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SHORT REPORT

Covid-19 vaccine dissemination: A public health ethical evaluation of Pennsylvania's plan during Phase 1A

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Received 26 November 2021; accepted 11 June 2022

Available online 17 June 2022

KEYWORDS

COVID;
 Coronavirus;
 Ethics;
 Public health;
 Vaccine;
 Pandemic

Summary

Background. – The novel COVID-19 pandemic afforded public health leaders an opportunity to expedite vaccine development and dissemination. The United States found itself faced with the arduous task of ensuring swift and equitable distribution of limited resources, in the midst of often-competing priorities, including public health ethics, medical ethics, economic demands, and societal strains.

Methodology. – Using the American Public Health Association's (APHA) newly revised public health code of ethics, which provides a decision-making framework and guidance for ethical analysis, we analyzed how Pennsylvania's COVID-19 vaccine dissemination plan aligned with the four core functions of public health ethics inquiry.

Results/Discussion. – Upon investigation, the state's plan evidenced use of public health ethics in goal setting and design. However, the core public health value given the highest priority, promoting health and safety, competed with the other core public health values of inclusivity and engagement, health justice and equity, and professionalism and trust. Despite known social disparities and risk factors, the state plan for COVID-19 vaccine dissemination aligned closely with federal guidance and prioritized all healthcare personnel and long-term care facility populations over high-risk individuals residing in the community.

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Conclusion/Perspectives. – Should another pandemic necessitate allocation of scarce resources, especially preventative measures such as vaccines, decision-making agencies must consider disparate populations in planning and dissemination of material to the public. Any anticipated limitations in the ability to fulfill public health ethical principles should be clearly communicated to the public prior to implementation, thereby increasing trust.

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Introduction

The novel Covid-19 pandemic afforded public health leaders an opportunity to expedite vaccine development and dissemination. With stay-at-home regulations in place to minimize the impact of Covid-19 on the health of the United States, creation of a vaccine needed to occur more quickly than ever before, involving rapid decision-making at many levels. The United States found itself faced with the arduous task of developing, testing, manufacturing, and disseminating a highly sought after vaccine, while needing to ensure swift and equitable distribution of limited resources. This work required substantial collaboration between governmental and non-governmental entities. Leaders needed to develop a national plan that addressed often-competing priorities, including public health ethics, medical ethics, economic demands, and societal strains from ongoing isolation requirements [1]. This paper focuses on the interplay of the Covid-19 vaccine dissemination plan with public health ethics. In light of the need to [2] “improve and innovate public health functions through ongoing evaluation, research, and continuous quality improvement”, we examined how the dissemination of the Covid-19 vaccine within the state of Pennsylvania during Phase 1A aligned with core public health values, noting areas for improvement in the future.

Covid-19 vaccine availability

The Covid-19 pandemic accelerated vaccine development resulting in governmental investment and absorption of financial risk in the needed manufacturing capacity [3]. In order to hasten the creation of reliable vaccines, the U.S. developed a coordinated strategy by combining efforts among governmental agencies, academia, nonprofit groups, pharmaceutical companies, and international organizations [3]. This work, and an outpouring of volunteers who participated in expedited clinical trials, facilitated rapid availability of the Covid-19 vaccine without compromising the U.S. Federal Drug Administration (FDA) strict quality and safety standards [3].

In addition to the speed of development, Covid-19 vaccines were the first messenger RNA (mRNA) vaccines authorized for use in the U.S [4]. Studied for many years by researchers, mRNA vaccines differ from traditional vaccines because they do not use inactivated or weakened strains of

viruses. Instead, the mRNA vaccines teach cells how to make a protein, initiating an immune response in the body that generates antibodies and protects individuals from infection by the real virus [4]. The faster data analysis associated with mRNA made it the perfect option for use during a pandemic.

However, novel use of an mRNA vaccine also caused skepticism among many individuals, and social media flooded with a myriad of claims, among them statements that the Covid-19 vaccine would alter DNA and cause infertility [5]. Attempting to mitigate fears associated with the use of an mRNA vaccine, the pharmaceutical companies and public health professionals shared scientific evidence that mRNA vaccines break down shortly after vaccination and leave the body [5]. Despite ongoing concerns among individuals about mRNA methodology, unified efforts of governmental and non-governmental organizations sped up the development and manufacturer availability of the Covid-19 vaccine.

