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Multisociety Statement on COVID-19 Vaccination as a Condition of Employment for Healthcare Personnel

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Executive Summary

Recommendation

This consensus statement by the Society for Healthcare Epidemiology of America (SHEA) and The Society for Post-Acute and Long-Term Care Medicine (AMDA), The Association for Professionals in Epidemiology and Infection Control (APIC), the HIV Medicine Association (HIVMA), the Infectious Diseases Society of America (IDSA), the Pediatric Infectious Diseases Society (PIDS), and the Society of Infectious Diseases Pharmacists (SIDP), recommends that COVID-19 vaccination should be a condition of employment for all healthcare personnel. Exemptions from this policy apply to those with medical contraindications to all COVID-19 vaccines available in the United States and other exemptions as specified by federal or state law. The consensus statement also supports COVID-19 vaccination of non-employees functioning at a healthcare facility (for example, students, contract workers, volunteers, etc.).

This recommendation is based on several points:

The COVID-19 vaccines available in the United States (US) under the Food and Drug Administration (FDA) emergency use authorization (EUA) have high efficacy to prevent symptomatic COVID-19, even higher efficacy to prevent serious COVID-19 (i.e., hospitalizations and deaths), and high effectiveness against symptomatic and asymptomatic COVID-19 infection.

The COVID-19 vaccines under FDA EUA have similar safety profiles to vaccines that are currently fully FDA-approved, shown by efficacy trials and effectiveness studies.

Full vaccination against COVID-19 offers several advantages to patient and healthcare personnel (HCP) safety: individual protection against COVID-19 infection; further protection for patients and HCP who are unable to receive COVID-19 vaccination or are not able to mount an adequate immune response; reduced risk of asymptomatic or pre-symptomatic transmission of SARS-CoV-2 between HCP, and from HCP to patients or patients to HCP; reduced risk of transmitting infection to household members and community contacts; increased protection for the healthcare workforce in the community setting.

The COVID-19 vaccines appear to retain good effectiveness against currently circulating SARS-CoV-2 variants against symptomatic illness and even higher effectiveness against severe disease.

Prior experience and current information suggest that a sufficient vaccination rate is unlikely to be achieved without making COVID-19 vaccination a condition of employment.

The statement is consistent with federal law and regulations.

The authors acknowledge that some information is not yet known. For example, additional data are needed on the duration of protection provided COVID-19 vaccines, and on the vaccines' effectiveness in immunocompromised persons. Data from randomized clinical trials in pregnancy are not available as of writing, although no maternal or fetal harm has yet been reported with over 120,000 pregnant people having received a COVID-19 vaccine (1).

The authors specify medical contraindications and other exemptions as specified by federal and state law that exempt HCP from being required to receive COVID-19 vaccination. Exemptions should be handled within the occupational health program with engagement of human resources and/or legal departments as appropriate. While not a contraindication, healthcare facilities may wish to allow pregnant HCP to postpone receipt of the vaccine until post-delivery. Pregnant HCP with questions or concerns about COVID-19 vaccination should be encouraged to speak to their healthcare provider(s) following their pregnancy. Pregnant and lactating HCP should be allowed to receive a vaccine because as noted by CDC "pregnant and recently pregnant people are more likely to get severely ill from COVID-19 compared to non-pregnant people" (2). It is important to specify that persons who have had COVID-19 should receive a COVID-19 vaccine, as recommended by CDC.

Healthcare facilities should provide an inclusive and transparent process that facilitates and acknowledges input from healthcare personnel and other stakeholders before reaching a decision to adopt a policy of vaccination as a condition of employment. If a healthcare facility decides that requiring a vaccine as a condition of employment is not possible at the present time, the facility should ensure that, following the principles of diversity, equity, and inclusion, it has implemented all methods to improve vaccine coverage described herein, including endorsement by senior leadership, appropriately educating HCP about the vaccine (as required under EUA), removing financial and physical barriers to access to the vaccine such as providing paid time for

vaccination and recovery from vaccine side effects (required by OSHA) (3), and providing locations and times convenient for HCP receive it. If minimal adequate coverage (e.g., >90% based on minimum influenza vaccination rates (4)) is not achieved within a reasonable time period (e.g., 1 to 3 months), the facility should implement a policy of requiring COVID-19 vaccination as a condition of employment.

Background

The COVID-19 pandemic has had a profound impact on the United States (US) and around the globe. More than 33 million Americans (over 1 in 10) have been documented to have acquired SARS-CoV-2 infection (5). The true percentage of the population that has been infected may never be known with certainty, given the large proportion of undocumented cases, but it is likely this number greatly exceeds the numbers reported in official accounts (6). More than 600,000 Americans have died from the disease (5). At the peak of the third wave of the pandemic in the US, nearly 260,000 cases were reported per day and nearly 160,000 COVID-19 patients were hospitalized in the US each week (5).

Historically, the most effective strategies for managing viral illnesses (e.g., measles, rubella, influenza) have been by vaccination, with vaccine manufacturers' being required to follow detailed procedures for demonstrating safety and efficacy before applying for licensure to the US Food and Drug Administration (FDA) (7). In emergent situations, pharmacotherapies, including vaccines, may be granted emergency use authorization (EUA) by FDA to allow vaccine administration in situations in which no effective alternatives are available (8). Reflecting the urgent need, EUA requires fewer months of safety and efficacy data (typically two to three months' experience), whereas full FDA approval requires at least six months of data that can be evaluated in detail by FDA before granting approval. In the US, three COVID-19 vaccines have been granted EUA.

At the time of this publication, these vaccines have not received formal FDA approval, although both Pfizer-BioNTech and Moderna have filed for formal FDA approval in 2021 (9, 10). According to the World Health Organization (WHO), nearly 100 companies around the world have vaccines in clinical evaluation that are built on various platforms (11). In addition to the

mRNA and adenovirus platforms, vaccines using protein subunits, DNA plasmids, and recombinant nanoparticles are in clinical trials in the US.

Vaccines recommended for healthcare personnel (HCP) by CDC's Advisory Committee on Immunization Practices (ACIP) have been offered to HCP for decades. In the last 15 years, increasing numbers of healthcare organizations have instituted a requirement for receipt of ACIP-recommended vaccines for HCP to reliably and sustainably raise HCP vaccination rates (12).

This consensus statement by the Society for Healthcare Epidemiology of America (SHEA) and endorsed by the SHEA Board of Trustees, The Society for Post-Acute and Long-Term Care Medicine (AMDA), The Association for Professionals in Epidemiology and Infection Control (APIC), the HIV Medicine Association (HIVMA), the Infectious Diseases Society of America (IDSA), the Pediatric Infectious Diseases Society (PIDS), and the Society of Infectious Diseases Pharmacists (SIDP), recommends that COVID-19 vaccination should be a condition of employment for all healthcare personnel. Exemptions from this policy apply to those with medical contraindications to all COVID-19 vaccines available in the United States and other exemptions as specified by federal or state law. The consensus statement also supports COVID-19 vaccination of non-employees functioning at a healthcare facility (for example, students, contract workers, volunteers, etc.).

