemic.

It is never easy for clinicians to allocate resources, yet we do it all the time - we make choices as to how we spend our time, attention, and energy, the expertise of our specialists and subspecialists, and who we believe can be saved with or without heroic measures. The unfortunate reality is that any scarcity of resources is exacerbated in a time of crisis. Almost by definition, resources are *more* limited in a time of crisis, requiring decisions that would not be made ordinarily. The scarcity questions that arise in a crisis may be the same as before only to a greater degree (e.g. more patients competing for limited clinician attention), or they may be different in kind (e.g. whether there are enough ventilators for sick patients is not entertained in normal times). Furthermore, there are some unique features of the COVID-19 pandemic that may exacerbate resource shortages. Many of the masks, testing kits, and ventilators that are in short supply are produced on a regional or even global scale and are thus affected by stockpiling, supply chain issues, and politics. Since the pandemic is predicted to be limited to a relatively short time period, governments and suppliers also face the economic question of whether it is worth it to buy or produce more resources if the investment or infrastructure will not be needed in the future. In short, although resources are very often scarce, it is not resource allocation as usual during a pandemic.

It is important to note that any discussion of resource allocation is incomplete without the appropriate historical, political, and geographical context. A truly just distribution would allocate resources according to some agreed-upon criterion, such as need or potential improvement in well-being, and would strike a fair bargain between various countries and regions of the world. In reality, resources are not distributed this way. Economic and political interests, to say nothing of long-standing imbalances of power, most often drive preferential access in times of scarcity. We therefore concern ourselves here with the non-ideal world in which we find ourselves; this is the world in which allocation decisions operate in times of crisis. A fuller account of the just distribution of resources might include the backdrop against which current allocation decisions are made, as well as whether recompense is owed for prior wrongs *as part* of allocation in a crisis, but we will bracket these issues for the time being.

Macroallocation of Scarce Resources

Macroallocation centers on the larger dimension of healthcare needs across a society or multiple societies. Disparities in critical infrastructure and government functions are exacerbated in a pandemic in a way that raises questions of key moral importance. For instance, the rapidly increasing number of confirmed COVID-19 cases in countries like Morocco, Nigeria, and Armenia raises a growing concern about how each country will manage the catastrophic impact COVID-19 will have on its health systems. Because the COVID-19 pandemic has already demonstrated the need for a highly interdependent global response, a widespread outbreak in low to middle income countries (LMIC) will not only impact their populations and health systems but will continue to exacerbate problems with the interdigitated health and economic systems of the world. Thus, macroallocation considers how scarce resources can be provided to safeguard the well-being of countries with more constraints and fewer resources.

Macroallocation places particular emphasis on priority setting across a population, with a focus on distributive justice as the underlying moral aim. Distributive justice is concerned with the *equal* distribution of goods across or between societies. Principles of distributive justice, such as various forms of Egalitarianism, are "therefore best thought of as providing moral guidance for the political processes and structures that affect the distribution of benefits and burdens in societies" (SEP). In practice, these processes are operationalized by governments or the relevant authorities in the hopes of achieving the statistically best outcome with the underlying principles as guidance. It is critical to note that these principles do not exist on their own but should be consistent with societal norms and values to be effective.

In response to COVID-19, a number of organizations and institutions have established recommendations about priority-setting in various contexts. Some of these are focused on the international setting. For instance, the Center for Disaster Philanthropy (CDP) addresses questions around the distribution of general funding, such as philanthropic and high-GDP country support for low- and middle-income countries (LMICs) as they try to afford critical treatments. USAid states that funding going to the WHO will help governments of developing countries prepare for large-scale testing, implement public health emergency plans, and equip rapid response teams. What are the roles of well-off governments in supporting LMICs during a global pandemic, if the outcome would be orders of magnitude worse in LMICs? How much funding should well-off countries divert from their own domestic efforts in order to fight the spread of disease overseas? There are also questions of differential access. The WHO has already explored the question of whether countries will have differential access to a vaccine in the early days after it has been developed, before it has been made in large enough quantities for all to share. Such actions can spark global controversies, as evidenced by reports of President

Donald Trump's attempt to buy exclusive rights to a German vaccine (BMJ). Thus, we must question: Who will be given vaccines first? Does that distributive strategy prioritize fairness, or power differentials?

Domestically, the United States Congress passed legislation that allocates funding for state and local health departments, pharmaceutical interventions, the National Institutes of Health, and hospital reimbursement, as well as non-health needs such as educational and economic stabilization and direct payments to Americans for unemployment relief. These relative contributions to various sectors entail value-laden choices about how to prioritize, for instance, economic recovery or early disease control.

Individual values can influence how participants in macroallocation agreements view the proceedings. The relative prioritization of values differs across certain parts of the world. Unaddressed differences in ethical perspectives amongst participants can cause conflict and a failure to successfully implement policies. Macroallocation and the equitable distribution of resources is therefore dependent on a contract between stakeholders - to negotiate in good faith and seek to understand each others' priorities and perspectives - in order to reach agreement on policies that allocate scarce resources fairly.

Thought Question:

- What are our responsibilities within our own country? Should we feel responsible for the rest of the world? If so, how could we be of assistance?

Additional Resources:
Fair Allocation of Scarce Medical Resources in the Time of Covid-19
The Toughest Triage — Allocating Ventilators in a Pandemic
Medicine and Social Justice: Essays on the Distribution of Health Care
COVID-19: Supporting Ethical Care and Responding to Moral Distress in a Public Health Emergency
Stanford Encyclopedia of Philosophy - Distributive Justice
Stanford Encyclopedia of Philosophy - Moral Particularism

Microallocation

In what follows, we examine three situations that have arisen during the COVID-19 pandemic in which microallocation of scarce resources is necessary. What all three scenarios have in common is that there are general practical strategies currently being employed in response to the resource scarcity that seek to obtain more of the resource, use less of it, or stretch available resources further. These allocation questions involve direct trade-offs, and often require choosing who from among various identifiable individuals will receive scarce resources. Furthermore, at a certain point, the available resources, no matter how agilely managed, will run out. How should these cases be managed? These situations will all require tough, morally-laden choices. In much of the conversation here, we draw from the section above on PRINCIPLES OF ALLOCATION**.**

Allocating Personal Protective Equipment (PPE)

As the case burden of COVID-19 continues to grow, supply shortages of PPE such as gowns, gloves, and masks have become increasingly acute. Governments and hospitals worldwide now confront the urgent necessity of rationing scarce PPE reserves. In some cases, healthcare workers are being trained to reuse PPE, improvise their own gear, and sterilize or re-sanitize masks after shifts are complete. If resource shortages continue to worsen, these individuals may be faced with a harrowing decision - do they work with substandard PPE, without PPE, or not at all? These decisions directly impact their own well-being as well as that of their patients.

Where there is still adequate PPE available, who should have priority access to it? A view shared by many sources is that frontline healthcare workers and first responders should have priority (examples: WHO, Strategic National Stockpile, Ranney et al., 2020). These individuals assume the critical mantle of treating patients and keeping the medical infrastructure intact; they have arguably the most instrumental value during a pandemic (Emanuel et al. 2020). A utilitarian approach also supports conservation of PPE for these personnel. Medical personnel, if infected, may transmit the virus and infect others. If they fall ill or succumb to the disease, many patients - both with and without COVID-19 - will receive insufficient care with ensuing increases in morbidity and mortality. Prioritizing PPE for frontline workers mitigates their own health risks and avoids asking them to treat patients with COVID-19 at a potentially tremendous personal cost.

There is some debate over how far the definition of “frontline” worker should extend. For example, Partners Healthcare and Beth Israel Lahey Health, both in Boston, have mandated that all hospital personnel wear surgical masks on the premises, regardless of whether they directly interact with COVID-19 patients. One argument in support of this approach is that various staff who do not have direct patient care responsibilities (e.g. hospital cleaning staff) perform vital services in a pandemic by keeping hospitals running smoothly. Outside the hospital, there is disagreement over whether “essential” workers such as grocery store employees should wear protective equipment. The CDC has stated that the general public including supermarket employees do not need to wear masks, though various locales in Massachusetts and elsewhere have encouraged all grocery store workers to do so. This is in part a disagreement over who constitutes “essential” personnel and how far available resources can be stretched.

Another question is how aggressively PPE should be diverted from general use to these “essential” settings. Amid acute PPE shortages in many U.S. states, governors have reportedly been forced to engage in bidding wars to secure federal shipments of supplies to their respective states. The National Stockpile has already been nearly depleted of protective gear, with few mechanisms in place to immediately replenish this emergency repository of medical supplies. However, the U.S. government has not yet issued any formal nationwide directive to consolidate and redistribute PPE to the frontlines of the pandemic. In recent weeks, agencies such as the CDC have discouraged the general public from purchasing and wearing medical masks in the interest of conserving these resources for healthcare workers. Yet this guidance has not directly prohibited large retailers from stocking and selling masks, including N95 masks, to the public. Similarly, the Centers for Medicare and Medicaid Services and professional societies like the American College of Surgeons have appealed to healthcare providers to defer non-emergent medical procedures in the interest of conserving PPE, yet not all medical centers have adhered to these requests. Only in Oregon has PPE redistribution been formally legislated, with Governor Kate Brown issuing an Executive Order requiring all healthcare providers in the state to donate surplus PPE for COVID-19 patient care. In the absence of a centralized approach that can direct these resources to where they are needed most, there has been a piecemeal response to the acquisition and provision of PPE.

