# COVID-19 vaccine mandate for healthcare workers in the United States: a social justice policy

K. Hagan<sup>a</sup>\*, R. Forman<sup>b</sup>\*, Elias Mossialos<sup>b,c</sup>, Paul Ndebele<sup>d</sup>, Adnan A. Hyder<sup>e</sup> and Khurram Nasir<sup>a,f,g</sup>

A. Division of Health Equity & Disparities Research, Center for Outcomes Research, Houston, TX, USA;

B. Department of Health Policy, London School of Economics and Political Sciences, UK;

C. Center for Health Policy, Imperial College London, UK;

D. Department of Global Health, The George Washington University, Washington, DC, USA;

E. Center on Commercial Determinants of Health, Milken Institute School of Public Health, The George Washington University, Washington, DC, USA;

F. Division of Cardiovascular Prevention and Wellness, Department of Cardiology, Houston Methodist DeBakey Heart & Vascular Center, Houston, TX, USA;

G. Center for Cardiovascular Computational & Precision Health (C3-PH), Houston Methodist DeBakey Heart & Vascular Center, Houston, TX, USA

## Abstract

Introduction: Vaccination is the most effective strategy to mitigating COVID-19 and restoring societal function. As the pandemic evolves with no certainty of a herd immunity threshold, universal vaccination of at-risk populations is desirable. However, vaccine hesitancy threatens the return to normalcy, and healthcare workers (HCWs) must embrace their ambassadorial role of shoring up vaccine confidence. Unfortunately, voluntary vaccination has been suboptimal among HCWs in the United States, a priority group for whom immunization is essential for maintaining health system capacity and the safety of high-risk patients in their care. Consequently, some health systems have implemented mandates to improve compliance.

Areas covered: This article discusses the ethical and practical considerations of mandatory COVID-19 vaccination policies for HCWs utilizing some components of the World Health Organization's framework and the unique context of a pandemic with evolving infection dynamics.

Expert opinion: COVID-19 vaccine mandates for universal immunization of HCWs raise ethical and practical debates about their appropriateness, especially when the vaccines are pending full approval in most jurisdictions. Given the superiority of the vaccines to safety and testing protocols and their favorable safety profile, we encourage health systems to adopt vaccination mandates through participatory processes that address the concerns of stakeholders.

## Article highlights

- COVID-19 vaccines approved for emergency use in the United States are safe and highly effective. They remain the best strategy to mitigate the pandemic and restore normalcy, with very few alternatives.
- With the emergence of more virulent coronavirus variants and significant vaccine hesitancy in several sections of the public, universal immunization of at-risk populations is the desired endpoint for public health agencies.
- Healthcare systems and personnel have the fiduciary, professional, and ethical duties to preserve the frontline workforce and minimize the risk of care-associated infections by vaccinating against COVID-19.
- Despite the free and sufficient supply of the vaccines to HCWs in the United States, voluntary vaccination has been subpar, prompting health systems to adopt mandatory vaccination policies with repercussions for non-exempted non-compliers.
- Mandating vaccines that are pending full approval from the Food and Drug Administration through a Biological Licenses Application raises ethical and legal debates about the appropriateness of such policies.
- The benefits of mandating the COVID-19 vaccines approved for emergency authorization far outweigh the minimal potential risks, and health systems are e

## 1. Background

Compulsory vaccination policies have existed since the 19th century when the United Kingdom government first passed the Vaccination Act of 1853, requiring all children whose health permitted to vaccinate against smallpox within the first three months of life [1]. The act further penalized offending parents with a fine of £1.00 [1]. Although no compulsory vaccination currently exists in the United Kingdom's national immunization program [2], many European countries have adopted vaccine mandates for specific groups. In a 2010 survey of European nations, nearly half had implemented at least one vaccination mandate in their national programs [3]. In 2017, Italy instituted mandatory vaccination policies against twelve diseases, including measles, tetanus, and rubella [4]. In the United States (U.S.), Massachusetts was the first state to enact a school vaccination requirement in 1855 [5]. Today, all fifty states require children enrolled in public schools to comply with immunization schedules for diphtheria, tetanus, and pertussis, polio, measles, mumps, and rubella, and varicella.

In recent months, debates have arisen around whether specific high-risk communities should be mandated to receive the COVID-19 vaccination. Worldwide, the current pandemic has triggered a near-total shutdown of social and economic activity and perpetuated disparities in health outcomes [6]. Early in the pandemic, the unflagging rates of infection and severe disease strained the crisis capacity of health systems as hospitals scuttled to adopt personnel and operational flexibilities to curtail morbidity and mortality excesses associated with the pandemic [7]. Healthcare workers (HCWs) are at a significantly increased risk of COVID-19 infection, mainly through community exposure and work-related exposure to a lesser extent [8]. Additionally, HCWs infected with COVID-19 have a four-fold higher risk of severe illness than other essential workers [9]. Indeed, as of May 2021, over 1,630 (0.3%) HCWs with COVID-19 had died in the U.S [10]. Besides the increased risk of infection and morbidity, infected HCWs also become potential sources of coronavirus infection to patients, colleagues, and the community. A recent study demonstrated lower rates of COVID-19 infections among the household members of immunized HCWs [11]. Therefore, as vaccination remains the most effective mitigation strategy, the safety of the public and the maintenance of health system capacity necessitate HCW vaccination.

COVID-19 vaccine enthusiasm continues to rise in the U.S. as areas with adequate vaccination coverage begin to ease restrictions. Unfortunately, despite continued sensitization efforts, there remains significant hesitancy and refusal in the public and, worryingly, in some quarters of HCWs. Several weeks after the COVID-19 vaccine rollout in the U.S., a nationally representative survey of frontline HCWs observed that barely half (52%) of this at-risk group had received at least one dose of COVID-19 vaccine, with the majority directly involved in patient care (physicians, nurses) [12]. Of those unvaccinated, one-third had no plan to vaccinate or were deliberating their vaccination [12]. Instructively, many of those who had not scheduled a vaccination appointment were concerned about potential side effects (82%) and the newness of the vaccine (81%) [12]. Thus, despite proactive voluntary initiatives, the threat of vaccination deficit among healthcare personnel has again aroused the debate on vaccine mandates in healthcare settings.

