

IFMBE Clinical Engineering Division

Q&A Report – January 27th, 2021 Webinar on Vaccines

#	Question	Answer(s)
1	If the vaccines are safe, why are governments being asked to sign a document not to hold the manufacturer of the vaccine a legal accountability for any side effects? This is not a normal practice we hear about in other vaccines.	Rigorous clinical studies are now underway to determine the safety and efficacy of COVID-19 vaccines. As with all clinical studies, manufacturers' first priority is to ensure safety. COVID-19 vaccines will be authorized for use only when their safety and efficacy are demonstrated to regulatory authorities. But as with any drug or vaccine, there could be rare or unexpected cases of adverse events. Generally, side effects related to vaccines are usually mild, and severe side effects are extremely rare, with a rate of only 1-2 per million doses given (a per-person risk of 0.00005%). Even so, as the number of people vaccinated rises, so does the likelihood that some people could experience an adverse health event – whether actually related to vaccination or not. People may mistake normally occurring health problems for vaccine-related side effects. This risk is heightened with COVID-19, because of the many and varied medical complications it can cause.
2	How long will the immunity last? We hear some news that this is not clear.	Indeed, it is not clear yet. There are trials underway. What is already important to note is that the effectiveness at 90 or 95% is way above the acceptable threshold of 50% (Ref FDA)
3	Are all vaccines developed so far meeting the same standard?	Those C-19 vaccines that have been approved by FDA and EMA, as well as by the WHO meet the same standards and any other approved vaccine.
4	Hello, has anything changed after the position statement dated Oct 2019?	It is fortunate that the mRNA vaccines appear to be as effective as they are. However, it remains important each vaccine is well evaluated. This is evidenced by the recent withdrawal of Merck's vaccines from development. I hope I was able to lay out why we need to continue to properly understand the adenovirus and recombinant protein vaccines too. Also, early reports of mRNA vaccine efficacy in people receiving a single dose is 33%-52% so there is a lot we still need to understand about the vaccines.
5	Has the ECRI Institute been engaged in the activities of researchers at UC Irvine who are reportedly developing a Coronavirus vaccine that will reportedly be effective against all Coronavirus variants? https://www-latimes-com.cdna.ampproject.org/c/s/www.latimes.com/social/daily-pilot/entertainment/story/2021-01-13/uc-irvine-developing-vaccine-that-targets-all-coronaviruses?_amp=true	Try this link https://www.pcori.org/evidence-synthesis/horizon-scanning
6	What is your view of the UK decision to delay the 2nd dose of the Pizer one to 12 weeks	Yadin will answer this "live." Also, CDC has just published a specific interim guidance for the USA, allowing two novel permissions: interchange of the two mRNA brands for second shots, and extending the delay for the second shot. The CDC link is https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html
7	Does a vaccinated person can still transmit the virus to other people?	Early reports of mRNA vaccine efficacy in people receiving a single dose is 33%-52% so there is a lot we still need to understand about the vaccines. So please maintain social distancing until the pandemic is under better control.
8	What is the minimum efficacy standard (%) required for a vaccine to be considered safe?	Sorry not competent to respond – think this needs an epidemiologist or vaccine expert, not a humble engineer!
9	So interesting presentations! Jonathan Gave, it'll be appreciated receiving your comments/recommendations on using mechanical ventilators for personal use (vortran) which avoid the patient to use an ICU bed, Rossana Rivas. rivasperupucp@gmail.com	I'm sorry that I'm not personally familiar with the vortran device. I'll look for additional information and will respond to you by e-mail if you send me your e-mail address. My address is jgaev@ecri.org . In the USA we have been using BIPAP devices and high flow oxygen devices to avoid the use of ventilators.
10	Side effects, are all the cards on the table?	All of the vaccines are still being evaluated. In the US there is unprecedented live reporting and adverse event tracking through the VERS https://vaers.hhs.gov/data.html
11	What side effects does the vaccine have, long term wise? How are you planning to roll out the vaccine in South Africa as it a demand?	Long-Term safety and efficacy are not known since these are novel vaccine platforms. This article might help regarding the South African vaccine rollout https://www.bbc.com/news/world-africa-55675806
12	What are some examples of success strategies being deployed to tackle vaccine hesitancy esp in light of the massive infodemic overlying the pandemic?	I'm not sure there is data supporting specific programs as effective, but Smartphone applications to Manage vaccine communications and scheduling is promising https://www.pcori.org/evidence-synthesis/horizon-scanning/covid-19-scan-january-9-22-2021
13	What were 2 key-factors for UK government to achieve the regulatory approval on time? Nice presentation Dan!, Rossana Rivas	(1) rolling approval, and (2) resources -MHRA worked around the clock - literally!
14	A person already affected by Covid need a vaccine?	The CDC recommends that people previously infected should still be vaccinated. This might eventually change, or different guidance might be offered by different countries based on vaccine availability and distribution strategies as well as how our understanding of immune responses to natural infection evolves. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/facts.html#:~:text=Yes,already%20had%20COVID%2D19%20infection.
15	One of the attendees has pointed out that UNICEF has published a vaccine misinformation document.	Information is here: https://www.unicefusa.org/stories/unicefs-guide-fighting-misinformation-about-vaccines/38082 . The full document is here: https://www.unicef.org/mena/reports/vaccine-misinformation-management-field-guide
16	Also, CDC has just published a specific interim guidance for the USA, allowing two novel permissions: interchange of the two mRNA brands for second shots, and extending the delay for the second shot.	The CDC link is https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

Together we can make it better!

<https://ced.ifmb.org/>