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Review Article

Misinformation and COVID Vaccine Hesitancy: The Viral Threat to COVID Vaccine Efficacy

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Abstract

Not long after the corona virus introduced itself in Wuhan, China, with all the subtlety and finesse of a bull in a China shop, efforts towards creating and distributing a vaccine reached fever pitch.

In fact, just a few months after the World Health Organization (WHO) declared COVID-19 a pandemic (on March 11, 2020), two major pharmaceutical and biotech giants: Pfizer (in partnership with BioNTech) and Moderna, Inc., announced their success following the primary efficacy analyses of their phase 3 COVID-19 vaccine trials.

Keywords: COVID-19; World Health Organization (WHO); Wuhan

Introduction

By mid-December of 2020, both Pfizer [1] and Moderna [2] received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA).

A few months later, another pharmaceutical company, Johnson and Johnson (J&J) also reported promising results from the phase 3 trials of their single dose vaccine, which by late February 2021 became the first single dose vaccine to receive EUA from the FDA [3].

All three of these vaccines have been authorized in several countries and are being actively distributed.

Frenzied efforts out of the US have yielded similar fruits including: Sputnik V, Sinovac, Gamaleya, Bharat-Biotech, and Oxford-AstraZeneca, all of which have received emergency use authorization. By March 11, 2021, there were 75 vaccines undergoing clinical trials, 21 of which were already at the final stages of trial [4].

However, all this effort from dedicated scientists and other stakeholders stands at risk of being for nought due to the sky high levels of vaccine hesitancy that exists whenever the COVID-19 vaccine is concerned.

In the wake of what are easily the most pivotal advancements in the fight against the novel corona virus, questions and doubts fueled by misinformation continue to persist among the general public particularly in developing countries where policy making somethings is based on sentiments and traditional beliefs instead of science and where social media stands to be the major source of information for the public. Vaccine hesitancy is rife among the same people who are most at risk of infection and whom the vaccines are meant to serve.

Vaccine hesitancy: definition and causes

Vaccine hesitancy refers to the refusal or delay in acceptance of vaccination despite the availability of vaccination services. Vaccine hesitancy is complex and context specific, varying across time, place, and vaccines. It is influenced by factors such as complacency, convenience, and confidence [5].

Complacency exists in situations where the perceived risks of vaccine-preventable diseases are low and therefore getting a vac-

cine just seems not that important. Ironically, complacency may sometimes be the product of past vaccine efficacy where a disease is no longer common and the population no longer deems it enough of a threat to go through the bother of getting vaccinated.

Convenience becomes a major issue when several factors like physical availability, willingness- to-pay, affordability, geographical accessibility, and the ability to understand the benefits of the vaccine affect the uptake. Cultural factors as well as contextual factors like time and location also determine whether or not people feel comfortable about getting a vaccine or not.

Confidence, as used in the definition for vaccine hesitancy, has to do with the amount of trust that the population has in:

- The effectiveness and safety of vaccines
- The system that develops, delivers, and distributes the vaccines, including the reliability and competence of health services and professionals
- The motivations of the policy-makers and stakeholders who make decisions concerning the vaccines.

Historically, all three of these factors have had a strong role to play in the continuing problem that is vaccine hesitancy. However, in the case of the COVID-19 pandemic people seem to throw a wary eye at anyone who mentions vaccines particularly because of the low confidence they have in the entire concept, be it safety, the development process, or the policy makers enforcing its distribution [6].

Social media, in particular has played the role of villain in this respect. The rise and subsequent sway of influencers among the population has been a bane for vaccination campaigns. There is still a significant section of the general population that either doesn't believe the corona virus exists or doesn't believe it is a credible threat to warrant the wearing of masks or taking a vaccine, because an influencer they identify with and trust said so. These influencers come from all works of life from politicians to athletes to actors, but seldom do they ever come from a scientific background sound enough to merit the level of seriousness with which their insights and beliefs are taken by their followers.

Differences in political rhetoric among the world's leading voices and as well as local politicians have left the general population divided as to whom to believe and follow. Populism and a blurring of the line between science and politics has meant that informed opinions from scientists at the front lines are often drowned out by the cacophony of rhetoric aimed at playing to the gallery and rousing specific emotions among the population often for political gains.

Cultural factors and age old practices in some communities are often factors that propagate hesitancy. A lot of the belief systems that animate the attitudes of local populations in developing countries are not science-backed, but still require extended periods of re-education in order for their stranglehold to loosen enough for locals to become comfortable with the thought of accepting vaccinations.

COVID-19 vaccines have become a victim of the speed with which they were produced

In order to better understand how COVID-19 vaccines have become a victim of their speed of production, it would suffice to examine the regular timeline for vaccine development.