Thought questions:

- Do healthcare providers who lack adequate access to PPE continue to have an obligation to care for patients?
- Should governments compel individuals and businesses to donate PPE to “frontline” efforts? What ethical principles or other circumstances might factor into that decision?

Allocating COVID-19 Testing Kits

Demand for COVID-19 diagnostic testing also continues to outpace supply in many countries. Worldwide, efforts to mass-produce test kits and augment testing volume have been stymied by shortages in collection swabs and testing reagents, as well as limitations in laboratory processing capabilities. In the U.S., testing has also been handicapped by multiple missteps in the initial government response, including costly technical and regulatory delays in deploying working tests. Confronted with significant testing shortages, hospitals and public health agencies have devised guidelines stipulating which individuals merit access to testing over others (examples: WHO, CDC, Beth Israel Lahey Health, Brigham/Mass General - access credentials required). These guidelines aim to use available testing kits in the most efficacious manner by triaging who receives testing.

Among most guidelines, two groups consistently emerge as top priorities for testing: patients with COVID-19 symptoms who require hospitalization, and healthcare workers who are directly caring for them. Patients who are hospitalized for presumptive COVID-19 tend to be the sickest and often have significant medical comorbidities. From a prioritarian perspective, these individuals should be tested first because they face the highest risk of morbidity and mortality from the disease, and are thus considered as the worst off (Emanuel et al. 2020). Ascertaining a diagnosis is paramount in guiding the next steps of their care, whereas it is far less critical for someone with mild disease recovering at home. According to many guidelines, members of the general public who are asymptomatic or who exhibit mild symptoms are currently lower priority for testing (CDC), particularly in areas where existing testing capacity is already inundated by cases from hospitalized patients. In these settings, it has become increasingly difficult to test many suspected cases of mild community-acquired COVID-19, to preemptively test close contacts of infected individuals, or to monitor local spread of the virus in real time, all of which are important public health goals (Emanuel et al., 2020). Thus, the current approach to prioritize testing of high-acuity patients over lower-acuity ones achieves certain valuable goals at the expense of others. These are the tradeoffs inherent in resource allocation, and highlight the importance of developing broad, communally-accessible testing.

A different rationale guides the preferential testing of frontline healthcare workers. They are at elevated risk of contracting and transmitting the virus yet have instrumental value in the response to a pandemic, and therefore require frequent testing in order to be able to function effectively and avoid contaminating others. Some have argued that this approach should extend to other personnel, such as first responders, who have assumed similarly indispensable duties and risks during the pandemic. It is less clear how to optimally balance the testing of hospitalized patients with that of essential personnel in the setting of acute test kit shortages. If many hospitalized patients remain untested, this may affect appropriate triaging of care and lead to unnecessary consumption of already-scarce PPE. Alternatively, if many essential personnel remain untested, they may be unnecessarily sidelined by mandatory quarantining or serve as vectors for infection, exacerbating healthcare and first responder staffing shortages.

It is unclear how consistently testing allocation schemes have been observed in practice. In the U.S., a number of prominent figures (e.g. members of Congress, NBA players) have been tested for COVID-19 despite being asymptomatic. One could argue that these individuals possess instrumental value (such as leadership or media influence during a pandemic) or associated risk factors (such as essential travel and extensive close contacts) that necessitate their testing. However, if the notion of "instrumental value" is broadened to this extent, this could arguably privilege the interests of the powerful and well-connected over the needs of the general public.

Thought questions:

- Given the current scarcity of diagnostic tests, communities will likely have differential access to early testing. How might disparities in access to early tests shape how the pandemic affects these communities in the long run?

Lifesaving Interventions

At the crux of resource allocation issues in a pandemic is who should have access to lifesaving interventions when they are in limited supply. That reality is most acute when it comes to life-saving interventions such as ventilators and extra-corporeal membrane oxygenation (ECMO) technology, as allocation decisions directly and acutely lead to saving certain lives while not saving others. These issues can be intensely personal for clinicians; it may be perceived as a failing if some patients die as a result of choices made on their watch. The current pandemic casts these choices into the sharpest relief. In what follows, we review several situations that could conceivably arise during the current pandemic in which the allocation of life-saving interventions is necessary. Our goal is not to reach conclusions here about the right choices to make in these cases. Rather, by highlighting various allocation issues that may arise, we hope to prepare readers for the possibility - or even the inevitability - that they will be called on to make those decisions or to support those who do.

There is a critical need for ventilators in the current pandemic. Why is that the case? It is a result of two key features of the disease: patients with COVID-19 require intubation early, and for long periods of time. Usually, when a patient's respiratory status is declining, there is a step-wise approach that gradually increases the invasiveness of the interventions they receive. However, several intermediate steps in that pathway - the use of nebulizer treatments, humidified oxygen therapy (e.g., high-flow nasal cannula) and BIPAP machines - are felt to be unsafe, as they are thought to aerosolize SARS-CoV-2 particles and place healthcare workers at risk. Many hospitals therefore skip directly to the intubation of any and all patients with COVID-19 who are in respiratory distress. Furthermore, patients who require mechanical ventilation need that support for an unusually long period of time - an average of two weeks. This is in contrast to the clinical course for most pneumonias (such as those caused by influenza), in which many patients' clinical status improves after several days on a ventilator. Thus, ventilators cannot be repurposed easily or after a short period of time.

A number of important ethical questions arise proximal to and around the question of who should get a ventilator. First, should ventilators be shared? New York State has started to share or 'split' ventilators between multiple patients. A tube is placed to split the output of the ventilator so it can, in theory, treat multiple patients. The downside to this approach is that a ventilator can be set to only one setting, whereas patients usually require highly-individualized settings that are fine-tuned by trial-and-error in the ICU to deliver optimal pulmonary support. Therefore, patients may not receive ideal care. The aim is to find patients who require similar settings, so that both receive at least appropriate care. However, this has never been rigorously tested in humans and is primarily a theoretical idea up to this point. The advantage of this approach is that it may be able to save more lives. The downside is that a larger number of patients may have worse outcomes, if they are all receiving treatments that are less efficacious as compared to typical standard of care for respiratory failure. Do the benefits of this approach outweigh the risks? The principle of non-maleficence suggests that clinicians should avoid causing harm to their patients. A corollary is that care is inappropriate if it is provided below a certain accepted standard. Non-maleficence opposes the splitting of ventilators as it means that some patients - who might survive if they were the only one on a ventilator - might suffer worse outcomes as a result and would therefore be harmed. This value is in tension with the idea of beneficence, which supports any attempt to save more lives. How should this tension be resolved? A common strategy is to turn to consequentialist approaches such as QALYs or DALYs to see which strategy has the greater expected net benefit. Other approaches hold that certain moral principles, such as nonmaleficence, carry greater moral weight given their relative centrality in the medical profession's canon (e.g. 'do no harm' supersedes an affirmative obligation to heal).

Second, should some patients not even be offered a ventilator? Some patients may arrive at the ED extremely sick, and a triage decision is made that they have a very low likelihood of survival due to multiple comorbidities or clinical status. Should these patients be offered ICU care with a ventilator? Once care is offered, it is difficult to revoke. Withdrawing life-sustaining care is typically done at a patient or family's request, or for reasons of medical futility. In contrast, during a pandemic, rationing may require the withdrawal of care in order to provide ventilators to patients who are given higher priority, a reason that may be foreign to many front-line clinicians (Truog et al, NEJM 2020) This raises the question of when that decision should be initiated. If it is apparent to ED clinicians that a particular patient, if intubated, would likely be removed from a ventilator in the near future because they are very sick and consequently lower priority, should they even offer mechanical ventilation as an option? If some patients will not be offered the option of aggressive care, when is that decision made, and who conveys it? These questions are likely to arise as an increasing number of precipitously ill patients arrive at the hospital.

Third, who gets a ventilator? If there are not enough ventilators for all patients, some patients will receive them while others will not. This will require tough decisions as to which patients may be saved. These allocation decisions can be made with a variety of ethical frameworks and principles in mind. An excellent approach to thinking through allocation decisions is provided above (See: PRINCIPLES OF ALLOCATION). Thus in this section we will limit ourselves to saying that decisions are often not standardized across institutions and may reflect local context. In contrast, the principles above are felt to be universal.

Finally, who should decide who gets a ventilator? There are various options. Some have suggested that clinicians intimately involved in the care of the patients in question should make those decisions - an approach known as ‘bedside rationing’. Such decisions can be fraught with bias as well as emotional entanglements with particular patients (e.g. ‘this patient reminds me of so-and-so’), and as a result can inflict a toll on clinical staff. In an effort to standardize allocation decisions and obviate the distress to frontline staff, there is a move for hospital committees to make allocation decisions (See Truog, et al NEJM 2020). Hospital committees, consisting of doctors, various other clinical staff, and administrators, would meet and review cases. One clear advantage of this approach is that it allows for involvement of various stakeholder views including that of ‘community representatives’. It may obviate the distress of bedside clinicians, but may also make them feel that life-or-death decisions about their patients have been taken out of their hands.

