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COVID-19 VACCINE

Key Considerations for Employers

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COVID-19 Vaccines: Key Considerations for Employers

The U.S. has reached a milestone in its vaccination efforts, with new data showing that more than 25% of adults have been fully vaccinated and approximately 40 percent of adults and 75 percent of seniors have received at least one dose.[1] As COVID-19 vaccine supply and distribution continues to improve, the U.S. is leading the world in total vaccines administered. Vaccination rates are climbing to an average of 3 million doses administered daily and drug makers have promised to deliver enough shots to vaccinate 300 million people by the end of May. With commitment from the federal government for increasing supply, all states have now opened eligibility to everyone over 16 years. As employers prepare for a safe return to the workplace, access to reliable and up-to-date health, safety, educational and compliance information is essential. It is important to note that the data reflected in this paper are captured at a point in time and could change rapidly in the current environment.

Vaccine Headlines

There are currently three vaccines authorized to be administered in the U.S.: Pfizer, Moderna, and Johnson & Johnson (J&J). *Note: On April 9, the FDA and CDC requested a pause in the use of the J&J vaccine in an abundance of caution related to six incidents of a rare type of blood clot that occurred following vaccination. On April 23, the FDA ended its recommended pause on the J&J vaccine and will add a warning to its label to note the potential risk of rare blood clots, clearing the way for states to use it again.*

All three vaccines are considered to be effective and will reduce the risk of severe illness. The Pfizer and Moderna vaccines authorized in December 2020 for individuals 16 or 18 years and older respectively, use a new technology known as messenger RNA (mRNA) that teach cells how to make a protein that triggers an immune response which then produces antibodies to guard against Covid-19 illness. Johnson & Johnson, a one-shot vaccination, was authorized for individuals 18 and older at the end of February 2021.

Vaccine Brand Name	Who Can Get this Vaccine[2]	How Many Shots You Will Need	When Are You Fully Vaccinated
Pfizer-BioNTech	People 16 years and older	2 shots given 3 weeks (21 days) apart[3]	2 weeks after your second shot
Moderna	People 18 years and older	2 shots given 4 weeks (28 days) apart[3]	2 weeks after your second shot
Johnson & Johnson's Janssen	People 18 years and older	1 shot	2 weeks after your shot

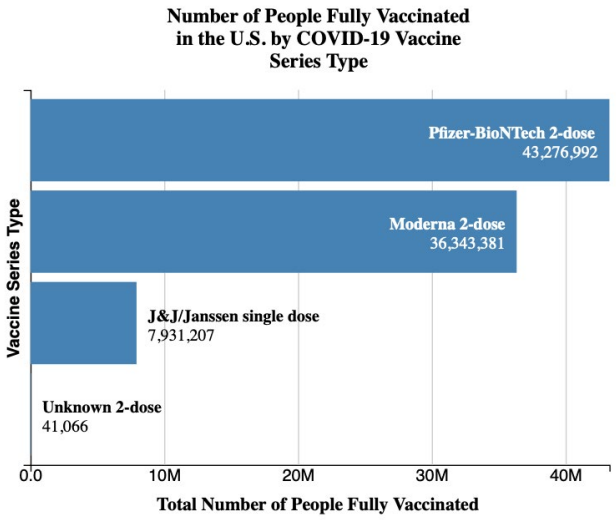
Source: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines.html

1 *https://www.nytimes.com/interactive/2020/us/covid-19-vaccine-doses.html*

2 *If you have any concerns regarding your personal medical history and conditions and whether it is safe for you to get COVID-19 vaccines you should consult your personal physician. If you have had a severe allergic reaction (anaphylaxis) or an immediate allergic reaction to any ingredient in the vaccine you are scheduled to receive, you should not get that vaccine. If you have been instructed not to get one type of COVID-19 vaccine, you may still be able to get another type as there are a couple of different mechanisms upon which COVID vaccines are based. Learn more information for people with allergies.*

3 *You should get your second shot as close to the recommended 3-week or 4-week interval as possible. However, your second shot may be given up to 6 weeks (42 days) after the first dose, if necessary.*

