

Joint IOGP-IPIECA position on COVID-19 vaccine usage

Introduction

Coronavirus disease 2019 (COVID-19), caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), continues to spread. SARS-CoV-2 is now present in every continent apart from Antarctica. To control the COVID-19 pandemic, governments, intergovernmental institutions, non-governmental organizations, and private enterprise are pursuing three strategies:

1. Effective preventive public health policies and vaccination
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 will be needed to move from the current pandemic state to a series of smaller and more manageable localized epidemics. Ultimately, 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.

In the near term, effective COVID-19 treatment remains essential for staff working in the industry who are affected by COVID-19. However, the industry's role in providing these treatments is often limited. Nevertheless, the IOGP-IPIECA Health Committee 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](#).

The purpose of this position paper is to map the current landscape of COVID-19 vaccine development and provide information for the oil and gas industry to assist decision making regarding vaccination usage. The choice not to present a conclusion or singular industry position on the use of vaccines was made because there is, as of November 2020, no proven effective COVID-19 vaccine and national regulations and contexts require tailored policies to be effective. Many of the complexities are driven by the unprecedented speed by which COVID-19 vaccines are being developed, which will be explained in the next section.¹

Vaccine development timelines

Historically, it has taken years to prove that vaccines are both safe and effective. Many vaccines that start clinical trials never make it to the end, either because they do not elicit an effective immune response or there is some safety concern. Even vaccines that do prove to be effective might not make it to mass production because they are not commercially viable, an important factor given the high cost of vaccine development. Figure 1 shows the expected compressed development timelines for COVID-19 vaccines compared to the much longer regular development process. Both processes contain three phases in which the vaccine is tested on increasing numbers

¹ The position paper is written in a rapidly evolving situation, with new sources of information becoming available daily. It has therefore gone through a fast-track IOGP-IPIECA review process, and will be reviewed as needed to remain abreast of current information and developments.

of volunteers and where the focus of the studies shifts from proving the safety of, and immune response to, the vaccine in the earlier phases, to proving its effectiveness in preventing disease in Phase 3.

This accelerated timeline for COVID-19 vaccine development is made possible by streamlining approval processes, developing next phase trials based on interim results from earlier phases, and ramping up mass production of vaccines even before final Phase 3 trial results are in. These ‘shortcuts’ come at significant financial cost but do not significantly shorten the duration of the actual clinical trials. Preliminary approvals of vaccines can be granted by regulators based on incomplete but promising Phase 3 trial results, which in the case of COVID-19 allows the use of the vaccine in vulnerable groups such as healthcare workers. Because these groups would get the vaccine on an exceptional basis when not all risks and benefits of the vaccine are fully understood, the participants need to be carefully monitored after receiving the vaccine. Although over 200 potential vaccines are at varying levels of development across the globe, with a handful at the more advanced Phase 3 clinical trial point, it is still too soon to say how effective a future COVID-19 vaccine will be.^{2,3} Once Phase 3 clinical trial data is published, the IOGP-IPIECA Health Committee will review this data and amend this document accordingly. For now, this paper will present an overview of the realities of COVID-19 vaccine development and deployment and the principles of vaccine use, which are relatively consistent between the different types of vaccines.

Accepted Vaccine Development Timeline							
Description	Design and exploratory pre-clinical	Development process, preclinical toxicology studies IND submission	Phase 1 Clinical trials	Phase 2 Clinical Trials	Phase 3 Clinical Trials	Regulatory review and approvals BLA	Large scale manufacture and distribution
Duration		2-4 years	1-2 years	2 years	2-3 years	1-2 years	Total 10-15 years

COVID-19 Accelerated Vaccine Development Timeline					
Description	Design and exploratory pre-clinical	Development process, preclinical toxicology studies. IND submission	Phase 1 - 2 - 3 Clinical Trials	Regulatory Review and approvals BLA	Large scale manufacture and distribution
Status	Pre-existing from SARS CoV 1 and MERS CoV	Partially pre-existing and parallel development	Overlapping clinical phases	BLA pre-submitted.	Manufacture commence at risk.
Duration	Months	Months	Months	Months	Total 10-18 Months

Figure 1 – Standard vaccine development timeline versus accelerated COVID-19 vaccine development timeline (BLA: Biological License Application; IND: Investigational New Drug)

² Vaccines in Phase 3 trials have a probability of success of about 25-30% <https://www.fda.gov/patients/drug-development-process/step-3-clinical-research> Accessed 14 September 2020

³ Landscape of COVID-19 candidate vaccines <https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines> Accessed 15 September 2020

COVID-19 vaccine landscape

The below conclusions summarize the constantly changing COVID-19 vaccine landscape and are based on what is currently (November 2020) known about the SARs-CoV-2 virus, 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 to navigate these policy decisions is the focus of the next section of this paper.

