Ethics for Lunch November 2020: Ethical issues in the Allocation of the COVID-19 Vaccine

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Vaccination for COVID-19 will be an important preventive step in the public health strategy against the pandemic. Several vaccines are currently under investigation as part of Operation Warp Speed. The hope is that these vaccines may be available for distribution in 2021. However, supplies may be limited in the early phases of distribution, so decisions will need to be made on how to prioritize who gets the vaccine first. The November Ethics for Lunch examined the ethical principles underlying vaccine allocation decisions and discussion the current vaccines under investigation.

Key Points:

1. Within the Johns Hopkins Health System (JHHS), allocation and distribution of any available COVID-19 vaccine will follow federal, state, and local rules on who is eligible for vaccine and the conditions set forth in an emergency use authorization (EUA).
    a. If a vaccine is under an EUA, it will be voluntary to receive it (NOT mandatory).
    b. Allotments may be earmarked by federal or state authorities, so JHHS will have to follow mandates per the jurisdiction where the JHHS entity is (Maryland, Washington D.C., Florida).
    c. Attempts will be made to coordinate distribution with other major health systems.
2. Recognizing that the initial supply of vaccine will not meet the demand, prioritization of who is eligible to receive the vaccine will be on a tiered approach; for individuals qualifying on multiple tiers, their highest priority tier will be used.
    a. JHHS has considered recommendations made by the National Academies of Science, Engineering, and Medicine (NASEM), the Centers for Disease Control and Prevention (CDC) and its Advisory Committee on Immunization Practices (ACIP), and the Johns Hopkins Center for Health Security (JHCHS).
    b. The prioritization plan may change with new data.
    c. Decisions about allocation will be based upon the best known scientific evidence at the time, with input from experts to reach a consensus opinion
    d. The JHHS plan will be promulgated with transparency to stakeholders, acknowledging the health system's ethical obligations to healthcare workers, patients, employees, students, family members of employees and students, and society.
3. JHHS has had previous experience of developing frameworks for distribution of limited supply vaccines--most notably in 2009 with the H1N1 vaccine. The tiered approach for the H1N1 vaccine was based on risk of contracting or transmitting influenza (in terms of both setting and personal characteristics) combined with the segment of the population at risk (health care worker, patients (including pregnant women and children), employees, students, and family members.
4. Recent reports are encouraging not only for COVID-19 vaccines but for vaccine development in general.
    a. Different platforms have been used to develop vaccines: live virus, viral vector (Astra Zeneca, Janssen, Merck), nucleic acid (e.g., messenger RNA like Moderna and Pfizer), protein-based (Novavax, Sanofi), and others.
    b. All vaccines will express the SARS-CoV-2 spike protein as the major antigen.
    c. Scientific advances with SARS-CoV-1 and MERS have enabled development of antigens with greater immunogenicity (e.g., both antibody production and T cell immunity).
    d. Progress has been rapid, from initial sequencing of the virus genome in January 2020 to now having 5 vaccine candidates currently in Phase III clinical trials (and 2 more on the way).