Regarding J&J, all six cases of rare blood clots occurred among women between the ages of 18 and 48, and symptoms occurred 6 to 13 days after vaccination. Treatment of this specific type of blood clot is different from the treatment that might typically be administered for clotting disorders. The CDC Advisory Committee on Immunization Practices (ACIP) and the FDA reviewed these cases along with 9 additional cases to assess their connection to the vaccine. They reported that the clotting disorder is rare but clinically serious. While the overall risk of developing the clotting disorder is extremely low, women between 30 and 39 appear to be at greatest risk. This is important, in part, to ensure that the health care provider community is aware of the potential for these adverse events and can plan for proper recognition and management due to the unique treatment required with this type of blood clot. Regarding the Pfizer and Moderna vaccines, the CDC does not recommend one vaccine over another and suggests the best Covid-19 vaccine is the first one that is available to you.



https://covid.cdc.gov/covid-data-tracker/#vaccinations

There are also two additional vaccines manufacturers that may apply for Emergency Use Authorization (EUA) in the U.S. in 2021:

- Astra Zeneca has received authorization for use in the U.K. and other countries. In the past several weeks their vaccine has been linked to "very rare" but dangerous blood clots. According to the European Medicines Agency the safety committee concluded that unusual blood clots with low platelets should be listed as very rare side effects. They also stressed that the benefits of 76% reduction in preventing COVID infections outweigh the risks. Astra Zeneca is expected to apply for EUA in the U.S. in Q2-Q3 2021.
- Novavax has not filed for authorization in any country to date. Application submission for the U.S. is estimated to be the second to third quarter of 2021.

Facts about COVID-19 mRNA Vaccines

They cannot give someone COVID-19.

- mRNA vaccines do not use the live not attenuated virus that causes COVID-19

They do not affect or interact with our DNA in any way.

- mRNA never enters the nucleus of the cell, which is where our DNA (genetic material) is kept
- The cell breaks down and gets rid of the mRNA soon after it is finished using the instructions

Understanding mRNA COVID-19 Vaccines | CDC

Vaccines for those under 16

Vaccine trials for use in children and adolescents are underway. Recent data suggests use of the Pfizer/BioNTech vaccine may be expanded to those 12 years of age and older; on April 9 the manufacturer requested the FDA review trial data for 12 to 15 year olds. Moderna and Johnson & Johnson vaccines are initiating studies with children, specifically with Moderna studying children over 6 months of age.

What about the safety of COVID-19 vaccines?

At this time, clinical trials and real-world data have shown that US emergency use authorized COVID-19 vaccines are safe and effective according to CDC and the FDA with specified guidelines and cautions. These vaccines met the FDA's rigorous scientific standards for safety, effectiveness, and manufacturing quality needed to support EUA. Some people have had no side effects at all, while others have reported side effects such as:

- swelling, redness and pain at injection site
- fever
- headache
- tiredness
- muscle pain
- chills
- nausea

A very small number of people have had a severe allergic reaction, otherwise known as "anaphylaxis," after vaccination but this is extremely rare. If this occurs, vaccination providers are required to have medicines available to effectively and immediately treat the reaction. When individuals are vaccinated, they are required to stay 15–30 minutes for observation to monitor for these types

of reactions. If an individual has had an anaphylactic reaction to a vaccine or vaccine components previously, they should consult their personal physician before agreeing to receive a COVID-19 vaccination.

Long-term side effects following any vaccination are extremely rare. As such, serious side effects that would cause a long-term health problem are extremely unlikely following a COVID-19 vaccination. Vaccine monitoring has historically shown that if side effects are going to happen, they generally happen within six weeks of receiving a vaccine dose. For this reason, the FDA required each of the authorized COVID-19 vaccines to be studied for at least two months (eight weeks) after the final dose. No long-term side effects have been detected for the mRNA vaccines and these vaccines will continue to undergo the most intensive safety monitoring in U.S. history. If scientists find a connection between a safety issue and a vaccine, FDA and the vaccine manufacturer will work toward an appropriate solution to address the specific safety concern, for example, a problem with a specific lot, a manufacturing issue, or the vaccine itself. This monitoring includes using both established and new safety monitoring systems to make sure that COVID-19 vaccines are and remain safe as they continue to become more broadly used in the population.