Vaccine development is a long and complex process. Under normal circumstances, it could take anywhere from 10 to 15 years, and several testing stages before a vaccine is fully ready for authorized distribution among the human population [7].

However, thanks to dedicated effort from governments and scientists around the world, particularly Operation Warp Speed, a program the US government launched with the aim of delivering 300 million doses of a safe and effective COVID-19 vaccine by January 2021, pharmaceutical companies have been able to shrink this decade-long development timeline to a mere months.

This is a laudable achievement by any measure, but sadly one which has led to concerns among the general population that political motives are being considered ahead of the safety of the general public [6].

Other factors that have led to heightened hesitancy against COVID vaccines include:

- Conflicting opinions concerning the COVID vaccines from the healthcare community
- Historical distrust among certain groups among ethnic and racial populations due to healthcare discrimination, medical malpractice, and medical experimentation in the past

- Social factors like inequalities in education and income levels, as well as differences in employment and housing options

What everybody should know about the COVID vaccines in production

Vaccine hesitancy has been a mainstay of the immunization landscape since inception [8]. However, properly educating the general public about the COVID-19 vaccines, their makeup, their mode of operations, and how they were developed could go a long way towards easing some of the fears that persist.

One can reasonably expect that once it is clear beyond a doubt that, in spite of the reduced development timelines and prevailing political climate, the various vaccines are safe for distribution and use, the overall level of hesitancy would reduce.

Thus, by that token, there are a few important facts that ought to be made know as a prelude to every vaccination campaign.

How do the Moderna, Pfizer, and J&J vaccines compare with each other?

The Moderna [9] and Pfizer [10] vaccines are similar in that they are both messenger RNA vaccines or mRNA vaccines.

These are a new type of vaccine against infectious diseases, and the way they work consists in teaching your body cells how to make a protein or even part of a protein which triggers an immune response in our bodies. Most importantly, like all vaccines the benefits of mRNA vaccines lie in the fact that they lend protection without causing infection.

In the absence of any precautionary factors, both Morderna and Pfizer's vaccine are recommended for people aged 12 and above, and have an efficacy rate of 94.1% and 95% respectively.

The J&J vaccine, on the other hand, is a viral vector vaccine [11]. These are vaccines that use a modified version of another virus (called a vector) to deliver important information to our cells.

Like all vaccines, viral-vector vaccines lend protection without infecting the recipient.

J&J actually have a history of using viral vector vaccines to great effect. For example, their initial dose of Ebola vaccine used viral vector technology and became the first FDA approved vaccine for the prevention of Ebola virus disease.

The J&J vaccine was shown to be 66.3% effective in clinical trials, and has a high efficacy at preventing hospitalization and death in those who do take it but still get sick. No one who contracted COVID-19 at least 4 weeks following the J&J vaccine needed to be hospitalized [11].

In the absence of any precautionary factors, the J&J vaccine is recommended for individuals older than 18 and older.

How do mRNA vaccines work?

The first thing to understand about mRNA vaccines is that they are a relatively new addition to the pharmaceutical and biotech landscape. Engineering challenges prevented the concept from ever producing much quantifiable success in the production of vaccines—until today.

Today, mRNA vaccines are here to stay, ushering new and exciting ways in which we can protect ourselves against infection.

mRNA vaccines are different from regular vaccines primarily in the way that they operate or go about their business. Traditionally, vaccines put an inactivated or weakened Germ into our bodies in order to trigger an immune response. mRNA vaccines instead teach our cells how to produce a protein or part of a protein that triggers and immune response in our bodies.

It is this immune response that produces the antibodies that protect us from getting infected if a virus enters our bodies.

Particularly, the Pfizer and Moderna vaccines are COVID-19 mRNA vaccines. And this is the non-techy version of how they work:

These vaccines are designed to give instructions to our cells to make a harmless piece of what is called a "spike protein". Normally, spike protein is found on the surface of the virus that causes COVID-19.

The following happens when you go for a COVID-19 mRNA shot:

- First of all, COVID-19 mRNA vaccines are given in the upper arm muscle. Once the vaccine passes the protein-making instructions on to the immune cells through the mRNA, the cells use the information to make the spike protein pieces.
- Once the protein piece is made, the cell breaks down the mRNA and gets rid of them.

- Next, the cell displays the manufactured spike protein on its surface. Your immune system recognizes the protein as something foreign and starts building an immune response by making antibodies—which is what happens when a natural infection of COVID-19 takes place.
- By the end of the process, your body would have learned how to respond against any future infection, making you essentially safe against COVID-19. At no time during the entire process are you, the receiver, ever at risk of getting infected with COVID-19.

