



COVID-19 Vaccine & The Role of Employers

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As COVID-19 clinical trials move closer to FDA approval, and the nation readies itself for a vaccine(s), employers are starting to think through how to best prepare operationally and support their employees from both an education and access perspective. This paper examines at a high level the science and process associated with vaccine development and approval, and identifies the areas employer plan sponsors will need to contemplate as the vaccine becomes widely available.



The Vaccine and Employer Economy

Never in history have employers realized how much public health impacts their bottom line. We are coexisting with the virus until we get to herd immunity, and that will take time. According to a recent McKinsey and Co study, the highest probability of reaching herd immunity in the U.S. is in the third or fourth quarter of 2021, however that timing could shift. Our on-going coexistence with the virus means continuing precautions, possible shutdowns and curtailing of business and social and cultural activity, and economic suffering for millions. Barriers to developing herd immunity include not only the challenges associated with producing an effective and safe vaccine, but also a growing lack of confidence from the American public that they will take the vaccine when it becomes available. To provide a sense of the effect the press and information on vaccines has had on the general public, the Pew Research Center data on the next page shows the willingness of the American public over the last several months to take a COVID vaccine.



IMPORTANT NOTE:

It is important to note that the data and the opinions reflected in this paper are captured in a point in time and could change rapidly based on the environment. For example, there could be some surprise vaccine entrant to the marketplace that is approved ahead of current projections, or there could be clinical trial data released next week that could change the course of vaccine development and timing.



HOW WILLING ARE PEOPLE TO TAKE A VACCINE?

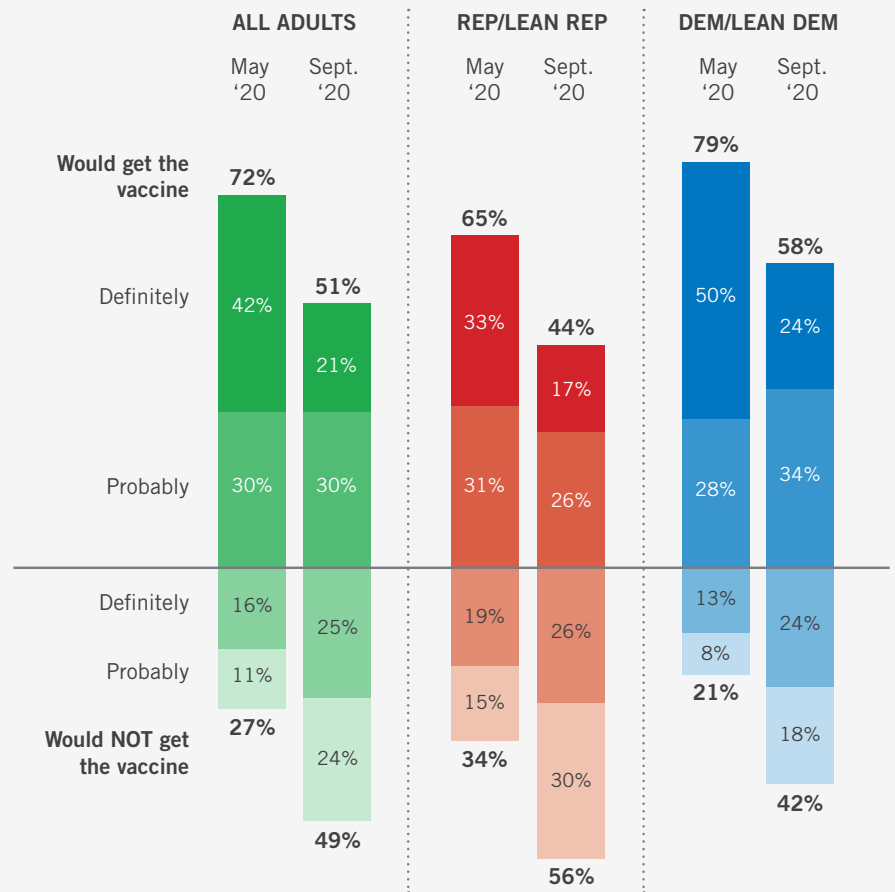
According to a Pew survey in May of this year, 72% of adults were willing to take a COVID vaccine. That number dropped to 51% in September's polling. In May 2020, 27% of people surveyed said they probably or would NOT take the vaccine. That number climbed to 49% last month.