5. Two vaccine candidates have shown excellent preliminary results on efficacy.
    a. Efficacy: vaccine performance under ideal circumstances (controlled clinical trial).
    b. Effectiveness: vaccine performance in the "real-world."
    c. Both the Moderna and Pfizer vaccine require two doses. Data from the trial about illness was collected 14 and 21 days after receiving the second dose of vaccine to be included in the analysis.
        i. Both the Moderna and Pfizer vaccines showed ~95% efficacy.
        ii. Reported efficacy will reflect the period of 4-8 weeks after vaccine administration
        iii. Long term efficacy is not known
    d. For future vaccine clinical trials, an ethical issue arises as to whether to permit placebo controls or whether these vaccines should be used as the control arm.
6. The ethics of allocating scarce COVID-19 vaccine was addressed in a framework created by the Johns Hopkins Center for Health Security (JHCHS). It identified broad ethical values:
    a. Promote the common good (guide allocation)
    b. Treat people fairly and promote equity (guide allocation, balance with common good)
    c. Promote legitimacy, trust, and sense of ownership in a pluralistic society (guide the process)
7. Ethical principles for promoting the common good and their associated goals include:
    a. Promote public health: prevent COVID-19 illness and death; prevent injury, illness, and death from other causes; protect the health system
    b. Promote economic and social wellbeing: protect essential services; enable economic activity more broadly; enable children to return to school and childcare
8. Ethical principles for treating people fairly and promoting equity and their associated goals include:
    a. Address background and emerging inequities between groups (e.g., higher rates of COVID illness and death in communities of color)
    b. Give priority to worst-off individuals
    c. Reciprocity (e.g., recognizing sacrifice essential workers have been making)
9. JHCHS identified priority groups, recognizing that selection of some groups advances multiple policy objectives and acknowledging that there will be trade-offs between different policy objectives.
    a. The JHCHS report did not make firm recommendations about priority groups
    b. The JHCHS report recommended that allocation decisions should emerge from a process of public deliberation
    c. Some of the allocation decisions may depend upon features of the vaccines that ultimately get approved and used first
    d. Examples of groups that might be prioritized include: those essential in sustaining the ongoing COVID-19 response, those at greatest risk of severe illness and death (and their caregivers), and those most essential to maintaining core societal functions
10. The National Academies (NASEM) report has foundational principles of maximum benefit, equal concern, mitigation of health inequities, fairness, transparency, and evidence-based. It espouses risk-based criteria for allocation:
    a. Risk of acquiring infection - e.g., based on setting where SARS-CoV-2 is circulating
    b. Risk of severe morbidity or mortality
    c. Risk of negative societal impact - e.g., individuals on whom others' lives or livelihood depend
    d. Risk of transmitting infection to others
11. Based on its framework, the NASEM report proposes 4 phases for vaccine allocation:
    a. Phase 1a (5% of population) - high risk health workers, first responders
    b. Phase1b (10% population) - people of all ages with 2 or more underlying conditions that put them at significantly higher risk; older adults living in congregate or overcrowded settings

    c. Phase 2 (30-35% population) - K-12 teachers/workers; critical workers in high risk settings; people of all ages with underlying conditions putting them at moderate risk; people living in high density settings like prisons or shelters, and all older adults not included in Phase 1
    d. Phase 3 - young adults; children; workers in industries/occupations important to functioning of society and at increased risk of exposure
    e. Phase 4 - everyone residing in the United States not included in previous phases
12. The NASEM framework recommends that equity be a crosscutting consideration by using the Social Vulnerability Index (SVI) to prioritize people in each phase. SVI takes into account poverty, unemployment rate, insurance, housing, transportation vulnerabilities, and other social determinants of health. This could be done in one of two ways:
    a. The federal government could reserve a certain amount of vaccine allotment to distribute to areas with high SVI and/or "hot spots."
    b. State and local municipalities makes special effort to deliver vaccine to high SVI areas
13. CDC ACIP [as of the time of the Ethics for Lunch] suggested potential allocation groups:
    a. Phase 1a (~20 million people) - health care personnel with direct or indirect exposure
    b. Phase 1b (~200 million people) - essential workers (60 million), people with high risk medical conditions (100 million), elderly people (53 million)
14. Two challenging ethical issues regarding vaccine allocation
    a. What's the best way to address social disadvantage and racial/ethnic inequity in vaccine allocation?
        i. Prioritizing to racial/ethnic groups with higher COVID-19 burden may not be legal, may undermine trust (feel like being used as guinea pig for new vaccine), and does not directly target factors related to social disadvantage
        ii. Allocating to high SVI areas does not guarantee that vaccine will be equitably allocated to people in those areas
    b. Do we save the most lives by prioritizing those most vulnerable to COVID or by prioritizing high transmitters? Which strategy saves most lives or which strategy saves most life-years?
        i. Prioritizing those at highest risk (direct protection of those most vulnerable)
        ii. Prioritizing high transmitters (indirect protection of most vulnerable by reducing transmission, but assumes we can identify high transmitters and that vaccine reduces transmission)
15. How do you determine risk?
    a. The Occupational Safety and Health Administration (OSHA) has stratified risk according to type of job:
        i. Low - minimal occupational contact with public and coworkers
        ii. Medium - contact with general public or travelers
        iii. High - Health care, medical transport, mortuary staff exposed to COVID patient
        iv. Very high - health care workers (lab or clinical) caring for COVID-19 patients
    b. It will be difficult to operationalize this in terms of identifying people's individual risk
16. What makes a person at elevated risk has multiple components including risk of exposure/infection and risk of severe disease or death if one gets infected, but occupational exposure is just aspect:
    a. There is also the possibility of acquiring infection in the community (living conditions, need for transportation, etc. all bear on risk outside of work). Non-occupational risk will travel with health inequities (e.g., health care workers with lower income are more likely to come from dense neighborhoods, live in more populated households, or use public/shared transportation putting them at higher risk)