In the fight against hesitancy for the Pfizer and Moderna vaccines, stakeholders and healthcare professionals must make the following clear to the general public:

- Both vaccines cannot infect you with COVID-19 because they do not use the live virus that causes COVID-19
- Both vaccines do not affect or interact with our DNA (genetic material) in any way. The mRNA never enters the nucleus of the cells which is where our DNA is stored.
- The cell breaks down the mRNA and gets rid of them soon after it is finished using the protein-making instructions they provide [12].

How do viral-vector vaccines work

Viral-vector vaccines use a modified version of another virus called a vector to deliver important instructions to our cells. They have been in use for several decades and are more stable and less expensive to manufacture than mRNA vaccines.

The use of a virus as a vector to transmit information and instructions is the main difference between viral vector vaccines and mRNA vaccines.

Particularly, J&J's viral vector vaccine:

- Uses a vector (not the virus that causes COVID-19, but another harmless virus to deliver important instructions to our cells. This modified virus enters a cell in your body and uses the mechanism of that cell to produce a harmless piece of spike protein—a type of protein found on the surface of the virus that causes COVID-19. It is worth noting this viral vector used is modified to be incapable of replication therefore it cannot infect whoever is receiving the vaccine.
- Next, the cell displays the spike protein on its surface. Your immune systems recognizes this protein as foreign, and triggers an immune response, creating antibodies and activating other immune cells to fight off what it thinks is real infection.
- By the end of the process, your body would have learned how to respond to and protect you against any infection with the virus that causes COVID-19. J&J's viral vector vaccine, like other vaccines, lends protection without the risk of contracting COVID-19. Any discomfort that comes after taking the vaccine is a normal part of the process and actually indicates that the vaccine is working as it should.

Efforts aimed at reducing hesitancy against J&J's COVID-19 vaccines need to emphasize the following when communicating with the general public:

- J&J's viral vector COVID-19 vaccines cannot give anyone COVID-19 or other infections.
- The viral vector does not affect or interact with our DNA at all. The genetic material that is delivered by the vector does not integrate into a person's DNA or genetic material.

Can you contract COVID-19 by using the three vaccines above?

None of the vaccines from Pfizer, Moderna, and J&J are capable of infecting recipients with COVID-19 because none of them uses the virus that causes COVID-19 in their operation [12,13].

How were studies conducted and what data exists?

By phase III of a vaccine trial, the product gets tested among large human population samples. For both Pfizer [14] and Moderna [15], phase III trials were:

- Randomized, meaning that participants or the members of the population sample were chosen randomly
- Placebo controlled, meaning that some among the participants of the trial received the vaccine, while others received a placebo—saline solution, in this case
- Observer blinded, meaning that researchers and observers were unaware of who among the sample population was receiving the vaccine and who was receiving the placebo.
- 1:1, meaning that each participant in the study received one dose of vaccine or one dose of the placebo product.

Predetermined vaccine dosage during the trial was 30 μg for Pfizer and 100 μg for Moderna. Both vaccines require 2 doses de-

livered 3 weeks apart in the case of Pfizer, and 4 weeks apart in the case of Moderna.

The primary aim of the phase III trials for Pfizer was to confirm the efficacy of their vaccine against confirmed COVID-19 cases as soon as 7 days after taking the vaccine. The second primary aim was to verify the efficacy in the patients with or without evidence of prior infection. The secondary aim was to test the efficacy of the vaccine against severe COVID-19 [14].

For the Moderna phase III trials, the primary aim was to evaluate the safety of their vaccine and to determine its efficacy at preventing symptomatic COVID-19 after two doses. Its secondary goals were to study whether the vaccine can prevent severe COVID-19 or lab confirmed COVID-19 whether or not symptomatic or not, and also to verify whether the vaccine could prevent death caused by COVID-19 [15].

In both these studies, researchers began evaluating participants after a set number of days (7 days for Pfizer, and 14 for Moderna). Whenever a patient developed symptoms of disease and tested positive for COVID-19, researchers referred from the trial records to determine if that participant had received a vaccine dose or a placebo.

In the case of Johnson and Johnson, their phase III trials were randomized, placebo-controlled, and double blinded. A double blinded study is one in which neither the researchers nor the participants know or are aware of crucial aspects of the study like hypothesis, expectations, allocation of subjects to experimental groups, and so on.

J&J's phase III trials had combined endpoints or goals, which was to study the efficacy of their vaccine against moderate and severe COVID-19. Enrolled participants of the study received a single dose of vaccine, after which evaluation of participants occurred 14 days and 28 days afterwards [16].

All these trials were a major success in that the products went on to receive FDA authorization. However, while Pfizer [14] and Moderna [17] have formally published the data from their phase III trials, J&J is yet to do same although details from their trials can be found in press releases.

Who analyzes the data from these vaccines?

