Joint IOGP-IPIECA position on COVID-19 vaccines

Introduction

Since late 2020, several COVID-19 vaccines have been approved by regulators in many countries. This document aims to help companies understand these developments, provide guidance for company policy development, and offer an assessment of the expected impact vaccines will have on the course of the pandemic. This guide will not provide an exhaustive list of current vaccines in the market, as the science is continuously developing. IOGP-IPIECA Members that seek to gain regular up-to-date insights in COVID-19 vaccine developments are invited to join the Health Committee’s weekly COVID-19 Calls (please contact Health Committee Manager Mariana Carvalho at mc@iogp.org).

Vaccinations are one of three strategies governments, intergovernmental institutions, non-governmental organisations, and private enterprise are pursuing to control the COVID-19 pandemic. The three strategies are:

1) Effective preventive public health policies and vaccinations
2) Accurate, early, and scalable testing for COVID-19
3) Effective treatment of symptomatic COVID-19 patients

None of these three strategies can by themselves stop the pandemic, and all three will be needed to move from the current pandemic state to a series of smaller and more manageable localised epidemics. By using all three strategies, a situation should emerge where COVID-19 – while likely not eradicated entirely - is managed to a point that it no longer causes the current health impacts and societal disruption.

The IOGP-IPIECA Health Committee has and will continue to share and discuss promising developments in treating COVID-19, such as the use of steroids, convalescent plasma, and monoclonal antibodies. At the same time, companies active in the oil and gas industry have significant roles to play in the first two strategic areas of prevention and testing. For the latter, the Health Committee has published a position statement which can be found here.
COVID-19 vaccine landscape

The below conclusions summarise the constantly changing COVID-19 vaccine landscape and are based on what is currently (February 2021) known about the SARs-CoV-2 virus, vaccine development, and previous coronavirus outbreaks. The impact and relevance of these conclusions and the policies to deal with them will vary from country to country. How organisations might navigate these policy decisions is the focus of the next section of this paper:

- With initial vaccination efforts ongoing it is not expected that vaccines will be widely available to most oil and gas workers before the second half of 2021, with a few local exceptions having earlier access.
- Different vaccines, with varying levels of effectiveness, are becoming available at different times in different countries. Early vaccine availability is skewed towards richer countries that have bilateral agreements with vaccine manufacturers.
- Competition between countries to acquire vaccines through pre-purchase contracts with manufacturers will limit availability of the vaccine in low- and middle-income countries (LMIC). The World Health Organization endorsed COVAX\(^1\) facility was set up to improve access to vaccines for LMICs.
- Companies should avoid purchasing vaccines exclusively for company use without alignment and collaboration with risk-based and equitable government vaccination programmes and policies.
- Different vaccines provide varying levels of immunity, with most widely approved vaccines effectively limiting the severity of COVID-19. Nevertheless, mostly mild or asymptomatic infections still occur in vaccinated people at varying degrees. This may also be depending on the type of vaccine used.
- No vaccine is expected to provide enough protection to completely stop COVID-19 from spreading between people. Human to human transmission will be decreased due to vaccines; nevertheless, herd immunity is unlikely to be achieved in 2021 in most countries.
- Access to any vaccine is likely to be initially limited to specific vulnerable groups, such as the elderly and essential workers in healthcare and groups prioritised by governments. Healthy, working-age oil and gas industry staff and contractors who have a lower chance of serious complications or death from COVID-19 will therefore likely have later access to vaccinations.
- The deployment of a vaccine to the wider population will face significant logistical hurdles in production, transportation, and the expected need for repeated administration of follow up vaccine doses.
- Offices and field operations will need to continue to implement COVID-19 barriers focused on physical distancing, hygiene, sickness absence management, mask wearing, and targeted testing for the foreseeable future.
- It is expected that reactions of pro- and anti-vaccine groups will influence decisions around vaccination at different levels. These debates will in part be driven by the extent of severity of vaccine side effects, as well as the accuracy of and transparency around research on vaccine safety and efficacy.