Methods

The panel that authored this statement is comprised of multiorganizational, multidisciplinary experts working in healthcare epidemiology, infection prevention, infectious diseases, pharmacy, public health, law, and human resources. It included representatives from the SHEA Board of Trustees, the SHEA Guidelines Committee, and other SHEA leaders, as well as organizational representatives from The Society for Post-Acute and Long-Term Care Medicine (AMDA), The Association for Professionals in Epidemiology and Infection Control (APIC), the HIV Medicine Association (HIVMA), the Infectious Diseases Society of America (IDSA), the Pediatric Infectious Diseases Society (PIDS), and the Society of Infectious Diseases Pharmacists (SIDP).

The recommendation that COVID-19 vaccination should be a condition of employment for all healthcare personnel, with exemptions applying for those with medical contraindications to all

COVID-19 vaccines available in the United States and other exemptions as specified by federal or state law, was reached through a three-round Delphi process. Consensus was achieved.

The statement was reviewed by the SHEA Board of Trustees and the SHEA Publications Committee, AMDA, APIC, HIVMA, IDSA, PIDS, and SIDP, and was endorsed by SHEA, AMDA, APIC, HIVMA, IDSA, PIDS, and SIDP.

Intended Use

This statement is intended for consideration for employers of healthcare personnel and others in the service of healthcare, who work or operate in healthcare settings. It identifies legal issues that should be considered; the statement is not legal advice. Employers should consult their own attorneys when making decisions regarding implementing a policy of COVID-19 vaccination as a condition of employment.

Likewise, this statement is not meant to be a substitute for judgment by qualified professionals regarding clinical decisions.

Finally, the recommendations and views are the authors', and do not necessarily reflect the positions of their affiliations.

Vaccine Efficacy and Real-World Effectiveness

Efficacy in Clinical Trials

Vaccine efficacy and real-world effectiveness study results and references are summarized in Table 1.

All three COVID-19 vaccines currently FDA EUA-authorized showed high overall vaccine efficacy by ≥14 days after receipt of the second vaccine dose for mRNA vaccines[1] or a single dose for the adenovirus vector vaccine[2] to prevent symptomatic COVID-19 infection in Phases 3

[1] The mRNA vaccines require two doses (21 days apart for Pfizer-BioNTech and 28 days apart for Moderna) (FDA). After injection of mRNA vaccines, host cells utilize the vaccine mRNA that contains the genetic code for the viral spike protein to produce either all or a large part of the SARS-CoV-2 spike protein, to which the body then responds immunologically (Baden, Polak).

2 The Johnson & Johnson (J&J)/Janssen vaccine requires a single dose. The adenovirus vector vaccines work by using a non-replicating adenovirus that has been altered to include the gene that codes for the spike protein. The nonreplicating adenovirus enters host cells and triggers the production of the SARS-CoV-2 spike protein (Sadoff), to which the body responds.

and 4 of the randomized placebo-controlled trials (94.1-95% for the two mRNA vaccines and 66.9% for the adenovirus vector vaccine) (13, 14). Similar vaccine efficacy was seen across subgroups based on age, gender, race/ethnicity, and co-existing medical conditions.

Real-World Effectiveness

The growing number of real-world studies show similar overall vaccine effectiveness for preventing symptomatic and asymptomatic COVID-19. Studies assessing immunogenicity and limited vaccine effectiveness data suggest that vaccine effectiveness is likely lower for immunocompromised persons (15-17). All FDA EUA vaccines have demonstrated comparable effectiveness against the Alpha (B.1.1.7) variant of SARS-CoV-2 with data continuing to evolve around other circulating variants. Several studies have demonstrated lower nasal specimen SARS-CoV-2 viral loads among fully vaccinated persons, compared to unvaccinated persons who develop COVID-19 (18, 19). These findings, amongst other real-world data, suggest that vaccination reduces the likelihood of COVID-19 transmission from infected persons to their contacts, including household contacts (20-22).

Boosters

Given the short duration of immunity to seasonal coronaviruses after infection (23) and the speed with which disparate viral variants with mutated spike proteins are emerging, at some point in the future, a booster may be required for waning immunity and/or improved coverage for emerging variants (24-26).

COVID-19 Vaccine Safety

Clinical Trial Data

While the pace of COVID-19 vaccine development has been unprecedented, the three vaccines currently available in the US were authorized after randomized controlled trials (27-29) – as large, or larger, than those undertaken for prior vaccines (30,000-44,000 participants per trial, randomized 1:1 vaccine vs. placebo), with diverse participants in terms of age, race, ethnicity, and comorbid conditions – that demonstrated their efficacy and safety. The three vaccines had similar rates of local and systemic reactogenicity, greater than those seen for the placebo arm of the trials (Table 2). This reactogenicity, resulting from the inflammatory response to vaccination,

tended to be greater with the second dose (when applicable), and was less frequent and less severe in older recipients. Nearly all reactions to the vaccines were considered mild to moderate, and resolved within several days. Serious adverse events were similar in vaccine and placebo arms, and no deaths seen as attributable to vaccination were reported in any of the trials (27-29). Each of the manufacturers will continue safety monitoring of participants for up to 2 years.

Post-authorization Safety Monitoring

Knowing that even large clinical trials cannot detect rare adverse events, FDA and the US Centers for Disease Control and Prevention (CDC) are conducting extensive post-authorization safety monitoring. CDC's ACIP convened the Vaccine Safety Technical (VaST) subgroup to review, evaluate, and interpret post-authorization vaccine safety data and to serve as the central hub for technical subject matter experts from federal agencies to share vaccine safety data. Vaccine safety surveillance typically has relied on passive surveillance (clinicians or even patients reporting adverse events after vaccination), primarily via the Vaccine Adverse Events Reporting System (VAERS), co-managed by CDC and FDA. To enhance this reporting system, CDC created v-safe, a smartphone-based after-vaccination health checker. All COVID-19 vaccine providers were asked to provide enrollment information to all recipients, and to encourage them to register at the time of their vaccination. This system allows for assessment of vaccine side effects of all severities. v-safe staff then contact those reporting serious adverse events and facilitate VAERS reporting, if appropriate. The safety monitoring systems in place are summarized in Table 3. Ultimately these combined systems allow for early safety signal detection, followed by rapid cycle analysis and case evaluations, as well as the ability to analyze large linked databases to further evaluate potential safety concerns in US populations.

Post-authorization Safety Monitoring Findings

Reported rates of expected side effects after receiving the Pfizer-BioNTech, Moderna, or J&J/Janssen COVID-19 vaccine have been similar to those reported in clinical trials (30). Several unanticipated side effects have been identified through post-authorization monitoring. As new data emerge regarding the durability of COVID-19 vaccine response, effectiveness and safety in special populations (e.g., pregnant people, immunocompromised persons, etc.), and spread of new SARS-CoV2 variants, ACIP will review and revise COVID-19 vaccine information.

Anaphylaxis

While not experienced in the clinical trials, anecdotal anaphylaxis or anaphylactoid reactions were reported shortly after the EUAs were granted for the mRNA vaccines. Further analysis quantified the rate of anaphylaxis at approximately 11 per 1,000,000 vaccine recipients for the Pfizer-BioNTech vaccine and 2.5 per 1,000,000 vaccine recipients for the Moderna vaccine (31-34), although higher rates have been reported via active surveillance (35). In these cases, anaphylaxis had an onset of less than 30 minutes in up to 90% of cases, and at least 80% of individuals with anaphylaxis had a documented allergy to drugs, medical products, food, or insect stings (31, 34). Of note, up to 30% of the general population has a documented allergy to a food or medication, suggesting that anaphylaxis to an mRNA vaccine remains rare even in individuals with a history of allergy (31). Anaphylactic reactions were reported after the J&J/Janssen vaccine in less than 0.5 per 1,000,000 vaccine recipients (36). For comparison, after most vaccines, anaphylaxis is estimated to occur at a rate of approximately 1.31 per 1,000,000 vaccine doses (95% CI, 0.90-1.84) (37).

