Summary Report

Shot Callers: A Virtual Event on COVID-19 Vaccines

28 January 2021

With the release and authorisation of several COVID-19 vaccines over the past few months, there are still several questions that patients and civil society need to be answered.

As the leading voice of patient organisations in Europe, EPF decided to use its expertise and leverage its network to host an informative session with high level experts to provide crucial answers regarding the vaccines for COVID-19 vaccines.

The event "Shot Callers: A Virtual Event on COVID-19 Vaccines" was held on 28 January 2021, featuring EPF President Marco Greco, Prof. Jean-Michel Dogne, Committee Member of WHO Global Advisory Board on Vaccine Safety and Dr. Guido Rasi, former Executive Director of European Medicines Agency (EMA). The discussion was moderated by EPF Special Advisor Nicola Bedlington.

Below, you will find a summary of the most relevant questions and the answers from our prominent speakers.

You may also want to review our recently launched patient guide "Let's Talk About Vaccination" which is useful to anyone who wishes to strengthen their knowledge on vaccination and their confidence in having meaningful conversations about vaccination.

If you have the time, you may also want to watch the full recording of the Shot Callers event, found here.

What types of vaccines are currently being developed for COVID-19 and how do they work?

The COVID-19 vaccine is produced to provide immunity against COVID-19, meaning it will mimic the immune response by the humans to SARS-CoV-2. The European Commission authorized two vaccines so far, the Pfizer/BioNTech and the Moderna vaccines. These vaccines work via the novel mRNA. The delivery of the mRNA to the cells is achieved by a formulation of the mRNA into lipid nanoparticles which protect the mRNA transfer and help the absorption in the cells. Once the vaccine is injected, the mRNA instructs those cells to create the spike protein. No virus is involved, there is no adjuvant in this vaccine, and most importantly no genetic material enters the nucleus of the cell.

Prof. Jean-Michel Dogne
Member of WHO Global Advisory Committee on Vaccine Safety

Some people are concerned that mRNA is an untested and risky technology to be used so quickly for the mass public. How new is this technology?

Before the COVID-19 pandemic, no mRNA vaccine was ever licensed for use on humans. This is a new technology, but it has been studied in clinical trials and tested before in real life. The use of mRNA vaccines goes back to the early '90s, and mRNA vaccines for human use have been developed to treat diseases such as rabis and influenza.
In December 2020, UK's MHRA became the first global medicine regulator in history to approve a mRNA vaccine for human use, the Pfizer/BioNTech vaccine. Even if it is a new technology, it is based on world-based data, on efficacy and safety, under highly scrutinized clinical trials.

Prof. Jean-Michel Dogne
Member of WHO Global Advisory Committee on Vaccine Safety

Are mRNA vaccines considered safe for everyone?

Yes, mRNA vaccines are considered safe for everyone. They are classically associated with iatrogenic reactions: The most common one is pain at the injection site; fatigue and headache are others relatively common adverse events. High fever, however, is less common. These events are generally resolved within a couple of days and are more common between younger vaccines recipients.

The second doses are also associated with more adverse events than the first ones. There have been reports in post-marketing on vaccines recipients experiencing severe allergic reactions, for instance anaphylaxis, shortly after receiving the first doses. These events are rare. The administration of the vaccine includes periods of at least 15 minutes of observation after the vaccination, and if a person experiences a severe reaction after the first shot, they should not receive the second dose.

Prof. Jean-Michel Dogne
Member of WHO Global Advisory Committee on Vaccine Safety

Are there any precautions, for example, for certain people with chronic conditions (immunocompromised too)?

"We have one single absolute contraindication to the vaccine which is known hypersensitivity to the vaccine component. The CDC considers immunocompromised patients to be at increased risk for severe COVID-19, so it is true that there is limited data on immunocompromised people, and they may not respond as well to the vaccine, but it is also true that there are no particular safety concerns to expect from this population.

In conclusion, immunocompromised people can still be vaccinated as they may be at higher risk for COVID-19."

Prof. Jean-Michel Dogne
Member of WHO Global Advisory Committee on Vaccine Safety

What can we do to better protect particular groups who cannot be vaccinated, because of their condition?