    b. Other characteristics that may confer more risk include age, gender, comorbidities (which may be higher in certain racial/ethnic groups), and pregnancy, so should these also be considered when allocating to health care workers in addition to their occupational risk?
17. Within a Phase, there will be people at equal rank in the priority scheme, but a question will arise whether to allocate to people within a community or outside it (for instance, should a university favor allocating to its own young people who are employees, staff or students or to young people who are family members of people in the university or are outside the university?)
18. In the United States, prioritization will be a short-lived problem (i.e., there will be enough quality vaccine for everyone who wants it over time), but for other parts of the world, there will be people who will either never have access to the vaccine or it will be extremely unlikely they can get it). Prioritization in some parts of the world will be profoundly consequential.
19. Corruption and cronyism are deeply worrying threats to the overall integrity and fairness of the vaccine allocation process. The World Health Organization (WHO) has specifically identified this as a concern and a temptation everywhere. Transparency will be key to prevent these abuses.
    a. Members of the community with historic distrust of institutions are worried that "they will not have a seat at the table" in receiving an efficacious vaccine.
    b. Directly prioritizing to historically disadvantaged groups may actually undermine trust. One way to avoid this is to prioritize to geographically disadvantaged areas
20. In any framework, it is always difficult to balance or resolve the tensions between two competing principles, and different groups may resolve the tension differently in reasonable and justifiable ways. Different societies may weight factors/principles differently.
21. Whether allocation should be based on additive characteristics that increase an individual's risk will depend on how much vaccine is available, how it will be rolled out, and how much discretion at the point of administration. How fine grained the allocation criteria will be will depend on discretion, judgment, and feasibility (e.g., how feasible is it to stratify people by comorbidities? how does one verify comorbidities?).
22. The clinical trials on vaccines were designed to get a representative sample but with some caveats
    a. Groups were targeted by age: 18-50, 51-65, older than 65
    b. People with comorbidities and ethnic minorities were encouraged to be study subjects
    c. Women of child bearing age were required to be on effective birth control
    d. Pregnant women were excluded (some companies have done animal testing that is needed before including pregnant women in vaccine trials)
23. Safety is learned from vaccine trials by the number of participants in the trial, so at least the short term safety can be confidently known from the trials that have been done. Longer term safety data will be acquired over time (trial participants will be followed for 2 years).
24. Whether to continue to use placebos in COVID-19 vaccine trials is a controversial topic. Several issues warrant consideration:
    a. Whether there is enhanced disease with subsequent natural exposure after vaccination versus whether there is a chance of more severe infection without vaccination.
    b. Whether to vaccinate people who received placebo in the clinical trial (current plans are to do crossover designs in which people who got vaccine will get placebo and people who got placebo will get efficacious vaccine in a blinded fashion)
25. The NASEM report explicitly recommended that the United States should contribute to the global effort to ensure vaccine equity, either by contributing to the COVAX facility or by providing bilateral aid to countries not positioned to get enough vaccine for its citizens that need it.

References:

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