



## Ethics in Challenging Times

# Ethics and Pitfalls of Vaccine Mandates

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As of November 24, 2021, there have been 47,916,623 total cases of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2 or COVID-19) and 773,779 deaths in the United States ([asamonitor.pub/3vkk3fs](https://asamonitor.pub/3vkk3fs)). Vaccination can potentially halt spread of the virus, prevent severe disease in individuals who develop breakthrough infections, and permit the return to normal economic and social life (*JAMA* 2021;325:532-3; [asamonitor.pub/3yZPLRB](https://asamonitor.pub/3yZPLRB)). The Food and Drug Administration has authorized three COVID-19 vaccines for administration under emergency use authorization (EUA): Pfizer-BioNTech, Moderna, and Janssen (Johnson & Johnson) ([asamonitor.pub/3rlS6FE](https://asamonitor.pub/3rlS6FE)).

Since late March 2021, the B.1.617.2 (Delta) variant of the SARS-CoV-2 virus has become the dominant variant globally ([asamonitor.pub/3yZPLRB](https://asamonitor.pub/3yZPLRB)). It is more contagious, causing a surge in new COVID-19 infections, hospitalizations, and deaths, particularly among unvaccinated individuals ([asamonitor.pub/3yZPLRB](https://asamonitor.pub/3yZPLRB); *J Travel Med* 2021;28:taab124; *J Travel Med* 2020;27:taaa021). Estimates of vaccine efficacy against the Delta variant vary. One study found the Pfizer-BioNTech vaccine to be 88.0% effective in preventing Delta variant infection after two doses, compared to 93.7% for the Alpha variant (*N Engl J Med* 2021;385:585-94). Another study found the Moderna vaccine to be 76% effective in preventing Delta variant infection, and the Pfizer-BioNTech vaccine to be only 42% effective (*medRxiv* August 2021). Regardless, these studies demonstrate vaccine-conferred protection against infection, and other studies show significant reduction of severe disease, hospitalization, and death ([asamonitor.pub/3xxMw40](https://asamonitor.pub/3xxMw40)).



To date, over 454 million total vaccine doses have been administered in the U.S. ([asamonitor.pub/3CZSXhr](https://asamonitor.pub/3CZSXhr)). Common side effects are mild and transient (e.g., injection site pain, fatigue, headache, muscle and joint pain, fever, nausea, vomiting, and lymphadenopathy). Severe side effects like anaphylaxis are extremely rare. Although all vaccines authorized under EUA are new, the likelihood of long-term side effects is extremely low ([asamonitor.pub/3D3yhVF](https://asamonitor.pub/3D3yhVF); [asamonitor.pub/3o5F50N](https://asamonitor.pub/3o5F50N)). Despite the documented safety, efficacy, and widespread availability of COVID-19 vaccines in the U.S., only 62.8% of the eligible population is fully vaccinated as of November 24, 2021 ([asamonitor.pub/3CZSXhr](https://asamonitor.pub/3CZSXhr)). In response to low vaccination rates but an increasing rate of infections and deaths, federal and state governments, health care systems, school districts, and private companies are instituting vaccine mandates. In this arti-

cle, we will explore some ethical issues involved in vaccine mandates.

### Ethical arguments supporting vaccine mandates

Traditional medical ethics focuses solely on the individual's health with little or no interference (e.g., resource rationing) using the four ethical principles characterized by Beauchamp and Childress: autonomy (respect for individual choice), beneficence (doing good), non-maleficence (avoiding harm), and justice (fairness) (*Principles of Biomedical Ethics*, 8<sup>th</sup> edition, 2019). However, public health ethics involves protecting community well-being. Therefore, traditional ethical frameworks are not appropriate for justifying public health initiatives (*Public Health Reviews* 2012;34:1-20).

