How ought we allocate unanticipated doses of COVID-19 vaccines? A proposal based on experience in the United States, 2020–2022

Henry Curtis

Abstract
With vaccination against COVID-19 well underway, providers in the United States (U.S.) found that vials of the Pfizer/BioNTech and Moderna vaccines contained more doses than listed. Because of limited vaccine shelf life, vaccine-providing institutions have thrown extra doses away or quickly distributed them using ad-hoc allocation schemes (drawing names from waiting lists or administering doses to whomever happened to be nearby). This Viewpoint argues that these practices are ethically inadequate and proposes an alternate distribution scheme based on the system in the U.S. to allocate donated organs. The proposal allows for the allocation of unanticipated doses in a way that maximizes societal benefits, is fair, and considerate of the sensitive time constraints for preserving vaccine effectiveness.

Keywords COVID-19 · Organ donation · Resource allocation · Resource scarcity · Vaccination policy

Key messages

- Methods used in the U.S. for dealing with extra, unanticipated doses of COVID-19 vaccines during the initial phase of vaccinations in late 2020 to mid-2021 fail to promote fairness and maximize societal benefits.
- An allocation system based on U.S. experience with donated organs may better promote these key values.

Henry Curtis
hcurtis@albany.edu

1 Department of Philosophy, University at Albany, State University of New York, 1400 Washington Avenue, Albany, NY 12222, USA
Introduction

With the rollout of COVID-19 vaccinations and boosters in the United States (U.S.) well underway, much attention has been paid to allocation schemes [1–3] and to scarcity of supply both domestically and internationally [4, 5]. Some pharmacies and those responsible for administering the vaccine have confronted the opposite problem. When quantities of the vaccine were more limited in 2020, labeling and preparation processes resulted in vaccine providers finding they had extra, unanticipated doses in each multi-dose vial. Due to very limited shelf life of mRNA vaccines, only rapid use avoids waste. Vaccination site workers have thrown away extra doses or devised ad-hoc systems for finding people to vaccinate. This Viewpoint aims to show why these piecemeal solutions are inadequate and to provide an alternate distribution scheme—one that accounts for the urgent time constraints while adhering closely to accepted priorities in allocation plans. A more unified proposal should benefit the public health goal to protect more individuals against COVID-19.

As of 4 March 2022, US providers had administered over 554 million doses of COVID-19 vaccines in the United States [6]. The vast majority of those vaccinated in the U.S. population received one of two mRNA vaccines: one manufactured by a joint effort between Pfizer and BioNTech or one produced by Moderna [6]. Those administering the vaccine found more doses per vial than advertised. Although the Pfizer/BioNTech vaccine label lists five 0.3 mL doses per vial, after dilution and preparation, vials often contained six to seven doses [7]. Moderna’s vaccine, labeled as having ten 0.5 mL doses, sometimes contained an extra dose as well [8].

Given the initial scarcity of vaccines and high demand, extra doses offered an opportunity to stretch the limited supply a bit further. Once efforts to follow the initial two doses with a third (sometimes called a ‘booster’) began in 2021, the extra doses should have been a welcome prospect. However, strict storage requirements for these two vaccines complicate their use [9, 10]. Once a vial has been opened and prepared for use, the vaccine maintains its effectiveness for only six hours, then must be discarded. Thus, if a prospective patient misses a scheduled appointment, or a vial contains extra doses, pressure mounts to use them rapidly to avoid wastage.

Vaccine providers ad-hoc actions

How should vaccine providers deal with extra doses under these circumstances? At the outset of vaccination in December 2020, before providers became aware of the existence of extra doses, many of them went to waste. The U.S. Centers for Disease Control and Prevention (CDC) was unable to collect accurate numbers of doses wasted due to differences in reporting standards from state to state [11]. Reports from the first few weeks of vaccination efforts indicate that hospital pharmacists had to throw away one in every six doses [12]. According to official public health reports in January 2021 from the state of Washington, at least 2315 doses were wasted since the start of vaccination for groups accorded highest priority [13].
Neither vaccine manufacturers nor the Food and Drug Administration had provided guidance for use of unanticipated doses in the vials of vaccines. In late December 2020, when existence of these extra doses became better known, the FDA suggested pharmacists should try to use these doses instead of discarding them [14]. With no person designated to receive the extra doses, pharmacists employed varied, ad-hoc solutions. Some pharmacies assembled waiting lists of people who wanted to be vaccinated and selected recipients from their lists by lottery [15]. Others offered the doses to any individual who happened to be nearby [15]. In one case, a lab coated worker from a grocery store pharmacy searched the grocery aisles and approached a man browsing there—and asked if he would like to be vaccinated right then [15].

To move beyond ad-hoc approaches, it is essential to examine the values inherent in allocation schemes intended to fairly prioritize use of the limited resource [16].

**What should we value when allocating doses?**

In allocation schemes operating in U.S. states, two principles appear most commonly:

1. Maximizing reduction of morbidity and mortality caused by the transmission of COVID-19 [16]: While there are various methods to determine societal benefit that are beyond the purview of this paper [17], at bare minimum, our vaccination campaigns should aim to reduce death and harm as much as possible [16].

2. Distributing vaccines fairly: allocation “should be impartial and evenhanded, avoiding arbitrary exceptions and opportunities for gaming the system” [16].