Thought Questions:
- If you had to allocate ventilator spots to a panel of patients, how would you decide? What criteria would you consider important, and why?
- When have you seen life-saving care rationed in the hospital on clinical rotations?

Vulnerable Populations

Overview:

This section will discuss ethical questions that are particularly relevant to a range of vulnerable patient populations. By "vulnerable," we mean patients who may be at particular risk to suffer physical or mental health consequences, financial hardship, or discrimination. Vulnerable populations may require additional aid and protection during a time of crisis, and yet can often be forgotten when public health measures are enacted for the population as a whole. This section will remind us of crucial issues and concerns affecting vulnerable groups.

Homeless and Low-income Populations

The low-income and homeless populations are particularly vulnerable in the era of pandemics due to their reliance at baseline on social support structures, more tenuous income streams, and a variety of other factors.

Many people with low income will not have accrued disposable income or economic savings, as prior to the pandemic many will have lived paycheck to paycheck. Thus, it will be no surprise that the economic impacts of a pandemic like COVID-19 affect the low-income population the most. To start, there is a higher proportion of individuals in this socioeconomic class that will have jobs that cannot be translated into remote work, such as jobs in the manufacturing, retail, transportation, and restaurant industry. Moreover, it should not be forgotten that socioeconomic status has also been correlated with a greater burden of chronic disease, a factor that can make one more susceptible to the virus. A 2018 paper by Kapiriri and Ross, which discussed the socioeconomic distribution of disease of prior epidemics such as SARS, Zika and Ebola, highlighted the influence of privilege on the experience of an epidemic. The review found that infectious disease outbreaks disproportionately affect the poor, specifically communities that have limited access to health services. It is likely that COVID-19 will have similar effects.

For the homeless population, the question arises how we can best address the needs of a population that has little to no control over their environment. How does one shelter in place, for instance, if one does not have a permanent shelter? Social distancing is virtually impossible for someone who has to remain in public spaces or in overcrowded homeless shelters.

Even marginal economic relief to a large number of these individuals would be in line with the utilitarian argument of providing the greatest good for the greatest number of people. However, amidst a pandemic when there will be other pressures to provide funding for other worthy causes, such as medical resources, the low-income and homeless populations can be easily marginalized. This marginalization has the potential to become even more pronounced if these individuals experience greater morbidity due to the virus because of baseline health risks.

Thought Questions:

- What long-term impacts on these populations can you predict months to years after the pandemic?

- What are some novel solutions to protect the homeless population from the risk of the virus if the CDC recommendations are often challenging to implement?

Pediatric Population

While it is predicted that, from a disease morbidity standpoint, children will be less affected by COVID-19, the downstream implications on this vulnerable population should not be forgotten. The most obvious impact may be on a child's educational progress. According to UNESCO, as of March 23rd, 2020, more than 1.3 billion learners were out of school due to COVID-19. While teachers and school boards are dedicated to trying not to disrupt a child's educational year, digital learning is an imperfect system, especially for children that do not have access to reliable internet or have had to step into new roles (childcare, cooking, etc.) due to the pressures on the adult population. Wang et al. stress that when kids are out of school, they are less active, have longer screen time, and have irregular sleep patterns. Moreover, the article points out that the psychological impact of such prolonged isolation must not be forgotten. Sprang and Silman in a 2013 article showed that the mean posttraumatic stress scores were four times higher in children that had been quarantined than in those who had not been. Lastly, the livelihood of children is closely connected to that of the adult population, which is severely affected by the pandemic. For instance, parents who have to continue to work outside of the home may have difficulty finding time or funding for childcare, as schools and daycare centers remain closed.

The pediatric population is a dependent, and thus vulnerable, population. The ethical discussion then becomes how one thinks through the allocation of resources to a population that will experience profound repercussions from the pandemic but 1) will be less affected from a purely health standpoint and 2) does not directly contribute to the current economy. While many may argue that there will be a substantial trickle-down effect of supporting the caregivers of children, and thus this should be the population targeted with funding and resources, it could be argued that failure to address the specific pediatric repercussion of COVID-19 will have substantial impact. Moreover, it will most likely be an impact that will continue to be felt far into the future, as the adults of tomorrow grapple with intellectual, social and emotional loss.

Thought Questions:
- Once things return to the status quo, how do we best repair the educational and psychological stressors that children will inevitably face during this period?
- Is a dependent population that is not directly linked to economic productivity inherently less deserving of resources during a pandemic?

People with Physical and Developmental Disabilities

Societal responsibility towards people with disabilities has historically been a focus of discussion when situations such as pandemics or mass disasters arise and force us to decide the most efficient and moral ways to distribute help amongst people. Past experiences from Hurricane Katrina have highlighted a disproportionate effect on people with disabilities in dire circumstances. Several US states have proposed guidelines for resource allocation during crises with limitations for certain groups; most notably, Alabama has outlined an emergency allocation plan that deems people with severe intellectual disability as "unlikely candidates" for ventilators. Several arguments have been made against the allocation of scarce resources to the disabled; these propose that people with disabilities require extended time of resource use, “have a limited long-term prognosis as a result of their disabilities,” and, in some cases, might have limited benefit from the medical intervention due to a pre-existing disability.

But people with disabilities may not always require additional resources, and we must be careful not to let unconscious bias keep us from prioritizing this population. As Edmund G. Howe discusses in *A Possible Application of Care-Based Ethics to People with Disabilities during a Pandemic,* care-providers experience “unwarranted pessimism” in seeing people with disabilities as “less likely to be happy with their life than is the case.” He also argues that non-disabled persons may have a tendency to “reflexively want to distance themselves from people with particularly visible and evident disabilities. **Thus, a policy regarding equality of access to treatment during a pandemic may be particularly warranted.”**

In his New York Times Op-Ed, Ari Ne’eman, a disability rights activist, advocates for a “first come first served” approach in efforts to avoid discriminatory behavior in healthcare delivery, especially during the COVID-19 crisis. Although he recognizes the sacrifice imposed by this approach (i.e. maintaining those on ventilators who require additional time with breathing assistance at the expense of treating more patients in the same given time), he argues that there is value in maintaining certain moral principles. He states, **“I believe that nondiscrimination is not just a tool to accomplish an end — it also is an end in and of itself.”**

Thought Questions:

- Do you agree with Howe’s argument that care-providers may incorrectly assume that those with disabilities live less happy lives? If so, how do you think this affects their health care management?
- What ethical approach would you implement in your policy and action to avoid discriminatory behaviors against those with disabilities?

Pregnant Women Seeking Abortion

As many states have called for ‘elective’ or non-essential surgeries to halt, some states’ governments have argued that surgical abortions are non-essential and therefore should be stopped in order to allow personnel and personal protective equipment to be re-allocated to the fight against COVID-19. The issue of whether surgical abortions should continue during this crisis strikes at a familiar and important question: is abortion an essential part of women’s health care? Or is it something that some women ‘elect’ to pursue, but is not crucial to women’s health and well-being?

The American College of Obstetricians and Gynecologists, along with other medical professional organizations representing OB/GYNs, published a statement that calls for surgical abortions to continue because they are a time-sensitive and essential part of women’s healthcare. Governors from conservative states disagree, and a handful of governors have already ordered surgical abortions to stop. Others are considering similar action.

In addition to the question of what consitutes ‘essential care,’ it is important to consider reasons why abortions may actually be in higher demand than usual during this pandemic. First, women may have difficulty accessing contraception if they are in quarantine, they have no safe way to travel to a pharmacy, or their pharmacy has a shortage of their contraceptive medications. Second, intimate partner violence often increases during disasters, and there may be higher rate of sexual assault and resulting pregnancies. Third, China has seen an increase in divorce rates after COVID-19, and times of marital instability and financial distress have been linked to greater demand for abortion. If demand for abortion increases while the availability of abortion decreases, many pregnant women seeking abortion will be unable to obtain one during this pandemic.

Thought Questions:

- Do you agree that abortion is an essential part of women’s healthcare? Why or why not?
- How should we think about the use of PPE for surgical abortions as compared to other uses during this pandemic? What kind of demand for PPE is imposed by an ongoing pregnancy and delivery?

References:

Joint Statement on Abortion Access During the COVID-19 Outbreak
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Finer LB, Frohwirth LF, Dauphinee LA, Singh S, Moore AM. Reasons U.S. Women Have Abortions: Quantitative and Qualitative Perspectives. Perspectives on Sexual and Reproductive Health 2005;37(3):110-8.

Communities Facing Racism and Xenophobia

All human beings have implicit biases, and clinical providers have a responsibility to keep these biases in check. It has been demonstrated that in times of increased stress and panic, such as during a global pandemic, providers are more likely to be influenced by racial prejudices and stereotypes, leading to poorer outcomes for minority populations. While many groups face discrimination on a daily basis, it is important to address the significant increase in anti-Asian sentiment brought on by this pandemic.

Notably, this is not the first time the Asian-American community has been targeted due to fears related to contagious disease. In 1900, as the bubonic plague resurged in California, the increasing Chinese immigrant population in San Francisco became a scapegoat for the disease. The official San Francisco Board of Health implemented policies for mass quarantine and experimental vaccinations limited to Chinatown. The Chinese population rioted in response to these infringements upon their human rights (Trauner, 1978).