"I would respond in two ways:
1) Protect yourself, avoid crowds, avoid poorly ventilated spaces, wash your hands often, and
2) Vaccinate as much and as quickly as possible so to hopefully generate herd immunity.

The aim is to achieve the immunity not via the infection but through the vaccination. It aims at lowering the overall amount of virus able to spread in the population and therefore keep the vulnerable population who can't be vaccinated safe and protected from the disease."

Prof. Jean-Michel Dogne
Member of WHO Global Advisory Committee on Vaccine Safety

The vaccines are approved based on their efficacy in preventing symptomatic COVID-19 – meaning that the individual who is vaccinated is less likely to get ill or have severe illness. However, it is not yet known if the vaccines also prevent transmission of the virus. What are your thoughts on this?

"The impact of the vaccination on the spread of the virus in the community is not yet known. Until we know that the vaccine protects from the asymptomatic infection, we should continue physical distancing, masking, avoiding crowds, and regular hand washing. Still, there are several good reasons to be optimistic about the vaccine effect on the disease's transmission. Some data shows that even after only one dose, the vaccine has protective effects in preventing asymptomatic infection, and secondly studies suggests that people with no symptoms or less symptoms are less likely to transmit the virus."

Prof. Jean-Michel Dogne
Member of WHO Global Advisory Committee on Vaccine Safety

What percentage of the population will need to be vaccinated before things can get back to 'normal?'

"The percentage of people that need to be vaccinated against COVID-19 to achieve herd immunity is not known accurately yet, especially since now we have new variants of the virus. Thanks to the available data, we know that vaccines with over 80% efficacy that grant long protection, herd immunity could be achieved with a coverage of 70% of the population and hopefully higher than that.

The time frame will depend on the vaccination rate of the different countries: No one is safe until everybody is safe. Many developers and many partnerships need to have a high coverage in different countries especially as today we have variants that develops in some geographical areas. We need to vaccinate as much as possible, as fast as possible, worldwide, and not only in some countries."

Prof. Jean-Michel Dogne
Member of WHO Global Advisory Committee on Vaccine Safety

New variants of the coronavirus have been reported across the world. Will the currently approved vaccines be effective against these variants?

"SARS-CoV-2 has many variants, and some are of particular interest. Indeed, when pharmaceutical industry develops the vaccines, they usually also test some linage to see if the vaccine produces neutralizing antibodies that will neutralize this variant as well. Current vaccines are designed around the earlier variants, and preliminary studies suggests that they could be protective against some of the variants than the others.

There are two major variants that we are discussing today, the so-called B117 (UK) and the B1351 (South Africa). We know that the mRNA vaccines work just as well against variant first detected in the UK, while they seem less protective against the South-African variant."

Prof. Jean-Michel Dogne
Member of WHO Global Advisory Committee on Vaccine Safety

Normally, the development of a vaccine takes several years. Can you explain how the EMA has been able to approve COVID-19 vaccines to quickly?

"The first and most important reason has been the availability of volunteers to be recruited in the clinical trials: Generally, the recruitment takes months, and in the case of an infectious disease you need to have this population exposed to the virus. The pandemic consented to have a high number of volunteers constantly exposed to the virus. It was easy to collect the data. Another reason is the incredible number of resources allocated to this initiative. If you allocate 10 people to build a bridge or if you allocate 1000 people to build the same bridge you can understand that the outcome and the speed of the construction will be very different – and that is what happened with the vaccine, also in terms of financial resources."

Prof. Guido Rasi
Former Executive Director of European Medicines Agency

Did EMA have different safety and efficacy requirements for COVID-19 vaccines compared to other vaccines and medicines?

In terms of the numbers and the magnitude of the study, it was much higher of all the vaccines that we have approved in the last 25 years. We never had 40 thousand volunteers per study in Phase 3 before. In May, we had a very important meeting with the FDA and other authorities worldwide, and we decided that we would not accept any studies without a proper, classical Phase 3. We also decided to not go below 50% efficacy. And as you know, we now enjoy two vaccines both with 90% efficacy.

Prof. Guido Rasi
Former Executive Director of European Medicines Agency

What can we know about the long-term effects of the vaccines?