Covid-19 vaccine dissemination plans

From the onset of the Covid-19 pandemic, U.S. federal agencies advised states on best practices and established an overarching dissemination plan. Housed within the U.S. Department of Health and Human Services (HHS), guidance occurred through two key agencies, the FDA and the Centers for Disease Control and Prevention (CDC). Dissemination plans hinged on determining safe use among priority populations (i.e., healthcare personnel and residents of long-term care facilities (LTCFs)), and the CDC relied on guidance provided by the Advisory Committee on Immunization Practices (ACIP). The ACIP is responsible for providing advice related to vaccinations [6,7]. including “on population groups and/or circumstances in which a vaccine or related agent is recommended.” [[7] (sec3)].

Although orders for vaccines were processed at the federal level using a centralized hub approach, the federal government deferred details surrounding administration of the Covid-19 vaccine to states. Yet, only states with evidence of specific dissemination plans outlining vaccination sites and necessary logistical considerations were approved to receive vaccine shipments [8]. When states received their vaccine supply, they determined how it was disseminated for administration. The Pennsylvania Department of Health (PADOH) developed its Covid-19 vaccination plan following CDC guidance [9]. Pennsylvania maintained the plan in an interim status, frequently updating it to align with

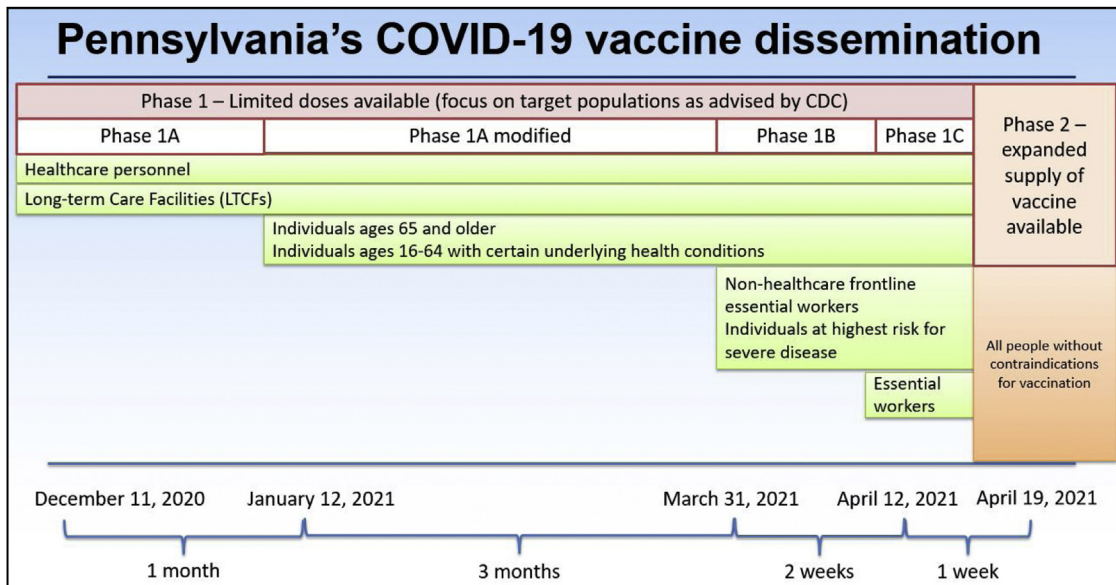


Figure 1. Pennsylvania Covid-19 Vaccine Dissemination Plan [9].

newly available information from the CDC and the ACIP [9]. Based on clearly stated goals to “prioritize persons, who receive the vaccine to maximize benefits and minimize harms caused by the virus, promote justice, mitigate health inequities, and promote transparency while the vaccine supply remained limited”, [9] (p2) the state prioritization plan included several phases and sub-phases (Fig. 1) that attempted to categorize individuals by risk of exposure to Covid-19. Identifying healthcare personnel and LTCF residents as the populations who should receive the vaccination first, the PADOH recognized that limited vaccine supply necessitated additional guidance. Therefore, PADOH developed the Phase 1A algorithm (Fig. 2), which assisted local level decision making during the initial dissemination.