An independent Data and Safety Monitoring Board is in charge of evaluating the safety and efficacy of vaccine trials. Members of this board are not owners of the company or participants of the trials under review—and this important because a conflict of interest arises when supervisors have vested interest in the products under review.

What is emergency use authorization

One of the things which the general population finds most concerning is the speed with which vaccines from Pfizer, Moderna, and J&J got authorization. Many people are yet to wrap their heads around what Emergency Use Authorization (EUA) is and why it was used in these cases.

The first thing to note is that EUA is not the same as an FDA approval. Rather, it is a tool which allows the unapproved use of medical products to diagnose, treat, or prevent serious life threatening diseases in times of emergency, given that no other alternatives are available.

In other words, it is a strictly monitored tool used by the authorities to quickly get ahead of a health crisis and save lives.

The FDA has provided guidelines for the development and licensure of COVID-19 vaccines, [18] and one of the requirements is "direct evidence of vaccine safety and efficacy in protecting humans from SARS-CoV-2 infection and/or clinical disease".

Which vaccine is most effective?

It would be a disservice to compare the three vaccines based on the numbers and data presented from their phase III trials, because all three trials had different endpoints or goals.

For example, J&J evaluated how effectively their vaccine prevented combined endpoints of moderate and severe COVID-19, while Pfizer evaluated how effectively their vaccines prevented symptomatic COVID-19.

However, all three vaccines have been proven to be effective at stimulating antibody production and inducing T-cell activity against the virus responsible for COVID-19.

Are there any side effects of COVID-19 vaccines?

The most common side effects that have been reported include:

- Injection site reactions like pain, swelling, and redness
- Fatigue
- Headache
- Muscle and joint pain

There have been a few cases of nausea.

Extremely rare cases of anaphylactic (allergic) reaction have occurred among recipients of Moderna's vaccine (2.5 cases per 1 million), Pfizer (4.7 cases per 1 million), and J&J (2 cases total as of Feb 26, 2021). And in most cases, these episodes have involved individuals with a history of severe allergic reactions.

Regrettable as these side effects are, it should be noted that they are signs of efficacy rather than signs of the vaccine being unsafe. No serious long term side effects have been reported yet, even as researchers continue to monitor the administration of the vaccine.

What are the key differences between the various vaccines mentioned above?

- **Viral-Vector Vaccines Are More Stable than mRNA Vaccines:** RNA by nature is unstable, and that has made it very difficult to effectively use them in vaccines. Most cells even have a mechanism that destroys RNA, so sophisticated bioengineering is required to create effective mRNA vaccines. In the case of Pfizer and Moderna's vaccine, the mRNA is coated in a lipid nanoparticle to ensure it gets to its destination safely.
- Viral vectors on the other hand have DNA which is environmentally stable and also protected naturally by the vector. As such viral-vector vaccines like that from J&J can be stored by simple refrigeration.
- **mRNA Vaccines Are Harder to Store than Viral-Vector Vaccines:** Unlike viral-vector vaccines like J&J's that can be stored at regular refrigeration temperatures because they are stable, mRNA vaccines require ultra-low temperatures up to about -80°C in order to be stored.
- Pfizer's vaccine requires, for example, requires storage temperatures of about -70°C— which poses a challenge for many healthcare facilities. So, Pfizer has designed its own packaging which uses dry ice to maintain low enough temperatures to keep their vaccines valid for a few weeks in the absence of specialized freezers.
- Moderna's vaccine also needs ultra-low temperatures for storage, but they have announced that their vaccine can remain viable for up to 6 months when stored at -20°C and up to 30 days at regular refrigeration temperatures of 2-8°C. This increased durability is most likely due to the structure of the lipid nanoparticle coating Moderna used in development.
- **Viral-Vector Vaccines Cost Less to Make than mRNA Vaccines:** Viral-vector vaccines are less expensive to manufacture than their mRNA counterparts; a factor which, when coupled with single dose administration, will favour J&J when considering cost of global supply.
- **mRNA Vaccines Can Be More Quickly Produced than Viral-Vector Vaccines:** mRNA vaccines are much easier to produce than viral-vector vaccines—a factor that has undoubtedly helped in their rapid deployment during this pandemic. Their ease of production is due to the fact that they are almost entirely synthetic. All that is needed is a genetic sequence of the desired protein and delivery platform. There's no need for live viruses, cultures, eggs, or bioreactors.

Conclusion

In light of the persistent reality that is hesitancy against vaccines and COVID 19 vaccines in particular, information—specifically, the right information—continues to be our best weapon. Healthcare professionals, politicians, and other stakeholders with a public voice and credible influence need to be made acutely aware of the risks that come with vaccine hesitancy, and urged to make a commitment towards spreading the verifiable truth about vaccines, how they are developed, and how they work as well as emphasize on the fact that vaccinated individuals will be protected from severe illness.

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