Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

Microbes and Infection 23 (2021) 104811

Contents lists available at ScienceDirect

Microbes and Infection

journal homepage: www.elsevier.com/locate/micinf

Commentary

COVID-19 vaccine decisions: considering the choices and opportunities

Keywords:
COVID-19
Vaccine distribution
Virus-neutralizing antibodies

A B S T R A C T

In the coming months, most American adults will have the opportunity to receive at least one of up to five different COVID-19 vaccines produced by Operation Warp Speed and released through emergency use authorization by the U.S. Food and Drug Administration (FDA). A similar group of vaccines will also be released in Europe by the European Medicines Agency (EMA) and in the United Kingdom by the Medicines & Healthcare products Regulatory Agency (MHRA). Those living outside of North America and Europe may not have access to those particular vaccines, but they will benefit from receiving vaccines produced in Brazil, China, India, or Russia. These vaccines and some of their major features based on clinical trials and testing are listed in Table 1 [1-25].

As vaccine scientists and policy experts working in the area of coronavirus disease 2019 (COVID-19), we are frequently asked about potential choices regarding the available vaccines, both in the U.S. and globally. Provided here is a summary and informal decision-making tool kit for considering the different vaccine options at this time.

1. General principles

Before going into the specifics for each of the different vaccine types, we have a few guiding principles when considering each vaccine (Table 1).

1.1. Stringent national regulatory authority

A top priority in considering each vaccine is whether it is approved or released for emergency use by a "stringent regulatory authority" or the World Health Organization (WHO). The WHO maintains a list of stringent regulatory authorities, which includes the United States Food & Drug Administration (FDA) as well as selected national regulatory authorities in Europe and Japan [26]. In addition, the major Indian vaccine manufacturers go to great lengths to obtain WHO prequalification for vaccine export. Beyond the vaccines, are those that transition exclusively through unrecognized national regulatory mechanisms or bypass WHO prequalification, although currently the WHO works to also engage the COVID-19 vaccine developers.

1.2. Levels of protection

A second essential consideration is information published in the biomedical literature or released by the companies regarding the levels of vaccine efficacy or protection. COVID-19 vaccines should induce greater than 60–70% protection against infection and symptomatic infection in order to help push virus caseloads into considerable decline and extinguish the pandemic [27].

1.3. Virus neutralizing antibodies (VNAs)

Currently all COVID-19 vaccines induce a special type of antibodies known as virus neutralizing antibodies (VNAs) [28]. These are antibodies that attack the spike protein of the virus and prevent the virus from invading body tissues, thereby from replicating. Although VNAs are not the only arm of the immune response required for protection, more than a decade of studies on coronavirus vaccines has determined that they comprise an essential component [28]. Moreover, those vaccines that induce high levels of VNAs may be more lasting in their protection or "durability". Having said this, comparing levels of VNAs between vaccines is difficult due to their use of different methods, readout, or interpretation. Therefore, we look to general trends at those vaccines inducing consistently high levels of VNAs, such as protein particle or mRNA vaccines.

1.4. Spike gene target failures (SGTFs)

SGTFs refer to the new variants of concern arising in areas of high virus transmission. For example, in the U.S., the B.1.1.7 variant originally from the U.K. is becoming increasingly dominant, especially in Florida, Texas, and Georgia. We worry about the B.1.1.7 variant because it has been shown to be more contagious and transmissible than the original SARS CoV2 virus types [29], and there is unpublished evidence from the U.K. Government that it may be more severe or lethal [30]. A unique feature of the B.1.1.7 variant is its spike protein aromatic amino acid (tyrosine) substitution that can potentially reduce the levels of VNA induced by any given vaccine [31]. Therefore factoring into any vaccine

https://doi.org/10.1016/j.micinf.2021.104811
1286-4579/

Table 1
Vaccine efficacies and virus neutralizing antibody titers for current vaccines completing phase 3 trials with pending our actual emergency use authorization.