Admittedly, mandating new vaccines presents ethical, legal, and practical challenges in a democratic society. Even more challenging is requiring a biological product not yet fully approved. In this viewpoint (Figure 1), we review the ethical considerations of a COVID-19 vaccination mandate for HCWs, utilizing some components of the framework on a mandatory vaccination policy by the World Health Organization [13], which must influence participatory decision-making on vaccination requirements. We also discuss the legal decisions made on mandatory HCW vaccination policies in

this pandemic and previous outbreaks. Finally, we describe some of the practical considerations unique to COVID-19 to appraise the appropriateness of such a mandate.

## 2. Methods

In this critical review, we appraised studies examining the efficacy and safety of COVID-19 vaccines and the ethical and legal considerations for a mandatory vaccination policy for healthcare personnel against COVID-19. A PubMed/Medline search was performed for published studies up to September 2021 using combinations of MESH terms, free text terms, and keywords relevant to the specific issues discussed in this article. Regarding the efficacy and safety of COVID-19 vaccines, we used the MESH term 'COVID-19 vaccines'; the free text terms 'BNT162b2,' 'mRNA-1273,' 'Ad26. COV2.S,' and 'ChAdOx1,' and the keywords 'safety,' 'efficacy,' 'effectiveness,' and 'adverse events.' We conducted the search on narrative and systematic reviews of mandatory vaccination policies using: the MESH terms, 'COVID-19,' 'Influenza, human,' 'influenza a virus, H1N1 subtype,' 'COVID-19 vaccines,' 'influenza vaccines,' 'vaccination,' 'mandatory programs,' 'health personnel': and the keywords 'seasonal influenza,' 'H1N1 pandemic influenza,' 'mandatory vaccination,' 'mandatory vaccination policy,' 'vaccine mandate,' 'compulsory vaccination,' 'ethics,' 'vaccine hesitancy,' 'vaccination coverage,' and 'healthcare workers.' Additionally, we scanned the reference lists of all the full texts

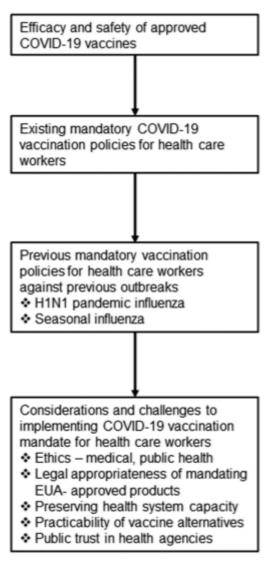


Figure 1. A framework of the present review. Note: EUA - Emergency Use Authorization. HCW - healthcare worker. for other publications and searched the web for news articles and legal cases relevant to this article. We excluded abstracts, articles without full texts, non-English language articles, immunogenicity and serological studies, preclinical trials, and efficacy trials (phase I and II trials). The search strategy is provided in the Supplementary Appendix. From the search strategy for efficacy and safety of the COVID-19 vaccines, 488 articles were screened by title and abstract. The full texts of 15 articles were identified as relevant to this review. Regarding mandatory vaccination policies for COVID-19 and previous outbreaks, the search strategy yielded 404 articles of which 68 were selected for full-text review and reference listing after screening.

## 3. Results

## 3.1. Effectiveness and safety of COVID-19 vaccines

Real-world data across the globe demonstrate vaccination to be highly effective (86% – 90%) against COVID-19 infection (including asymptomatic and symptomatic cases) in HCWs, even when community transmission rises [14–16]. Additionally, the vaccines may reduce viral load in vaccinated people who develop COVID-19, suggesting reduced infectivity in vaccinated individuals [17,18]. For now, the threshold for COVID-19 vaccination coverage remains a moving target as the pandemic evolves with the emergence of new strains, and uncertainty surrounds the duration of seroprotection. Model simulations in the U.S. and other countries initially estimated a 65% – 80% vaccination threshold for herd immunity, but this now seems unlikely [19,20]. Essentially, universal vaccination of at-risk populations is desirable and remains the target of vaccination-related efforts. The safety evidence submitted for the emergency approval of COVID-19 was extensive [21–23]. With most vaccine-related adverse events occurring within six weeks of receiving a dose, vaccine developers were required to produce at least eight weeks of safety data before EUA approval. Additionally, existing vaccine safety monitoring programs like the Vaccine Adverse Event Reporting System (with a liberal reporting threshold) and Vaccine Safety Datalink (more robust) allow for the continual collection and prompt evaluation of adverse events, including the thrombotic events associated with the Johnson & Johnson/Janssen COVID-19 vaccine [24–26]. The thrombotic events are rare [27], and any potential serious long-term side effects have been described as unlikely and do not outweigh the benefits of vaccination [28].

## 3.2. COVID-19 vaccine mandates in healthcare

This spring, healthcare organizations around the globe began implementing COVID-19 vaccine mandates. In early March, Israel's Hadassah Medical Organization announced it would bar all unvaccinated staff from contact with patients unless legitimately exempted [29]. Then in April, Italy became the first country in Europe to make vaccination against COVID-19 mandatory for HCWs to contain the infection [30]. Later in the summer, France and Greece announced the requirement for all health workers to get vaccinated [31]. The United Kingdom government also passed legislation mandating care-home workers to fully vaccinate [32]. Further, the government launched a public consultation on extending the mandate to other health and social care settings in England [33]. In the U.S., Houston Methodist became the first hospital to mandate COVID-19 vaccination for all current employees and as a precondition for prospective employees [34]. Subsequently, a wave of U.S. hospitals requiring COVID-19 vaccination for present and future personnel ensued [35]. Also, a few weeks after the U.S. Food and Drug Administration granted the first Biologics License Application (full) approval for a COVID-19 vaccine, President Biden issued an executive order mandating all federal employees, including healthcare personnel, to vaccinate against COVID-19 [36].