Public health ethical analysis of Covid-19 vaccine Phase 1A plan

Guidance on how to apply an ethical framework to public health policies and actions varies among professional organizations; however, key elements highlighted by the CDC [10] align with those captured in the American Public Health Association’s (APHA) public health code of ethics [11]. The code addresses the increasing complexity of public health policy making and provides a decision-making framework [12]. Furthermore, it provides guidance for ethical analysis, outlining four core functions of public health ethics inquiry. These core functions are: determination of the public health goals of the proposed (or taken) action; identification of ethically relevant facts; analysis of implications of the action on the health and rights of affected persons and populations; and analysis of how the action fits with core public health values [13].

Federal and state agencies employed public health ethics in Covid-19 vaccine planning and goal development [9,10]. Key public health values are referenced throughout the documents and implementation plans, and core ethical

principles influenced the design and decision-making of vaccine dissemination plans, especially at the state level within Pennsylvania. The explicit goal of the PADOH Covid-19 interim vaccination plan was, “to provide a transparent strategy to vaccinate all Pennsylvanians who want to be vaccinated so that Pennsylvanians can return to everyday activities as quickly and safely as possible” [9] (p4)]. While the ethics within this statement are latent and open to interpretation, the state outlined specific ethical principles for meeting this goal. Noting consistency between the ACIP ethical principles for vaccine allocation, Pennsylvania’s Phase 1A decision tool identified four guiding ethical principles:

- Maximize benefits (beneficence) and minimize harms (nonmaleficence);
- Promote justice;
- Mitigate health inequities;
- Promote transparency.

Use of federal guidance and epidemiological data, as available, is evident in the documents outlining the Phase 1A Covid-19 vaccine dissemination plan within the state of Pennsylvania. However, in relation to public health principles and guidance for ethical analysis, some key topics warrant additional evaluation.

First, choosing to prioritize healthcare personnel before residents of LTCFs in vaccine dissemination may have caused more deaths. Knowing limited vaccine supply would not permit initial vaccination for everyone within Phase 1A, Pennsylvania defined and prioritized “Covid-19 facing healthcare personnel” as a way to further sub-divide the population (see Figs. 1 and 2). The state also encouraged local entities to develop fair allocation methodologies should vaccine supply require additional sub-groups within Phase 1A [9]. This more defined prioritization plan within Phase 1A assured vaccine access for healthcare personnel with direct patient contact before those without because such personnel were at great risk of infection and were needed to treat other infected members of the population. However, it failed to address the impact on LTCF