With regards to the current pandemic, a report from San Francisco State University demonstrated that news coverage of anti-Asian discrimination increased by 50% in the month of February. These reports cited acts against Asian-American individuals and the community at large, as well as xenophobic labels employed by the media and political leaders. Asian-American establishments have seen a particular decline in business. Between January and February, Manhattan’s Chinatown sales reportedly dropped between 40-80% as news of the virus spread in the U.S., even before there were any confirmed cases of COVID-19 in New York City itself. On multiple occasions, President Trump called the virus "The Chinese Virus," despite recommendations from the WHO to avoid geographical descriptors, as prior nomenclature, such as the Middle East Respiratory Syndrome, has resulted in stigmatization of particular communities. Amidst these large-scale acts of discrimination, interpersonal attacks have escalated globally, ranging from accounts of school bullying and verbal harassment to physical assault.

Fear may amplify implicit bias, which fuels stigmatizing misconceptions that entire cultural communities are innately more likely to have or spread the disease. The CDC affirms that people of Asian heritage are not at greater risk of spreading COVID-19 than other Americans. They recommend educating people on factual evidence and speaking out against discriminatory behaviors.

Thought questions:
- Given widespread anti-Asian sentiment, it is possible that a patient would request to be in a different room from another patient who is of Asian descent. How would you respond to this situation?
- What role do healthcare workers play in mitigating acts of discrimination?

Commitment of Healthcare Professionals and Trainees During Crisis

Overview

This section will discuss the responsibility of clinicians to patients, and by extension, the responsibility of medical trainees to patients, during this pandemic. In addition to clinical responsibilities, we also discuss the importance of maintaining individual patient rights and humanity and any responsibilities toward broader advocacy efforts.

Duty of Clinicians to Treat Patients Despite Personal Risk

The COVID-19 outbreak poses a very real ethical dilemma: what is a physician's responsibility to serve patients despite personal risk? Responses during the 2003 SARS epidemic and previous influenza pandemics raise a number of complex and sometimes conflicting issues that can help guide our present thinking.

In addition to the principles of beneficence and altruism, there are several arguments in favor of the duty to care for patients. First, healthcare professionals have a unique expertise and ability to serve in this setting. We essentially have a monopoly on the right to practice medicine, and this right comes with a moral obligation to practice in emergencies when society needs us the most. Second, some might argue that we freely choose a profession which assumes a level of risk. Third, if a physician refuses to come for work because of personal risk, some might argue that the risk will be passed onto a colleague, and the already significant burden on the healthcare system will increase. The AMA Code of Ethics specifically states that a physician's responsibility to provide urgent care during disaster situations holds "even in the face of greater than usual risk to the physicians' own safety, health or life."

However, is there a certain level of acceptable risk beyond which this duty no longer holds? Some physicians might have significant comorbidities themselves, or live with elderly or immunocompromised individuals where the consequence of transmitting COVID-19 would be very serious. In addition to a duty to their COVID-19 patients, clinicians also have a duty to themselves, their loved ones, and their non-COVID patients, both present and future. Furthermore, the duty to serve typically implies reciprocity from the hospital system including adequate training, support, and protective equipment to minimize risk of harm, which is not holding true in this pandemic in some areas. In fact, a Seattle ED physician was recently fired, presumably in retaliation for speaking out about lack of PPE and infection control practices in his hospital. Overall, it is important to acknowledge that physicians and other healthcare workers are quite vulnerable to coercion during the current pandemic. In a culture that expects selflessness and heroism from physicians, anyone who is hesitant to continue working in hospitals based on personal risk might feel worried about openly expressing their opinion for fear of damaging their professional reputation, risking their jobs, and appearing selfish.

Aside from PPE, there are ongoing discussions regarding other ways to support healthcare workers during this challenging time. The current stance of the Accreditation Council for Graduate Medical Education (ACGME) is to maintain normal work hour restrictions for residents and fellows despite the pandemic, although there are growing concerns that this might not hold true as the number of patients continues to rise. Breaking work hours would increase the number of available staff, but would likely come at the cost of more medical errors and lapses in infection control per the ACGME, which would adversely affect not only residents and fellows, but also patients. Recently, some hospitals have started considering universal do-not-resuscitate orders for COVID-19 patients in the setting of limited PPE and significant risk of exposing multiple healthcare workers during a code. If infected, these healthcare workers would be unable to care for other patients. While instituting a universal DNR for COVID-19 patients would be consistent with the utilitarian approach of placing the needs of many over the needs of an individual patient, it also involves violating a patient's autonomy when he or she is most vulnerable. Finally, there are also a couple of online petitions to provide hazard pay for frontline healthcare workers at increased risk of exposure, but it is unclear whether these will lead to actual change within hospital systems. A case could be made that the high salaries which physicians enjoy at baseline are pre-payment for taking on this risk when needed, but that is definitely not the case for residents, fellows, nurses, and other hospital staff.

Ultimately, it is important to acknowledge that we have a professional obligation as healthcare workers to put our patients first, but we are also human beings with legitimate concerns about our own safety and that of our loved ones. In return, we also expect our hospital systems to value our expertise, our time, and our lives, and adequately train, support, and protect us. These conflicting priorities are well summarized in the words of an Ohio intern who describes her work in the current pandemic as “a terrifying privilege”.

Thought Questions:

- Are the standards set by the AMA Code of Ethics too much to ask of clinicians when there is insufficient protective equipment and support? How should healthcare workers combat feelings of guilt or shame if they find themselves unable or hesitant to fulfill this professional obligation?
- If a critical care physician's child has recently had organ transplantation and is immunocompromised, is it acceptable for this physician to not come into work in the setting of this pandemic? Or should he/she be held to the same standards as everyone else and be expected to put patients' needs first?
- How can we ensure that hospital administration holds up their end of this social contract? How do we protect healthcare workers, who often are intrinsically altruistic, from administrative exploitation during a pandemic?

Role of Healthcare Workers in Supporting Patients' Individual Rights and Humanity in a Crisis

One of the foundational ethical principles essential to doctoring is balancing respect for patients' wishes with concern for their welfare. Most of the time when patients seek care from healthcare professionals, their wishes are aligned with what would be in the best interest for their welfare. However, right now we are facing a pandemic where patients with COVID-19 could infect others and pose a serious risk to public health and even people who are asymptomatic may be possible vectors for disease. Autonomy can be overridden in circumstances such as these in the interests of protecting the health of the community. Many hospitals are, therefore, enforcing strict visitor policy guidelines for greater infection control. At Brigham and Women's Hospital in Boston MA, for example, routine visitors are currently being restricted. Other visitors must be screened for risk of COVID-19 and are allowed in only during special circumstances outlined in their policy, such as a partner to a mother who is laboring or a parent of a child under 18. Initially, New York Presbyterian issued an even more restrictive policy barring all visitors to adult patients, including partners or support persons to mothers giving birth. On March 28th, New York State issued an executive order requiring all hospital systems to allow a support person during labor and following the birth.

A new recommendation from the Centers for Disease Control and the American College of Obstetricians and Gynecology recommends separating a new mother who has confirmed COVID-19 or is a person under investigation from her newborn until transmission-based precautions are discontinued, which can last up to 14 days. These visitor policies also mean that patients are dying alone as visitors are not allowed to see them.

These policies are important for protecting the safety of patients and our communities but may also have serious costs. Researchers have found many positive patient outcomes related to having visitors in the hospital, including faster recovery times, reduced length of stay, and decreased anxiety and delirium in the ICU. Families serve as key advocates for their loved ones and can help with transitions between care teams and can reduce medical errors. The power of emotional support from loved ones is incredibly healing and important in supporting a patient's sense of humanity in the hospital. With healthcare workers pressed for time and needing to adhere to strict infection control guidelines, there is little time to spend with patients. The difficult choices we make during this outbreak go against our strong desire to deliver compassionate, patient-centered care. Are there other alternatives? Could we imagine an informed consent process so that visitors to dying patients would acknowledge the risk and then self-quarantine afterwards? What is the role of a physician during an overwhelming pandemic with limited resources and time? Is what it means to deliver empathetic care redefined under the current circumstances, and if so what does that look like?

Thought Questions:

- How do we maintain a patient's humanity during pandemics? When should we consider policies that protect the health of the population but might sacrifice the individual healing and dignity of patients?

Role of Medical Students

In response to the COVID-19 crisis, American hospitals and medical schools have opted to temporarily halt student clinical involvement. As per guidelines of the Association of American Medical Colleges (AAMC), this suspension has been deemed necessary to allow medical schools "a window of opportunity" to educate students on safety precautions for return to the wards and to also reserve personal protective equipment (PPE) for licensed hospital staff. Given previous cases of medical student exposure to COVID-19 patients, these restrictions also help limit risk of infection and spread to students. With their clinical education and training set to pause, students are left questioning their roles and responsibilities during the pandemic.