Vaccine (Type)	Efficacy vs original strains 2 doses	Efficacy vs original strains 1 dose	Virus neutralizing antibodies vs original	Efficacy vs B.1.351 from ZA 2 Doses	Efficacy vs B.1.351 from ZA 1 Dose	Virus neutralizing antibodies vs B.1.351
Pfizer BNT162b2 (mRNA)	95% [1]	52% [12 days after immunization] [1] Israel study 51% infection [3,4], Alternative analysis 92.6% later analysis after 14 days [7]	Geometric mean titer (GMT), plaque reduction neutralizing titers (PRNT) vs USA −WA1/2020 = 532 [2] GMT PRNT 437 in Phase 1 [5]	Not available (N.A.)	N.A.	GMT PRNT vs USA - B.1.351 = 194 [2]
Moderna (mRNA-1273)	94% [6]	92% 14 days after immunization [7]	GMT PRNT 340-654 range in 100 ug dose [8]	N.A.	N.A.	VSV Pseudovirus neutralization assay 6.4X reduction [9]
J&J (Ad26)	N.A.	72% in US [10]	827-1266 in 2 doses [11]	N.A.	57% in ZA [10]	N.A.
AZOx (ChAdOx1)	Overall 70% [12] 62% in 2 standard doses [12] 90% low dose followed by standard dose [12]	N.A.	GMT 218 [14]	10.4% [13]	N.A.	N.A.
Novavax (Particle)	89.3% [15]	N.A.	GMT 3305−3906 [16]	60% [15]	N.A.	N.A.
Russia Gemalaya (Ad26/Ad5)	92% [18]	N.A.	GMT 45−49 [17]	N.A.	N.A.	N.A.
Chinese Sinovac (WIV)	50% in Brazil [19]	N.A.	GMT 50 (over age of 60) [20]	N.A.	N.A.	N.A.
Chinese Sinopharm (WIV)	79% [21]	N.A.	GMT 218−282 [22]	N.A.	N.A.	N.A.
Chinese CanSinoBio (Ad5)	N.A.	66% in Pakistan, 90% severe disease [23]	GMT 18−19 [24]	N.A.	N.A.	N.A.
Bharat	N.A.	N.A.	GMT 48−66 [25]	N.A.	N.A.	N.A.

recommendations (and in the absence of published data on its efficacy versus B.1.1.7) is the potential for vaccines that induce high levels of VNAs against the original strain are more likely to retain sufficient VNAs against the variant. Note that this statement represents an "opinion" and there is not consensus in the scientific community, as some prefer to emphasize the levels of cellular immunity. Currently, the good news is that most of the COVID-19 vaccines developed against original strains also likely work well versus the B.1.1.7 variant. A more problematic variant is the B.1.351 from South Africa, which appears to be more resistant to currently available vaccines [2,9,10,13,15]. There is concern that B.1.351 will eventually dominate the African continent and dramatically worsen the situation there, even though up until now the continent has been spared the worst of the COVID-19 pandemic [32]. Regarding the U.S., again there is no consensus, but for now some scientists believe that the B.1.1.7 variant from the U.K. will dominate this spring and summer, compared to some of the other variants of concern [33].

1.5. Two doses versus a single dose

This issue appears to be among the more divisive ones in the scientific community. All of the major vaccine developers aspired to develop a single dose vaccine, given its obvious advantages in fighting a pandemic under duress. However, based on both laboratory animal studies and the early phase 1 and phase 2 data it became clear (for most of the vaccines) that two doses spaced a few weeks apart would be necessary to induce robust and reliable levels of VNAs [2,5,8,14,16]. In contrast, a single dose typically produced inconsistent levels of VNAs [2,5,8,14,16]. An exception is the Johnson and Johnson (J&J) vaccine, which has now been released for single dose use [10,11]. Thus, many individuals receiving a single dose of the mRNA vaccine require a second dose, an observation factored into company decisions to conduct their large phase 3 trials with two doses. However, some scientists have examined company data submitted to the FDA, uncovering some evidence that a single dose of some vaccines may still provide high levels of protection beginning around 2 weeks after immunization [3,4,7]. More recently, a study from Israel demonstrated clear inferiority of the Pfizer-BioNTech vaccine when given in a single dose compared to two doses [34]. Given the concerns about the rapidly accelerating B.1.1.7 variant and the limited availability of the mRNA vaccines from Pfizer and Moderna, some scientists have called for delays in the second dose in order to administer more first doses and provide some level of protection to more people [35]. So far, the FDA has not favored this viewpoint given that the Phase 3 studies were not designed to specifically examine long-term protection offered by a single dose, nor its durability [36]. Additionally, there is no specific information on whether a single dose will protect against the B.1.1.7 variant.

2. Specific decisions

With these general principals in mind, we can now evaluate each vaccine type.

2.1. mRNA vaccines

The mRNA vaccines from Pfizer-BioNTech and Moderna were the first ones released for emergency use in the U.S. They both offer excellent protection (against symptomatic infection) of greater than 90% versus the original or U.K. strains [1,5,34] and a good safety profile. The CDC recently published its analysis of severe allergic reactions or anaphylaxis following the first dose, and calculated rates near 2.5 cases per million for the Moderna vaccine [37] and 11.1 cases per million for the Pfizer-BioNTech vaccine [38].

