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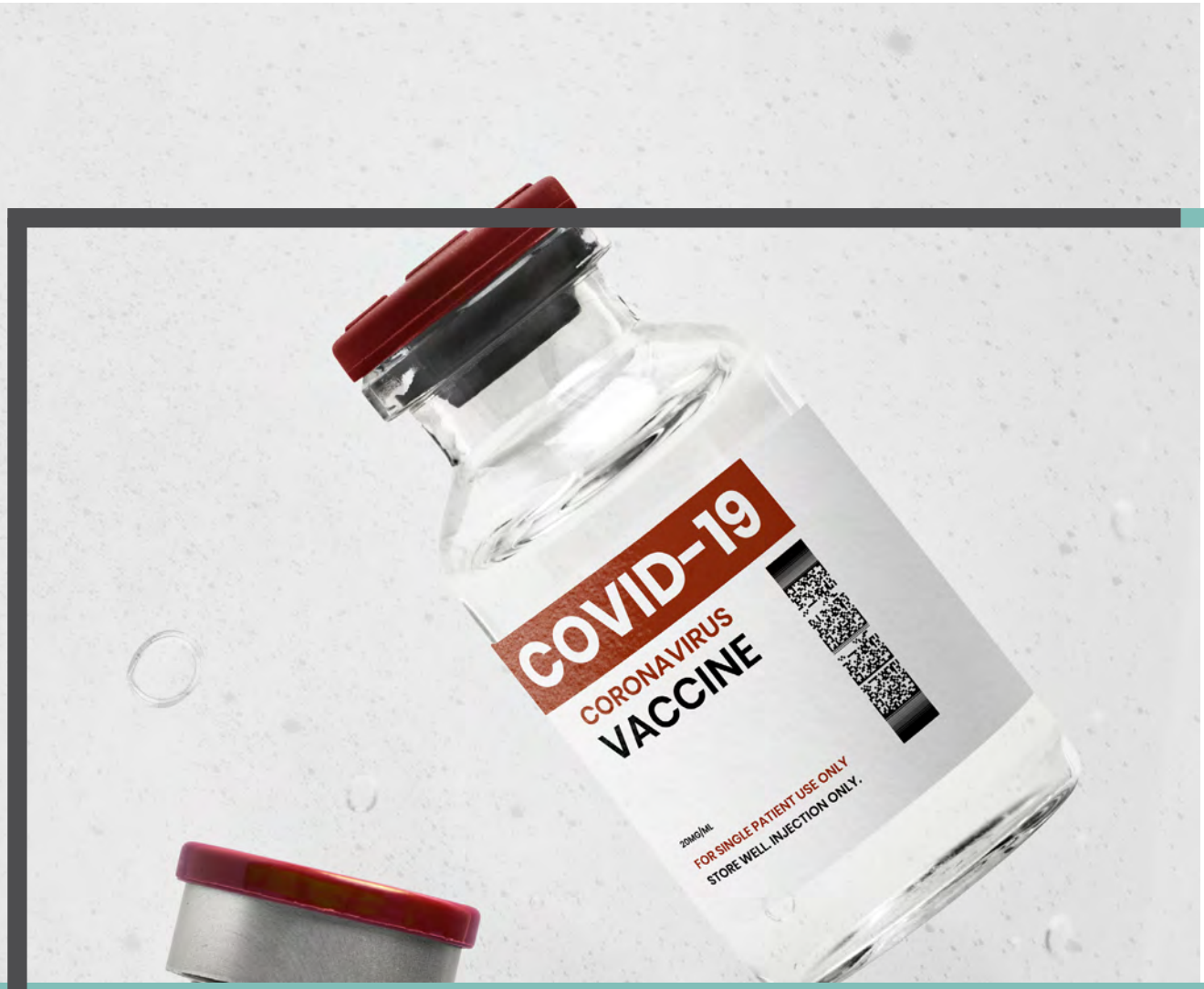
A CLOSER LOOK AT COVID-19 VACCINES: THE KNOWN, THE UNKNOWN, AND THE UNCERTAIN



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AIM

Since its onset in December 2019, the COVID-19 pandemic has disrupted the world, with a heavy toll on human lives and economic activities. The COVID-19 pandemic is believed to be the largest global public health crisis in a century (UNFPA, 2020) and has been described as the greatest challenge experienced since World War Two (UNDP, 2020). As a result, rapid development of an effective and safe vaccine became a global imperative. After an unconventionally expedited production track, COVID-19 vaccines have arrived, and with them the biggest vaccination campaign in history has begun. As of February 9th, 2021, more than 134 million vaccine doses in 73 countries have been administered (Bloomberg, 2021). In Lebanon, the first batch of COVID-19 vaccines is expected to arrive during the first half of February 2021. Preparations are underway for optimal vaccine deployment. The plan includes details on set priority groups, deployment centers, and other related instructions (MOPH, 2021).