\(^1\) The COVAX facility is a global initiative that brings together governments and manufacturers to ensure eventual COVID-19 vaccines reach those in greatest need, whoever they are and wherever they live.
Industry vaccine policy development

Globally, governments are conducting and planning risk-based strategies for domestic vaccine deployment. A cautious approach should be applied by companies when considering the use of vaccines, utilising a science- and evidence-based approach for all recommendations. When company staff are provided with the opportunity to access vaccines, or a company is considering participating in a government vaccination programme, the company first needs to review the specific vaccine being considered before deciding how best to support government strategies. As safe and effective vaccines become widely available, further consideration must be given to medical ethics, equitable access and distribution, racial and socioeconomic disparities, and effective awareness campaigns. The specifics of these concerns in this context are discussed later in this paper.

Companies are encouraged to develop a robust global campaign for educating their workforce about vaccines, vaccine evaluation and leverage existing programmes, complemented by a location-specific risk assessment of vulnerable staff.

When developing and deciding on COVID-19 vaccination policies and positions, companies should aim to follow two guiding principles:

1) Companies should only support vaccines that have been proven to be safe and effective through rigorous scientific research and approved for use by the relevant national governing bodies.

2) Companies should only develop and participate in vaccination programmes that distribute vaccines in a risk-based and equitable way, respecting an individual’s right to choose not to be vaccinated against COVID-19, in accordance with local legislation.

The rationale behind these principles is that both scientific and regulatory conditions must be met before a vaccine is used in a company to manage the risk of politicised decision making on vaccine approvals. The scientific threshold can be met when the vaccine in question is part of the approved COVAX portfolio endorsed by the WHO, or if several other governing bodies in OECD countries have also approved the vaccine under consideration for use.

In practice, these guiding principles will encounter numerous grey areas when applied, such as debate around the science supporting a vaccine and what ‘equitable’ means in a specific culture. To deal with this ambiguity a further list of considerations and advice is provided below to allow companies to assess and shape all relevant aspects of vaccine policy making.

Assessing vaccines: safety, efficacy, regulatory approval, and practical considerations

Before using a vaccine approved by national regulators, the methods used by the regulators, and in some cases the scientific details underpinning this approval, need to be understood. While some vaccines have been widely approved and used for millions of people without major incidents, company medical staff should monitor the latest scientific literature to remain informed of any developments or complications, such as lack of efficacy against certain virus variants or side effects.

Double blind trials and efficacy

- Vaccines under consideration should have gone through all mandated stages of clinical trials, including phase 3 clinical trials. Participants in phase 3 vaccine trials are either administered the vaccine or a placebo, and neither the person administering the dose nor the person receiving it know if it is the vaccine or the placebo. The trial’s participants are monitored to see if they develop the illness, produce antibodies against the virus, are admitted to hospital, or die.

- Once a predetermined number of COVID-19 cases (usually ±150) have occurred in the study population, the researchers analyze the case numbers in the treatment and placebo groups.
  - If 95% of the total number of COVID-19 cases happened in the placebo group, this is referred to as an effectiveness of 95%. This allows for the conclusion that those taking the vaccines are protected from getting the disease.
Most studies define COVID-19 cases as individuals with symptoms and a positive COVID-19 polymerase chain reaction (PCR) test, and only some actively look for asymptomatic COVID-19 cases in both treatment and placebo groups. It is therefore less clear if, and if so by how much, the vaccines reduce the rate of asymptomatic infections.

Vaccine’s effectiveness in preventing the spread of the virus will determine if and how herd immunity can be achieved. Herd immunity is achieved in a population when the number of people who can get the virus is so low that it cannot sustain the spread of the disease, so that the unvaccinated are protected by the immunity of the ‘herd’. For this to work, a COVID-19 vaccine must not only stop illness from happening in the individual, but also stop the vaccinated person from spreading the disease as an asymptomatic carrier of the virus. Herd immunity for COVID-19 is unlikely to be achieved in 2021 in most countries.

Efficacy of vaccines might differ between age and ethnic groups. These differences in efficacy need to be understood in relation to the workforce for whom vaccines are being considered.