1. No fully tested, safe, and effective COVID-19 vaccine is likely to be available to most oil and gas workers before Q2 2021.
2. Different vaccines, with varying levels of effectiveness, will become available at different times in different countries.
3. Vaccines will likely only provide partial immunity, limiting the severity of COVID-19, but not stopping the illness completely.
4. 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.
5. Healthy working-age staff and contractors who have a very low chance of serious complications or death from COVID-19, may have relatively limited benefit from a vaccine due to the above limitations of vaccine effectiveness, although long term health effects may warrant the need for vaccination.
6. 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 prioritized by governments.
7. Roll out 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.
8. Competition between countries to acquire vaccines through pre purchase contracts with manufacturers will limit availability of the vaccine in low- and middle-income countries.
9. 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.
10. 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.

Industry vaccine policy development

Globally, governments are planning risk-based strategies for in-country vaccine deployment. A cautious approach should be applied by companies when considering the use of vaccines, utilizing a science- and evidence-based approach for all recommendations. Medical ethics, efficacy/safety, racial and socioeconomic disparities, equitable access and distribution, and effective awareness campaigns will be key considerations in any company vaccine policy. Companies are encouraged to develop a robust global campaign for workforce education and awareness, vaccine evaluation and leverage on existing programs, 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 programs that distribute vaccines in a risk-based and equitable way, respecting an individual's right to choose not to be vaccinated against COVID-19 as much as possible 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 politicized decision making on vaccine approvals. The scientific threshold can be met when the vaccine in question is part of the approved COVAX⁴ portfolio endorsed by the WHO, or if several other reputable governing bodies in OECD countries⁵ 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.

Efficacy/safety

Before using a vaccine approved by national regulators the scientific details underpinning this approval need to be studied. Provisional approval is often based on limited evidence of vaccine efficacy and safety and the use of such higher risk vaccines therefore often only makes sense for those who have most to benefit from the vaccine such as frontline medical workers with high COVID exposure risk and those with significant vulnerabilities such as the elderly. Companies should:

- Study the impacts of ineffective vaccines on vaccine hesitancy and undermining vaccination programs. Early adoption of a vaccine that is not widely used might make it harder for people to accept it as safe.
- Look for opportunity presented by the large variability in COVID-19 vaccines. There are several promising vaccines using different methods of creating immunity that will likely benefit different age groups and possibly ethnicities in different ways.
- If effectiveness and safety have not been proven adequately for the demographic profile of a workforce being considered for vaccination, a cautious approach is advised.
- The potential consequence of taking one vaccine and then taking another later. 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.

Medical ethics related to vaccination programs:

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
- **Justice** - addresses equity of access. Can a vaccine program assure equity of access?

⁴ 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.

- **Personal autonomy** – personal choices to maintain health must be respected in line with local laws and regulations
- **Consenting before vaccinating** – 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 marginalized populations, especially those in low- and middle-income countries. Key considerations are:

- Distribution strategies to include plans for emergency and humanitarian use
- A prioritization framework for allocation should ensure a fair and standardized distribution, and promote solidarity and trust, protecting those who are most in need and fostering a sustainable system⁶

Understanding racial and socioeconomic disparities:

When designing and/or supporting a vaccination program, the racial and socioeconomic differences in society should be considered. There is evidence that COVID-19 results in disproportionate impact on marginalized and vulnerable populations, impacts due to pre-existing health conditions, and social stigma and psychological effects. Companies should consider:

- Holistic targeting of unintended social consequences (including the impacts of income, gender and socioeconomic status) will be needed
- Stronger and more resilient systems to address issues of health equity and access to care are needed
- Strategies for preventing disruption of existing mental and behavioral health services and increase in the capacity of telehealth services are essential

Health surveillance and vaccination:

For company run/sponsored vaccination programs, 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 consider:

- What safety surveillance will be required for rare adverse events (passive and active)?
- What is the impact of vaccines on the need to maintain current preventive barriers, such as physical distancing and mask wearing?
- What is the risk of a false sense of protection if the vaccine provides only partial immunity?

⁶ The WHO's '[Fair Allocation Mechanism for COVID-19 Vaccines](#)' and other prioritization guidelines based on population at greatest risk (healthcare workers, vulnerable groups), country need, vulnerability and COVID-19 threat provide a model for oil and gas companies.

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, leveraging effective social media and faith-based and existing community networks
- Leveraging lessons from other public health campaigns and health behavior change theories
- Delivery strategies, resources, and operational factors
- Addressing and integration with the healthcare infrastructure
- Improving acceptability and feasibility
- Addressing culture and local nuances