In addition to the Vaccine Adverse Event Reporting System (VAERS), **the CDC has also expanded new safety surveillance systems that include**:

CDC | V-safe—A new smartphone-based, after-vaccination health checker for people who receive COVID-19 vaccines. V-safe uses text messaging and web surveys from the CDC to check-in with recipients following COVID-19 vaccination. V-safe also provides second vaccine dose reminders if needed, and telephone follow-up to anyone who reports medically significant (important) adverse events.

CDC | National Healthcare Safety Network (NHSN)—An acute and long-term care facility monitoring system with reporting to the Vaccine Adverse Event Reporting System (VAERS) that will allow for determination of COVID-19 vaccine adverse event reporting rates.

FDA | **Other large insurer/payer databases**—A system of administrative and claims-based data for surveillance and research.

What does the vaccine mean for the future?

At present it is unclear how long protection from these vaccines will last, and whether people who get the vaccine could still be asymptomatic carriers and spread COVID-19. As of April 13, 2021, more than 75 million people in the United States had been fully vaccinated against COVID-19 since December 14, 2020. During the same time, CDC received 5,814 reports of vaccine breakthrough infections from 43 U.S. states and territories. Vaccine breakthrough infections were reported among people of all ages eligible for vaccination:

- 2,622 (45%) of the reported infections were among people ≥60 years of age
- 3,752 (65%) of the people experiencing a breakthrough infection were female
- 1,695 (29%) of the vaccine breakthrough infections were reported as asymptomatic
- 396 (7%) people with breakthrough infections were known to be hospitalized and 74 (1%) died.

Vaccine breakthrough cases occur in only a small percentage of vaccinated persons. To date, no unexpected patterns have been identified in the case demographics or vaccine characteristics among people with reported vaccine breakthrough infections. COVID-19 vaccines are effective and the CDC recommends that all eligible people get a COVID-19 vaccine as soon as one is available to them. The recommendation remains that fully vaccinated people continue taking steps to protect themselves and others in many situations, including wearing a mask, maintaining an appropriate social distance from others, avoiding crowds and poorly ventilated spaces, and washing hands often.[1]

Based on what we know about COVID-19 vaccines, people who have been fully vaccinated can start to do some things that they had stopped doing because of the pandemic.[2] People are considered fully vaccinated for COVID-19 once they have reached at least two weeks after they received the final dose of the vaccine.

1 https://www.cdc.gov/vaccines/covid-19/health-departments/breakthrough-cases.html
2 https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

FULLY VACCINATED PEOPLE CAN:

- Visit inside a home or private setting without a mask with other fully vaccinated people of any age
- Can travel "at low risk to themselves."
- Don't need to quarantine after returning to the U.S. unless symptomatic or required to do so by local jurisdictions.
- Refrain from quarantine/testing following a known exposure if asymptomatic.
- Monitor for symptoms for 14 days following known exposure, get tested if symptomatic.

THEY SHOULD ALSO:

- Continue standard COVID precautions in public places or when visiting with unvaccinated people.
- Avoid medium- and large-sized in-person gatherings.
- Monitor for symptoms and get tested if experiencing COVID-19 symptoms.
- Have a negative COVID test before returning from travel abroad.
- Follow guidance issued by employers.

Fully vaccinated persons who do not quarantine should still watch for symptoms of COVID-19 for 14 days following an exposure. If they experience symptoms, they should be clinically evaluated for COVID-19, including testing if indicated. In addition, vaccinated persons should continue to follow current guidance to protect themselves and others.

What about the variants?

Over the course of the pandemic, several variants of COVID-19 have arisen. The CDC in collaboration with other public health agencies are monitoring the situation closely. The information is rapidly emerging. Some of the potential concerns of emerging variants include their ability to spread more quickly, cause more severe disease, evade detection, result in reduction of efficacy of current therapeutics and natural or vaccine induced immunity. There are currently five variants classified as variants of concern, as noted in the chart below.