Community-level directives require an authority to force all members to act according to the public health initiative. The authority to coerce individuals to act



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in specific ways is clarified by J.S. Mill, "The only purpose for which power can rightfully be exercised over any member of a civilized community, against his will, is to prevent harm to others" (*On Liberty and Utilitarianism*, 1993). In such a situation, the authority (e.g., government) can mandate through policy, regulation, or law that all citizens, even against their individual choice, must follow the public health initiative to prevent harm to others. For example, the police can forcibly lock a citizen into a sanitarium to prevent him/her from actively spreading tuberculosis in the community.

Public health ethics focuses on collective beneficence, nonmaleficence, and justice over individual autonomy. Justice in society involves fairly distributing benefits and burdens among people. One of several theories of justice (e.g., utilitarianism, libertarianism, communitarianism, egalitarianism, etc.) is applied to deter-

### Decision-Making Regarding CPR

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Society, and the Society for Perioperative Assessment and Quality Improvement as they promote screening for geriatric-specific vulnerabilities, shared decision-making, and interdisciplinary care planning ([asamonitor.pub/3xruCiE](https://asamonitor.pub/3xruCiE); *J Am*

*Coll Surg* 2012;215:453-66; *J Clin Anesth* 2018;47:33-42). The barriers to implementation are not insignificant. Surmounting them will require not only the will of professional societies like ASA, but also multidisciplinary efforts at institutional levels to develop practices that are sensible in the context of local culture, resources, and infrastructure.

Because there is a growing, identifiable subset of surgical patients who are less likely to survive and more likely to suffer complications and changes in quality of life after perioperative CPR, we should not assume that all elements of resuscitation are concordant with high-risk patients' goals and preferences. Instead, we favor implementing an approach to

perioperative decision-making regarding CPR that is focused on patient-specific preferences and vulnerabilities. Doing so will take time and a multidisciplinary effort, but is an essential step toward realizing "the traditional medical practice of responding individually and compassionately to the unique needs of each patient" (*Anesthesiology* 1991;74:606-8). ■

mine fair distribution. Interestingly, which theory applies in health care is controversial. Therefore, transparent public communication is crucial to preserve trust (*J Law Med Ethics* 2002;30:170-8).

One public health ethics approach to justifying vaccine mandates is to set maximizing community well-being as the goal, which involves fairly minimizing individual and communal harms, at the expense of individual autonomy (*J Law Med Ethics* 2002;30:170-8). This justice-driven approach to vaccine mandates prioritizes utilitarianism (right acts should produce the greatest amount of good for the greatest number of people) over individual goals. This population-centered approach is reasonable if the communal benefits outweigh any burdens on individual liberties, such as the right to autonomous decision-making. Mandating vaccines is justified under the utilitarian theory of justice, since they are an effective and safe intervention whose benefit is protecting whole communities as well as individuals with few burdens (minor transient side effects).

Diekema and Marcuse propose another ethical justification for vaccine mandates based on nonmaleficence (*Public Health Ethics: Theory, Policy, and Practice*. 2007). A vaccine mandate is ethically justified if it benefits the person being vaccinated, minimizes harms to vaccinated individuals, vaccination benefits outweigh any potential burdens, and it is the most effective and least risky method to prevent disease spread compared to other potential interventions. Existing vaccines meet all these criteria; therefore, vaccine mandates are ethically justified.

A final ethical justification uses the “precautionary principle” proposed by Gostin et al., which asserts that public health professionals must “protect populations against reasonably foreseeable threats, even under conditions of uncer-

tainty.... Given the potential costs of inaction, it is the failure to implement preventive measures that requires justification” (*JAMA* 2003;290:3229-37). Thus, despite the uncertainty of the long-term effects of the vaccines, it is the failure to vaccinate that must be ethically justified.

Therefore, vaccine mandates are ethically justified under utilitarian theory by maximizing benefit to the greatest number of people and under the principle of nonmaleficence by protecting the community while minimizing the burdens to any individual. Furthermore, it is the failure to mandate vaccination under a “precautionary principle” that requires ethical justification.