Despite the societal upheaval the pandemic has triggered, and the hopes built on the COVID-19 vaccines, considerable vaccine hesitancy has been witnessed. A study from Arab countries reported that the general public acceptance rate for COVID-19 vaccines was only 29.4% (Sallam et al., 2021). In Lebanon, based on the results of an unpublished study employing social media surveys, a substantial proportion (79%) of the Lebanese population has shown hesitancy towards the COVID-19 vaccines (Halabi et al., submitted article). Both conspiracy theories (Ball & Maxmen, 2020) and misinformation (Lockyer et al, 2020) lie at the very base of vaccine hesitancy. Additionally, considerable ambiguity remains in relation to different aspects and characteristic of COVID-19 vaccines.

The aim of this product is to present the latest evidence on COVID-19 vaccines. The aim is not to advocate for or against COVID-19 vaccines in general or a specific COVID-19 vaccine, but rather to present the known, the unknown, and the uncertain. Information in this product can also serve as a base for informational campaigns, thereby promoting mindful and informed decision-making. The evidence presented in this product is based on the evidence available by February 10, 2021.

COVID-19 VACCINES AVAILABLE FOR PUBLIC USE

Until February 2nd 2021, 63 candidate vaccines are undergoing clinical evaluation with 177 other candidate vaccines in the preclinical evaluation phase (WHO, 2020). A summary of characteristics of vaccines in public use is presented in the Table 1 (WHO, 2020; Observer, 2020; BBC, 2021; Reuters, 2020a; Fierce Pharma, 2020; FDA, 2020b; FDA, 2020c, Zhang et al., 2020; Zhu et al., 2020; Xia et al., 2020; Logunov et al., 2021). Further details related to indication, administration, efficacy, and safety of vaccine are presented in the following sections of this product.

SELECTION PROCESS

A comprehensive search of the literature was undertaken to identify articles focusing on the topic of COVID-19 vaccines. Search strategy consisted of reviewing the following databases: Medline/Pubmed (MeSH term: Coronavirus Infections and Viral Vaccines; keywords: COVID-19 vaccine, coronavirus vaccine), IMEMR (keywords: COVID-19 vaccine, coronavirus vaccine), Health Evidence (keywords: COVID-19 vaccine, coronavirus vaccine), and Embase (keywords: COVID-19 vaccine, coronavirus vaccine). In addition, data retrieved from grey literature websites including WHO, FDA, CDC, clinical trials, websites of professional groups, media websites, and others were included. Articles and data sources included in this product where those that focused on COVID-19 vaccine characteristics including efficacy, safety, indications, and administration. Handsearching was also performed with two objectives: 1) searching for supporting data and 2) conducting fine searches. As a result of this methodology, 84 articles and data sources were included in this product.

Table 1: COVID-19 Vaccines Available for Public Use

COVID-19 Vaccine developer/ manufacturer (Country)	Vaccine Platform	Number, Route, & Timing of doses	Storage	Indications
Pfizer-BioNTech (USA)	mRNA	2 IM doses separated by 21 days	-70oC for 6 months and 2-5oC for up to 5 days	16 years of age and older
Moderna (USA)	mRNA	2 IM doses separated by 28 days	-20oC for 6 months and 2-8oC for 30 days	18 years of age and older
AstraZeneca-Oxford (UK)	Non-Replicating Viral Vector Adenoviral vector-based platform	2 IM doses separated by 29 days	Standard refrigeration 2-8oC	18 years of age and older
Sinovac Biotech (China)	Inactivated	2 IM doses separated by 14 days or 28 days	Standard refrigeration 2-8oC	18 years of age and older
Gamaleya Sputnik (Russia)	Non-Replicating Viral Vector Adenoviral vector-based platform	2 IM doses separated by 21 days	Standard refrigeration 2-8oC	18 years of age and older
CanSino Biologics (China)	Non-Replicating Viral Vector Adenoviral vector-based platform	1 IM injection	Standard refrigeration 2-8oC	18 years of age and older
Sinopharm (China)	Inactivated	2 IM doses separated by 21 days	Standard refrigeration 2-8oC	18 years of age and older