Name	Origin	Predicted Attributes[1]
B.1.1.7	United Kingdom	~50% increased transmission Likely increased severity based on hospitalizations and case fatality rates Minimal impact on neutralization by EUA monoclonal antibody therapeutics Minimal impact on neutralization by convalescent and post-vaccination
P.1	Brazil/Japan	Moderate impact on neutralization by EUA monoclonal antibody therapeutics Reduced neutralization by convalescent and post-vaccination sera
B.1.351	South Africa	~50% increased transmission Moderate impact on neutralization by EUA monoclonal antibody therapeutics Moderate reduction on neutralization by convalescent and post-vaccination sera
B.1.427	U.S./CA	~20% increased transmissibility Significant impact on neutralization by some, but not all, EUA therapeutics Moderate reduction in neutralization using convalescent and post-vaccination sera
B.1.429	U.S./CA	~20% increased transmissibility Significant impact on neutralization by some, but not all, EUA therapeutics Moderate reduction in neutralization using convalescent and post-vaccination sera

The CDC is also monitoring two additional variants identified in New York (B.1.525 and B.1.526) and one from Brazil (P.2).

Fortunately, while the three vaccines that have EUA in the U.S. have slightly less coverage for some of the variants, they still have very high efficacy in preventing severe disease, hospitalizations, and death due to these variants.[2]

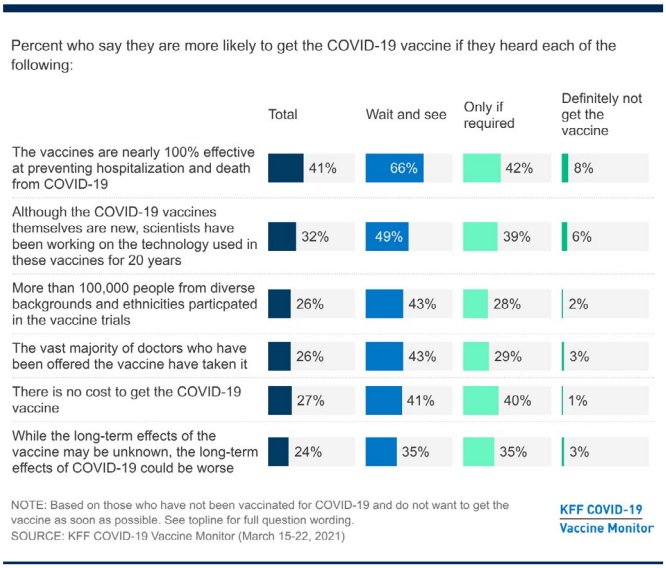
1 https://www.cdc.gov/coronavirus/2019-ncov/transmission/variant.html

2 https://www.nytimes.com/2021/01/25/health/coronavirus-moderna-vaccine-variant.html

Vaccine Distribution

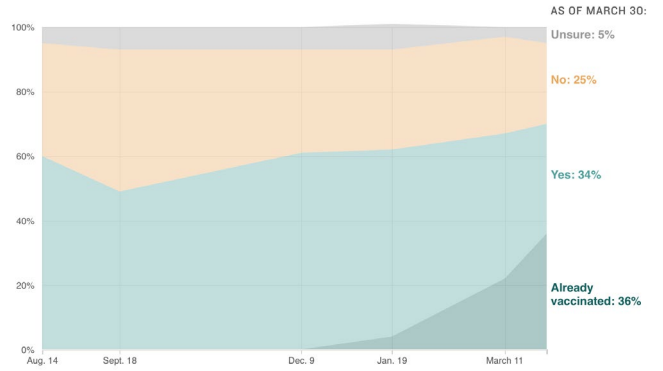
The federal government and the CDC are currently overseeing all vaccine supply to individual states, and each state then controls how the vaccine will be distributed and administered. As of April 19, 2021 more than 265M vaccine doses have been distributed nationwide, and approximately 209M of those have been administered (79% of distributed doses).[1]

Each state has its own vaccination plan and partners. While challenges remain in vaccine deployment within states and jurisdictions, attention to expanding and creating additional vaccine sites is beginning. Individuals can find vaccine providers by visiting VaccineFinder - Find COVID-19 vaccine locations near you, checking with your local state health department and local pharmacy website, or checking with local news outlets.



How willing are people to take a vaccine?

According to an NPR/Marist poll conducted in March 2021, one in four of the 1,309 American adults polled indicated that they would refuse a COVID-19 vaccine if offered. Another 5% are undecided.[2]



Source: NPR/Marist polls. Data for March 30 are from a poll of 1,309 U.S. adults conducted between March 22 and March 25. The margin of error for the overall sample is 3.4 percentage points. Totals may not add up to 100% because of rounding.