## 3.3. Previous pandemic vaccination mandates for HCWs

The controversy around mandating HCWs to vaccinate is not a new phenomenon. For example, in 2009, five vaccines to mitigate the pandemic H1N1 influenza virus received full approval by the FDA within seven months of the first recorded case in the U.S [37]. Like COVID-19, HCWs were designated high-risk and prioritized to receive the (H1N1)pdm09 vaccine [38]. Together with state and local health agencies, the U.S. Centers for Disease Control and Prevention intensified campaigns to encourage voluntary vaccination compliance among groups prioritized for phased vaccine allocation. Unfortunately, despite ample vaccine supply and encouragement from employers, vaccination rates among HCWs merely approached seasonal influenza rates [39]. As a result, many hospitals instituted mandates with penalties varying from masking to dismissal.

In New York, the State Department of Health ordered all HCWs to vaccinate against H1N1 and seasonal influenza by November 2009 [40]. However, workers' associations and unions opposed the mandate, and some nurses individually filed lawsuits to challenge the order [41]. A presiding judge issued a temporary restraining order against the mandate's enforcement [42]. Although a trial was scheduled, the cases which were consolidated eventually were never heard. In addition to the lawsuits, a civil rights organization argued to the New York State Assembly that the H1N1 vaccination Figure 1. A framework of the present review. Note: EUA - Emergency Use Authorization. HCW -

healthcare worker. EXPERT REVIEW OF VACCINES 39 requirement violated the right to medical autonomy [43]. It further argued that a mandate was not necessary since the H1N1 mortality rate was relatively low and vaccine efficacy was not impressive enough. The state ultimately suspended the policy citing inadequate vaccine supply as the extenuating reason [44].

In 2005, Virginia Mason Medical Center effected the first influenza vaccine mandate for HCWs as a fit-for-duty condition with religious or medical exemptions [45]. The mandate heralded a jump in the seasonal influenza vaccination rate from 54% to 98% [45]. This policy produced similar rates in other health systems, and professional bodies like the American College of Physicians now mandate vaccination with legitimate exceptions. Currently, more than two-thirds of non Veterans Affairs hospitals have instituted a mandatory seasonal influenza vaccination policy [46].

## 3.4. Ethics of mandatory COVID-19 vaccination of healthcare workers

## 3.4.1 Clinical ethics of non-maleficence

By the nature of their profession, health workers are often exposed to patients at high risk of severe COVD-19 illness and related death, such as the elderly, frail, and immunocompromised. In these high-risk patients, there is the biological plausibility of reduced vaccine efficacy. Indeed, preliminary data from nursing home residents show blunted immune response to COVID-19 vaccines [47,48]. Further, a significant proportion of the public is likely not to vaccinate in the immediate future due to vaccine hesitancy. To satisfy their moral duty to 'do no harm,' HCWs have a professional obligation to take all reasonable measures to prevent COVID-19 transmission. Nevertheless, to ethically justify mandatory HCW vaccination, there must be a valid demonstration of substantial patient benefit relative to the infringement on the medical autonomy of the personnel.

There is currently not enough evidence to robustly quantify the effectiveness of HCW COVID-19 vaccination against nosocomial (or care-associated) infections for hospitalized patients. However, as vaccination reduces asymptomatic infections and is associated with lower viral loads, vaccination may minimize the risk of care-associated transmission in the setting of regular testing and safety protocols. Additionally, the association observed between HCW vaccination and lower rates of COVID19 infection and related hospitalization in unvaccinated household members adds to the effectiveness of the COVID19 vaccines in interrupting transmission across various settings [11]. These results encourage the adoption of COVID-19 vaccination as part of all reasonable measures to mitigate the pandemic.

## 3.4.2 Public health ethics: infection mitigation and autonomy

Opponents of vaccine mandates mainly premise their resistance to the infringement of autonomy and personal liberty. Though not compulsory, a mandatory vaccination policy inevitably involves constraints to individual choice by imposing some form of repercussion for non-compliance. Any curtailment of individual freedom, a constitutionally enshrined liberty, requires justification: in this case, we believe the safety of the patients indeed justifies vaccine mandates in healthcare settings.

Vaccine compliance among healthcare personnel is vital to individual patient safety and, broadly, to the continued functioning of the health system. COVID-19 has been a global health concern in the last year, and its disruptive impact on society justifies a proactive and persuasive immunization policy to attain community immunity. In the U.S., the Model State Emergency Health Powers Act grants 'public health powers to state and local public health authorities to ensure strong, effective, and timely planning, prevention, and response mechanisms to public health emergencies (including bioterrorism) while also respecting individual rights [49].' In the landmark Supreme Court case of

Jacobson vs. Massachusetts, the court upheld an ordinance in Cambridge, Massachusetts, that required all adult citizens to vaccinate against smallpox in the wake of an epidemic. The court found that notwithstanding the Constitution's guarantee of liberty, every person might be subject to 'manifold restraints' when needed 'for the public good [50].' This broad ruling gives health care workers limited legal ground to object. Thus, there may be precedential and legal grounding to legitimize a COVID-19 vaccine mandate for HCWs in the U.S. Otherwise, the ability of HCWs to oppose an organizational policy that maintains a safe work environment (e.g. universal vaccination coverage) could dampen the ability of health systems to protect their patients and the public at large. In brief, mitigating infections and preserving the healthcare workforce are reasonable communal justifications for a mandatory vaccination policy in healthcare organizations.

## 3.4.3 Ethical and Legal Appropriateness of mandating EUA-approved agents

Many have questioned the ethical and legal appropriateness of mandating vaccines authorized for temporary emergency use. First, for the FDA to issue a EUA for a vaccine in the absence of an approved and adequate alternate countermeasure or biological product, the FDA must determine that the known and potential benefits of the vaccine outweigh its known and potential risks during the public health emergency [51]. Then, adequate chemistry and manufacturing information must be available to ensure the consistent production of lots similar to those initially shown in trials to be effective and safe. Additionally, the authority reviews safety data from phase I and II trials and data from a phase III trial where at least half the vaccine recipients are followed for at least two months. In the review of safety data, the FDA expects the phase III safety database to include over three thousand vaccine recipients observed for adverse events of serious nature and those of special interest at least four weeks after completing the full vaccination regimen.