COVID-19 Vaccine developer/ manufacturer (Country)	Claimed Efficacy (Type of trial)	Common Side Effects	Approximate Price
Pfizer-BioNTech (USA)	95%* (Phase 3)	Pain at the injection site, tiredness, headache, muscle pain, chills, joint pain, and fever	20$ per dose
Moderna (USA)	94.1% (Phase 3)	Pain at the injection site, tiredness, headache, muscle pain, chills, joint pain, swollen lymph nodes in the same arm as the injection, nausea and vomiting, and fever	33$ per dose
AstraZeneca-Oxford (UK)	70.4% (Phase 3)	Pain at the injection site, fatigue, headache, muscle ache, malaise, feverish, chills, joint pain; reported for participants who received 2 doses of vaccine; adverse events were less frequent in older adults	4$ per dose
Sinovac Biotech (China)	50.4-91.75% (Phase ½)	Pain at the injection site No serious adverse events and no common adverse events at ≥ 25% prevalence	30$ per dose
Gamaleya Sputnik (Russia)	91.6% (Phase 3)	Pain at the injection site, changes in laboratory variables, hyperthermia, headache, asthenia, muscle or joint pain, palpitation	7.5$ per dose
CanSino Biologics (China)	Not reported	Pain at the injection site, fatigue, fever, headache	Not reported
Sinopharm (China)	79-86%* (Phase 1/2)	No reported local side effects, no serious side effects, and no common adverse events at ≥ 25% prevalence	72.5$ per dose

* For more details, check section titled 'Alterations and Concerns Regarding Reported Efficacy'

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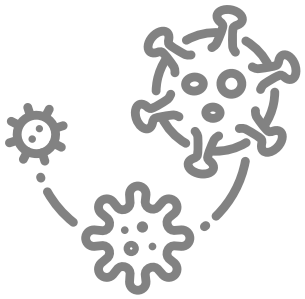


EFFICACY OF COVID-19 VACCINES

DELINEATION OF THE CONCEPT OF EFFICACY

Phase 3 vaccine trials are designed to assess individual-level efficacy and safety. These trials typically focus on the endpoint of laboratory confirmed, symptomatic disease to capture the direct benefit of the vaccine and form the basis for regulatory decisions. However, a safe and effective vaccine could help to protect communities in two distinct ways (Lipstich & Dean, 2020):

Direct Protection

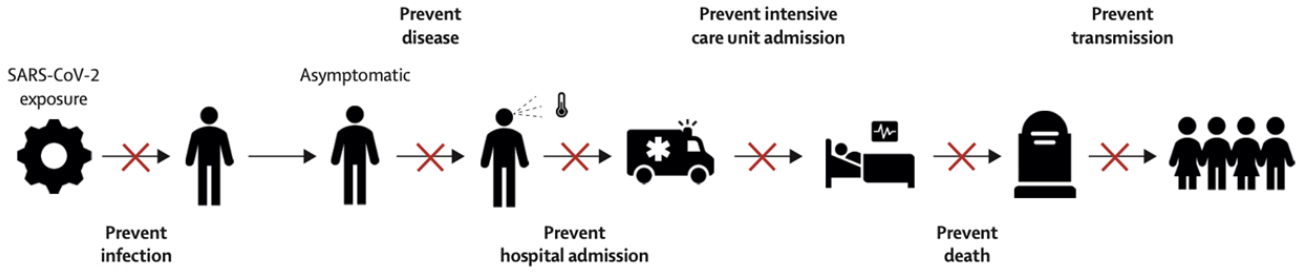
- High-risk groups are vaccinated to prevent disease
- Ability of vaccine to protect high-risk groups can be measured

Indirect Protection

- Those in contact with high-risk individuals are vaccinated to reduce transmission
- Assessment of the ability of a vaccine to protect high-risk groups is challenging

In addition, a candidate vaccine against COVID-19 might act to protect from infection, disease, or death. As such, a vaccine capable of reducing any of these elements could contribute to disease control. Vaccines that act to reduce the transmissibility of COVID-19, are valuable interventions at the population level (Hodgson et al., 2020).

With the AstraZeneca-Oxford vaccine, the overall number of cases of any positive PCR was reduced by 67% after a single dose, suggesting the potential for a substantial reduction in transmission (Voysey et al., 2021).



Adopted from Hodgson et al., 2020

ALTERATIONS AND CONCERNS REGARDING REPORTED EFFICACY

Initial reports of COVID-19 vaccines efficacy have been very promising, with a significant number of vaccines reporting efficacies above 90% (Table 1), much higher than the 50% cutoff needed for authorization (FDA, 2020a). However, with vaccine rollout, there has been changes in some of the reported vaccine efficacies, while concerns were raised with others, as summarized in the table below. It should be noted here that more accurate information will be hopefully revealed in the future from real-life phase 4 or long-term observational studies.