Many are mobilizing efforts to participate in non-clinical ways that include spreading useful COVID-19 information (such as this curriculum), supporting healthcare workers with non-clinical work, and offering help to community organizations. However, as students continue to remain outside of the clinical arena, it becomes necessary to consider the consequences of lost educational experiences in the clinic on the quality of medical training for future physicians versus the risk of infection for students and necessary conservation of PPE. Furthermore, as hospital staff struggle with increasing patient cases, should medical students be re-introduced to the hospitals and help offset some of the workload? Medical schools in Massachusetts and New York City have responded and are now graduating fourth year students early to immediately increase the pool of healthcare workers. European medical schools have taken similar measures. With these steps underway, should junior students who are much less qualified also be considered to help fill the growing need for healthcare workers? If this decision ever comes about, one must consider: what are the implications for patient safety of having trainees in the hospitals with limited experience in high-risk clinical decision making? Are there enough physicians to provide oversight for these students? Historical examples of the like exist from the 1918 Spanish Flu, during which volunteer medical students in Spain were sent to villages with limited medical oversight.

Thought Questions:

- At what point would it truly be ethically appropriate to allow medical students to practice medicine independently with limited oversight?
- What if early graduation and starting on a COVID-19 floor during the peak of the epidemic was mandatory? How does that change things ethically?

Responsibilities of Physicians in Broader Advocacy Efforts

With the current surge of COVID-19 cases and urgent need for care, the chief of staff for MassHealth catalyzed policy changes in telemedicine to help triage COVID-19 cases. At the same time, a dermatologist noted a 50% follow-up absentee rate in her clinic and advocated for an expansion of telehealth to include specialists. This would allow many physicians to continue monitoring patients with chronic conditions, even as they are advised to stay home to reduce hospital exposure and burden. If she had not advocated for expanded telehealth coverage during these extenuating circumstances, speciality care likely would have been compromised.

Physicians have already begun collaborating to advocate for policy changes in the wake of this pandemic. States have been encouraged to waive the Medicare telemedicine requirement that a provider be licensed in the state where care is delivered. In doing so, physicians can enhance national telehealth triage efforts to efficiently identify COVID-19 cases and refer for proper testing. The obligation of healthcare workers to not only educate their patient population, but also share information with one another on best practices, is critical for tackling this crisis. If healthcare workers are given access to multimedia resources to share learned practices - such as how to efficiently set up COVID-19 wards, adopt alternate staffing models, and facilitate screening - we can help save lives. However, with additional multimedia resources, however, we would need to adopt policy changes to maintain principles of patient privacy.

While the virtual world evolves to meet emerging healthcare demands, the physical needs of hospital facilities continue to grow, necessitating further policy change. Physicians have pointed out that establishing remote facilities, such as drive-through testing centers and temporary COVID-19-specific wards, would help mitigate the burden on hospitals, especially when capacity is reached. Licensure for such facilities, however, is a lengthy process, and triaging of COVID-19 patients who present to the ED with mild symptoms may be considered an EMTALA violation.

One way in which healthcare workers are responding to the national shortage of personal protective equipment is by advocating for and actively engaging in its acquisition. #GetUsPPE is a grassroots movement initiated by leaders in the healthcare field to organize and distribute donated protective equipment to those on the front lines of the COVID-19 pandemic. The organization is also pioneering 3D printed mask designs to help meet the high demand. Nonetheless, the projected shortage given epidemiologic trends is daunting. Whose responsibility is it for resources, such as the Strategic National Stockpile, to be mobilized to ensure that healthcare workers are properly protected?

Thought Questions:
- Do we, as healthcare workers, have an ethical obligation to advocate for policy changes on behalf of our patients? What policies might you advocate for?
- Within the limitations of federal policies and national shortages of human and material resources, what is the most efficient and ethical way to triage and treat such patients?

Clinical Trials, Research, and Treatments

Overview:

As COVID-19 spreads across the globe, scientists are desperately trying to develop novel pharmaceuticals and vaccines that might treat the disease. While everyone hopes for as rapid a discovery as possible, this quest to identify new therapeutics and prove their efficacy raises important ethical considerations. Furthermore, the interests of patients and their families, the scientific community, the general public, and government officials may at times conflict with each other.

Thought questions:

- What are the main ethical considerations in carrying out medical research on human populations?
- How are these challenged in times of crises, and how does a society balance these immediate needs of the population while maintaining core ethical principles that protect human study subjects?

What makes an ethical research trial design?

Over the course of modern medical history, the use of human subjects in research studies has undergone substantial ethical regulation and reform. In the U.S., efforts to reform research guidelines culminated in the National Research Act of 1974 and the resulting Belmont Report, which outlines 3 core and legally actionable principles of human research: respect for persons, beneficence, and justice. The principle of **respect for persons** involves determining capacity and informed consent, as well as protecting autonomy and privacy of the individual. **Beneficence** encompasses ensuring treatments and studies are beneficial to patients and society in comparison to the risks undertaken. Finally, the principle of **justice** helps protect vulnerable populations while equally distributing benefits to all.

While the Belmont Report has helped provide important standards for ethical clinical research design, some have pointed out that these principles are too broad to ensure in practice. To this end, bioethicists at the NIH Clinical Center published seven criteria that ensure that the above three principles are met. These criteria are deemed necessary for ethical clinical research:

1. **Respect for potential and enrolled subjects** -- allow subjects to withdraw, protect privacy, inform subjects of newly discovered risks or benefits, inform subjects of results of clinical research, maintain welfare of subjects
2. **Informed consent** -- provision of information to subjects about purposes of the research, its procedures, potential risks, benefits, and alternatives, so that the individual understands and can make voluntary decisions
3. **Social or scientific value** -- evaluation of treatment, intervention, or theory will improve health and well-being or increase knowledge
4. **Scientific validity** -- use of accepted scientific principles and methods, including statistical techniques, to produce reliable and valid data

5. **Favorable risk-benefit ratio** -- minimization of risks, enhancement of potential benefits, risks to the subject are proportionate to benefits to the subject and society
6. **Independent review** -- review of the design of the research trial, its proposed subject population, and risk-benefit ratio by individuals unaffiliated with the research
7. **Fair subject selection** -- selection of subjects so that stigmatized and vulnerable individuals are not targeted for risky research and the rich and socially powerful are not favored for potentially beneficial research

Challenges to the Principle of Respect for Persons

Providing Informed Consent:

Even under ordinary circumstances, ensuring proper informed consent can be difficult, especially as the term may be interpreted in different ways. In 1979, American philosophers Beauchamp and Childress offered one definition of informed consent that is still referenced today: "an individual's autonomous authorization of a medical intervention or of participation in research." According to these philosophers, informed consent must be more than just agreeing to a study. It must involve authorizing an act through the act of voluntary consent. In particular, Beauchamp and Childress stated that the following seven elements are thought to capture informed consent:

I. **Threshold Elements (Preconditions)**
    1. Competence (to understand and decide)
    2. Voluntariness (in deciding)

II. **Information Elements**
    3. Disclosure (of material information)
    4. Recommendation (of a plan)
    5. Understanding (of 3 and 4)

III. **Consent Elements**
    6. Decision (in favor of a plan)
    7. Authorization (of the chosen plan)

As we understand these elements that comprise informed consent, it begins to become clear how conditions of crisis may place constraints on these principles. In the context of the current COVID-19 pandemic, there are already a number of clinical trials being conducted, from testing antiviral drugs to conducting vaccine trials to evaluating passive antibody transfer (see Modules 1 and 3 for more information regarding ongoing trials). Given the rapid rate of COVID-19 spread, many of these trials do not have preliminary data on the risks of treatments for human subjects. In addition, while some therapeutics, such as the anti-malarial drug hydroxychloroquine, have already been FDA-approved and are being tested on COVID-19 patients, these medications may have significant toxic side effects. Given the unknown risks of new or unproven treatments for COVID-19, how does a researcher ensure that a potential study participant has received appropriate disclosure, and how does a researcher assess a potential study participant's understanding of the risks of participating?

Another ethical challenge that surrounds the issue of informed consent is determining whether severely ill COVID-19 patients may have the capacity to agree to clinical trials or experimental therapies. It has been reported that after the initial onset of dyspnea, many COVID-19 patients can rapidly deteriorate and develop Acute Respiratory Distress Syndrome (ARDS). Given the possible sudden decline in respiratory function in this subset of patients, many individuals may not have the opportunity to designate a health care proxy (if they had none prior). Thus for recent, expedited trials such as the convalescent plasma study (providing plasma from recovered COVID-19 patients to those who are critically ill), it may be difficult to determine whether patients who are severely sick (but potentially may derive the greatest benefit) would agree to part of the research trial.

Challenges to the Principle of Beneficence

One of the key questions currently being raised by COVID-19 research trials is what risks to human subjects are we willing to accept in order to find treatments that can help the rest of society? This is not the first disease in recent history for which this ethical question has been posed. During the AIDS crisis in the 1980s, as well as Ebola and Zika epidemics of the past decade, there were similar pressures to expedite research studies in order to find vaccines or therapeutics. Even in non-pandemic scenarios, experimental drugs developed for terminal illnesses such as metastatic melanoma may be fast-tracked in order to help critically ill patients. Here, we will discuss some of the adaptations in research guidelines that are made in situations where time is even more limited, as well as the risks and benefits of these different standards.

Phases of Clinical Trials:

There are four phases of clinical trials:

- **Phase 1:** Test drug or treatment in a small group of people (20-80) for the first time. Goal of this phase is to learn about safety and identify side effects.
- **Phase 2:** Drug or treatment is given to a larger group of people (100-300). Goal of this phase is to determine efficacy and further identify safety risks.
- **Phase 3:** Drug or treatment is given to an even larger group of volunteers (1000-3000) to confirm effectiveness, monitor side effects, and compare to the standard of care or similar treatments. The treatment may be approved by the FDA following the success of this phase.
- **Phase 4:** After the drug or treatment is made available to the public, researchers track its safety in the general population and seek information from patients about benefits, optimal use, and other side effects.