Safety

During Phase 1, 2 and 3 vaccine trials, the safety of the vaccine is the priority and a key condition to advance from one stage to the next.

In none of the major trials before or during December 2020 did researchers find serious side effects at such rates that it would render the vaccine unsafe to use in the general population.

Common side effects such as fever, muscle pain, and injection site pain are consistently observed. Very rare side effects, including fatal allergic reactions, may only come to light once millions of people have been vaccinated. As the phase 3 trials typically include ‘only’ tens of thousands of people, these rare side effects may not be observed during the trial. Therefore, ongoing observation and registration of side effects is essential (phase 4) Regulatory approval process.

- Each national or transnational regulator has its own processes and procedures for assessing the efficacy and safety of vaccines to determine if they can be used in a specific jurisdiction.
- This could mean that one regulator has approved a vaccine, while another has not. This could be due to technicalities in process, or the fact that a manufacturer has not applied for approval from a certain regulator. It can also be due to more fundamental difference in the assessment of a vaccine’s safety and efficacy.

One practical way to understand the quality of the regulatory process is to use the World Health Organization’s `List of Stringent Regulatory Authorities (SRAs)´ as a benchmark². Vaccines approved by the listed SRAs can be regarded as safe and effective, while those lacking approvals from SRAs need more stringent internal review before a company considers using it or advising staff to use it.

Vaccine characteristics impacting vaccine use

The different types of vaccines require varying levels of refrigeration (including deep freezing) between manufacturing and administration. The duration of transport and the number of transit points along the way complicate a cold chain and risk spoiling the supply of vaccines. The colder the chain needs to be, the more vulnerable it is to disruption. Companies should account for this cold chain risk when participating in vaccination programmes, and could consider vaccines that might have lower levels of effectiveness but are less likely to spoil. For example, from an outcome point of view, it is better to vaccinate staff with a vaccine that is 70% effective but can safely be transported, than vaccinating with one that is 90% effective but where cold chain disruption will likely lead to 30% of doses being ineffective due to premature thawing.

Different vaccines require different administration regimes. Most will require an initial vaccination followed by a booster three to four weeks later. Some countries are experimenting with delaying the second booster dose in order to vaccinate more people with the available doses. The effectiveness of this approach is still the subject of scientific debate. A few vaccines are designed to work with only one dose, which would be especially practical for remote populations.

² https://www.who.int/medicines/regulation/sras/en/
The potential consequence of taking one vaccine and then taking another later are still being studied. If a more effective vaccine becomes available after someone has already been vaccinated with another COVID-19 vaccine, there is a risk of interaction between the two vaccines that can limit the effect of the vaccine or even cause adverse health effects.

Ethical and legal considerations for vaccination programmes

With supplies and vaccine delivery capacity limited at least in the early months of vaccine rollout, it is paramount that regulators and companies address all relevant factors that can impact the delivery and health impact of a vaccination programme.

Vaccination campaigns

Key elements of a successful vaccination campaign include:

- A communication plan with clear messaging, with segmentation that represents the stratification of risk in the population and includes specific calls to action
- Proactive targeting of misinformation, working with community/employee networks and leveraging effective social media to increase social (or individual) acceptance of vaccines
- Leveraging lessons from other public health campaigns and health behavior change theories
- Delivery strategies that account for available resources and operational factors, such as integration with healthcare infrastructure
- Consideration of local culture and nuances

Medical ethics related to vaccination programmes

The following should be taken into consideration when developing or participating in local vaccination campaigns.  

- Beneficence - moral obligations to act for the benefit of others, as part of a company’s duty of care
- Equity - can a vaccine programme ensure equitable access to the vaccine?
- Personal Autonomy – personal choices to maintain health must be respected, subject to local laws and regulations
- Consent – allow people considering taking a vaccine to make a properly informed decision and avoid the perception of being experimental subjects

Equitable distribution and allocation of vaccine

Partnerships among governments, major public health institutions, and the private sector, such as the COVAX Facility, are needed to ensure affordable, equitable solutions that will enable global access to safe vaccines for vulnerable and marginalised populations, especially those in low- and middle-income countries. Key considerations are:

- Distribution strategies to include plans for emergency and humanitarian use
- A prioritisation framework for allocation to ensure a fair and standardised distribution, promote solidarity and trust, protect those who are most in need, and foster a sustainable system.  