On the other hand, full FDA approval of a biological product requires safety data from the phase III trial to be at least six months long [52,53]. Further, manufacturers must provide more detailed chemistry, manufacturing plans, and processes to ensure the product's purity remains during commerce production. The authority also offers a higher level of oversight in facility inspections. These processes typically take a more extended period to complete.

Generally, the less stringent and shorter temporal span of evidence of efficacy and safety for EUA approval, as opposed to the evidence of long-term safety, effectiveness, and purity associated with full approval, can raise reasonable apprehension about mandating products earmarked for temporary emergency use. For example, on 28 May 2021, 117 employees joined a lawsuit against Houston Methodist's policy requiring all employees to vaccinate against COVID-19 when the vaccines are pending full approval [54]. The plaintiffs argued that the health system was unlawfully forcing its employees to vaccinate with COVID-19 vaccines that were 'experimental' and 'dangerous.' Nevertheless, the safety and efficacy evidence evaluated to approve COVID-19 vaccines for temporary emergency use was quite exhaustive. With over 700 million vaccine doses administered as of April 2021 under stringent safety monitoring efforts worldwide [55], we would expect nearly all adverse events documented by now. Fortunately, the immediate and long-term safety profiles of the COVID-19 vaccines approved for emergency use are very favorable.

The U.S. Emergency Use Authorization statute provides that individuals be informed: 'of the option to accept or refuse the EUA product, and of any consequences, of refusing administration of the product; and any available alternatives to the product and of the risks and benefits of available alternatives [56].' Opposers of COVID-19 vaccine mandates cite the first segment of the provision as a rationale to prohibit a mandate, as it states a person must have 'the option to accept or refuse.' However, proponents of policies mandating EUA-approved vaccines offer a different interpretation

which considers the second segment about consequences and argues that this insinuates a legal place for a mandate – especially in the healthcare setting. Until recently, there was no legislative precedent to the interpretation of this statute. In the lawsuit against Houston Methodist, the sitting judge upheld the hospital's vaccination policy [57]. The Court averred that while the EUA statute grants the Secretary of Health and Human Services public health powers in an emergency, it does not apply to private employers. The Court further ruled that the requirement of COVID-19 vaccines, hitherto under EUA approval, did not constitute a human trial and did not violate the federal law requiring human study participants to give legal and informed consent before participating in a trial [58].

Since the Pfizer/BioNTech vaccine received full approval from the FDA in the U.S [59]., many organizations that hesitated to mandate COVID-19 vaccination have now implemented mandatory vaccination policies [35].

## 3.5. Preserving health system capacity

Beyond the professional duties of HCWs, healthcare organizations must maintain the capacity to deliver care and protect their employees during humanitarian emergencies. At the height of the pandemic, we witnessed healthcare staff shortages and burnout so desperate that asymptomatic COVID-19 positive HCWs were permitted to work in some healthcare institutions [60]. Maintaining a healthy workforce during a public health emergency bolsters the argument for a COVID-19 vaccination requirement within the healthcare setting. Furthermore, with the most dramatic effect of COVID-19 vaccination observed on symptomatic and severe illness, vaccinated health workers who contract COVID-19 are less likely to suffer from severe symptoms and more likely to quickly recover (and return to work). There are also preliminary reports of vaccination improving symptoms of 'long COVID' [61], which further the argument for a mandatory vaccination policy for HCWs. Lastly, borrowing from the protective association observed between influenza vaccination and absenteeism and health service cost, the potential value of HCW vaccination against COVID-19 rationalizes universal vaccination through mandates in healthcare settings [62].

## 3.6. Practical considerations for mandatory COVID-19 vaccination of healthcare workers

## 3.6.1 Impracticability of alternative measures

Many existing mandatory influenza vaccination programs in health institutions use masking as an alternative for exempted workers and conscientious objectors. In the case of COVID-19, there are such alternatives as masking, social distancing, and regular testing that have been at play since the pandemic and will remain in the foreseeable future regardless of vaccination status. Another tactic used in some healthcare settings with influenza requires personnel who have refused vaccination to wear badge identifiers [63,64]. This policy might have unintended consequences if translated to the COVID-19 context though since patients who may already be hesitant about the vaccines could lose even more confidence in them when they see their provider also has reservations about the jabs. Alternatives like reassigning unvaccinated HCWs to nonpatient-facing roles and rewarding vaccinated HCWs may have the drawbacks of worsening provider fatigue and presenting a picture of discrimination. Therefore, there are very few practical alternatives to COVID-19 vaccination mandate for incentivizing HCWs to vaccinate against COVID-19.

## 3.7. Public trust

The U.S. is plagued by a history of inequalities and unethical research in some minority populations. In the health worker population, people of color overrepresent [65], and studies on vaccine hesitancy and acceptance consistently show sociodemographic differences [66,67]. Additionally, the hyperpoliticization of the pandemic and vaccination in the U.S. and other countries [68,69] further deepens the demographic differences in vaccine confidence [70]. Nevertheless, a significant proportion of organizations in the non-healthcare sector have adopted vaccine mandates for the immediate future. Literature on attitudes towards a COVID-19 vaccine mandate, albeit scant, suggests that most HCWs accept a mandatory vaccination policy [71,72]. Also, major health care organizations and professional bodies also recently endorsed such policies [73].

The public generally perceives health workers to be more aware of health-related issues, and health workers are opportune ambassadors of COVID-19 vaccine acceptance. Considering the hesitancy/refusal in the public to voluntarily vaccinate against COVID-19, any equivocation by healthcare organizations on a vaccine requirement can lower vaccine EXPERT REVIEW OF VACCINES 41 confidence, especially among people who trust the health system. We believe that healthcare organizations, through vaccine requirements, can exemplify the professional obligation to maximize immunity as a public good for vulnerable patients (communitarian altruism) while fulfilling the duty to protect employees [74].