Credit: Zach Levitt/NPR

There are numerous obstacles to getting to the estimated 70-80% needed for herd immunity. The reasons for hesitancy or refusal are often complex.

According to the Kaiser Family Foundation (KFF) "potential side effects of the vaccine continue to be the top concern across racial and ethnic groups. Among those who are not convinced to get vaccinated right away, about half of Black adults (50%) and Hispanic adults (52%) are concerned they might get COVID-19 from the vaccine, higher than the share of White adults who express this concern (33%). In addition, four in ten Black adults (38%) and one-quarter of Hispanic adults (27%) are concerned they won't be able to get the vaccine from a place they trust, and about one in five are concerned they will have difficulty traveling to a vaccination site." Understanding the rationale for hesitancy and providing accurate, understandable, information from trusted resources to address concerns is essential.

How are employers approaching vaccination rollout?

Employers can play a critical role in breaking down vaccine hesitancy through two key efforts: ***education*** and ***access***.

Approaches to managing vaccination preparation may vary from providing educational material to partnering with vendors or other community organizations to hosting on-site clinics. Options for partnering on on-site near site vaccine resources include local health systems, national and local retail pharmacies, local health departments and independent vaccine vendors. Employer vaccination strategies and options will likely differ based on employer size, employee distribution, and each state's specific plans for distribution/allocation and authorized providers. Education could include reinforcing the fundamental components of precautions and safe practices, as well as providing proactive, factual information about vaccine safety. Most employers will want to tailor communications to their specific populations to supplement the guidance being provided by federal, state, and local government resources.

1 https://www.bloomberg.com/graphics/covid-vaccine-tracker-global-distribution/

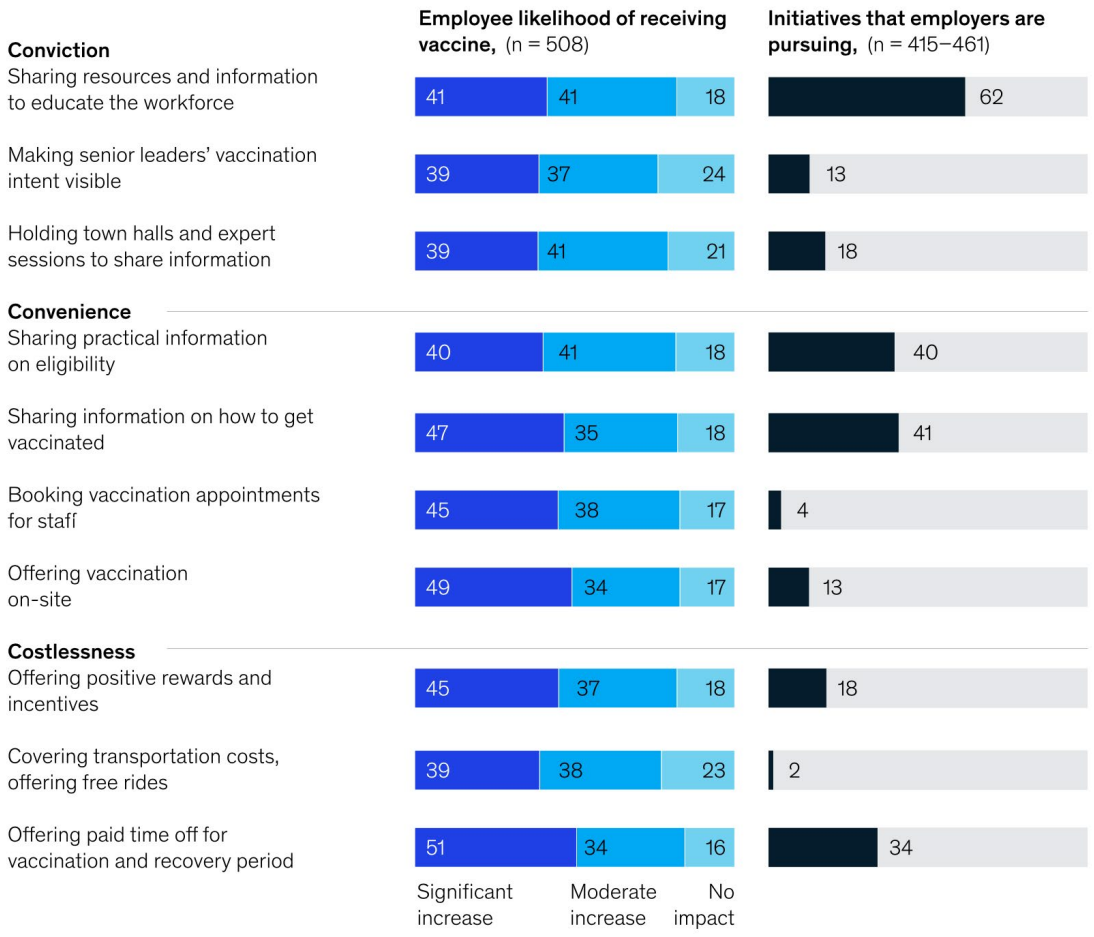
2 1 in 4 Americans Don't Want A Vaccine, Putting Herd Immunity At Risk : Shots - Health News : NPR