J&J/Janssen and Thrombosis with Thrombocytopenia Syndrome

In April 2021, CDC and FDA paused administration of the J&J/Janssen vaccine due to reports of unusual clotting events, now known as Thrombosis with Thrombocytopenia Syndrome (TTS) (36). Similar cases had been reported previously with the AstraZeneca COVID-19 vaccine, another adenovirus vector vaccine not currently authorized for use in the US (38, 39). Patients presented with either venous thromboembolic disease or unusual thrombotic events such as cerebral venous sinus thrombosis, splanchnic vein thrombosis, hepatic vein thrombosis, or splenic vein thrombosis, associated with thrombocytopenia (36, 40). The majority of cases were detected in women under the age of 50 (females, 18-49 years old, incidence 7 per 1,000,000 vaccine doses; males, 18-49 years old, incidence 1 per 1,000,000 vaccine doses) (41). The combination of these rare clotting events with thrombocytopenia is notable, and suggests a mechanism similar to heparin-induced anti-platelet autoantibodies (38). FDA and CDC resumed administration after a 10-day pause in April 2021 without age or gender restrictions (41).

Myocarditis/Pericarditis

In May 2021, CDC issued a health advisory to inform vaccine providers and clinicians of a recent increase in reports of myocarditis and/or pericarditis after mRNA COVID-19 vaccination received in VAERS (42). Most cases were reported in adolescent and young adult males within 4 days after the second dose, and resolved without known sequelae. Israel's Health Ministry has also reported 275 cases of myocarditis after the Pfizer-BioNTech vaccine between December 2020 and May 2021, among more than 5 million vaccinated people (43). Similar to the U.S. reports, most cases were in men aged 16 to 30 years, and were mild (44-46). At the time of this writing, the relationship between mRNA vaccines and myocarditis/pericarditis continues to be investigated. CDC and American Academy of Pediatrics (AAP) continue to recommend COVID-19 vaccination of adolescents and young men (42, 44).

Safety in Pregnancy and Lactation

Pregnant and lactating people were not included in the vaccine trials, but were not prohibited from receiving the vaccines once they were authorized for emergency use. Post-authorization, safety of the mRNA vaccines in pregnancy has been assessed using the v-safe pregnancy registry (1). Adverse events after vaccination were similar between pregnant and nonpregnant recipients, with more injection site pain reported among pregnant recipients and more systemic reactions reported among nonpregnant recipients (30, 47). Pregnancy and neonatal outcomes were reported in a subset of the v-safe registry. Rates of pregnancy loss (12.6%) and stillbirth (0.1%) were similar to published rates in the population (10-26% and <1% respectively) (47). Rates of preterm birth (9.4%) and infants who were small for gestational age (3.2%) were also similar to those in the published literature (47). Safety of the J&J/Janssen vaccine in pregnancy and lactation has not been studied to date (48-50). The American College of Obstetricians and Gynecologists (ACOG) and the Society for Maternal-Fetal Medicine (SMFM) recommend COVID-19 vaccination be offered to pregnant and lactating women (48).

Dispelling Vaccine Myths

Because of the rapid development and deployment of the COVID-19 vaccines, some of which use technologies not previously employed for vaccines licensed in the US, a number of novel vaccine myths have circulated, including those regarding concerns about DNA integration and infertility. In addition, many people remain hesitant due to concerns about long-term side effects of vaccination. While we must be mindful that long-term side effects will remain unknown until sufficient time has elapsed to assess for such possible effects, it is important to recognize that, among other vaccines that have had adverse events historically, nearly all side effects occurred within 6-8 weeks of vaccination (51). Communication guides and handbooks are available to assist vaccine program planners in how best to communicate to debunk myths and encourage vaccination (52-55).

Benefits of a Fully Vaccinated Workforce

Vaccination can be considered an elimination strategy in the framework of the Hierarchy of Controls (56). As such, it is expected to be one of the most effective interventions employed to reduce the risk of transmission. This is because the protective effect of vaccination is not contingent upon individual HCP practices such as the correct and consistent use of PPE (Figure 1.).

For routine vaccinations, and specifically for COVID-19 vaccines, the benefits of a fully vaccinated workforce can be categorized broadly into: 1) reducing the risk of transmission within healthcare facilities among HCP and patients, and from the community to healthcare facilities and from healthcare facilities to the community; 2) maintaining a healthy workforce and supporting HCP wellness; 3) maintaining the trustworthiness of HCP and healthcare institutions (Table 4).

Improving Coverage without Vaccination as a Condition of Employment

Some healthcare facilities have achieved high rates of HCP compliance with routinely recommended vaccines in the absence of vaccination as a CoE. A combination of strategies is more effective than a single strategy (57, 58); Table 5 describes typical strategies. Notably, most programs reporting immunization rates of 90% or higher used one or more soft mandates, including mandatory declination forms or the requirement for use of face masks by unvaccinated

HCP during close contact with patients. Current universal masking by HCP as part of COVID-19 pandemic precautions precludes the use of a "vaccinate or mask" strategy to promote COVID-19 vaccination. State statutes may positively impact HCP COVID-19 vaccination rates, as seen with examples specific to influenza vaccination of HCP in the absence of facility mandates (59). Laws requiring hospitals to assess HCP influenza immunization status or to offer vaccine to HCP also increased facility immunization rates (59).

Incentives

Many healthcare facilities and systems, with and without vaccination as a CoE, have used incentives to encourage staff to receive recommended vaccines (60-62). According to EEOC guidance, employers may offer non-coercive incentives for voluntarily providing proof of vaccination or for receiving the vaccination itself (63). Although incentives generally are not permitted for receipt of federally funded services such as Medicaid or Medicare, most facilities provide vaccines free of charge to their employees and do not bill Medicaid or Medicare for them, so these rules do not appear to apply to employee incentive programs.

The considerations discussed above apply to all healthcare employers in the country, public and private. Employers must also consult with their attorneys to make sure they are complying with any state laws and local ordinances or orders specific to their location and public or private status. Although incentives have been successful in some centers to boost immunization rates (see Table 5), their use may be subject to certain limitations when applied to increasing uptake of COVID-19 vaccines.

Advantages of Vaccination as a Condition of Employment

The experience to date with voluntary influenza vaccination, as opposed to influenza vaccination as a CoE, suggests that without requiring COVID-19 vaccination, target coverage will rarely be achieved (64). In the most recent season for which data are available, 80.6% of HCP reported receiving influenza vaccination during the 2019-2020 season (65). Compliance among those who were required by their employer to receive the vaccination was 94.4%, compared to 69.6% among those without vaccination as a CoE (66). While vaccinations represent one of the most effective strategies to mitigate risk of transmission of communicable diseases, vaccination of HCP with ACIP-recommended vaccines prior to the COVID-19 pandemic has been suboptimal,

with approximately 50% of surveyed HCP in March 2021 remaining unvaccinated (67). The National Vaccine Advisory Committee has recommended that employers consider requirements if their facilities are unable to achieve the Healthy People goal of at least 90% of HCP vaccinated for influenza (64). In 2020, SHEA recommended that medical contraindications should be accepted as a reason for not receiving all routine immunizations as recommended by CDC (68). Federal statute Title VII[3] regulates exemption from a vaccination policy on the basis of religious objection. Exemption requests should be evaluated by the appropriate department (e.g., human resources and/or legal) on a case-by-case basis (63).