While these rates are greater than for severe reactions from the influenza vaccine or the HPV vaccine to prevent cervical and other cancers (around 1–2 per million [39]) severe allergy or anaphylaxis following an mRNA vaccination is still a rare event.

The American College of Obstetrics and Gynecology currently recommends that the mRNA vaccines "should not be withheld" from pregnant women [40] and the Society for Maternal Fetal Medicine "strongly recommends that pregnant women have access to COVID-19 vaccines in all phases of future vaccine campaigns" [41]. Such considerations reflect data showing significant adverse consequences of COVID-19 infection during pregnancy [42] even though a full safety analysis of these vaccines in pregnancy awaits completion. Along those lines, Pfizer-BioNTech recently announced its intention to commence clinical trials in pregnant women.

It is likely that two doses of either of the mRNA vaccines will protect against the B.1.1.7 variant – this variant is widespread in Israel, for instance where the Pfizer-BioNTech vaccine was shown to work [34] - and, based on levels of VNAs, offer at least partial protection against B.1.351 from South Africa [2,9]. The durability of protection for both mRNA vaccines is unknown, and there is a possibility that a third immunization may be required, possibly with the third booster shot tailored specifically for one of the variants of concern. Overall, both are excellent vaccines, although the technology is still not robust enough to scale production in sufficient quantities to vaccinate significant numbers of individuals in low- and middle-income countries (LMICs) [43].

2.2. Adenovirus vaccines

The J&J vaccine was just released in the U.S. for emergency use, thereby becoming the first non-mRNA vaccine for COVID-19 in the country. It is the first single-dose vaccine, and provides protection levels almost as high as the two dose mRNA vaccines. It also induces some protection against the B.1.351 variant from South Africa [10]. In addition, a Phase 3 clinical trial of the J&J vaccine in two doses will be completed later in the year. In two doses, this vaccine may provide protection equivalent to the mRNA vaccines and potentially higher levels of protection versus B.1.351. The J&J vaccine might find use in the U.S., Europe, and globally. Regarding the latter, its ability to work in a single dose and simpler refrigeration requirements make it ideal for LMICs. For similar reasons, there is enthusiasm regarding the AstraZeneca-Oxford vaccine. It works well against the UK variant [44] and may be released for emergency use in the U.S. It is also being scaled for production and distribution to LMICs (and Canada) by the Serum Institute of India (Pune). The one drawback is that it may not induce protection against the B.1.351 variant, thereby potentially limiting its use on the African continent [13], although it may be possible to develop boosters for this purpose using other vaccine platforms. Finally, there are the two adenovirus vaccines from China (CanSinoBio) and Russia (Sputnik V from Gemalaya), respectively. So far, they have not been released through a stringent regulatory authority or by the WHO. In clinical trials, however, they appear to offer significant protection against COVID-19 even though they induce relatively low levels of VNAs [17,18,23,24]. Their performance versus the variants of concern, including B.1.351, is not known.

2.3. Particle and protein vaccines

The Novavax particle vaccine is expected to be released for emergency use in the U.S. in a few months. It induces among the highest levels of VNAs seen to date and in clinical trials offers levels of protection approaching 90% [15,16]. Several other recombinant protein vaccines are also in development and may offer advantages in terms of low cost and easy accessibility [44–46]. They include vaccines from Biological E in collaboration with Baylor College of Medicine (India), Medicago (Canada), Clover (China) and possibly others.

2.4. Whole inactivated virus (WIV) vaccines

Several WIV vaccines are under development including two from China (Sinovac and Sinopharm) offering a range of protective immunity, and a vaccine from India (Bharat) still in early stages [19–22,25] that could become important vaccines for LMICs.

3. Concluding statement

The COVID-19 vaccine landscape is complicated but the current picture is becoming clearer as candidates are either approved for use by stringent regulatory authorities or drop out due to lack of immunogenicity, protection, or other considerations. Our guiding principles remain that they all work by inducing VNAs and those VNAs are life-saving. Quality control and regulatory oversight by stringent regulatory authorities and the WHO represent an essential element of global governance.

Declaration of competing interest

PH is an inventor on a COVID-19 vaccine technology (recombinant protein vaccine) owned by Baylor College of Medicine that was recently licensed non-exclusively to Biological E Ltd., a commercial vaccine manufacturer for scale up, production, testing and licensure.

No other authors have any conflicting interests to declare.

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1 March 2021
Available online 17 March 2021