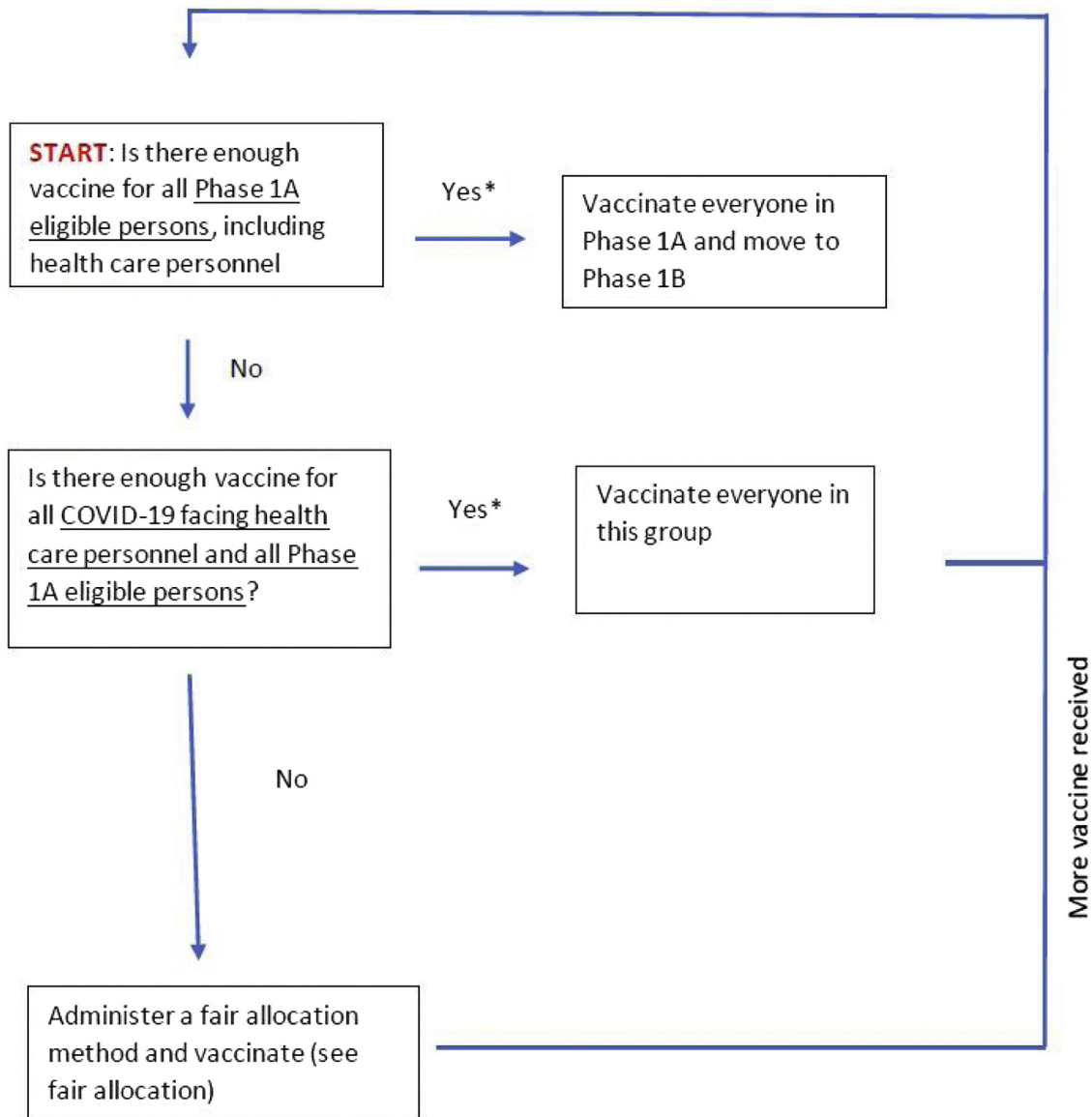


Figure 2. Summary diagram for Phase 1A distribution in the state of Pennsylvania [9] (p65).

residents, who were a lower priority for vaccination than healthcare personnel yet potentially at higher risk if exposed to Covid-19 due to medical comorbidities and communal living without an option to live elsewhere. Placing LTCF residents lower within Phase 1A may have led to increased cases of Covid-19 within LTCFs in Pennsylvania. State data (Fig. 3a and b) demonstrate spikes in LTCF resident Covid-19 infections and mortalities from December 2020 to February 2021, the timeframe when healthcare personnel were prioritized [14].

Second, prioritizing certain subpopulations necessarily means deprioritizing other subpopulations, and with respect to vaccine dissemination, there were disparities by social class and race/ethnicity. As noted by PADOH in the "Ethical Allocation Framework for Emerging Treatments of Covid-19," [15] there is ethical justification in proactively mitigating health disparities. Health inequities related to Covid-19 arise from multiple causes, and the government

often uses public health interventions to diminish inequities among impacted populations [15]. "The rationale is that a core goal of public health is to redress inequities that make health and safety less accessible to disadvantaged groups." [15] (sec4)]. In fact, the state of Pennsylvania's ethical allocation committee identified five ethical goals as part of the ethical allocation framework for emerging treatments of Covid-19. The ethical goals outlined below apply to all Covid-19 treatments and are not specific to the vaccine:

- Safeguard the public's health by allocating scarce treatments to maximize community benefit;
- Create meaningful access for all patients;
- Ensure that no one is excluded from access based on age, disability, religion, race, ethnicity, national origin, immigration status, gender, sexual orientation, or gender identity and to ensure that no one is denied access based on stereotypes, perceived quality of life, or judgements about a person's worth;

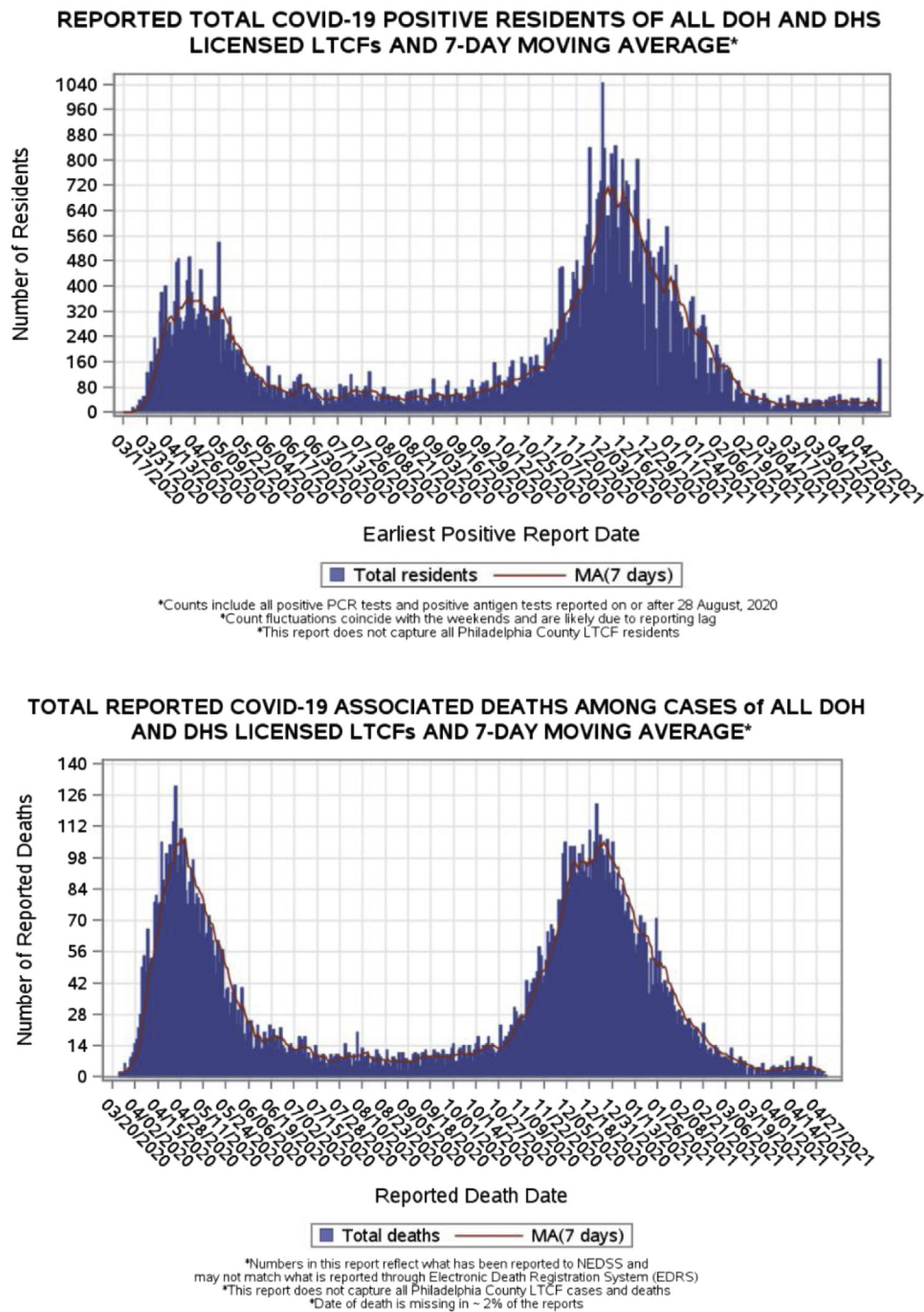


Figure 3. a: reported total Covid-19 positive LTCF residents and 7-Day moving average [14]; b: total reported LTCF Covid-19 associated deaths and 7-Day moving average [14].