The volunteers used for a clinical trial depend on the researchers' inclusion/exclusion criteria. These factors include age, gender, type and stage of disease, treatment history, and other medical conditions. It may take several years for a treatment to eventually become FDA-approved, and many will end up failing in the earliest phases.

Approving Off-label Treatments:

Even after a therapeutic is FDA-approved, this does not mean that the treatment may be used to treat any medical conditions. According to the FDA, the term “off-label” refers to the unapproved use of an approved drug or treatment. This may include when the treatment is used for a medical condition that it is not approved to treat, when the treatment is administered in a different form than which it was approved (ex: capsule vs oral solution), or when the treatment is provided at a different dose. During times of crises, there is often an increased impetus to use medications approved for similar illnesses in the hopes that this previously FDA-approved therapeutic may be beneficial. In the context of the COVID-19 pandemic, an example of an off-label drug currently being tested is hydroxychloroquine, an antimalarial agent.

The FDA guidelines for “off-label” use of currently approved drugs for another purpose leave discretion up to the individual treating physician with oversight by the local institutions including its Institutional Review Boards (IRBs), stating, “*Good medical practice and the best interests of the patient require that physicians use legally available drugs, biologics and devices* ***according to their best knowledge and judgement***.” A physician’s responsibilities in using an approved product in such a way are three-fold: 1) awareness of the product and its effects, 2) use based on “firm scientific rationale and sound medical evidence,” 3) keeping a record of the drug’s usage and its effects.

While the off-label use of FDA-approved drugs and therapies is less stringently regulated, the testing of experimental drugs, therapies, and devices currently in the U.S. is bound by both the Health and Human Service (HHS) Common Rule and FDA guidelines to ensure proper beneficence of any new drug or therapy. While a harmonized rule-set is currently expected, the expectation is that the more stringent and protective rule-set be followed by investigators.

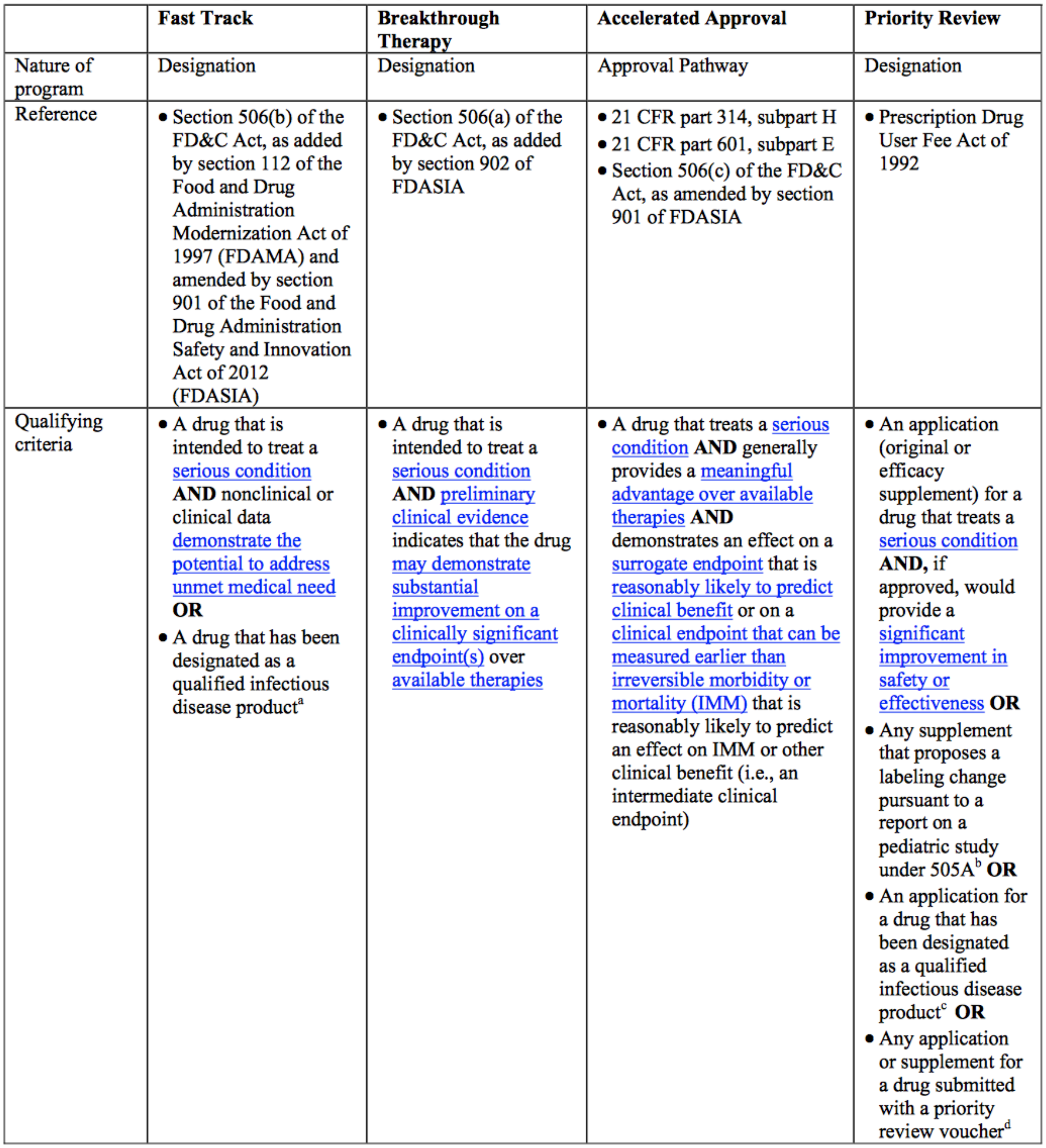
Expediting FDA Approval of Treatments for Experimental Use:

Despite the increased use of off-label drugs to treat COVID-19, the reality is that because this virus emerged so rapidly, there are very few FDA-approved treatment options. Although many companies are racing to develop vaccines or develop similar antiviral agents that were effective for treating Ebola or SARS, these new therapeutics could remain on hold while undergoing a normal clinical trial timeline. The FDA does, however, have a process for the expedited approval of therapeutics to treat critical illnesses.

There are currently five tiers of approval tracks for emergency and expedited FDA approval of any investigational new drug (IND), including vaccines. These encompass the treatment of a serious disease, which is defined as:

> “a disease or condition associated with morbidity that has substantial impact on day-to-day functioning. Short-lived and self-limiting morbidity will usually not be sufficient, but the morbidity need not be irreversible if it is persistent or recurrent. Whether a disease or condition is serious is a matter of clinical judgment, based on its impact on such factors as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one.”

The four tracks of expedited review are Fast Track, Breakthrough Therapy, Accelerated Approval, and Priority Review. The qualifying criteria are noted in the table below. The FDA has 60 calendar days to review and approve such applications. Given that COVID-19 meets criteria for a serious disease and has unmet medical needs, drugs and therapies to treat COVID-19 would qualify for Fast Track review.



	Fast Track	Breakthrough Therapy	Accelerated Approval	Priority Review
Nature of program	Designation	Designation	Approval Pathway	Designation
Reference	• Section 506(b) of the FD&C Act, as added by section 112 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) and amended by section 901 of the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA)	• Section 506(a) of the FD&C Act, as added by section 902 of FDASIA	• 21 CFR part 314, subpart H • 21 CFR part 601, subpart E • Section 506(c) of the FD&C Act, as amended by section 901 of FDASIA	• Prescription Drug User Fee Act of 1992
Qualifying criteria	• A drug that is intended to treat a serious condition **AND** nonclinical or clinical data demonstrate the potential to address unmet medical need **OR** • A drug that has been designated as a qualified infectious disease product[a]	• A drug that is intended to treat a serious condition **AND** preliminary clinical evidence indicates that the drug may demonstrate substantial improvement on a clinically significant endpoint(s) over available therapies	• A drug that treats a serious condition **AND** generally provides a meaningful advantage over available therapies **AND** demonstrates an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality (IMM) that is reasonably likely to predict an effect on IMM or other clinical benefit (i.e., an intermediate clinical endpoint)	• An application (original or efficacy supplement) for a drug that treats a serious condition **AND, if** approved, would provide a significant improvement in safety or effectiveness **OR** • Any supplement that proposes a labeling change pursuant to a report on a pediatric study under 505A[b] **OR** • An application for a drug that has been designated as a qualified infectious disease product[c] **OR** • Any application or supplement for a drug submitted with a priority review voucher[d]

A Fast Track designation allows for FDA facilitation of the IND application, including more immediate access to FDA communications to ensure efficient and appropriate data collection and rolling review of applications without full completion of the entire application.