### Ethical argument refuting vaccine mandates

Mandating the COVID-19 vaccine available under EUA could be ethically problematic while it is experimental. Since an EUA uses less safety and efficacy data than is required to achieve Biologics License Application (BLA) approval (i.e., to be licensed for “on-label” use), they remain experimental until data collection is complete. While under EUA, vaccine mandates may be viewed as compulsory participation in ongoing medical research, which is ethically proscribed ([asamonitor.pub/3D8GvM8](http://asamonitor.pub/3D8GvM8); [asamonitor.pub/3I41q6K](http://asamonitor.pub/3I41q6K)). This argument became unfounded on August 23, 2021, when the Pfizer-BioNTech vaccine received BLA approval.

Initially, the goal of vaccination was to decrease individual morbidity and mortality based on existing data. Mandates to protect individuals could not be ethically justified under public health initiatives, which are only justified to prevent harming others. However, with the February 2021 announcement that two Israeli studies had demonstrated decreased vi-

ral transmission following vaccination, public health initiatives became ethically justifiable by preventing harm to others ([asamonitor.pub/3lkS5xM](http://asamonitor.pub/3lkS5xM)). Therefore, the two predominate refuting arguments (mandates equate to compulsory research participation, and public health initiatives cannot be used to protect individuals, only communities) fail to provide ethical justification proscribing vaccine mandates.

### Impact of vaccine mandates

Conflict has arisen between mandating agencies and individuals regarding the legality of vaccine mandates. A lawsuit was filed by 117 Houston Methodist Hospital employees to prevent that institution from requiring employee vaccination. That case was dismissed by U.S. District Judge Lynn Hughes on the grounds that “This is not coercion. Methodist is trying to do their business of saving lives without giving them the COVID-19 virus. It is a choice made to keep staff, patients, and their families safer.... Every employment includes limits on the worker’s behavior in exchange for his remuneration” ([asamonitor.pub/319KiLZ](http://asamonitor.pub/319KiLZ)). This ruling follows from Supreme Court precedent upholding vaccine mandates under the argument that individual autonomy is not absolute and can be usurped by the policing power of the state in the interest of public health and safety (*Public Health Reviews* 2012;34:1-20). The SARS-CoV-2 virus, particularly the Delta variant, is highly transmissible and potentially lethal ([asamonitor.pub/3yZPLRB](http://asamonitor.pub/3yZPLRB)). It therefore poses a serious threat to public health and safety, which qualifies for vaccine mandates. The Houston Methodist judgment highlights the parallel legal and ethical argument supporting vaccine mandates; through frequent exposure to sick patients, unvaccinated employees are at increased risk of con-

tracting COVID-19 and transmitting it to vulnerable populations.

Health care facilities have ethical and legal obligations to maintain a safe environment for staff and patients. These obligations are met through infection control protocols, including mandatory vaccination against preventable illnesses (e.g., hepatitis B virus, varicella virus, influenza virus) for employees with patient contact (*JAMA* 2021;325:532-3). Health care employees have the option either to be vaccinated or seek employment elsewhere. This upholds the principle of justice provided the mandate is non-discriminatory and fair (i.e., it applies to all employees equally, including exemptions for employees with medical contraindications and reasonable accommodation for conscientious objection).

Conversely, vaccine mandates may worsen scarce resource allocation when health care workers are defined as a valuable, scarce resource. The stress of working during a pandemic combined with staff shortages created by COVID-19-infected colleagues has led to attrition. Mandates could further exacerbate staff shortages if employees refusing vaccination are terminated, although this may be offset by fewer infections among a fully vaccinated staff (*JAMA* 2021;325:532-3). Offering nonmedical exemptions (e.g., religious or personal belief) could support individual autonomy and reduce vaccine mandate anxiety but leaves a susceptible population to spread the infection. Any provision for nonmedical exemptions should compel the unvaccinated to take preventative measures, including wearing masks and undergoing frequent testing, to minimize the risk of infecting vulnerable patients and staff members (*JAMA* 2021;325:532-3).

Mandates are ethically (and legally) supportable because vaccines decrease COVID-19 transmission, thereby protecting the community. ■

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