Table 2: Alterations and Concerns Regarding Reported Efficacy

Sinovac	Interim data from late-stage phase 3 trials in various countries (BBC, 2021): • Turkey reported 91.25% efficacy • Indonesia reported 65.3% efficacy • Brazil initially claimed that was 78% effective, but in January 2021 revised the figure to 50.4% after including more data in their calculations The efficacy of the Sinovac vaccine have been viewed with some skepticism as results were published via press releases rather than a peer-reviewed data, which makes it difficult to assess validity of results (BBC, 2021).
Sinopharm	• Announced on December 30th that phase 3 trials of the vaccine revealed an efficacy of 79% • The United Arab Emirates reported that the vaccine was 86% efficacious, according to interim results of its phase 3 trial (BBC, 2021).
Gemalya Sputnik V	Before publishing the results of phase 3 trials, the journey of the Sputnik V vaccine was characterized by concern due to the lack of transparency on the results of preclinical and clinical trials (Balakrishnan, 2020; Bucci et al., 2020). Premature approval, granted before the initiation of phase 3 trials or the dissemination of the results of earlier stage trials was believed to entail numerous risks (Burki, 2020; Caddy, 2020).
Pfizer-BioNtech	Concerns of inappropriate trial statistical calculation through: • Ignoring of suspected cases of COVID-19 • Excluding more patients due to major protocol deviation in the vaccine group as compared to control group As per an opinion article, this may have resulted in heightened efficacy results. Also, according to the article, a rough estimate of vaccine efficacy against developing COVID-19 symptoms would be a relative risk reduction of 19-29%, which is far below the 50% effectiveness threshold for authorization (Doshi, 2021).
AstraZeneca-Oxford	The German government challenged the efficacy reports of the Oxford-AstraZeneca vaccine for older people, stating that the efficacy may be below 10% for this population (The Guardian, 2021).

TIMING OF PROTECTION

The exact timing of protection initiation post-COVID-19 vaccine is still uncertain. Despite evidence of protection as early as 12 days with the Pfizer-BioNtech vaccine (Polack et al., 2020) and 14 days with the Moderna vaccine (Baden et al., 2021), the general understanding is that it takes few weeks for the immune system to respond to the vaccine and provide protection against the infectious disease (CDC, 2021a).

DURATION OF PROTECTION

The duration of protection of COVID-19 vaccine is still yet to be determined. Preliminary evidence suggests waning antibody titers in those who have recovered from COVID-19 infection (Ward et al, 2020). Early data from the Moderna vaccine suggested that neutralizing antibodies persisted for around 4 months with titers declining slightly over time (Jackson et al., 2020). However, effectiveness and duration of protection are to be identified following vaccination in real-life settings.

Antibodies are protective proteins produced by the immune system in response to the presence of a foreign body or a vaccine.

PROTECTION AGAINST THE NEW COVID-19 VARIANTS

With the emergence of new variants of COVID-19, the scientific community was reassured that since vaccines produce polyclonal antibodies that target several parts of the spike protein, the virus would likely need to accumulate multiple mutations to evade immunity induced by vaccines or by natural infection (CDC, 2020a). However, more recently, there is growing concern that some coronavirus variants could eventually evade immune responses triggered by vaccines and previous infections (Callaway, 2021). In addition, some preliminary studies suggest that some vaccines may be more protective against some of the strains than others (Shi et al., 2021; Wibmer et al., 2021; Wang et al., 2021).

SUBGROUPS VACCINE EFFICACY

Phase 3 vaccine trials are designed to assess individual-level efficacy and safety. Despite that some subgroup differences were noted in phase 3 COVID-19 vaccines trials, inferences cannot be made with confidence. Of particular interest are the high-risk subgroups, such as the older population. One way to address efficacy in this population is by setting minimum enrollment targets for older adults (Lipstich & Dean, 2020). As revealed below, reviewing the baseline characteristics of participants in three phase 3 trials, it was noted that there was substantial variation in the proportion of older population participation.

Moderna	Pfizer-BioNtech	AstraZeneca-Oxford
25% of trial participants were older than 65 years (Baden, 2021)	42% of trial participants were older than 55 years (Polack et al., 2020)	4% of trial participants were older than 69 years (Voysey, 2020)

Thus, to assess efficacy with some degree of certainty, high-risk groups, i.e., those for whom the vaccine is primarily designed to protect, should be well represented in any vaccine trial. Post-approval observational studies should also ensure significant inclusion of the older population. Similarly, conclusions cannot be drawn with confidence for other sub-groups such as pregnant women and the immunocompromised unless satisfactory participation in clinical trials is guaranteed.

02

SAFETY OF COVID-19 VACCINES

COMMON ADVERSE EFFECTS

The scientific literature has been generally reassuring regarding serious side effects of COVID-19 vaccines. The vast majority of side effects of COVID-19 vaccines are comparable to those of other well-known vaccines. These typically occur in the first few days post vaccination and include local reactions, fever, headache, muscle pains, and fatigue (Table 1).