## 4. Discussion

Vaccination is the best restorative strategy in the COVID-19 era. While there is no universal consensus when considering a vaccine mandate, decision-makers must weigh the benefits to society against the potential limitations to individual liberties and ensure that the mandate is necessary for and proportionate to the public health goal in question. We support health systems in the U.S. and worldwide that have assessed these dimensions and caveats and have decided that mandatory HCW vaccination against COVID-19 is ethically justified, fair, and necessary for the desired endpoint of universal vaccination.

We note some limitations of this article. First, this review was neither a systematic review nor a meta-analysis, and therefore the search strategies and criteria for selecting literature do not mitigate bias. However, the scope of our search strategies for each topic – efficacy and safety, medical and public health ethics, the practicality of alternative measures, legal decisions, and precedents – was extensive enough for a critique of mandatory COVID-19 vaccination policy for healthcare workers. Second, we limited our literature search of databases to PubMed. Nevertheless, our liberal inclusion/ exclusion criterion of the studies afforded a significant scope of literature for a critical review.

## 5. Conclusion

Although there is no one-size-fits-all approach to COVID-19 vaccination uptake, it is counterintuitive and questionable to justify the hesitation to require HCWs to vaccinate against COVID-19, especially when most health systems in the U.S. have vaccination requirements for less virulent infections like seasonal influenza. In the spirit of social justice, we encourage stakeholders to continue deliberating the far-reaching benefits and the potential but rare harms of universal COVID-19 vaccination coverage of healthcare workers and build a consensus that champions the public's health.

#### 6. Expert Opinion

As new coronavirus variants emerge and spread, the vaccination threshold for herd immunity remains elusive. It is unclear the duration and extent of protection from the various vaccines and boosters or repeat schedules may be needed. Thus, universal immunization is the primary goal of the public health community to reduce COVID-19 transmission, severe illness, and mortality. Health

agencies continue to implement well-designed vaccination campaigns, but voluntary vaccination coverage has been suboptimal, especially in the healthcare community. Mandatory vaccination policies have been utilized in some healthcare systems to improve coverage in HCWs. Although the list of health systems mandating COVID19 vaccines for health workers grows, the adoption of this mandatory policy faces ethical and legal barriers.

While introducing vaccine mandates can be a successful strategy to increase vaccination coverage, these decisions are complex and should take several key challenges. There are potential risks involved with introducing vaccine mandates, including the erosion of trust and exacerbation of inequalities. As COVID-19 vaccines are still under temporary emergency authorization use in most jurisdictions, there is reasonable apprehension about the vaccines that mandatory COVID-19 policies – many of which require job suspension or termination for non-exempted non-compliers – may not necessarily address. Also, the repercussions of not complying with a vaccine mandate could disproportionately affect minority HCWs and worsen existing structural inequalities. Hesitancy to COVID-19 and previous vaccines is observed to be more likely among minority healthcare workers (Black, Latino or Hispanic) [75,76], who themselves overrepresent in nonclinical jobs. Such hesitancy is shown to be related to subpar knowledge about the efficacy and safety of vaccines and mistrust that stems from the unethical conduct of medical research in minority groups in the past. Thus, implementing a mandatory COVID-19 vaccination policy with repercussions of work suspension or termination for non-exempted noncompliers without competently engaging the hesitant groups to address their apprehensions may be construed as unjust.

In our opinion, through the prism of non-maleficence, the fiduciary duty of health systems towards their vulnerable patients, the impracticability of alternative measures, and the professional responsibility of HCWs as role models to their patients and the community, the benefits of universal vaccination of HCWs through a mandatory COVID-19 vaccination policy far outweigh the potential risks. The COVID-19 vaccines work – less than 1% of COVID-19 deaths in the U.S. were fully vaccinated in May 2021 – and universal immunization of HCWs has the potential to significantly minimize care-associated transmission to high-risk patients and fellow workers and contribute to reducing household (and community) transmission. Additionally, the preservation of the frontline workforce is vital to the emergency preparedness of health systems for any looming COVID-19 related crisis as waves of infection by new variants have been recorded. We cannot afford to lose so much of the progress chalked in the COVID-19 fight. Despite the ravages of the pandemic and the highly favorable safety and effectiveness profiles of the vaccines, voluntary COVID-19 vaccination coverage in HCWs has mirrored the suboptimal rates seen with less virulent outbreaks like seasonal influenza and the pandemic H1N1 influenza. Herein lies the relevance of a mandatory policy, as caution from history makes this policy indispensable to the achievement of universal vaccine compliance among HCWs.

Throughout the COVID-19 pandemic, many people and institutions have had to make concessions for the greater good of population health. We believe that thoughtful mandatory vaccination policies in healthcare settings that account for ethical, legal, and equity challenges and involve participatory processes with various stakeholders are justifiable under the current pandemic circumstances. Implementing mandatory COVID-19 vaccination policies by health systems and across other industry sectors in this public health emergency tests the boundaries of personal autonomy. Health system decision-makers have made the bold call to mandate new vaccines pending full approval and have legal backing from at least one court in Texas. As the extent and duration of protection by the vaccines continue to evolve, the successful adoption of these mandates bodes well for acceptance and compliance with any future revaccination schedules that may be needed. We also envisage that healthcare institutions would embrace mandates at the earliest for future pandemics of this caliber, especially when safety and effectiveness data are exhaustive. Employers may also be encouraged to assess the benefits and risks of existing vaccination policies for other infections.

## Abbreviations

COVID-19, Coronavirus disease-2019; EUA, Emergency Use Authorization; FDA, Food and Drug Administration; HCW, Healthcare worker; U.S., United States.

## **Declaration of Interest**

K Nasir is on the advisory board of Amgen, Novartis, Medicine Company, and his research is partly supported by the Jerold B. Katz Academy of Translational Research. The authors have no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.

#### **Reviewer disclosures**

Peer reviewers on this manuscript have no relevant financial or other relationships to disclose.