WHY?

Most likely confusion about vaccine information, the number of vaccines being developed, information about the approval process and fast tracking of that process, and conflicting messages about how much that process will be modified by the White House and/or the FDA to get a vaccine to market quickly. Employers will likely need to play a role in the education around the safety and efficacy of the COVID-19 vaccine once it becomes widely available.

Drop in share of Americans who say they would get a COVID-19 vaccine if it were available to them today

% of U.S. adults who say if a vaccine to prevent COVID-19 were available today they...



Note: Respondents who did not give an answer are not shown.
 Source: Survey conducted Sept. 8-13, 2020.
 U.S. Public Now Divided Over Whether To Get COVID-19 Vaccine

PEW RESEARCH CENTER



A VACCINE IS APPROVED. NOW WHAT?

Once a vaccine is approved and marketed with access to the general population, phase IV trials start — this is also called post-marketing surveillance. In this phase, the CDC and FDA work together to monitor adverse events and safety and gather information from patients, healthcare providers, and others. During this phase, in addition to monitoring, specific studies will be performed on efficacy and safety of the vaccine in real world settings.

The typical vaccine development process from inception to approval and manufacturing takes 15 years. Vaccines that have been developed previously in 5 years have been accelerated. In contrast, the COVID-19 vaccine may be developed and approved in a year or less. Typically FDA review in different phases can take a long time, however because of the public health emergency, the FDA has been giving emergency authorization use to medications for COVID and will likely give that authorization to one or more of the vaccines in development. As of today, there are 11 vaccines in phase III trials and 6 that have been approved for limited use. All those that have been approved for limited use are outside of the U.S., primarily China and Russia. Important to note, these two countries do not require phase III trials, which are trials in larger populations, before approval.

Once FDA approval is given, the initial supply of vaccine will be limited, and likely available only to specific populations. It is anticipated there will be phased approach to vaccine distribution that could look like the chart breakouts to the right. This staggered approach to vaccine availability will challenge employers from an operational perspective as on-going infection risk will continue until a full access phase is reached and potentially beyond depending upon the efficacy of the vaccines approved, and the length of immunity conferred, among other factors.

Post-vaccine planning is also important to consider, as acceptable efficacy of the vaccine for approval is set at 50%, and two doses will likely be needed. This encompasses evaluating measures in place pre-vaccine (for example face masks) and whether these measures need to continue, be reduced, or whether other controls need to be put in place.

Equity is a Crosscutting Consideration:
In each population group, vaccine access should be prioritized for geographical areas identified through CDC’s Social Vulnerability Index.



PHASE 1

Phase 1a “Jumpstart Phase”:

- + High-risk workers in health care facilities
- + First Responders

Phase 1b:

- + People of all ages with comorbid and underlying conditions that put them at significantly higher risk
- + Older adults living in congregate or overcrowded settings

PHASE 2

- + Critical risk workers-workers who are both in industries essential to the functioning of society and at substantially high risk of exposure
- + Teacher and school staff
- + People of all ages with comorbid and underlying conditions that put them at moderately higher risk
- + All older adults not included in Phase 1
- + People in homeless shelters or group homes for individuals with physical or mental disabilities or in recovery
- + People in prisons, jails, detention centers, and similar facilities, and staff who work in such settings

PHASE 3

- + Young adults
- + Children
- + Workers in industries essential to the functioning of society and at increased risk of exposure not included in Phase 1 or 2

PHASE 4

- + Everyone residing in the United States who did not receive the vaccine in previous phases



The Employer Response

As clinical trials wrap up and the distribution preparations begin, what is the employer's responsibility and how can an employer prepare?

COST AND COVERAGE

The Federal Government's Operation Warp Speed has a goal of no upfront costs to providers and no out-of-pocket cost to the vaccine recipient. The federal government is procuring hundreds of millions of doses of vaccines, and no American will be charged for either the COVID-19 vaccine or its distribution.

COMPLIANCE

COVID-19 vaccines will present workforce compliance challenges that have not yet been identified by regulatory or legislative direction. For example, can an employer require an employee to take the vaccine? Legal counsel should be consulted on this important question.