- Ensure that all patients receive individualized assessments by clinicians, based on the best available objective medical evidence;
- Proactively mitigate health disparities in Covid-19 outcomes [[15] (sec3)].

Despite promoting these goals in printed materials and other forms of media, Pennsylvania could not vaccinate all at-risk populations during initial Phase 1A implementation, because of limited vaccine supplies. Although noting a disproportionate burden of Covid-19 in low-income

communities and certain racial/ethnic minorities [16], the state did not globally prioritize these populations over healthcare personnel or LTCF residents. Therefore, certain populations living in the community continued to bear a greater burden of severe Covid-19 disease and mortality [16]. Of note, one month after the vaccine was first available, the state added individuals age 65 and older and those age 16–64 with certain medical conditions to Phase 1A in Version 5.0 of the Pennsylvania Covid-19 Interim Vaccination Plan, citing the need to better align with recommendations communicated by the federal government;

yet, this modification to the plan did not actively consider other disproportionately burdened populations, such as racial minorities or those of lower socioeconomic status, in part because U.S. law prohibits explicit racially preferential policies [9].

The fact that a scarce, life-saving vaccine was not available to all who needed and wanted it in the early stages of dissemination illuminates tensions in public health policy making. The APHA Public Health Code of Ethics (2019) delineates essential values that inform public health practice, research, education, policy, and science [12]. These core public health values are professionalism and trust; health and safety; health justice and equity; interdependence and solidarity; human rights and civil liberties; and inclusivity and engagement [13]. The values often complement each other; however, they may compete or conflict in areas of public health practice. Thus, public health professionals must assess values when faced with specific situations to make the best decisions possible [12]. For example, as noted by Lee et al., "Public health efforts such as isolation and quarantine to prevent the spread of serious infectious diseases... can result in conflict between the obligation to promote population health and safety and the obligation to protect human rights and civil liberties" [12] (p489). Furthermore, when weighing and balancing the benefits and risks of ethical values, several options may be valid, and determining the "best" approach is often challenging [13].

The Covid-19 vaccine Phase 1A allocation plan in the state of Pennsylvania illustrates competing core public health values. In an attempt to focus on the health and safety of an entire population, select core values assumed a lower priority. As previously noted, the limited supply of the Covid-19 vaccine required a prioritization plan, which is by its very nature non-inclusive. In addition, the exclusionary approach of Covid-19 vaccine distribution proved inequitable when implemented, despite efforts to employ public health guiding principles.

The priority-based approach for dissemination of the Covid-19 vaccine created a sense of "rationing," and the use of a phased administration plan created mixed public opinion. Many people are accustomed to a more individualized approach to medicine, with vaccines readily available for administration during office visits. Therefore, in the midst of a mandated quarantine restrictions, the additional limitations on access to a vaccine caused varying opinions, and some individuals found the process less than ideal. A County Commissioner summarized public opinion in the Philadelphia area, where vaccine supply and dissemination was managed separately from other parts of the state, "I would like to have confidence that the Pennsylvania Department of Health is doing everything in their power to make sure that this scarce resource is distributed equitably... my confidence is starting to become shaky" [17] (paras15-17).

In addition, historical evidence during pandemics demonstrates that risk-averse governments pursue proactive policies, especially during elections, because voters "punish governments for inadequate disaster responses" [18] (p81)]. Developing a vaccine dissemination plan during a changing political climate and new presidential administration may have influenced state decisions. At the time of

vaccine dissemination, the federal government was transitioning from a Republican president and cabinet to a Democratic executive and legislative majority. With recommendations on prioritization and phased approached coming from the federal government, states with predominantly democratic representation were more likely to align with the federal recommendations. Although the state of Pennsylvania is directed by a Democratic governor, it has a primarily Republican legislature with rural and suburban areas maintaining strong Republican influences. It appears subject matter experts rather than politicians led strategies employed by Pennsylvania during the Covid-19 vaccine Phase 1A. However, the strong political undercurrents at the time contributed to public distrust and varying opinions.