## Funding

This paper was not funded.

## References

1. The National Archives. Victorian Health Reform. How did the Victorians view compulsory vaccination?. The National Archives. [cited 2021 May 25]. Available from https://www.nationalarchives.gov.uk/education/resources/victorian-health-reform/

2. Rough E, Vagnoni C, and Bunn S . UK Vaccination Policy. Number CBP 9076, 21 January 2021 (London: House of Commons Library) . [cited 2021 May 25]. Available from https://researchbriefings.files.parliament.uk/documents/CBP-9076/CBP-9076.pdf

3. Haverkate M, D'Ancona F, Giambi C, et al. Mandatory and recommended vaccination in the EU, Iceland, and Norway: results of the VENICE 2010 survey on the ways of implementing national vaccination programmes. Eurosurveillance. 2012;17 (22):20183.

4. Christopher L. Amid measles outbreak, Italy makes childhood vaccinations mandatory. NPR.org. Published 19 June 2017. [cited 2021 Jun 15]. Available from https://www.npr.org/sections/parallels/ 2017/06/19/533481635/amid-measles-outbreak-Italy-makes-child hoodvaccinations-mandatory

5. Duffy J. School Vaccination: the Precursor to School Medical Inspection. J Hist Med Allied Sci. 1978;XXXIII(3):344–355.

6. Cutler DM, Summers LH. The COVID- 19 Pandemic and the \$16 Trillion Virus. JAMA. 2020;324(15):1495–1496.

7. Nicolás D, Coloma E, Pericàs JM. Alternatives to conventional hos-pitalisation that enhance health systems' capacity to treat COVID- 19. Lancet Infect Dis. 2021;21(5):591–593.

8. Braun KM, Moreno GK, Buys A, et al. Viral sequencing reveals US healthcare personnel rarely become infected with SARS-CoV-2 through patient contact. Clin Infect Dis. 2021;73(ciab281):e1329–e1336.

9. Mutambudzi M, Niedzwiedz C, Macdonald EB, et al. Occupation and risk of severe COVID-19: prospective cohort study of 120 075 UK Biobank participants. Occup Environ Med. 2021;78 (5):307–314.

10. Centers for Disease Control and Prevention. Cases & Deaths among healthcare personnel. COVID data tracker. Published March; 2020 28 [cited 2021 May 28]; https://covid.cdc.gov/covid- data-tracker

11. Shah ASV, Gribben C, Bishop J, et al. Effect of Vaccination on Transmission of SARS-CoV-2. N Engl J Med. 2021;null. DOI:10.1056/NEJMc2106757.

12. Kirzinger, A, Kearney, A, Hamel, L, et al. KFF/The Washington Post Frontline Health Care Workers Survey. Published March 2021. [cited 2021 May 25]. Available from https://files.kff.org/attachment/ Frontline%20Health%20Care%20Workers\_Full%20Report\_FINAL.pdf

13. World Health Organization Ethics and COVID-19 Working Group, COVID-19 and mandatory vaccination: ethical considerations and caveats: policy brief, 13 April 2021 WHO/2019nCoV/Policy\_brief/ Mandatory\_vaccination/2021.1 . Geneva: World Health Organization [cited 2021 May 5]. Available from https://apps.who. int/iris/handle/10665/340841 .

14. Benenson S, Oster Y, Cohen MJ, et al. BNT162b2 mRNA Covid-19 vaccine effectiveness among health care workers. N Engl J Med. 2021;384(18):1775–1777.

15. Daniel W, Nivet M, Warner J, et al. Early evidence of the effect of SARS-CoV-2 vaccine at one medical center. N Engl J Med. 2021;384 (20):1962–1963.

16.Le JK, Ma P H, Pfeffer MA, et al. SARS-CoV-2 Infection after vaccina-tion in health care workers in California. N Engl J Med. 2021;384 (18):1774–1775.

17. Levine-Tiefenbrun M, Yelin I, Katz R, et al. Initial report of decreased SARS-CoV-2 viral load after inoculation with the BNT162b2 vaccine. Nat Med. 2021;27(5):790–792.

18. McEllistrem MC, Clancy CJ, Buehrle DJ, et al. Single dose of a mRNA SARS-CoV-2 vaccine is associated with lower nasopharyngeal viral load among nursing home residents with asymptomatic COVID-19. Clin Infect Dis Off Publ Infect Dis Soc Am. 2021March26; Published online DOI:10.1093/cid/ciab263.

19. Kwok KO, Lai F, Wei WI, et al. Herd immunity – estimating the level required to halt the COVID-19 epidemics in affected countries. J Infect. 2020;80(6):e32–e33.

20. Aschwanden C. Five reasons why COVID herd immunity is probably impossible. Nature. 2021;591(7851):520–522.

21. Polack FP, Thomas SJ, Kitchin N, et al. Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. N Engl J Med. 2020;383 (27):2603–2615.

22. Baden LR, El Sahly HM, Essink B, et al. Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine. N Engl J Med. 2021;384(5):403–416.

23. Sadoff J, Gray G, Vandebosch A, et al. Safety and Efficacy of Single-Dose Ad26.COV2.S Vaccine against Covid-19. N Engl J Med. 2021 April 21;384(23):2187–2201. Published online

24. Schultz NH, Sørvoll IH, Michelsen AE, et al. Thrombosis and Thrombocytopenia after ChAdOx1 nCoV-19 Vaccination. N Engl J Med. 2021 April 9;384(22):2124–2130. Published online

25. Greinacher A, Thiele T, Warkentin TE, et al. Thrombotic Thrombocytopenia after ChAdOx1 nCov-19 Vaccination. N Engl J Med. 2021 April 9;384(22):2092–2101. Published online

26. See I, Su JR, Lale A, et al. US case reports of cerebral venous sinus Thrombosis with Thrombocytopenia After Ad26.COV2.S Vaccination, March 2 to April 21, 2021. JAMA. 2021 April 30;325 (24):2448. Published online

27. MacNeil JR, Su JR, Broder KR, et al. Updated recommendations from the advisory committee on immunization practices for use of the Janssen (Johnson & Johnson) COVID-19 Vaccine After Reports of Thrombosis with Thrombocytopenia Syndrome among Vaccine recipients - United States, April 2021. MMWR Morb Mortal Wkly Rep. 2021;70(17):651–656.