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3 The WHO’s “Fair Allocation Mechanism for COVID-19 Vaccines” and other prioritisation guidelines provides a model for equitable vaccine distribution programmes.
Understanding racial and socioeconomic disparities

When designing and/or supporting a vaccination programme, social inequalities should be considered. There is evidence that COVID-19, both the disease itself and the negative economic consequences of the resulting pandemic, has had a disproportionate impact on marginalised and vulnerable populations. Companies should consider:

- How the pandemic’s socioeconomic impacts have unevenly affected society along the lines of race, gender, and class, and how a company-supported vaccination program might account for these differences
- Stronger and more resilient systems to address issues of health equity and access to care
- Strategies for preventing disruption of existing mental and behavioral health services and increase in the capacity of telehealth services

Legal and regulatory aspects of vaccination programmes

Each country has their unique set of regulations managing the rollout of vaccines. As this is still a developing situation, no definitive guidance can be provided at this time. Five central regulatory and legal questions that companies are encouraged to monitor and study are:

- Whether any local laws oblige or permit employers to require staff to be vaccinated
- To what extent a company can protect an individual’s right to choose to be vaccinated or not in an environment where (some) people are required to be vaccinated by law
- Whether staff can prove that they have been vaccinated and whether a company may collect and process any proof of vaccination (documentation and data privacy)
- How a company can avoid ‘return to worksite’ policies (in)directly requiring staff to be vaccinated (if these policies are unlawful in a given jurisdiction)

The above questions should be considered for each jurisdiction where vaccination campaigns are being considered by a company. Additionally, supranational regulation is expected to emerge throughout 2021, governing questions such as vaccination and/or COVID-19 immunity requirements for international travel. As these regulations emerge, this guidance will be updated.

Health surveillance and vaccination

For company run/sponsored vaccination programmes, health surveillance is advisable. The rationale for such surveillance includes, but is not limited to, guiding deployment, ensuring vaccine coverage, and conducting impact monitoring. It is understood that there is global variation in safety surveillance around vaccines. Companies should ask:

- What safety surveillance will be required for rare adverse events?
- What is the impact of vaccines on the need to maintain current preventive barriers, such as physical distancing and mask wearing, quarantining prior to deployment, or isolation after being a close contact?
- What is the risk of a false sense of protection if the vaccine provides only partial immunity?

Any surveillance must be permitted by local legislation.
Vaccine impact on society and operations

Companies will benefit from the rollout of COVID-19 vaccines along with the rest of society. Other than the disease itself, key COVID-19 risks companies are faced with stem from the disease’s secondary effects. Overwhelmed healthcare systems leave society and companies vulnerable in cases of non-COVID-19 emergencies. Lockdowns preventing travel and restricting economic activity have a broader impact on companies than individual cases of COVID-19.

Vaccinations will reduce the burden on healthcare systems the most if healthcare workers and the vulnerable (the elderly and those with underlying health concerns) are prioritised for vaccination. Vaccinations will allow for reopening of economies once there is more understanding of a vaccine’s ability to stop the spread of the disease and once the flow of COVID-19 patients into the health system has been brought under control. The sooner health systems are stabilised and economies reopen, the better it is for all. It is therefore in companies’ best interest to support the rollout of vaccines to those groups who need it the most, even if this is not company staff. Supporting broad government vaccination programmes or international efforts such as COVAX is therefore advised.

Regardless of how well the vaccines stop the spread of the disease, they can be used to manage COVID-19 risks in remote and isolated worksites, such as offshore platforms when they effectively stop severe illness in individuals. The risk mitigation in this scenario would come from lowering the risk of having to conduct medical evacuation for COVID-19 cases.