Additionally, for emergency situations which have received designation as such by the Secretary for HHS, the FDA can grant an Emergency Use Authorization (EUA) for any drug or device before full FDA approval. The requirements for use under an EUA are less stringent:

> "1) the agent can cause a **serious or life-threatening disease** or condition;
> 2) it is reasonable to believe, based on the totality of the scientific evidence available,

that:

a) The product **may be effective** (vs having demonstrated effectiveness) in diagnosing, treating, or preventing the disease or condition caused by the BCRN agent; and

b) The known and potential **benefits of the product outweigh** the known and potential **risks**; and

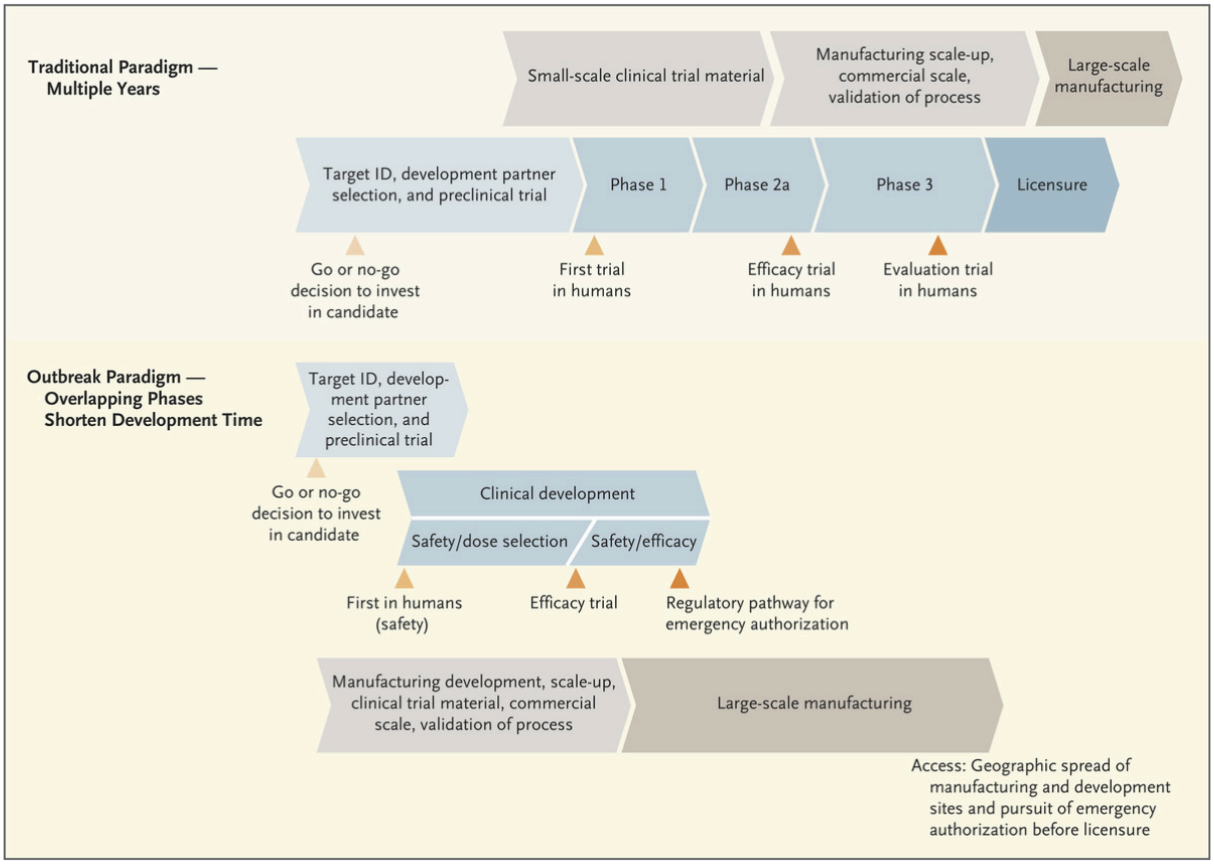
3) there is **no adequate, approved, and available alternative** to the product."

It is possible that any new drug or vaccine under investigation for COVID-19 would be approved for EUA use, especially if the designated risk category is "minimal." COVID-19 received emergency designation by the HHS secretary on Feb 4, 2020, and has at least two instances of EUA approval, first for the use of yet unapproved diagnostic tests, and a second for the use of yet unapproved PPE.

Ethics of Vaccine Development

We will now focus the discussion on ethical questions more specific to vaccine development. Below shows an outline comparison of traditional vaccine development timelines versus that of a pandemic strategy. Some of the main differences involve the parallelization of the steps seen normally, which reduces time at the same time increasing risk for the developers [4]. Despite the condensed timelines, many of the recent vaccine development efforts for outbreaks such as Ebola, Zika, and MERS were not concluded in time for relevant intervention of their respective epidemics.

Difference between Traditional Vaccine Development and Development Using a Pandemic Paradigm.



To achieve optimally time efficient vaccine development, intentional infectious inoculation of human subjects is one of many methods to obtain efficacy data. These studies, known as vaccine challenge experiments, have the advantage of being substantially more expedient over natural infection studies, which can be useful during time-sensitive pandemic scenarios. However, given that these trials require the deliberate infectious inoculation of healthy volunteers, thorough and careful ethical consideration has been warranted, particularly when exposing subjects to diseases with significant risk of morbidity and/or mortality, and in scenarios with no treatment options.

For these human challenge trials, an independent ethical review is deemed essential, particularly to assess the risks of exposure versus the benefit of data, as well as the robustness of informed consent. These trials are truly an arena in which the considerations of beneficence (risk versus benefit), respect for persons (informed consent and true understanding of potential risks by studied individuals), and justice (ensuring fair population recruitment for risk burden) must be carefully balanced. For this reason, human challenge trials are not deemed acceptable in vulnerable populations, particularly those that cannot give clear informed consent [5]. However, these trials have been performed in specific circumstances. For example, in a recent NIH malaria vaccine trial, the benefits of the study were determined to be acceptable relative to the risk of infection, particularly allowing for treatment and monitoring of the exposed group. However, as a counterexample, a human challenge study for a Zika vaccine was ultimately not conducted due to increased risk to potential non-consenting individuals (ie, sexual partners of participants, fetuses) [6].

Given that no treatments for COVID-19 currently exist, in addition to chance of morbidity and non-negligible chance of mortality, the discussion around a potential human challenge trial, which would greatly expedite efficacy data collection, has only just begun to weigh the risks to the experimental population vs the benefits of the population as a whole [6,7]. Further, even the fundamental design of a randomized clinical trial can be problematic in diseases with significant morbidity and mortality with regards to the placebo control arm. For example, during the Ebola vaccine efficacy trials, it was deemed unethical to employ placebo for control, and alternative methods were sought, including using early and delayed phase vaccination groups in an effort to determine efficacy. Design of efficacy trials for SARS-CoV-2 are currently under discussions [4].

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Challenges to the Principle of Justice

The principle of justice is to ensure that those who bear the risks of research benefit from it and, correspondingly, those who benefit from research should bear some risk. Vulnerable and stigmatized populations should be protected from being exploited, and privileged groups should not be favored. There are many examples from U.S. history that illustrate how this ethical principle is often threatened in the settings of wartime and epidemics. In the 18th century, Edward Jenner and Benjamin Waterhouse tested smallpox vaccines on children, while Thomas Jefferson conducted preliminary inoculation studies on his domestic enslaved persons. During the Spanish-American War, volunteers amongst American soldiers and recent Spanish immigrants to Cuba were exposed to yellow fever in order to understand the methods of transmission of yellow fever, a disease that ravaged the U.S. army at the time. The infamous Tuskegee Syphilis Experiment, conducted from the 1930s to 1970s, actively deceived black patients by withholding standard-of-care treatments for several decades, in order to study the progression of the disease in these individuals. At the Terre Haute U.S. penitentiary, researchers infected federal inmates with gonorrhea in order to test the effectiveness of post-exposure prophylaxis, a treatment they hoped to provide to American soldiers afflicted with the disease. In the 1950s, at Willowbrook State School, a school specifically for children with intellectual disabilities and where many children developed hepatitis after arrival due to overcrowded conditions, a research study was conducted to test the effectiveness of the novel treatment gamma-globulin. Some of these children were given the treatment and then deliberately infected with hepatitis.

In the context of the current COVID-19 pandemic, it will be crucial to ensure that vulnerable populations are not targeted at the expense of rapid scientific discoveries, as has often occurred in the past. While many of these clinical trials are recruiting volunteers, in some cases this may not be as equitable as it sounds. Take, for instance, the passive antibody transfer studies. Even though antibodies are currently being isolated from the plasma of patients who volunteer for the study, the reality is that COVID-19 does not affect individuals equally. Patients from more vulnerable populations, such as the elderly living in crowded nursing homes or the homeless, may be at greater risk of COVID-19 exposure and infection. Thus these individuals may represent a greater proportion of study participants. As the Atlantic pointed out in a recent article, there are no guidelines on who would own potentially therapeutic antibodies -- will the patients from whom these antibodies were obtained get to choose to immunize their loved ones? Or might the rich be able to buy the plasma of the poor who were infected with COVID-19? Furthermore, if compensation is offered to increase the number of volunteers, particularly for vaccine trials, which typically require a large number of participants, will this bias for selecting subjects of a lower socio-economic background? Currently, people cannot be financially compensated for donating blood or organs, but can be compensated for plasma, and harvested eggs and sperm in the U.S. When might compensation be considered coercive, limiting an individual's ability to make a truly voluntary choice?