Despite the dictates of public health ethics to develop policies and programs that promote and maintain trust within a community [12], during Phase 1A, public trust of the Covid-19 vaccine program in the state of Pennsylvania wavered. Countless editorials flooded social media and newspapers, and the opinions varied from "[We] have been handed a clunky and lumbering 'plan' by the commonwealth" [17] (para5)] to "Pennsylvania should stick to its plan to vaccinate in phases." [19] (para5)]. It is arguable that any dissemination plan would have created societal mistrust and an imbalance in public health values, because the rapid nature of the Covid-19 vaccine dissemination initially made it difficult to adjudicate which populations warranted prioritization. Indeed, the disparity between stated ethical goals and actual practice implemented by the state, because of limited availability of the vaccine, perpetuated beliefs that government-led processes are prone to corruption. The state found itself in a position where public misinformation and distrust of vaccine safety and efficacy increased because of an inherent distrust in the process [20].

Conclusion

One benefit of federalism is that states can address specific needs within their microsystem. Pennsylvania opted to align its Covid-19 vaccine Phase 1A plan with federal guidance. However, this alignment does not reflect an absence of consideration for the needs of the population, nor for the role of public health ethics. The state referenced public health ethics throughout Covid-19 vaccine planning. However, retrospective evaluation of the effectiveness, accessibility, and quality of the Covid-19 Phase 1A vaccination plan highlights the state's inability to address identified disparities, uphold proclaimed goals, and maintain public trust. The state did not adhere to the key public health concept of distributive justice (i.e. equitable distribution of risks, benefits, and burdens of public health action) [11]. Pennsylvania identified the need to prioritize certain populations over other at-risk groups, yet failed to fully recognize or acknowledge the risk when preparing dissemination plans and goal statements released to the public. Should another pandemic necessitate allocation of scarce resources, especially preventative measures such as vaccines, decision-making agencies must consider disparate populations in planning and dissemination of material to the public. Any anticipated limitations in

the ability to fulfill public health ethical principles should be clearly communicated to the public prior to implementation, thereby increasing trust. Leveraging public health core values of inclusivity and engagement as well as health justice and equity will help provide for the community's health and safety while accounting for social disparities.

Human and animal rights

The authors declare that the work described has not involved experimentation on humans or animals.

Informed consent and patient details

The authors declare that the work described does not involve patients or volunteers.

Funding

This work did not receive any grant from funding agencies in the public, commercial, or not-for-profit sectors.

Financial disclosure:

Cheryl L. Richardson has no financial disclosures.
Megan S. Wright has no financial disclosures.
Casey N. Pinto has no financial disclosures.

Author contributions

All authors attest that they meet the current International Committee of Medical Journal Editors (ICMJE) criteria for Authorship.

Disclosure of interest

Cheryl L. Richardson is the primary author of this paper and has no conflicts of interest to disclose. No funding sources or sponsors assisted in any element of this paper.

Megan S. Wright served as a subject matter expert and editor. There are no conflicts of interest to disclose.

Casey N. Pinto is the doctoral committee chair and academic advisor for Cheryl Richardson who is a DrPH candidate. She provided support in editing and decisions related to journal submission.