Legal Considerations

There is long-standing constitutional support for vaccine mandates, and many state laws also support such mandates. According to published guidance of the Equal Employment Opportunity Commission (EEOC), the federal civil rights laws it enforces do not prevent an employer from requiring employees to be vaccinated for COVID-19, subject to a limited set of legally required exceptions (medical contraindication based on CDC and manufacturer guidelines, disability, and religion) (63). This section reviews key issues that a healthcare employer should discuss with legal counsel before making vaccination a CoE.

Legal debate has surrounded the fact that the COVID-19 vaccines are currently approved for use under an FDA EUA. EEOC has referred employers to the FDA's posted guidance concerning EUAs. FDA promulgates the regulatory scheme governing EUAs. As of June 2021 there is only one trial court decision addressing a legal challenge to an employee vaccination requirement on the basis of the EUA regulation: while the court concluded that the regulation does not prohibit a private hospital system from requiring that its employees receive vaccines under an EUA as a CoE, it does not establish a precedent.[4] The regulation by its terms requires FDA to establish the

[3] 42 U.S.C. § 2000e-2 (Title VII) is the federal statute prohibiting discrimination on the basis of religion, and regulates the employer's treatment of employees as "individuals."

[4] See *Bridges v. Houston Methodist Hosp.,* No. CV H-21-1774, 2021 WL 2399994, at *2 (S.D. Tex. Jun. 12, 2021) (where private hospital employer required all employees to receive the COVID-19 vaccination by June 7, 2021, federal district court in Texas ruled that the EUA regulation confers certain powers to the Secretary of Health and Human Services in an emergency, without affecting the responsibilities of the private employer or conferring a right of private action to the employees; the regulation furthermore does not require employees to participate in a human trial, but only requires that informed consent be obtained from the recipient of the vaccine before administering it).

conditions under which an EUA product is administered by the medical provider, including by obtaining the recipient's informed consent; there is no mention of employers or employment policies in the regulation, including requirements of employers.[5] The FDA guidance concerning the COVID-19 vaccines also makes no mention of employees, but rather states that the required information concerning an EUA product is typically communicated to the recipient in a "patient 'fact sheet'," which FDA makes available on its website (69). The text of the EUA regulation does not, in other words, require that individuals electing to receive a product approved under EUA undergo the informed consent process required for participation in clinical trials. The debate concerning the EUA status of the COVID-19 vaccines highlights the distinction between a healthcare organization's role as medical provider versus its role as employer. An employer's requirement that its employees be vaccinated as a CoE is distinct from requiring them to be vaccinated without consent; that is, an individual has a right to refuse vaccination, but has no right to a particular job. In at-will employment, an employee may always pursue alternative employment if they do not wish to be vaccinated as a CoE. The same is true of a CoE that is established in a unionized environment, although the employer should review its collective bargaining agreement – including, for example, the clauses concerning management rights, health and safety, and exigent circumstances – to determine whether bargaining is or is not required before establishing a CoE. At the same time, to try to avoid negative side-effects, such as the loss of talented team members in whom employers have invested time and money or a decrease in employee morale or engagement, employers should take steps to address employee concerns around safety, efficacy, equity, and inclusion.

Federal and State Rules

Any employer's requirement of vaccination as a CoE will be subject to federal employment laws, namely the Americans with Disabilities Act (ADA) and Title VII of the Civil Rights Act of

[5] The informed consent provision in the EUA regulation reads in full: "With respect to emergency use of an unapproved product, the [FDA], to the extent practicable given the applicable circumstances … shall, for a person who carries out any activity for which the authorization is issued, establish such conditions on an [EUA] as the [FDA] finds necessary and appropriate to protect public health, including the following: … (ii) Appropriate conditions designed to ensure that individuals to whom the product is administered are informed – (I) that the [FDA] has authorized the emergency use of the product; (II) of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; and (III) of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks." (21 U.S.C. § 360bbb-3(e)(1)(A)(ii).)

1964 (63). As relevant to the vaccine context, these statutes prohibit employers from discriminating against their employees on the basis of disability or religion, and require employers to provide reasonable accommodations to any employee with a disability or religious objection. A reasonable accommodation is decided by the employer on a case-by-case basis, and does not include measures that would result in undue hardship or significant difficulty or expense for the employer, or measures that pose a direct threat to the health and safety of others. While these federal laws set the baseline for all employers, state laws may impose additional requirements.

The standards imposed by the Occupational Safety and Health Administration (OSHA) are also relevant to any employer considering a policy of vaccination as a CoE. OSHA recently published an Emergency Temporary Standard that addresses COVID-19 vaccination, but without explicitly endorsing or prohibiting employer mandates. The Standard requires employers to "support" COVID-19 vaccination for their employees by providing them with paid time off to receive the vaccine and to recover from associated side effects (3). The Standard also suggests support for a vaccinated workforce: for example, it does not extend to "fully vaccinated" ambulatory or home health care settings, and it does not require vaccinated HCP who have been exposed to the virus to be removed from work.

Exemptions

Critical to the success of any vaccine requirement is a clear and consistent process by which employers receive, review, and respond to the exemption and accommodation requests that are required by the ADA, Title VII, and parallel state employment discrimination laws. If an exemption is granted, an employer may require employees to comply with accommodations in lieu of receiving the vaccine. Accommodations may include providing an alternative form of the vaccine, requiring an exempted employee to wear a face masks, or requiring an exempted employee to follow physical distancing measures (including reassignment away from vulnerable patient populations, curtailing job duties to lessen or eliminate direct patient contact, or allowing the employee to work remotely if feasible). The law requires that accommodations be tailored to the individual employee and their particular job duties[6]; for that reason, employers should try to

[6] The federal statutes prohibiting discrimination on the basis of disability (ADA) and religion (Title VII). Both regulate the employer's treatment of employees as "individuals." See 42 U.S.C. § 12102(2), (2)(A) (ADA); 42 U.S.C.

avoid making blanket statements about what they will or will not do if an employee qualifies as exempt from a vaccination requirement. To mitigate the risk of liability based on alleged retaliatory or discriminatory denials of such requests, and to maintain confidentiality, medical exemption and accommodation requests are usually reviewed by occupational health, and religious requests are commonly routed to the employer's legal and/or human resources department(s) for review. Those departments also typically keep records of what accommodations have been requested, considered, and discussed with the employee, and either granted or rejected. They may have an appeal process. Employers often require the qualifying employee to read and sign their acknowledgement of the accommodation plan, which may include a statement of the risks of remaining unvaccinated.

Religious Exemption

For religious exemption requests, an employer should consider making a form available for objectors to describe their sincerely held religious belief, practice, or observance (whether connected to a traditionally recognized religion or held with the strength of traditional religious views) on which basis they seek an exemption from vaccination. While affiliation with a traditionally organized religion may be evidence to support a claim of a sincerely held religious belief, the lack of such an affiliation cannot be the basis for rejecting an exemption request.