Employers will want to create awareness for where, when, and how employees and their families can get the COVID-19 vaccine. Employers should consider development of FAQs and appropriate training materials for both HR business partners and benefits center representatives who will likely be fielding many of the employee questions. Building trust and vaccine confidence is an essential part of successful vaccine implementation and uptake.

As noted by McKinsey, employers can play a key role in supporting vaccine adoption among employees by building conviction and making vaccination as convenient and costless as possible.

Most impactful messaging was that the vaccine was **nearly 100% effective against preventing death and hospitalization** from COVID- 19 and that the technology used has been **under development for over 20 years**, over **100,000 people from diverse backgrounds** participated in the clinical trials and there is **no out-of-pocket cost** to the individual.

Impact of different US employer initiatives on employees' likelihood of receiving COVID-19 vaccination, %



Note: Figures may not sum to 100%, because of rounding.
Source: McKinsey 2021 Consumer Health Insights Survey, March 21, 2021

https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/getting-to-work-employers-role-in-covid-19-vaccination#

As employers prepare for vaccine accessibility, there are several items to consider: Evaluate establishing a cross-functional work stream vaccination team within your organization.

- Determine if the vaccine will be required, encouraged, or incentivized for your workforce.
- Leverage your vendor and health plan partnerships.
- Plan for cost and coverage of vaccine administration.
- Develop a communication and engagement strategy leveraging CDC and other resources.
- Determine if your organization will provide/or pay for the vaccine for employees and family members not on the plan, and others including contractors.
- Promote and enforce ongoing precautions against the spread.

Cost and Coverage

The Federal Government, through Operation Warp Speed (OWS), set a goal of no upfront costs to providers and no out-of-pocket cost for vaccine recipients. The government has funded the cost of the vaccine serum, supplies, and distribution, but self-insured employers and fully-insured health plans are required to cover the cost of administration of the vaccine. At this time most health plans, PBMs and vendors are following the approved CMS rate for administration of each injection at about $40.

Compliance

COVID-19 vaccines may present complex workforce compliance challenges. For example, can an employer require an employee to take the vaccine?

In general, an employer can mandate that employees receive the COVID-19 vaccine, although many employers appear to be encouraging rather than mandating. Still, employers may find themselves in situations where work status is impacted for non-vaccinated employees. The EEOC issued a publication on December 16, 2020, What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws, which provides updated guidance on the responsibilities and rights of employers and employees.

Whether making decisions about mandates or incentives there are several compliance and anti-discrimination laws that must be considered. In addition, COVID-19 concerns will span across broader Human Resources policy risks, including privacy, discrimination, and employee relations. It is critical for employers to coordinate with legal counsel to have a clear position that is communicated to employees. Recent Society for Human Resource Management (SHRM) research shows that 88 percent of employers either are unsure about whether they will offer incentives to encourage employees to get the vaccine or are not offering or planning to offer such incentives. Given this legal uncertainty, reducing barriers to vaccination by interventions such as paid time off that roughly mirrors the amount of time that an employee has to take in getting a COVID-19 vaccine shot is what they have seen many larger employers offering.[1]

Monitoring and Reporting

A key factor to consider in employer return to workplace strategy is if and how employers plan to monitor vaccination status of the workforce. To make it easier for individuals to demonstrate their vaccination status, organizations around the world are collaborating to develop secure and verifiable "vaccine passports", accessible via an app on a smart phone or in physical form.