Public Health

Overview:

This section will discuss public health ethics, which explores the tension between individual rights and the public good in a time of crisis. During a public health crisis, there is typically an ethical shift between care of individuals and care of the population as a whole. The different moral calculus introduces numerous ethical issues, including: how do we weigh the interests of the few against the interests of the many? What do we owe each other, and what can our government ask of us?

Is the Cure Worse Than the Disease?

Some have suggested, including President Trump, that we have to be careful that the ‘cure’ for COVID-19 is not worse than the disease itself. By this, he means that public health measures, including social distancing, are taking a dramatic toll on our economy, causing a significant rise in unemployment and bringing whole sectors of the economy to a halt. Many fear that we are at the beginning of a very serious recession, which will cause untold hardship for millions of Americans over the course of months to years. Is this worth it?

Let us think through the alternative. If we stop social distancing and let the virus spread throughout the population, a large number of Americans are projected to die, primarily people older than 60 with pre-existing medical conditions, but also many younger people. In the process, hospitals around the country will be forced to make tragic choices regarding who should get a ventilator, whether patients with COVID-19 should automatically be made DNR (to reduce exposure to the virus for code teams), and many of the other rationing issues raised in an earlier section. Most likely, we will all personally know someone who has died of the virus if it continues to spread. However, Americans may develop herd immunity soon and be able to return to working and socializing as before. At the same time, it is important to remember that we are not yet sure how long immunity lasts and whether people can get reinfected.

It is hard to carefully consider such catastrophic consequences. Most of us living in America have never experienced a pandemic this severe, but perhaps the subsequent recession will be greater than any recession in American history. With a large portion of the population unemployed, suicide rates could increase, crime could rise, many people could develop food insecurity. It is highly improbable that millions of Americans would die of suicide or starvation, but almost everyone’s lives will be affected for the worse, and those of us who are already the most vulnerable may find ourselves in very dire straits.

We have to ask ourselves, are the lives of a smaller group of people (those who may die from COVID) worth immense hardship for a larger group of people (the country as a whole)? Do we value life above all other goods, or is it possible for quality of life considerations to outweigh life *per se*? A utilitarian, who values utility or happiness, and aims to achieve the greatest utility for the greatest number of people, may prefer to let the virus sweep through the population. A deontologist, who supports the morally correct option over the option with the best results, may prefer to avoid allowing millions of Americans to die. Now approach the problem the other way: how could a utilitarian prefer social distancing and a deontologist prefer allowing the virus to spread?

References:
https://www.theatlantic.com/health/archive/2020/03/how-will-coronavirus-end/608719/

Legal Authority During A Pandemic to Enforce Isolation and Quarantine

Historically, broad powers granted to the government to enforce quarantine have been used to target minority immigrant communities. Therefore, it is important to consider the legal authority the government has to enforce isolation and quarantine. Federal isolation and quarantine are authorized by the Executive Order of the president. This authority is derived from the Commerce Clause of the Constitution and from the Public Health Service Act of 1944, which clearly established the federal government's quarantine authority. After the outbreaks of Ebola and MERS, laws were updated to give authority to the U.S. Secretary of Health and Human Services to take measures to prevent the entry and spread of communicable diseases from foreign countries into and within the United States. This authority has been delegated to the CDC which can detain and medically examine people who are suspected of carrying communicable diseases. Public health powers also stem from the Supreme Court Decision, Jacobson v. Massachusetts which upheld the Massachusetts Board of Health's authority to require vaccination against smallpox during a smallpox epidemic. Though there is legal authority for the government to enforce quarantine, there is no legal requirement for the government to provide guaranteed salary or other essential support such as medications and food during quarantine.

This federal authority is limited to isolation and quarantine of individuals who are suspected to have communicable disease, and those quarantined must be tested within 72 hours and their length of stay must be defined from the outset. Quarantine orders may be challenged in court. During the Ebola outbreak, a nurse in New Jersey returned from West Africa where she treated patients with Ebola and was quarantined against her will, and she successfully challenged the imposed quarantine. The last time large-scale isolation and quarantine were enforced was during the influenza ("Spanish flu") pandemic in 1918-1919. During the Spanish flu, many cities closed public spaces and prohibited public gatherings. Since then, the CDC has mostly issued health warnings. The last federal quarantine was in the 1960s during an outbreak of the smallpox virus.

Thus far during the COVID-19 pandemic, a national quarantine has not been issued, and isolation and quarantine have been left up to individual states, which have broad authority. This authority is derived from "police powers" granted to states to protect public health. Laws vary from state to state. Thus far, many governors have issued shelter-in-place orders for cities. For instance, California State Gov. Gavin Newsom has issued a shelter-in-place order, and violating the mandate is a misdemeanor punishable by fine, imprisonment, or both. The federal government doesn't have the authority to overrule state orders.

Police and law enforcement officers are authorized to help enforce public health orders. The U.S. Customs and Border Protection and U.S. Coast Guard are authorized to help enforce federal quarantine orders. In most states, breaking a quarantine order is a criminal misdemeanor. Breaking a federal quarantine order is punishable with fines and imprisonment.

References:
https://www.cdc.gov/quarantine/aboutlawsregulationsquarantineisolation.html

What Do We Owe Each Other?

While much of the debate over the COVID-19 public health response centers on the appropriate use of government power, we can also think about what we, as people and members of communities, owe each other in a time of crisis. In particular, what do the healthiest among us owe to the most vulnerable?

The U.S. has broken into two camps: those that are observant of social distancing and hopeful of flattening the curve, and those that have pushed back against public officials' pleas to stay home to protect others. In China, social distancing policies were harder to evade, as officials closed off apartment complexes and screened millions for elevated temperatures. Yet in the U.S., there is a strong sense of letting individual liberties prevail in some parts of the country and "carrying on" despite the ongoing crisis. For example, the Washington Metro issued strong statements asking people to not take the Metro to see the cherry blossoms this year. However, the cherry blossoms continued to draw crowds of people, despite the recommendations of government and public health officials. There are countless examples in the news and media of people, including business owners and government officials, pushing back against the increasing policies to enforce social distancing. These opposing views bring up a common debate in American politics: when do we sacrifice our own personal liberties to protect the safety of our communities?

How we react to this crisis ultimately depends on our understanding of when our individual rights must be limited in favor of supporting other more vulnerable populations in the community. We are social creatures that thrive in groups, but that means that we must make certain sacrifices to be a part of that group. Thomas Hobbes, for example, argues as part of his social contract theory that we intentionally surrender some of our rights to the government for security and other benefits. T.M. Scanlon, a moral philosopher, argues that "The idea is that actions are wrong if a principle that permitted the action couldn't be justified to the affected people in the right way." In other words, people that go against the social distancing rules would have to justify these decisions to the rest of the community, particularly the older and sicker individuals in our community. Communitarianism is a school of thought that emphasizes the connection between individuals and the community. The principle of "solidarity" asks that we act in a way that supports the most vulnerable members of our community, and that we not abandon those who are most needy in a time of crisis. A more personal way to think about this, is: we all have a friend or a loved one who is vulnerable to this infection - what would we want others to do to protect them?

Thought questions:

- What arguments do you see in favor of social distancing measures? How about arguments against those measures? What do we owe each other as members of a community during a crisis?

SUMMARY & FINAL THOUGHT QUESTIONS

The situation around the world continues to evolve rapidly. For individuals like **Brian** and **Diane** - the central case characters in our curriculum - the ethical questions and challenges are different and constantly changing. For instance, given her older age and general condition, Diane is worried that she will not have access to a ventilator if she needs one. Brian is concerned about whether the government is ethically justified in imposing strict public health measures. Both understand how ethically complex many decisions around COVID-19 are, and empathize with physicians and policymakers who need to grapple with them daily. As the disease continues to spread, they wonder whether their perspectives will also need to change, and realize that the field of ethics is constantly evolving based on context.

Diane is afraid about what will happen if she tests positive for COVID-19. Given her age and other health conditions, would she not be given access to a ventilator over someone else younger and healthier? What are some of the ethical frameworks to approach resource allocation, especially during a public health crisis?

Brian has many friends and family who have pre-existing health conditions. In addition, as part of his community service work in college, he visited a prison and worked on a literacy project. He remembers one prisoner in particular, whose name was Dan. Dan was in his mid-20s and suffered from type I diabetes. Brian wonders how this pandemic is affecting Dan and his ability to obtain his diabetes medications.

Diane's daughter is a respiratory therapist at a New York hospital that is now recommending its healthcare workers to wear their face mask for one week at a time. Her daughter wants to "do the right thing" but is nervous she will now not see Diane for months. Diane wonders how many other healthcare workers are in similar situations, and what "the right thing" to do is.

Brian thinks back to his canceled trip and original plans for after graduation. While he understands the importance of social distancing, he is unsure whether the government is ethically justified to impose such stringent public health measures. What are the ethical considerations in the field of public health, especially as they relate to infectious disease outbreaks?

We hope this module helped capture the ethical complexity of COVID-19. We recognize this module's bias towards U.S. biomedical ethics and are working on subsequent chapters that will include additional frameworks prevalent throughout the world. Nonetheless, we think many of the ethical questions are universal, and we encourage you to think closely about the presented themes as the pandemic grows.

Click here to return to our Overview.

We welcome your feedback on this module and on the curriculum overall. Please share it here.