Medical Exemptions

A medical exemption is based on contraindications and precautions set forth by the manufacturer or CDC and usually requires review and signature by a medical professional (70). Many organizations also will allow for deferrals during pregnancy, if requested, or for other time-limited conditions upon request. Medical exemption request submissions citing other reasons for exemption should be permitted and reviewed for special circumstances. The substantive basis of all requests for an exemption based on a medical contraindication or precaution are ideally reviewed by an organization's occupational health medical director or committee of clinicians.

Enforcement

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§ 2000e-2 (Title VII); see also, for example, *Albertson v. Kirkingburg*, 527 U.S. 555, 566 [wherein U.S. Supreme Court explains that ADA by its terms applies to "individuals" and therefore imposes statutory obligations that must be assessed on a "case-by-case basis"].

Some employees may not qualify for any of the employers' exemptions and decline to be vaccinated. The consequences of non-compliance with a vaccination policy as a CoE should be clearly defined and understood by leadership, the legal team, and human resources department(s) before the policy is enacted – and clearly communicated to employees. Enforcement mechanisms may include, for example, letters of warning, suspension without pay, or termination. For facilities or systems with unionized employees, it is important to engage union representatives early in this process (71, 72).

Privacy Concerns

Some employees may object to providing information about their vaccination status on privacy grounds. In its COVID-19 guidance, EEOC has stated that an employer may, without violating the applicable federal laws, ask an employee about their vaccination status and require proof of vaccination as long as it is stored as confidential medical information.

Visual Cues

Healthcare employers may use visual cues such as stickers to indicate work authorization and work restrictions appropriate to an employee's vaccination status, provided that any visual cues do not make explicit reference to whether or not the employee has been vaccinated[7].

With or without the use of visual cues, employers with policies of vaccination as a CoE should clearly communicate and remind employees that harassment or retaliatory behavior against coworkers is never tolerated, including with regards to suspected COVID-19 vaccination status. Before implementing a COVID-19 vaccination policy that utilizes visual cues, facilities should plan for what they will do if a patient or family member suspects an HCP is unvaccinated and refuses care. These plans should include communications protocols that explain which precautions are in place to protect them. Facilities should also communicate clearly that unvaccinated persons do not need to disclose the reason for not being vaccinated to other HCP or to patients.

[7] See 29 CFR 1630.14(c)(1) – Medical examinations and inquiries specifically permitted

Implementing COVID-19 Vaccine as a Condition of Employment

Healthcare facilities face a complex and strategic decision regarding COVID-19 vaccine as a CoE, requiring consideration of a healthcare facility's mission and culture. Transparency by leadership during the decision process garners trust and credibility among staff and medical staff, as does an inclusive approach that reflects the diversity of opinion and backgrounds of HCP, while visibly engaging stakeholders and facilitating input. Leaders must assess perceptions among HCP, upholding principles of respect and inclusivity that reflect diversity of opinion and background.

If adopted, operationalizing a CoE requires facilities to have systems in place for tracking healthcare personnel vaccination status both at the facility and offsite locations, establishing policies and processes for exemption request and review, and addressing important topics such as equity, compensation for vaccination, and post-vaccination sick days.

In a recent policy brief, WHO recommended that local context be considered to determine whether a mandate is necessary, proportionate, and would not undermine trust (73). While not likely to influence the requirement itself, facilities should acknowledge issues at the organizational and individual levels in order for implementation to go smoothly. Many of these issues are addressed throughout this document, including safety and efficacy, institutional culture of respect and inclusivity, consistent and transparent exemption review, and collaboration with unions and other stakeholders. A framework for implementation is provided via a SHEA implementation guide.

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Conflict of Interest Disclosure Statement

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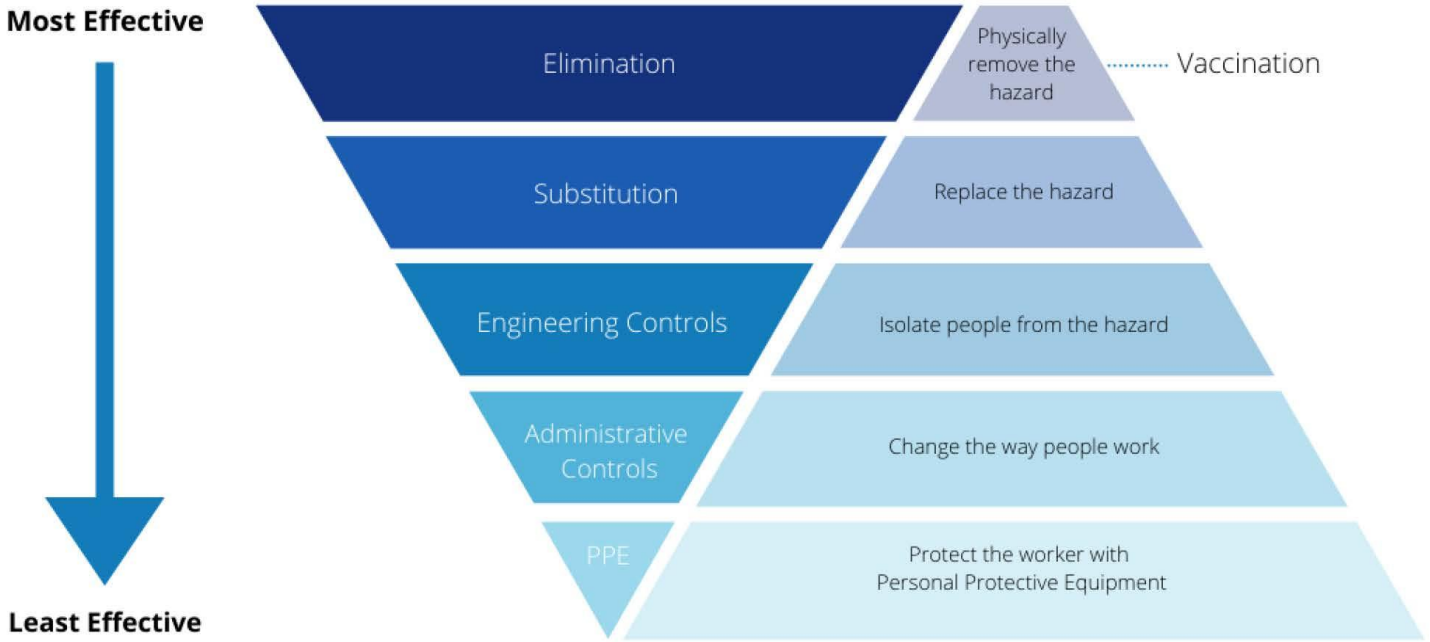
Appendices: COVID-19 Vaccination as a Condition of Employment for Healthcare Personnel

Contents

Figure 1. Hierarchy of Controls



This graphic is adapted from the National Institute for Occupational Safety and Health (NIOSH) "Hierarchy of Controls" (1). As explained by NIOSH, the control methods that fall into the highest tier of the graphic are potentially more effective and protective than those that are lower. Following this hierarchy normally leads to the implementation of inherently safer systems, with reduction of illness and injury in workplaces.

Vaccines are an elimination method in the top tier and thus are highly effective at reducing risk of hazard to HCP.