EXAMPLES OF DEVELOPMENT OF SECURE AND VERIFIABLE COVID-19 VACCINATION STATUS AROUND THE WORLD

- **Vaccination Credential Initiative (VCI)** | Coalition of health and technology organizations working to harmonize standards for enabling vaccination records in digital or paper form in a private, secure and verifiable way. Partners include CARIN Alliance, Cerner, Change Healthcare, The Commons Project Foundation, Epic, Evernorth, Mayo Clinic, Microsoft, MITRE, Oracle, Safe Health, and Salesforce.
- **CommonPass** | A mobile app by the Commons Project Foundation and the World Economic Forum enables travelers to share their COVID test or vaccination status across countries.
- **AOKpass** | International Chamber of Commerce and International SOS, medical and security services firm are joining forces to create a digitally trusted, private and verifiable app for COVID-19 compliance
- **PathCheck** | This non-profit organization is taking a paper-first approach and provides both an electronic vaccine app and a physical card containing a digitally-signed QR code of an individual's vaccination status. Skyflow, a digital privacy platform recently entered the healthcare business and has joined VCI and PathCheck to align its technology to support COVID-19 solutions.

1 https://www.shrm.org/resourcesandtools/legal-and-compliance/employment-law/pages/employers-offer-covid-19-vaccine-incentives.aspx

There are concerns for use of vaccine passports that citizens, governments, employers, technology, legal and regulatory communities are raising. Some of these concerns include:

- Privacy and security of individually identifiable information and health data
- Legality of use in requiring passports to participate in events or for employment purposes
- Equity and creating a tiered society
- Protection against fraud

Even as these are passport initiatives are still in development, pilot use has already begun with many learnings along the way.

- Nationally, Walmart is making vaccination records available to those who are vaccinated in its stores with apps, such as the one by the Commons Project.[1]
- The State of New York is rolling out the voluntary use of Excelsior Pass, a free app that provides digital proof of COVID-19 vaccination or a negative test result.[2] Many venues are required to screen participants for COVID-19. Madison Square Garden lists the use of Excelsior Pass as one of the options for entry.
- Some universities have stated that they will require proof of vaccination status in the fall.[3]
- The travel industry has started piloting the use of different vaccine passport apps. These include Cathy Pacific, JetBlue and United on select routes.[3]
- Israel has implemented a "green pass", an app that demonstrates an individual's vaccine status which allows them to participate in many activities.

As developments continue and uses of these passports expand, employers will need to consider:

- Do employers plan to monitor employee vaccination status – at an aggregate level or individual level? How will the data be used? What will be the source(s) of data?
- Will vaccination be required in certain industries or based on the type of job? What accommodations, if any, will be made?
- How do employers monitor across geographies (States and countries) that may have different rules and regulations?

What is clear is that any form or use of a "passport" will need to adapt to the ever-changing science and nature of COVID-19. How will vaccination passports adapt to capture to the durability of the vaccine which at this time is unknown (i.e., the expiration date of the passport) and other variables? Will there be a time that it becomes redundant when most of the population is vaccinated?

In addition to global initiatives, organizations are developing and incorporating vaccination status services for the employer market as part of their solutions, such as IBM Digital Health Pass with Salesforce's web-based employee management platform, Wellcast.Health's Well.Pass, Emocha Health, Return Safe, and EHE Health just to name a few.

Conclusion

The U.S. continues efforts to curtail the pandemic and move closer to a more normal state. We are still gathering evidence and discovering new information regarding the COVID-19 virus, vaccines, and side effects. Surveys show employers may play a valuable role for employees as leaders and role models, providing resources and other incentives to support a safe return to work strategy. Staying informed on the changing environment is critical. Communication is key as we navigate with vendor partners, federal agencies, and local communities.

Please contact your local Brown & Brown service team with any questions.

1 https://www.fiercehealthcare.com/tech/walmart-partners-commons-project-clear-to-launch-digital-covid-19-vaccine-records

2 https://covid19vaccine.health.ny.gov/excelsior-pass

3 https://www.nytimes.com/2021/04/06/us/politics/vaccine-passports-coronavirus.html