28. Centers for Disease Control and Prevention. Safety of COVID- 19 Vaccines. COVID-19. Published; 2020 February 11 [cited 2021 May 28]; https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/ safety-of-vaccines.html

29. Efrati I. Eighty Hadassah hospital workers furloughed for refusing COVID vaccine. Haaretz. Published 2021 March 8 [cited 2021 May 28]; https://www.haaretz.com/Israel-news/eighty-hadassah-hospital -workers-furloughed-for-refusing-covid-vaccine-1.9602204

30. Paterlini M. Covid- 19: Italy makes vaccination mandatory for healthcare workers. BMJ 2021;373:n905.

31. Wise J. Covid-19: France and Greece make vaccination mandatory for healthcare workers. BMJ 2021;384:n1797.

32. Everyone working in care homes to be fully vaccinated under new law to protect residents. GOV.UK. [cited 2021 Sept 21]; https:// www.gov.uk/government/news/everyone-working-in-care-homes- to-be-fully-vaccinated-under-new-law-to-protect-residents

33. Making vaccination a condition of deployment in the health and wider social care sector. GOV.UK. [cited September 21, 2021]; https://www.gov.uk/government/consultations/making-vaccination-a-condition-of-deployment-in-the-health-and-wider- social-care-sector

34. Gooch K. Houston Methodist implements mandatory COVID-19 vaccinations. Becker's Hospital Review. Published 2021 March 31 [cited 2021 May 28];

https://www.beckershospitalreview.com/work force/houston-methodist-implements-mandatory-covid-19- vaccinations.html

35.Gooch K, and Mitchell H. Hospitals, health systems mandating vac-cines for workers. Becker's Hospital Review. [cited 2021 Sep 14]. Available from

https://www.beckershospitalreview.com/workforce/ hospitals-health-systems-mandating-vaccines-forworkersjune17.html

36. Executive Order on Requiring Coronavirus Disease 2019 Vaccination for Federal Employees. The white house. Published 2021 September 9 [cited 2021 Sept 14];. https://www.whitehouse. gov/briefing-room/presidential-actions/2021/09/09/executive- order-on-requiring-coronavirus-disease-2019-vaccination-for- federal-employees

37. Update on Influenza A (H1N1). 2009. Monovalent vaccines. [cited 2021 May 29]; https://www.cdc.gov/mmwr/preview/mmwrhtml/ mm5839a3.htm

38. National Center for Immunization and Respiratory Diseases, CDC. Centers for Disease Control and Prevention (CDC). Use of influenza A (H1N1) 2009 monovalent vaccine: recommendations of the Advisory Committee on Immunization Practices (ACIP), 2009. MMWR Recomm Rep Morb Mortal Wkly Rep Recomm Rep. 2009;58(RR–10):1–8.

39. Interim Results: Influenza A (H1N1). 2009. Monovalent vaccination coverage — united States, October–December 2009. [cited 2021 May 28]; https://www.cdc.gov/mmwr/preview/mmwrhtml/mm59e0115a1.htm

40. Hartocollis A. State Requires Flu Vaccination for Caregivers. The New York Times. https://www.nytimes.com/2009/08/19/health/pol icy/19swine.html. Published August 18, 2009. Accessed 2021 Sept 21

41. Lowenberg K. Update on New York mandatory H1N1 vaccinations. stanford law school. Published 2009 October 22 [cited 2021 Sept 21]; https://law.stanford.edu/2009/10/22/update-on-new-york-mandatory-h1n1-vaccinations/

42. Hartocollis A, Chan S. Albany judge blocks vaccination rule. The New York Times. https://www.nytimes.com/2009/10/17/nyregion/ 17vaccine.html. Published October 16 2009. Accessed 2021 Sept 21

43. NYCLU. NYCLU urges public education and voluntary vaccine for H1N1 Flu, warns vaccine mandate violates privacy rights. NYCLU | ACLU of New York. Published 2009 October 13 [cited 2021]

Sept 21]; https://www.nyclu.org/en/press-releases/nyclu-urges-public- education-and-voluntary-vaccine-h1n1-flu-warns-vaccine-mandate

44. Lowenberg K. New York Flu Shot mandate suspended. Stanford Law School. Published 2009 November 2 [cited 2021 Sept 21]; https://law.stanford.edu/2009/11/02/new-york-flu-shotmandate- suspended

45. Talbot TR, Schaffner W. On being the first: virginia mason medical center and mandatory influenza vaccination of healthcare workers. Infect Control Hosp Epidemiol. 2010;31(9):889–892.

46. Greene MT, Fowler KE, Ratz D, et al. Changes in influenza Vaccination requirements for health care personnel in US Hospitals. JAMA Network Open. 2018;1(2):e180143.

47.Boyarsky BJ, Ou MT, Werbel WA, et al. Early development and dur-ability of SARS-CoV-2 antibodies among solid organ transplant reci-pients: a pilot study. Transplantation. 2021;105(5):e52–e53.

48. Boyarsky BJ, Werbel WA, Avery RK, et al. Immunogenicity of a single dose of SARS-CoV-2 messenger rna vaccine in solid organ transplant recipients. JAMA. 2021;325(17):1784.