Table 1. Vaccine Efficacy and Real-World Effectiveness

Setting	Outcome(s)	Vaccine Efficacy (95% confidence interval)[a]
Phase-3/4 Clinical Trials Experience		
mRNA Vaccines		
BNT162b2 (Pfizer)		
Polack (2) Multinational randomized placebo-controlled trial • Symptomatic infection ≥7 days after dose 2 in persons ≥16 years of age • No significant difference in VE by age, gender, race/ethnicity, BMI, coexisting conditions • Only one case in vaccinated, 4 cases in placebo group (vaccine efficacy 75% [95% CI -152.6-99.5])	1. Symptomatic Infection 2. Severe Disease, Hospitalization, Death 3. Asymptomatic Infection	1. 95% (90.3-97.6%) 2. 75% (-152.6-99.5%) 3. Not assessed
mRNA-1273 (Moderna)		
Baden (3) US multisite randomized, stratified, placebo-controlled trial • Symptomatic infection ≥14 days after dose 2 in persons age >18 years of age • 30 (including one death) in placebo group, none in vaccine group	1. Symptomatic Infection 2. Severe Disease, Hospitalization, Death 3. Asymptomatic Infection	1. 94.1% (89.3-96.8%) 2. 100% 3. Not assessed
Viral Vector Vaccines		
Ad26.COV2.S (J&J)		

Sadoff (4)
Multinational (US, South Africa, Brazil, Chile, Argentina, Colombia, Peru, Mexico) randomized, placebo-controlled trial
• Symptomatic infection ≥14 days and ≥28 days after dose in persons ≥18 years of age
• Similar efficacy across age, gender, race/ethnicity, comorbidities
• Severe disease, hospitalization, or death ≥14 days after vaccine administration:
  ○ 5 COVID-19-related deaths in placebo group
  ○ None in vaccine group
• Asymptomatic infection:
  ○ Based on subset with SARS-CoV-2 serology results 71 days after vaccination, 0.7% of vaccine recipients had no symptoms of COVID-19 but had documented seroconversion to a non–spike protein compared with 2.8% of placebo recipients.
	1. Symptomatic Infection
	2. Severe Disease
	3. Hospitalization
	4. Death
	5. Asymptomatic infection
		1. *Global*: at ≥14 days: 66.9% (59.1-73.4%)
		US: at ≥14 days: 74.4% (65.0-81.6%)
		2. 76.7% (54.6-89.1%)
		3. 93.1% (72.7-99.2%)
		4. 100%
		5. 65.5% (39.9-81.1%)

Real-world Experience / Vaccine Effectiveness Studies		
Healthcare Personnel (HCP)		
mRNA Vaccines		
BNT162b2 (Pfizer)		
Tang (5) US; HCP at St Jude Children's Research Hospital: ≥7 days after dose 2	1. Asymptomatic or Symptomatic[a] 2. Asymptomatic 3. Symptomatic or after known exposure	1. 96% (91-98%) 2. 90% (78-96%) 3. 100% (N/A)
Angel (6) Israel; HCP at a tertiary medical center in Tel Aviv: ≥7 days after dose 2	1. Symptomatic 2. Asymptomatic	1. 98% (93-100%) 2. 91% (75-97%)
Hall (7) England; HCP in publicly funded hospitals: ≥7 days after dose 2.	1. Asymptomatic or Symptomatic	1. 86% (76-97%)
Swift (8) US: HCP at Mayo Clinic Health System: >14 days after dose 2.	1. Asymptomatic or Symptomatic	1. 96.8% (95.3-97.8%)
Keehner (9) US: HCP at University of California, San Diego and the University of California, Los Angeles health systems: >14 days after dose 2.	1. Asymptomatic or Symptomatic	1. Absolute risk of testing positive after vaccination was 1.19%

		among HCP at UCSD and 0.97% among HCP at UCLA
Fabiani (10) Italy: HCP, Treviso province, Veneto region: ≥7 days after dose 2.	1. Asymptomatic or Symptomatic 2. Symptomatic	1. 95.1% (62.4-99.4%) 2. 93.7% (50.8-99.2%)
mRNA-1273 (Moderna)		
Swift (8) US: HCP at Mayo Clinic Health System: >14 days after dose 2.	1. Asymptomatic or Symptomatic	1. 98.6% (90-100%)
Either mRNA Vaccine		
Daniel (11) US: HCP at the University of Texas Southwestern Medical Center: BNT162b2 vaccine ≥7 days after dose 2 or mRNA-1273 ≥14 days after dose 2.	1. Asymptomatic or Symptomatic	1. *Non-vaccinated employees:* (2.61%; 2.29-2.96) *Vaccinated employees*: (0.05%; 0.01-0.13)
Thompson (12) US: HCP, first responders, and other essential and frontline workers in 8 cities: ≥14 days after dose 2.	1. Asymptomatic or Symptomatic	1. 90% (68-97%)
Pilishvili (13) US: HCP in 33 sites (interim analysis): ≥7 days after dose 2.	1. Symptomatic	1. 93.5% (86.5-96.9%)
Population-wide Surveillance		
mRNA Vaccines		
BNT162b2 (Pfizer)		
Haas (14) Israel; national surveillance data in residents of Israel 16 years and older: ≥7 days after dose 2.	1. Asymptomatic or Symptomatic 2. Asymptomatic 3. Symptomatic 4. Hospitalization 5. Severe/Critical Hospitalization 6. Death	1. 95.3% (94.9–95.7%) 2. 91.5% (90.7-92.2%) 3. 97% (96.7-97.2%) 4. 97.2% (96.8–97.5%) 5. 97.5% (97.1–97.8%) 6. 96.7% (96–97.3%)
Dagan (15) Israel; data from subjects 16 years and older from Clalit Health Services, large integrated healthcare organization: ≥7 days after dose 2.	1. Asymptomatic or Symptomatic 2. Symptomatic 3. Hospitalization 4. Severe disease	1. 92% (88–95%) 2. 94% (87–98%) 3. 87% (55–100%) 4. 92% (75–100%)
Chodick (16) Israel; cohort study of members of a large health provider in Israel: 7 to 27 days after dose 2.	1. Asymptomatic or Symptomatic 2. Symptomatic	1. 90% (79-95%) 2. 94% (88-97%)
Viral Vector Vaccines		
Ad26.COV2.S (J&J)		
Corchado-Garcia (17) US; longitudinal data from Mayo Clinic health system: ≥15 days after dose.	1. Asymptomatic or Symptomatic	1. 76.7% (30.3-95.3%)
Elderly Individuals		
mRNA Vaccines		
BNT162b2 (Pfizer)		
Haas (14) Israel; national surveillance data in residents of Israel 65 years and older: ≥7 days after dose 2.	1. Asymptomatic or Symptomatic 2. Asymptomatic 3. Symptomatic 4. Hospitalization 5. Severe/Critical Hospitalization 6. Death	1. 95% (93.9–95.5%) 2. 88.5% (86.4–90.3%) 3. 96.4% (95.9–97%) 4. 96.8% (96.2–97.3%) 5. 97.3% (96.8–97.8%) 6. 96.9% (96–97.6%)
Lopez Bernal (18) Scotland; community surveillance of patients 70 years and older: ≥14 days after dose 2.	1. Symptomatic	1. 80 years and older: 89% (85-93%)
Chodick (16) Israel; cohort study of members of a large health provider in Israel: 7 to 27 days after dose 2.	1. Asymptomatic or Symptomatic	1. *65-74 years*: 82% (63-92%) *75 years and older*: 82% (61-91%)