SERIOUS SIDE EFFECTS OF COVID-19 VACCINES

A number of concerns have been raised of other more serious side effects. Some associations were denied, while others need more time and further studies to determine causal associations. A summary of safety findings is presented below:

- Bell's palsy was reported more frequently in mRNA vaccine recipients than in controls, but there was not a sufficiently large number of cases to conclude that this was beyond what would naturally be observed in populations of this size by chance (CDC, 2020c).
- No increased occurrence of Guillain-Barre syndrome was detected (CDC, 2020c).
- Three cases of transverse myelitis occurred following vaccination with the AstraZeneca-Oxford vaccine, one of which occurred 14 days after the second dose while the two other cases were considered to be unlikely related to the vaccine (Knoll et al, 2021).
- No association has been proven yet with immune enhancement (Flanagan et al., 2020) or female fertility problems (WebMD, 2021), despite ongoing deliberations.

- Bell's palsy is a condition that causes temporary weakness or paralysis of the muscles in the face.
- Guillain-Barre and transverse myelitis are autoimmune neurological diseases resulting in weakness.
- Immune enhancement, also known as immune backfiring, occurs when components of the immune system that usually protect against viral infections end up backfiring.

ALLERGY AND ANAPHYLAXIS

The rates of anaphylaxis (severe allergic reaction) were 5 cases per million with the Pfizer-BioNtech vaccine and 2.8 cases per million with the Moderna vaccine (Reuters, 2021b).

Anaphylaxis is a serious allergic reaction to a trigger that results in symptoms including rash, facial swelling, dizziness, and difficulty breathing.

DEATH OUTCOME

The most important efficacy endpoint, protection against severe disease and death, is difficult to assess in phase 3 clinical trials (Hodgson et al., 2020). So far, it is still unknown whether any of the developed vaccines confers protection against COVID-19 mortality. On the other hand, there were reports of about 30 deaths in over 40,000 elderly individuals in Norway vaccinated with the Pfizer-BioNTech vaccine. The deaths were recorded among very frail patients, including some who were anticipated to only have weeks or months to live. The deaths were associated with fever, nausea and diarrhea (TGA, 2021), which are common side effects of the vaccine. This report questioned whether the Pfizer-BioNtech vaccine is an appropriate choice for the elderly, very frail patients.

NEED FOR LONG-TERM SAFETY DATA

Previous experience with other vaccines has taught us that despite their very low frequency, some side effects can be major while others might happen several months post-vaccination. Examples of such reactions are presented below (WHO, 2010; WHO, 2004; WHO, 2003; WHO, 2005; WHO, 2009):

Table 3: Serious and Long-Term Side Effects of Common Vaccines

Vaccine	Reaction	Onset interval	Frequency per dose given
BCG	Fatal dissemination of BCG infection	1-12 months	0.19-1.56/1,000,000
OPV	Vaccine associated paralytic poliomyelitis	4-30 days	2-4/1,000,000
DTwP	Prolonged crying and seizures	0-24 hours	< 1/100
	HHE	0-24 hours	< 1/1,000 – 2/1,000
Measles	Febrile seizures	6-12 days	1/3,000
	Thrombocytopenia	15-35 days	1/30,000

BCG: Bacillus Calmette-Guérin (vaccine against Tuberculosis)
OPV: Oral Polio Vaccine
DTwP: Diphtheria, Tetanus, whole cell inactivated Pertussis
HHE: Hypotonoic Hyporesponsive Episode

Given the novelty of the COVID-19 vaccines and in the absence of long-term follow-up data, the probability of long-term adverse effects, despite likely to be low, cannot be nulled.

CONCERNS REGARDING TECHNOLOGY USED

Safety concerns have been raised regarding some of the technologies used for the development of COVID-19 vaccines, namely the use of adenovirus-vectored vaccines and mRNA. The currently available knowledge on these subjects is summarized below.

Use of Adenovirus-vectored Vaccines

Some vaccines rely on using an adenoviral vector to deliver a DNA molecule that encodes the COVID-19 spike protein. Vaccines which have adopted this technology include the vaccines produced by CanSino, AstraZeneca-Oxford, and Gamaleya. Despite the reported efficacy and safety of several recombinant adenovirus vaccines (Zhu et al., 2020; Voysey et al., 2020), there has been some fears regarding their use. These concerns date back to around a decade ago, when two phase 2b studies evaluated an adenovirus type-5 Ad5 vectored HIV-1 vaccine administered in three immunisations for efficacy against HIV-1 acquisition (Buchbinder et al., 2008; Gray et al., 2011). Both international studies found an increased risk of HIV-1 acquisition among vaccinated men (Buchbinder et al., 2008; Moodie et al., 2015). However, this remains a controversial issue as other studies have provided alternative explanations for the increased incidence of HIV positivity among vaccine recepients (D'Souza & Frahm, 2010).