49.Cole JP, Kathleen SS. Mandatory vaccinations: precedent and cur-rent laws. Congressional Research Service; 2014:1–11. [cited 2021 May 25]; <u>https://fas.org/sgp/crs/misc/RS21414.pdf</u>

50. Jacobson V. Massachusetts, 197 U.S. 11. Justia Law. 1905 [cited 2021 May 25]; https://supreme.justia.com/cases/federal/us/197/ 11

51. Research C for BE and. Emergency Use Authorization for Vaccines Explained. FDA. Published online 2020 December 14 [cited 2021 Sept 21]; https://www.fda.gov/vaccines-blood-biologics/vaccines/ emergency-use-authorization-vaccines-explained

52. Staff TP-FC. What's the difference between vaccine approval (BLA) and authorization (EUA)? Bill of Health. Published 2021 June 15 [cited 2021 Sept 21. http://blog.petrieflom.law.harvard.edu/2021/06/15/whats-the-difference-between-vaccine-

approval-bla-and- authorization-eua

53. 42 U.S. Code § 262 - Regulation of biological products. LII/Legal Information Institute. [cited 2021 Sept 21]; https://www.law.cornell.edu/uscode/text/42/262

54. Gooch K. 117 houston methodist employees sue over COVID-19 vaccine mandate. Becker's Hospital Review. Published 2021 June 1 [cited 2021 Jun 4]; https://www.beckershospitalreview.com/legal- regulatory-issues/117-houston-methodistemployees-sue-over- covid-19-vaccine-mandate.html

55. Mathieu E, Ritchie H, Ortiz-Ospina E, et al. A global database of COVID-19 vaccinations. Nat Hum Behav. Published online May 10, 2021:1–7.

56. Office of the Commissioner, Office of the Chief Scientist, Office of Counterterrorism and Emerging Threats. Emergency use authoriza-tion of medical products and related authorities. Guidance for Industry and Other Stakeholders. U.S. Food & Drug Administration; 2017 Accessed24 5 2021:1–45. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emer gency-use-authorization-medical-products-and-related-authorities

57. United States District Court Southern District of Texas. Jennifer Bridges et al., versus Houston Methodist et al. H-21-1774 12 June 2021 [cited 2021 jun 12]. Available from https://www.document cloud.org/documents/20860669-houston-methodist-lawsuit-order- of-dismissal

58. 45 CFR § 690. 117 - Documentation of informed consent. LII/Legal Information Institute. [cited Jun 15 2021]; https://www.law.cornell. edu/cfr/text/45/690.117

59. Commissioner O of the. FDA Approves First COVID-19 Vaccine. FDA. Published 2021 August 23 [cited 2021 Sept 21]; https:// www.fda.gov/news-events/press-announcements/fda-approves- first-covid-19-vaccine

60. Silberner J. Covid-19: north Dakota and Belgium have let infected health staff work on wards. BMJ. 2020;371:m4455.

61. Arnold DT, Milne A, Samms E, et al. Are vaccines safe in patients with Long COVID? A prospective observational study. medRxiv. 2021March14; Published online DOI:10.1101/2021.03.11.21253225.

62. Zaffina S, Gilardi F, Rizzo C, et al. Seasonal influenza vaccination and absenteeism in health-care workers in two subsequent influenza seasons (2016/17 and 2017/18) in an Italian pediatric hospital. Expert Rev Vaccines. 2019;18(4):411–418.

63. Drees M, Wroten K, Smedley M, et al. Carrots and sticks: achieving high healthcare personnel influenza vaccination rates without a mandate. Infect Control Hosp Epidemiol. 2015;36(6):717–724.

64.Modak RM, Parris SM, Dilisi JP, et al. Increasing influenza vaccina-tion rates among hospital employees without a mandatory policy. Infect Control Hosp Epidemiol. 2012;33(12):1288–1289.

65.Claxton G. Key characteristics of health care workers and implica-tions for COVID-19 Vaccination. KFF. Published 2021 January 21 [cited May 29, 2021]; https://www.kff.org/coronavirus-covid-19/ issue-brief/key-characteristics-of-health-care-workers-and- implications-for-covid-19-vaccination/

66. Bogart LM, Dong L, Gandhi P, et al. What contributes to COVID-19 vaccine hesitancy in black communities, and how can it be addressed? Published online 2021 March 1 [cited 2021 May 29]; https://www.rand.org/pubs/research\_reports/ RRA1110-1.html

67 Grumbach K, Judson T, Desai M, et al. Association of Race/ Ethnicity with Likeliness of COVID-19 vaccine uptake among health workers and the general population in the san francisco bay area. JAMA Intern Med. 2021 March30; 181(7):1008. Published online

68. Halpern LW. The Politicization of COVID-19. AJN Am J Nurs. 2020;120(11):19-20.

69. Fridman A, Gershon R, Gneezy A. COVID-19 and vaccine hesitancy: a longitudinal study. PLOS ONE. 2021;16(4):e0250123.

70. Forman R, Shah S, Jeurissen P, et al. COVID-19 vaccine challenges: what have we learned so far and what remains to be done? Health Policy Amst Neth. 2021;125(5):553–567.

71. Largent EA, Persad G, Sangenito S, et al. US Public Attitudes Toward COVID-19 Vaccine Mandates. JAMA Network Open. 2020;3 (12):e2033324.

72.Jones JM, Agrawal S. Workers have strong views on vaccine man-dates; more in favor. Gallup.com. Published 2021 August 18 [cited 2021 Sept 14]; https://news.gallup.com/poll/353825/workers- strong-views-vaccine-mandates-favor.aspx 73. AAMC. Major health care professional organizations call for COVID-19 vaccine mandates for all health workers. Association of American Medical Colleges. 2021. [cited 2021 Sept 14]; https://www.aamc.org/news-insights/press-releases/major-health-care- professional-organizations-call-covid-19-vaccine-mandates-all- health-workers

74. Van Hooste WLC, Bekaert M. To be or not to be vaccinated? The Ethical aspects of influenza vaccination among healthcare workers. Int J Environ Res Public Health. 2019;16(20):3981.

75. Momplaisir FM, Kuter BJ, Ghadimi F, et al. Racial/Ethnic differences in COVID-19 vaccine hesitancy among health care workers in 2 large academic hospitals. JAMA Network Open. 2021;4(8): e2121931–e2121931.

76. Momplaisir F, Haynes N, Nkwihoreze H, et al. Understanding drivers of COVID-19 vaccine hesitancy among blacks. Clin Infect Dis Off Publ Infect Dis Soc Am, 2021;ciab102. DOI:10.1093/cid/ ciab102.