Either mRNA Vaccine		
Tenforde (19) US; evaluation at 24 hospitals in 14 states of patients 65 years and older: ≥14 days after dose 2.	1. Hospitalization	1. 94% (49-99%)
Nursing Homes – Congregate Settings		
mRNA Vaccines		
BNT162b2 (Pfizer)		
Britton (20) US; residents of 2 skilled nursing facilities in Connecticut: ≥14 days after dose 1 through 14 days after dose 2.	1. Asymptomatic and Symptomatic	1. 60% (33-77%)
Cavanaugh (21) US; residents and workers of skilled nursing facility in Kentucky: ≥14 days after dose 2.	1. Symptomatic	1. Residents 87% (66–95%) Workers 87% (46-97%)
Immunosuppressed Individuals		
mRNA Vaccines		
BNT162b2 (Pfizer)		
Chodick (16) Israel; cohort study of members of a large health provider in Israel: 7 to 27 days after dose 2.	1. Asymptomatic and Symptomatic 2. Symptomatic	1. 71% (37-87%) 2. 75% (44-88%)
Impact of Variant Status on Vaccine Efficacy		
mRNA Vaccines		
BNT162b 2 (Pfizer)		
Alpha (B.1.1.7) Abu-Raddad (22) Qatar; mass immunization campaign in Qatar. VE determined 2 weeks after dose 2.	1. Documented Infection 2. Severe, Critical, or Fatal disease	1. 90% (85.9-92.3%) 2. 100% (81.7–100%)
Alpha (B.1.1.7) Sheikh (23) Scotland; real-world population surveillance from Scotland. VE determined at least 2 weeks after dose 2.	1. Documented infection	1. 92% (90-93%)
Beta (B.1.351) Abu-Raddad (22) Qatar; mass immunization campaign in Qatar. VE determined 2 weeks after dose 2.	1. Documented Infection 2. Severe, Critical, or Fatal disease	1. 75% (70.5-78.9%) 2. 100% (73.7–100%)
Delta (B.1617.2) Sheikh (23) Scotland; real-world population surveillance from Scotland. VE determined at least 2 weeks after dose 2.	1. Documented infection	1. 79% (75-82%)
Viral Vector Vaccines		
Ad26.COV2.S (J&J)		
Beta (B.1.351) Sadoff (4) Multinational; randomized, placebo-controlled trial data from South Africa, 95% cases from Beta (B.1.351) Infection ≥14 days after dose.	1. Symptomatic Infection 2. Severe/Critical Disease	1. 52% (30.3-67.4%) 2. 73% (40–89.4%)
Zeta (P.2) Sadoff (4) Multinational; randomized, placebo-controlled trial data from Brazil, 69% cases from Zeta (P.2) Infection ≥14 days after dose.	1. Symptomatic Infection 2. Severe/Critical Disease	1. 66.2% (51-77.1%) 2. 81.9% (17-98.1%)

[a] Asymptomatic or Symptomatic: encompasses reported outcomes that do not distinguish vaccine efficacy between asymptomatic and symptomatic infections including outcomes labeled as any positive test or documented infection.

Table 2. Summary of COVID-19 Side Effects Reported in Phase 3 Clinical Trials for Pfizer-BioNTech, Moderna, and Johnson & Johnson/Janssen Vaccines

Side Effect	Pfizer-BioNtech (2) %	Moderna (3) %	J&J/Janssen (4) %	Placebo (2-4) %
Local (any)	NR	84-89	38-60	18-20*
Pain	66-83	84-88	32-60	8-18
Erythema	5-7	3-9	4-8	0.4-1
Systemic (any)	NR	55-79	45-60	35-42*
Fever ≥38° C	1-16	1-16	2-10	0-1
Headache	39-52	33-59	32-42	14-34
Fatigue	34-59	37-65	32-42	17-33
Myalgia	14-37	23-58	28-38	5-15
Serious AEs (≥ grade 3)	0.6	1.5	0.4	0.4-1.3

Note: Adverse events were reported slightly differently in each trial; some reported for entire study population, others had reactogenicity subset. Ranges include first versus second doses and/or younger versus older populations. Some data were only presented in graphical format; thus, exact percentages were not available. When available, numbers were rounded. The placebo column represents ranges from all 3 trials.

*reported only for Moderna, J&J.

NR, not reported.

Table 3. Summary of Post-authorization Safety Monitoring Systems in the US for COVID-19 Vaccines

Name of Safety Monitoring System	Type of Safety Surveillance	Population(s) included	Major Strengths	Major Weaknesses
CDC/FDA, Vaccine Adverse Event Reporting System (VAERS)	Passive	Entire US population	Early signal detection	Cannot determine causality
CDC, National Healthcare Safety Network (NHSN)	Passive	17,000 LTCF Includes HCP	Early signal detection Directs VAERS reporting	Aggregate voluntary reporting of doses administered and counts of non-specific AEs; Cannot determine causality
DoD, Vaccine Adverse Event Clinical System (VAECS)	Passive	Military	Early signal detection	Cannot determine causality
VA, Adverse Drug Event Reporting System (ADERS)	Passive	VA HCP 8000 residents/day in VA LTCF	Early signal detection	Cannot determine causality
CDC, Clinical Immunization Safety Assessment (CISA)	Clinical consultation service	General population	Review of high-priority AEs of special interest and clinical questions	Cannot determine causality
CDC, v-safe	Active	All vaccine recipients with smartphones	Early signal detection	Relies on recipients to sign up and complete surveys; recipients without smartphones cannot participate
CDC, Vaccine Safety Datalink (VSD)	Linked database monitoring	>12 million persons/year in 9 integrated health systems	Data refreshed weekly with weekly sequential analyses (RCA)	1 to 2-week data lag (up to 6 weeks for hospitalized)
VA Electronic Health Record & Active Surveillance System	Linked database monitoring	Veterans 8000 residents/day in VA LTCF	Data refreshed weekly with weekly sequential analyses (RCA)	~1 week data lag (up to 4 weeks for hospitalized)
FDA, Biologics Effectiveness and Safety (BEST) System	Linked database monitoring	Commercial & CMS medical/pharmacy databases, >100 million beneficiaries	Multiple partners, variety of healthcare settings	1 to 4-months data lag, depending on source
FDA/CMS, Medicare data	Linked database monitoring	55-60 million (92% of US elderly) Includes ~650K LTCF residents	Data refreshed weekly with weekly sequential analyses (RCA)	CMS data lag ~4 weeks
FDA, Post-licensure Rapid Immunization Safety Monitoring (PRISM) program	Linked database monitoring	>70 million individuals/year, all 50 states represented		
Genesis Healthcare (24)	Linked database monitoring	LTCF residents in 284 Genesis long-term care facilities	Near real-time monitoring of adverse events and safety during rapid vaccine deployment in vulnerable LTCF population	
DoD, Electronic Health Record and Defense Medical Surveillance System	Linked database monitoring	Active duty/ Reserves/Guard personnel		

CDC, Centers for Disease Control and Prevention. CMS, Centers for Medicare and Medicaid Services. DoD, Department of Defense. EMR, electronic medical record. FDA, Food and Drug Administration. LTCF, long-term care facilities. RCA, rapid cycle analysis. VA, Department of Veterans Affairs.