To protect legitimacy of the process and to ensure public acceptance, fairness applies to how the overall planning prioritizes groups for earlier or later vaccine administration, and to how vaccine is distributed to members within each group. That is, all those in a given priority group (for example, first responders or the elderly) should have equal opportunity to get their allotted doses from the start of the time period designated for their group. These two values may come into conflict. A full discussion of appropriate balancing of fairness and maximizing benefit appears elsewhere [18, 19]. For the purposes of this Viewpoint, the fact that these two values appear in almost every state’s allocation scheme and are of high priority in the National Academy of Sciences, Engineering, and Medicine’s recommendations is sufficient justification to proceed to the argument and proposal.

Using these principles, how do current ‘solutions’ to the problem of extra doses fare? Even though throwing away extra doses produces ‘fairness’ in a technical sense, as it is impartial, evenhanded, and non-arbitrary, this approach fails to maximize potential benefit. Wasting a lifesaving resource for preventing serious disease in the name of objective fairness is an option to avoid. Maximizing benefit may sacrifice fairness. For maximizing benefit, an option in which institutions responsible for administering vaccine determine their own allotment systems to avoid waste,
may seem reasonable. However, such a disjointed approach to allocation violates both principles.

Because the principle of fairness requires impartial allocation, allocation schemes must avoid the possibility of ‘gaming the system’. The practice of some vaccine providers who assembled waiting lists, then drew names from them, has compromised fairness. Websites and Facebook groups for “vaccine hunting” alert people to opportunities to sign up for these lists [20]. In some instances, individuals living in one state have signed up for lists in other states, thus taking supplies parceled out by health departments for needs in a different community [21]. Fairness is not achieved by inadvertently affording ‘priority’ to individuals able to find and add their names to such lists, and who, if called, have the ability to travel some distance to get vaccinated.

Waiting lists often lack adherence to allocation phases. Prioritization categories exist to reduce potential harm that COVID-19 infection can cause at a societal level. For example, ensuring that frontline health care workers will be vaccinated ahead of the general population enables the medical infrastructure to operate as efficiently and optimally as possible under the strain of the pandemic. But waiting lists may allow individuals to skip ahead of the priority group to which public health policy makers have assigned them for vaccination. Thus, individuals previously determined to have priority do not get doses intended for them, compromising the principle of maximizing societal benefit. While one pharmacy may use waiting lists, another may invite whoever happens to be nearby. This too likely violates the principle of fairness.

**A proposal for consistency**

What might a more ethical approach look like? A few features are key:

- It needs to take into account the time-sensitivity for administering these vaccines.
- It should abide by local allocation phases as closely as possible.
- It should avoid allowing people to advance ahead of their priority group designation if at all possible.
- It should be standardized and followed by all vaccine-giving institutions.

I propose drawing on another instance where a scarce, time-sensitive medical resource needs to be distributed in a structured manner based upon certain qualifying criteria: the allocation of donated organs. Typically, this process involves taking into account both the level of need for a particular patient (for example, someone who could survive with a valve replacement, or a stent has lower priority than someone who needs a full heart transplant) as well as distance of the organ recipient from the donated organ, to maximize organ viability.

Use of level of need and distance for determining organ allocation provides a fair foundation for delivering scarce resources while also accounting for time-sensitivity and viability. One way to build on the experience with a systematic process for
organ allocation is to create a centralized database of individuals who wish to be vaccinated that includes where they live or work, or both, and the priority category assigned based on accepted allocation policy. As with organ allocation, this information could be collected using an opt-in system for individuals to sign up. Then, a hospital, pharmacy, or other vaccination site with extra doses of vaccine on hand could use this database to create a pool of ‘eligible’ individuals—those in category of prioritization to get vaccinated at the time who are within a distance to enable them to arrive within the window of time before the doses must be discarded. By lottery or some other fair method, individuals so identified can be invited to come in to be vaccinated. If any doses remain after this step (for example, if individuals in the group identified for contact from the database are unavailable or have already been vaccinated), providers can then expand the search to include people from further distances or those assigned a lower prioritization category.

How does this proposal compare to the ad-hoc systems for dealing with extra doses? It would clearly be better for maximizing benefit than pouring vaccine down the drain. Advantages include limiting arbitrariness and building on accepted allocation schemes, as follows.

Limiting arbitrariness:

- less arbitrariness than approaches varying across vaccination sites.
- avoids reliance on waiting lists accessed by those with better computer skills or arbitrariness of one’s presence near a vaccination site when doses become available.

Building on accepted allocation schemes:

- Just as someone needing aorta replacement should not receive a heart before someone surviving only by cardiopulmonary bypass and life support, a relatively healthy young adult working from home should not receive a COVID-19 vaccine before a nurse or an EMT.
- Level of prioritization would only deviate if no one in the higher priority group were available before expiry of the vaccine.
- A system based on distance as a weighting metric prevents increased access merely from someone having time and means to travel.
- It also increases use of resources specifically allocated for a particular community’s within that community.

**Conclusion**

Any allocation system for a scarce resource should maximize benefit and fairness. Two commonly used approaches fail to maintain fairness. By building on the framework and experience used to allocate donated organs in the U.S., the country can achieve a system for distributing extra doses of COVID-19 vaccine that more closely aligns with the principles of fairness and maximizing benefit. Though vaccination efforts around the globe have emerged from the initial struggle to keep up with
demand, the lessons learned from the experience with unanticipated doses in the U.S. should provide valuable insight to the construction of allocation schemes and other future public health efforts going forward.

Declarations

Conflict of interest  As the sole author of this manuscript, I have no conflicts of interest to disclose.

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