References

- [1] Cioffi A, Cioffi F. Covid-19 vaccine: risk of inequality and failure of public health strategies. *Ethics, Med Public Heal* 2021;17, <http://dx.doi.org/10.1016/j.jemep.2021.100653>.
- [2] Centers for Disease Control and Prevention. 10 essential public health services. Public health professionals gateway. Published 2021. Accessed May 30, 2021. <https://www.cdc.gov/publichealthgateway/publichealthservices/essentialhealthservices.html>.
- [3] U.S. Food & Drug Administration. Emergency use authorization for vaccines explained. Published 2020. <https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained>.
- [4] Centers for Disease Control and Prevention. Understanding mRNA Covid-19 vaccines. Published 2021. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/mRNA.html?s_cid=10506:mrna_vaccine:sem.ga:p:RG:GM:gen:PTN:FY21.
- [5] Reuters Fact Check. Fact Check-mRNA vaccines do not turn humans into 'hybrids' or alter recipients' DNA. Reuters. Published 2021. Accessed May 22, 2021. <https://www.reuters.com/article/factcheck-mrna-megamix/fact-check-mrna-vaccines-do-not-turn-humans-into-hybrids-or-alter-recipients-dna-idUSL1N2M61HW>.
- [6] Dooling K, McClung N, Chamberland M, et al. The Advisory Committee on Immunization Practices' ethical principles for allocating initial supplies of Covid-19 vaccine - United States, 2020. *Morb Mortal Wkly Rep* 2020;69:1857–9, <http://dx.doi.org/10.1111/ajt.16438>.
- [7] Centers for Disease Control and Prevention. ACIP Charter.; 2021. Accessed May 2, 2021. <https://www.cdc.gov/vaccines/acip/committee/charter.html>.
- [8] U.S. Department of Health and Human Services. From the factory to the frontlines: the operation warp speed strategy for distributing a Covid-19 vaccine; 2021.
- [9] Pennsylvania Department of Health Covid-19 Vaccine Task Force. Covid-19 Interim Vaccination Plan V8.0.; 2021.
- [10] Centers for Disease Control and Prevention. Public health ethics. Office of Science. Published 2017. <https://www.cdc.gov/os/integrity/phethics/index.htm>.
- [11] Thomas JC, Miller R. Codes of ethics in public health. *Int Encycl Public Heal* 2016;1:71–4, <http://dx.doi.org/10.1016/B978-0-12-803678-5.00079-5>.
- [12] Lee LM, Ortiz SE, Pavela G, Jennings B. Public health code of ethics: Deliberative decision-making and reflective practice. *Am J Public Health* 2020;110:489–91, <http://dx.doi.org/10.2105/AJPH.2020.305568>.
- [13] American Public Health Association. Public Health Code of Ethics. APHA Code Ethics. Published online 2019. https://www.apha.org/-/media/files/pdf/membergroups/ethics/code_of_ethics.ashx.
- [14] Pennsylvania Department of Health. Covid-19 Long-Term Care Facilities Data for Pennsylvania. Published 2021. Accessed May 5, 2021. <https://www.health.pa.gov/topics/disease/coronavirus/Pages/LTCF-Data.aspx>.
- [15] Pennsylvania Department of Health. Ethical allocation framework for emerging treatments of Covid-19. Published 2021. <https://www.health.pa.gov/topics/disease/coronavirus/Pages/Guidance/Ethical-Allocation-Framework.aspx>.
- [16] Hardeman A, Wong T, Denson JL, Postelnicu R, Rojas JC. Evaluation of health equity in Covid-19 vaccine distribution plans in the United States. *JAMA Netw Open* 2021;4:8–10, <http://dx.doi.org/10.1001/jamanetworkopen.2021.15653>.
- [17] Panaritis M. Messy suburban vaccine rollout: Does the PA Health Department have control of this situation or not? *The Philadelphia Inquirer*. <https://www.inquirer.com/opinion/covid-19-vaccine-supply-problems-suburban-philadelphia-pennsylvania-wolf-beam-20210306.html>. Published April 24, 2021.

- [18] Baekkeskov E, Rubin O. Why pandemic response is unique: Powerful experts and hands-off political leaders. *Disaster Prev Manag An Int J* 2014;23:81–93, <http://dx.doi.org/10.1108/DPM-05-2012-0060>.
- [19] Muschick P. Why Pennsylvania should not yet allow everyone to get Covid vaccinations. *The Morning Call*. <https://www.mcall.com/opinion/mc-opi-pennsylvania-covid-vaccine-plan-muschick-20210326-csynlkeennd5zhjhhkizxx5wfa-story.html>. Published March 26, 2021.
- [20] Goel RK, Nelson MA, Goel VY. Covid-19 vaccine rollout-scale and speed carry different implications for corruption. *J Policy Model* 2021;43:503–20, <http://dx.doi.org/10.1016/j.jpolmod.2021.04.003>.