Use of mRNA Vaccines

Fears of incorporation of genetic material into the DNA of the vaccine recipient has been recently voiced with the use of the mRNA technology for vaccine development. mRNA vaccines targeting infectious agents such as flu, Zika, rabies, and cytomegalovirus (CDC, 2020b) as well as non-infectious diseases such as cancer (Wellcome, 2021) have been previously studied. However, The Pfizer-BioNTech and Moderna vaccines are the first RNA vaccines ever to be approved for use against any disease (Wellcome, 2021).

mRNA from the vaccine does not enter the nucleus of the cell, and thereby does not possess the ability to integrate with DNA. Instead, COVID-19 mRNA vaccines work with the body's natural defenses to safely develop immunity to disease (CDC, 2020b). In addition, RNA vaccines hold the promise of being faster, cheaper, more adaptable, and easier to mass-produce than other vaccines (Wellcome, 2021).

COVID-19 VACCINE AS A CAUSE OF COVID-19 INFECTION

None of the authorized and recommended COVID-19 vaccines contain the live virus that causes COVID-19. As a result, currently available COVID-19 vaccines cannot induce the disease. To note, since it typically takes a few weeks for the body to build immunity after vaccination, a person could be infected with the virus just before or after vaccination and still get sick. This is because the vaccine has not had enough time to provide protection (CDC, 2021a).

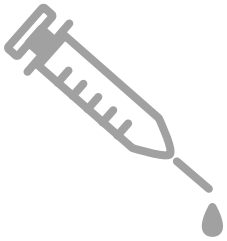
SUBGROUP SAFETY DATA

Similar to the discussion in the 'Subgroup Vaccine Efficacy', subgroup safety conclusions cannot be made with confidence in phase 3 clinical trials as such trials do not secure adequate participation and representation of subgroups.

03

INDICATIONS FOR USE OF COVID-19 VACCINES

The majority of COVID-19 vaccines in use are recommended for persons 18 years of age and older. Only the Pfizer-BioNtech vaccine is recommend for individuals 16 years of age and older. Vaccine rollout plans have been developed by many countries including Lebanon, which included segregation of the population into priority groups and vaccine deployment accordingly (MOPH, 2021). Recommendations for vaccination of various populations are summarized in the following section.



VACCINATION OF INDIVIDUALS WITH PREVIOUS COVID-19 INFECTION

Studies have demonstrated declining neutralizing antibodies over the course of few months, for patients who were previously infected with COVID-19 (Wajnberg et al., 2020; Crawford et al., 2020). Moreover, reinfections have been reported throughout the world despite that the virus has been present in the human population for less than a year (Tomassini et al, 2020).

CDC Guidelines for Vaccination of Individuals with Previous COVID-19 Infection (CDC, 2021b)

- Vaccination should be offered to persons regardless of a history of prior symptomatic or asymptomatic COVID-19 infection.
- Viral testing to assess for acute COVID-19 infection or serologic testing to assess for prior infection is not recommended.
- Vaccination of persons with known current COVID-19 infection should be deferred until the person has recovered from the acute illness and criteria have been met for them to discontinue isolation. This recommendation applies to persons who develop COVID-19 infection before receiving any vaccine doses as well as those who develop COVID-19 infection after the first dose but before receipt of the second dose.
- Persons with documented acute COVID-19 infection in the preceding 90 days may delay vaccination until near the end of this period, if desired.

VACCINATION OF PRIOR RECIPIENTS OF PASSIVE ANTIBODY THERAPY

Currently, there are no data on the safety and efficacy of COVID-19 vaccines in persons who received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment (CDC, 2021b).

CDC Guidelines for Vaccination of Prior Recipients of Passive Antibody Therapy (CDC, 2021b)

- Vaccination should be deferred for at least 90 days, as a precautionary measure until additional information becomes available, to avoid potential interference of the antibody therapy with vaccine-induced immune responses.
- This recommendation applies to persons who received passive antibody therapy before receiving any vaccine doses as well as those who received passive antibody therapy after the first dose but before the second dose, in which case the second dose should be deferred for at least 90 days following receipt of the antibody therapy.

Convalescent plasma therapy uses plasma rich with antibodies from individuals who have recovered from COVID-19 to help other patients recover.

VACCINATION OF SPECIAL POPULATIONS

Table 4: Vaccination of Children, Pregnant Women, and Immunosuppressed Patients

Children	Initial COVID-19 vaccine clinical trials have categorically excluded the participation of children. More recently, inclusion of children in COVID-19 vaccine studies have been initiated, some with already preliminary results produced. A clinical trial by Sinopharm reported the vaccine to be safe in children aged 3-17 years, according to Chinese state media. As a result, it is anticipated that the vaccine could be cleared for use before March 2021 (Reuters, 2021). Moderna also announced that it would soon begin testing its vaccine in children ages 12-17. In addition, Pfizer has enrolled children down to age 12, while AstraZeneca has approval to enroll children in the UK ages 5-12 (The New York Times, 2021b). The American Academy of Pediatrics has advocated for the inclusion of children in COVID-19 vaccine trials (AAP, 2021).