Employers do have the power to mandate inoculations that come from the U.S. Labor Department's Occupational Safety & Health Administration (OSHA) and the Equal Employment Opportunity Commission (EEOC). The EEOC issued its [guidance](#) on employee vaccinations on March 21 of this year, during the pandemic's early days in the U.S. The EEOC restricted its guidance to employers covered by the Americans With Disabilities Act (ADA) and Title VII of the Civil Rights Act – meaning those with 15 or more employees—and concluded that they should “encourage” employees to be vaccinated.

The EEOC noted that under the ADA, an employee can be exempted if they have a disability that prevents them from taking the vaccine, and under Title VII they can if they can demonstrate a “sincerely held religious belief, practice, or observance.”



ESTIMATED VACCINE COST

The 5 Frontrunners

- 1) **Moderna:** \$32 to \$37 per dose (for some customers)
- 2) **Johnson & Johnson:** \$10 per dose
- 3) **Pfizer:** \$19.50 per dose
- 4) **Novavax:** \$16 per dose
- 5) **AstraZeneca:** “A few dollars” per dose

What does this mean for self-insured plans?

CARES Act requires health insurance issuers and plans to cover any CDC-recommended COVID-19 preventive service, including vaccines, without cost-sharing.

Employers will be required to cover and may be required to pay for vaccinations under the health plan.

It is too early to tell if and what exclusions or parameters for coverage will be allowed (i.e. will coverage need to align to federal distribution plan for at risk population first?).

<https://observer.com/2020/08/covid19-vaccine-price-comparison-moderna-pfizer-novavax-johnson-astrazeneca/>

EMPLOYEE CONSIDERATION:

Employers should begin preparing to budget costs for covering vaccinations for their enrolled health plan membership with consideration for non-enrolled employees as well.



In addition to the compliance issues associated with employee benefits, COVID-19 concerns will span across broader HR policy risks, i.e. privacy, discrimination, employee relations, etc. It will be critical for employers to prepare with legal counsel and external partners to have a clear position that is communicated to employees.

STRATEGIC CONSIDERATIONS FOR EMPLOYERS

- + Will we require employees to be vaccinated and how will that process be tracked and administered?
- + Develop a plan to address at risk employees and those required to be in person/ front line workers as priority
- + Do we want to develop and deploy on-site or near-site COVID-19 vaccination clinics for employees?
 - + What vendor partnerships do we need to consider forming to plan for this in 2021?
 - + How can we leverage existing health plan and other vendor partners to facilitate COVID-19 vaccination clinics for employees?
 - + What will the administrative costs be for clinics?
- + Comprehensive communication and engagement strategy for employee population should be developed well in advance of vaccination availability
- + Consider setting up a cross-work stream vaccination team within HR and Benefits
 - + Identify key stakeholders
 - + Develop and present plan to executive leadership
 - + Plan must be flexible and have fluidity based on evolving vaccination timelines, safety, compliance concerns and federal/state government regulations
- + Employers should begin preparing to budget for internal workgroup costs, vendor costs and health plan vaccination costs
- + For organizations that face the public there are special considerations regarding whether they will require proof of vaccination or a negative COVID-19 test for entrance into facilities
- + Global employers will have further challenges to consider while addressing country specific vaccine approvals and mechanisms of distribution



CLOSING THOUGHTS:

The return to normalcy for employers from COVID-19 will create multi-faceted challenges across the organization, most of which are unknown today. In the interim, employers will need to proactively identify and align resources within their organization to build the infrastructure to tackle the associated operational, financial, compliance and human resource issues ahead to ensure the best possible outcome for their workforce.

Please be advised that any and all information, comments, analysis, and/or recommendations set forth above relative to the possible impact of COVID-19 on potential insurance coverage or other policy implications are intended solely for informational purposes and should not be relied upon as legal or medical advice. As an insurance broker, we have no authority to make coverage decisions as that ability rests solely with the issuing carrier. Therefore, all claims should be submitted to the carrier for evaluation. The positions expressed herein are opinions only and are not to be construed as any form of guarantee or warranty. Finally, given the extremely dynamic and rapidly evolving COVID-19 situation, comments above do not take into account any applicable pending or future legislation introduced with the intent to override, alter or amend current policy language.