Table 4. Advantages of a Fully Vaccinated Workforce

Domain	Description	References
Reduced Risk of SARS-CoV-2 Transmission and Impact of Exposures on Vulnerable Populations	**Reduce risk of transmission from HCP-to-HCP.** Risk of transmission from HCP-to-HCP has been associated with lack of masking both in healthcare facilities and in social gatherings outside of work.	(25-29)
	Reduce risk of transmission from HCP-to-patient. Risk of transmission from HCP-to-patient has been reported to be low, however, risk can be further reduced through reduction of infection in HCP, especially when patients are unable to mask or may remain at risk of infection despite being vaccinated (i.e., congregate care settings, including post-acute and long-term care, assisted living, and behavioral health settings as well as individuals with impaired response to vaccination due to immunocompromising conditions or to age-related immunosenescence).	(21, 30, 31)
	Reduce risk of patient-to-HCP transmission. Reported risk of exposure from an infected patient leading to HCP infection is low; however, this can be reduced further through vaccination of HCP.	(32)
	Reduce risk of within-household transmission. Risk of transmission in households settings ranges from 10-50% of exposures. HCP who are fully vaccinated are less likely to become infected due to household exposure; they are also, if vaccinated less likely to become infected and transmit within the household.	(30, 32-36)
	Reduce incidence and impact of exposures. For residents of post-acute and long-term care settings, the consequences of unvaccinated HCP extend beyond the risk of infection. Any new case of SARS-CoV-2 infection among HCP represents a potential. The response to an outbreak of SARS-CoV-2 in long-term care facilities includes suspending visitation until the affected unit in the nursing home has had 14 days without a new case of SARS-CoV-2 infection among residents or HCP. Visitation of family and friends for nursing homes residents has only recently resumed. A return to quarantine has profound negative consequences on the emotional well-being, cognitive function, and physical health of nursing home residents. Through vaccination, HCP working in long-term care settings mitigate the risk of both infection and exposure of frail elders who have suffered social isolation during the pandemic.	(37-39)
Promotion of HCP wellness and maintaining a healthy workplace	**Prevention of morbidity and mortality among HCP.** COVID-19 among HCP has followed same trend as general population. HCP are essential workers, and during the pandemic, their role is critical. A reduction in workforce during a pandemic impacts all HCP, resulting in increased stress and increased work load, and decreased capacity to care for patients. Early data suggest decreased number of infections in HCP, beginning soon after the first dose of the two-dose series. Vaccination prevents COVID-19 infection and its long term sequalae.	(6, 7, 9, 11, 40-45)
	Reduce the disruption in workforce. Reduction in HCP infections and exposures can ensure sufficient staffing levels to support patient safety and HCP wellness. In the absence of fully vaccinated workforce, challenges with absenteeism and presenteeism will persist.	(46-50)
	Return to pre-pandemic workplace social and professional interactions. The CDC recently released guidance supporting unmasked and non-distanced interactions between fully vaccinated HCP in breakrooms and meetings however cautioned that if unvaccinated HCP are present, everyone should wear source control and unvaccinated HCP should physically distance from others.	(51)
	Decrease resource burden of exposure investigations and management. A fully vaccinated healthcare workforce will have a reduced number of exposures from HCP-to-patient and thus reduce the resources required to identify exposed HCP and patients, refer for testing, and complete follow up.	(52)
	HCP wellbeing. HCP who are fully vaccinated have reported decreased mental stress after vaccination.	(53)
Maintaining trust in HCP and healthcare institutions	**HCP vaccination can increase overall trust in vaccination.** HCP are trusted messengers and their role modeling of vaccination uptake can reduce vaccine hesitancy among patients.	(54-56)
	Affirmation of patient safety. HCP and institutions that prioritize patient safety recognize vaccinations as important to preventing disease transmission.	(57)
	Recognition of evidenced-based practices. Medical science supports the efficacy and safety of vaccines. HCP who accept vaccines embody the prioritization of evidence-based practices over misinformation.	(58)
	Professional reputation. HCPs may be perceived as representing others in the profession and of their entire institution. Just as professional behavior and appearance reflect well on the entire organization, the professionalism of HCP accepting vaccines may also enhance the positive regard for others in their role, their institution, and healthcare in general.	(59)

Table 5. Strategies to Increase Vaccination Rates

Study	Country	Setting	Ads/ Promo	Educational Materials	Enhanced Access	Incentives	Formal Program and/or Leadership Support	Data	Enforcement and/or Punitive Action	Mandatory Declination	Mandatory Masking	Post-Intervention Annual Immunization Rate (%)
Bennett, 2020 (60)	Australia	Healthcare facilities (hospitals, ambulatory, skilled nursing facilities)						✓				87.7
Drees, 2015 (61)	US (DE)	Academic health system (hospitals, ambulatory, home care)	✓	✓	✓	✓		✓	✓	✓	✓	92.4-93.5
Esolen, 2011 (62)	US (PA)	Academic health system (hospital, ambulatory, surgical center)			✓		✓	✓	✓		✓	92-95
Esolen, 2014 (63)	US (PA)	Academic health system (hospital, ambulatory, surgical center)	✓		✓		✓	✓	✓		✓	95-97
Fricke, 2013 (64)	US (LA)	Hospitals (public, private and academic)	✓		✓					✓	✓	81-91
Frisina, 2019 (65)	US (NJ)	University health center (ambulatory)	✓	✓	✓							91.1
Heinrich-Morrison, 2015 (66)	Australia	Health system (3 hospitals)	✓		✓	✓		✓				80.3
Honda, 2013 (67)	Japan	Academic hospital	✓		✓			✓	✓	✓		96.9
Jiang, 2018 (68)	US (TN)	Pediatric hospital		✓	✓		✓	✓				90
Jung, 2017 (69)	Korea	Academic hospital		✓	✓				✓	✓	✓	94.7
Kim, 2015 (70)	US (RI)	Healthcare facilities (hospitals, skilled nursing facilities, home care)		✓	✓	✓		✓	✓	✓	✓	87.20
Ksienski, 2014 (71)	Canada	Healthcare facilities (hospital, long term care)			✓		✓				✓	74 (hospital), 75 (long-term care)
Marshall, 2019 (72)	Australia	Academic health system (hospital, skilled nursing facility, long term care)	✓		✓		✓	✓		✓		78.6-82.4
McCullers, 2006 (73)	US (TN)	Academic pediatric hospital/research center (oncology)	✓	✓	✓		✓	✓				80 to 96
Modak, 2012 (74)	US (VA)	Academic hospital	✓	✓	✓			✓	✓	✓	✓	85

Palmore, 2009 (75)	US (MD)	Hospital (research center)	✓		✓		✓	✓	✓	✓		88
Perlin, 2013 (76)	US (nat'l)	Health system (hospitals, ambulatory, surgical centers)	✓	✓			✓	✓	✓	✓	✓	90.7 -94.7
Podczervinski, 2015 (77)	US (WA)	Ambulatory (oncology research center)		✓	✓	✓			✓	✓		92 (incentive-based), 96 (penalty-based)

- Examples of enhanced access: Expanded hours of vaccination clinics to all shifts/days, mobile vaccination units, ability to report vaccination obtained outside of work place
- Examples of formal program and leadership support: Unit-based champions; peer vaccinators; institutional vaccination targets; participation of key opinion leaders and/or hospital leadership in vaccination campaign
- Examples of enforcement or punitive action: Badge marking of unvaccinated employees; mandatory education or counseling; disciplinary action; loss of eligibility for annual raises for non-compliance with mandatory masking or declination process
- Examples of mandatory masking: Unvaccinated employees required to mask when face-to-face contact with patient anticipated; during direct clinical care; when in clinical care area; when in facility

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