Pregnant women	Available data suggest that symptomatic pregnant patients with COVID-19 are at increased risk of more severe illness compared with nonpregnant peers (Ellington et al., 2020; Collin, Byström, Carnahan, & Ahrne, 2020; Delahoy et al., 2020; Panagiotakopoulos et al., 2020; Zambrano et al., 2020). However, there is no substantial safety data in the pregnant woman, fetuses, or infants at this time, and no pregnancy related data have yet been released (CDC, 2021c). The WHO (WHO, 2021), CDC (CDC, 2021c), the American Academy of Pediatrics (AAP, 2021), and the American College of Obstetricians and Gynecologists (ACOG, 2020) recommend that if a pregnant woman is part of a group that is recommended to receive a COVID-19 vaccine, such as a healthcare worker, she may choose to be vaccinated. The same recommendation applies for lactating mothers.
Immunocompromised persons and patients with autoimmune diseases	Persons with HIV infection or other immunocompromising conditions or who take immunosuppressive therapies might be at increased risk of severe complications from COVID-19 (Dai et al., 2020). Persons with stable HIV infection and autoimmune diseases were eligible for enrollment in COVID-19 vaccine clinical trials. However, data are not currently available to establish vaccine safety and efficacy in these groups (ASH, 2020). COVID-19 vaccination might provide a lower level of protection in people who are immunosuppressed or immunocompromised compared with the rest of the population (BSI, 2021). CDC guidelines for vaccination of immunocompromised persons and patients with autoimmune diseases (CDC, 2021b): • Immunocompromised individuals and patients with autoimmune diseases may receive COVID-19 vaccination if they have no contraindications to vaccination. • Patients should be counseled about the unknown vaccine safety profile and effectiveness in immunocompromised populations, as well as the potential for reduced immune responses • Antibody testing is not recommended to assess for immunity to COVID-19 following mRNA COVID-19 vaccination. • Re-vaccination is not recommended after immune competence is regained in persons who received mRNA COVID-19 vaccines during chemotherapy or treatment with other immunosuppressive drugs.

CONTRAINDICATIONS TO COVID-19 VACCINES

CDC considers the following to be a contraindication to vaccination with both the Pfizer-BioNTech and Moderna COVID-19 vaccines (CDC, 2021b):

- Severe allergic reaction after a previous dose of an mRNA COVID-19 vaccine or any of its components
- Immediate allergic reaction of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components (including polyethylene glycol)
- Immediate allergic reaction of any severity to polysorbate, due to potential cross-reactive hypersensitivity with the vaccine ingredient polyethylene glycol.

04

ADMINISTRATION AND TESTING POST COVID-19 VACCINES

DOSING OF COVID-19 VACCINES

Amid the worldwide vaccine shortage, consideration and evaluation was undertaken to administer one vaccine dose instead of two injections, hoping to cover a larger proportion of the population in a shorter period of time. As revealed in Table 5 (Fernando et al., 2020; Voysey et al., 2020; FDA, 2020d; Logunov et al., 2021), a considerable difference exists in efficacy following the 1st dose and 2nd dose. Duration of protection might also be affected. As a result, the available data continue to support the use of the two specified doses of each vaccine at the specified intervals (FDA, 2021).

Table 5: Single versus Double-dosed Vaccine Efficacy

Vaccine	Efficacy after 1st Dose	Efficacy after 2nd Dose
Pfizer-BioNtech	52.4%	95%
Moderna	80.2%	94.1%
AstraZeneca-Oxford	64.1%	70.4%
Sputnik	91.6% (on day of dose 2)	91.1% (one week after dose 2)

Another perspective on this issue comes from the Joint Committee on Vaccination and Immunization, which decided to calculate the efficacy of the Pfizer-BioNtech vaccine differently. Instead of using all the data on the number of infections (through including from days when the first dose hadn't yet started to work), they looked at days 15-21. Using this method, the efficacy of the vaccine after the first dose jumped up to 89% because it was not being diluted by the number of infections before the vaccine begins to have an effect. Taking things even further and only looking at the first seven days after the second dose (days 21-28) since the second dose might not have kicked in yet by then, the efficacy jumps to 92% (JCVI, 2020).

The benefits of single versus double dosing at the population level may be read differently. Given the relatively acceptable level of protection afforded by the first dose, initially vaccinating a greater number of people with a single dose will prevent more deaths and hospitalizations than vaccinating a smaller number of people with two doses (JCVI, 2020). Along the same line, a modeling study estimated that -considering only a 6-month duration of protection conferred- a single-dose vaccine with 55% effectiveness may confer greater population benefit than a 95%-effective vaccine requiring 2 doses (Paltiel, Zheng, & Schwartz, 2021). However, assuming that protection from the first dose will wane in the medium term, the second dose will still be required to provide durable protection. As a result, despite evidence of some efficacy after the first dose, it is still recommended that all individuals receive their two-dose regimens (CDC, 2021b).