Of course, we cannot predict everything, but we can extrapolate some predictions from other technologies. This is the first vaccine that uses mRNA technology, however, it is not the first medication that uses it. We already have cancer medicine that uses mRNA technology so we can have some observation on its effects on the long term. The data show us that the mRNA effect lasts too briefly to have concerns about long term.

For the other vaccines, we can say that all the technologies are quite well known and used, and we can be confident that there are not going to be any surprises in the long term. We cannot know yet if immunity will last but it is reassuring to see that every month we can see that the first people we enrolled in the trial studies seem to maintain the protection.

Prof. Guido Rasi
Former Executive Director of European Medicines Agency

How is the EMA monitoring the safety and efficacy of the COVID-19 vaccines?

We have the traditional pharmacovigilance that is imposed by the company, and we have an additional Safety Programme in cooperation with EMA and the ECDC. A lot of initiatives in the Member States are linked to the EMA's and the ECDC's work with the support of the European Commission.
In addition, EMA is very keen to maintain the conditional marketing authorization for each vaccine.

Prof. Guido Rasi
Former Executive Director of European Medicines Agency

Have the new vaccines been tested in enough diverse groups of people, for example old people and ethnic minorities?

"There are different vaccine uses for different population, and when the authorisation will be released, it will state clearly if there are restrictions or gaps of knowledge. Not all of the subgroups and not all the ethnic minorities have been studied, even if some of the studies have been held in different countries. It is a conditional market authorisation, which means that one of the requirements is to keep going to fill the knowledge gap in ethnic groups and minorities. This is to give the health authorities a tool so they know in which populations it can be used and the ones it cannot."

Prof. Guido Rasi
Former Executive Director of European Medicines Agency

What about possible issues linked to fertility and pregnancy?

"The concern for fertility was born mainly because when it was first authorized there was no information regarding effects on fertility. Now we have enough studies that confirm that there are no effects on fertility. When it was authorized first in the UK there was an initial recommendation to not use it in case of pregnancy and to wait for two months before getting pregnant after being vaccinated.

At the EU level we have also adapted based on the non-clinical data. Of course, there was limited experience with pregnant women because they were excluded from clinical trials, but animal studies do not indicate harmful or not harmful effects with respects with the vaccines on the fetal development."

Prof. Jean-Michel Dogne
Member of WHO Global Advisory Committee on Vaccine Safety

What should one do if one suspects an adverse reaction to a vaccine?

"There are many channels for a patient to flag a suspect adverse reaction. It can be reported to the doctor, and the doctor knows generally how to fill this data into the system. In some countries the channels are the pharmacies, or you can go directly in the EMA system. But the easiest way is to tell your doctor, and to avoid reporting it to more than one channel."

Prof. Guido Rasi
Former Executive Director of European Medicines Agency

What should one do if one suspects an adverse reaction to a vaccine?

Direct reporting from the patients is possible, so the data will be collected at the Member State level. Of course, if we want a more detailed report, it is better to have a report from a healthcare professional. Patients may also report directly to the pharmaceutical industry, and then the pharmaceutical industry has the obligation to report these events to the EMA. It is important to report any negative events that could be associated with the vaccine, and to report it in the system, while avoiding to not complain about it in the media.

Prof. Jean-Michel Dogne
Member of WHO Global Advisory Committee on Vaccine Safety

Some people are concerned that the EMA approves vaccines more slowly than other regulators. Why is that?

It is very important to consider when and which data are coming in. Let's take the example of the first vaccine approved, the Pfizer/BioNTech. It was approved in the US ten days before the EMA did, and it was submitted to the FDA ten days before it was submitted to the EMA. The same set of data was submitted with a ten-day gap. The timing in this case is a very good example of the perception vs. the reality: We used exactly the same time when we had the same three sets of data.

In contrast, the MHRA used an emergency use, which is a completely different setting. They authorized only one batch of data, the one that was used for the clinical trials, which means that was an already approved batch of vials, of vaccines. EMA must approve the same quality for the entire plan, from Finland to Cyprus you need to have the same quality of the vials. We do not use a single batch approval in an emergency use, it is a full approval. The MHRA took a risk, as it is in their capacity, they approved the vials in one day. I do not think this was a speed contest, and at the end of the day we use the same kind of data in the same time that is need for a very stringent authority such as the FDA.

Prof. Guido Rasi
Former Executive Director of European Medicines Agency