SPACING OF COVID-19 DOSES

One study found that the AstraZeneca vaccine efficacy 14 days after the second dose was higher in the group that had more than six weeks between the two doses (65.4%) than in the group that had less than six weeks between doses (53.4%) (Voysey et al., 2020). As a result, an extended interval between vaccine doses together with initial prioritization of the first vaccine dose would increase the flow of vaccine supply in the short term and allow for more first doses to be delivered to more people earlier.
The current recommendation is that the second dose of the vaccine should be administered as close to the set interval as possible. However, if it is not feasible to adhere to the recommended interval, the second dose of Pfizer-BioNTech and Moderna COVID-19 vaccines may be scheduled for administration up to 6 weeks after the first dose (CDC, 2021b).

INTERCHANGEABILITY WITH OTHER COVID-19 VACCINE PRODUCTS

COVID-19 vaccines are not interchangeable with each other as the safety and efficacy of a mixed-product series have not been evaluated. Both doses of the series should be completed using the same vaccine (CDC, 2021b).

NEED FOR POST-VACCINATION TESTING

The need for and timing of booster doses for COVID-19 vaccines has not been established. No additional doses beyond the current vaccine regimens are recommended at this stage (CDC, 2021b).

NEED FOR BOOSTER DOSES

There is no role for post-vaccination testing for COVID-19 unless clinically indicated. Individuals may have local and systemic reactions such as fever, chills, fatigue, headache in the first one to two days after vaccination. However, respiratory symptoms or systemic symptoms that occur after the first couple days following vaccination could be indicative of COVID-19 infection and warrant testing (UpToDate, 2021).

TESTING RESULTS FOR COVID-19 POST VACCINATION

None of the recently authorized and recommended vaccines can cause an individual to test positive on viral tests, which are used to detect current infection. Once the body develops an immune response post-vaccination, there is the possibility of testing positive on some antibody tests (CDC, 2021a).

05

IMPACT OF COVID-19 VACCINE ON PUBLIC HEALTH OUTCOMES

A very limited number of the trials currently underway are designed to detect a change in public health outcomes such as the use of intensive care or deaths (Doshi, 2020). Whether COVID-19 vaccines confer public health benefit is yet to be determined. Early real-life studies from a high-income country revealed that when the majority of people aged 60 years and above were vaccinated, the number of new COVID-19 cases dropped by 41% compared to that three weeks earlier. That drop was accompanied by a 31% drop in hospitalizations from COVID-19, and a 24% drop in the number of those who became critically ill (The New York Times, 2021a).

A number of considerations remain when evaluating COVID-19 vaccines from a public health perspective. The availability of multiple vaccine options would be a welcome development but would also create policy dilemmas. Determining how best to define vaccine efficacy and whether national health authorities should require all imported and deployed vaccines to meet or exceed the 90% efficacy benchmark established by the vaccine frontrunners is a challenging undertaking. In other words, it is difficult to determine how ethical it is to accept a vaccine with an efficacy just above 50%, which is the cutoff for emergency authorization, when other available vaccines have demonstrated much higher efficacies. Moreover, the question remains whether administering a single-dose vaccine is able to achieve better population protection and contain the pandemic than two doses. The speed-versus-efficacy tradeoff should be accurately weighed, while factoring-in important considerations such as current disease status, the success of currently implemented public health interventions in controlling the epidemic, and the residual capacity of the health system.

FOR MANY REASONS, A COVID-19 VACCINE BY ITSELF, WILL NOT END THE EPIDEMIC:

COVID-19 vaccines are not 100% effective; therefore, some people will still contract the virus

The unvaccinated proportion of the population, such as children, the vaccine hesitant, and those who can not access vaccine, who can still acquire and transmit the virus

Undetermined ability of the vaccine to halt transmission

The waning duration of protection

Achieving herd immunity needed for stopping the propagation of the infection will depend on the efficacy of the vaccine, the proportion of population vaccinated, the duration of protection, and the ability of the vaccine to stop asymptomatic transmission and not only active infection.

While the benefit of a safe and effective COVID-19 vaccine is irrefutable, the unknowns and uncertainties surrounding some aspects of some vaccines have rendered this public health intervention less than perfect. Whilst focusing on impactful COVID-19 vaccine deployment, efforts should not be diverted away from the implementation of well-known effective public health interventions such as wearing masks, social distancing, case isolation, and others. Equally important is strengthening of the health sector which is instrumental for curbing the adversities caused by the epidemic, at least until the public benefit of a vaccine has kicked in. Likewise, while focusing on the fight against the COVID-19 pandemic, other equally essential health priorities should not be overlooked.

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