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Commentary

# Planning for COVID-19 vaccines safety surveillance

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ABSTRACT

COVID-19 vaccines are the most important tool to stem the pandemic. They are being developed with unprecedented global collaboration and accelerated timelines to achieve WHO Emergency Use Listing, while using regulatory pathways through national regulatory authorities. Alongside preparations to ensure equitable access to the vaccines among people globally, preparations must be made within countries for COVID-19 vaccines safety surveillance on an urgent basis. Safety surveillance must be capable of investigating adverse events of special interest (AESI) and adverse events following immunization to determine a change in the benefit-risk profile of the vaccine, and to be able to anticipate coincidental events that might be attributed to the vaccine.

Active surveillance systems should calculate the incidence of background rates of AESI prior to vaccine roll out. These background rates vary tremendously across regions, populations and case ascertainment methods. Active surveillance systems must be established or strengthened now, (including in LMIC), to calculate the background rates. Utilizing standardized case definitions and global standards for AESI will help in harmonization. Vaccine safety communication plans should be developed. Expanding the global vaccine safety system to meet the needs of COVID-19 and other emergency and routine use vaccines is a priority currently.



The coronavirus disease 2019 (COVID-19) pandemic, caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), has led to over 13 million cases. COVID-19 vaccines development is occurring with unprecedented speed. This is partially due to the Coalition for Epidemic Preparedness Innovations (CEPI) [1]. CEPI, formed in 2017, is a novel partnership between private, public, philanthropic and civil society organizations. It aims to develop vaccines for future epidemics and enable equitable access to vaccines for people during epidemics. CEPI is mandated to accelerate the development and manufacture of vaccines against previously unknown pathogens with 16 weeks from identification of antigen to vaccine candidate release for clinical trials [1]. CEPI has announced the initiation of nine COVID-19 vaccine programs [2]. Rapid response platforms for vaccine development supported by CEPI are being utilized. Platform technology use systems with the same basic components as a backbone and insert new protein or genetic sequences to adapt for use against different pathogens [3]. The vaccine candidates include a DNA vaccine (administered with electroporation); a molecular-clamp vaccine (synthesis of viral surface proteins, which attach to host cells during infection and clamps them into shape, so that the immune system can recognize them as the correct antigen); recombinant protein nanoparticle technology to generate antigens derived from the coronavirus spike (S) protein (proprietary saponin-based adjuvant); a recombinant protein vaccine with the S Trimer, a replication-deficient simian adenoviral vaccine (ChAdOx1-S); a measles-vector vaccine, a live-attenuated influenza vaccine and two mRNA vaccines. A pandemic vaccine adjuvant will be available to enhance development [2].

CEPI has also launched a call for organisations with large manufacturing capabilities for vaccine candidates, to advance an

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**Table 1**
COVID-19 Vaccine Candidates in Clinical Development (21 as of June 29, 2020).

| Vaccine Candidate | Platform | Phase of Clinical Development | Developer |
|---|---|---|---|
| ChAdOx1-S expressing S protein | Non Replicating Viral Vector | Phase 3 | University of Oxford, AstraZeneca |
| Adenovirus Type 5 Vector expressing S protein | Non Replicating Viral Vector | Phase 2 | CanSino Biological Inc., Beijing Institute of Biotechnology |
| Lipid nanoparticle (LNP) encapsulated mRNA encoding S protein | RNA | Phase 2 | Moderna, NIAID |
| Inactivated | Inactivated | Phase 1/2 | Beijing Institute of Biological Products, Sinopharm |
| Inactivated | Inactivated | Phase 1/2 | Wuhan Institute of Biological Products, Sinopharm |
| Inactivated with alum | Inactivated | Phase 1/2 | Sinovac |
| Full length recombinant SARS CoV-2 glycoprotein nanoparticle vaccine adjuvanted with Matrix M | Protein Subunit | Phase 1/2 | Novavax |
| 3 LNP-mRNAs | RNA | Phase 1/2 | BioNTech, Fosun Pharma, Pfizer |
| Inactivated | Inactivated | Phase 1/2 | Institute of Medical Biology, Chinese Academy of Medical Sciences |
| Adeno-based | Non Replicating Viral Vector | Phase 1 | Gamaleya Research Institute |
| DNA plasmid encoding S protein delivered by electroporation | DNA | Phase 1 | Inovio Pharmaceuticals |
| DNA Vaccine (GX-19) | DNA | Phase 1 | Genexine Consortium |
| LNP-nCoVsaRNA | Self-amplifying RNA | Phase 1 | Imperial College London |
| mRNA | RNA | Phase 1 | Curevac |
| mRNA | RNA | Phase 1 | People's Liberation Army (PLA) Academy of Military Sciences, Walvax Biotech |
| S-Trimer subunit vaccine adjuvanted | Protein Subunit | Phase 1 | Clover Biopharmaceuticals, GSK, Dynavax |
| Adjuvanted recombinant protein (RBD Dimer) | Protein Subunit | Phase 1 | Anhui Zhifei Longcom Biopharmaceutical, Institute of Microbiology, Chinese Academy of Sciences |
| Autologous Dendritic Cells with SARS-CoV-2 antigens, administered with granulocyte–macrophage colony-stimulating factor (GM-CSF) | Dendritic cell vaccine | Phase 1 | Aivita Biomedical |
| Dendritic cells (DC) modified with lentivirus vector, expressing synthetic minigene based on domains of selected viral proteins, administered with antigen specific cytotoxic T lymphocytes (CTLs) | Modified DC | Phase 1 | Shenzhen Geno-Immune Medical Institute |
| Artificial antigen-presenting cells (aAPCs) modified with lentiviral vector, expressing synthetic minigene based on domains of selected proteins | Modified APCs | Phase 1 | Shenzhen Geno-Immune Medical Institute |
| bac-TRL Spike, orally delivered | Live Bifidobacterium longum to deliver plasmids of synthetic DNA encoding SARS-CoV-2 spike protein | Phase 1 | Symvivo |

Source- ClinicalTrials.gov, London School of Hygiene and Tropical Medicine [4], WHO [5].

effective vaccine and transfer the vaccine platform to a global network of large-scale manufacturing [2].

There are currently 21 COVID-19 vaccines candidates in clinical trials, including four funded by CEPI (including the mRNA (the first to enter clinical trials, co-developed with the National Institute of Allergy and Infectious Diseases (NIAID), USA), DNA, ChAdOx1-S and protein subunit vaccine) as shown in Table 1 [4,5]. Table 2 shows the candidates in preclinical development [4,5].

The US Government's Biomedical Advanced Research and Development Authority (BARDA) is funding the development and manufacturing of the ChAdOx1-S vaccine, the Phase 2 and 3 trials for the mRNA vaccine and the developed of recombinant vesicular stomatitis virus (rVSV), Adenovirus 26 (Ad26) and RNA vaccine candidates (in preclinical development). The US Department of Defense and other country governments are also funding vaccine development and manufacturing.

Most vaccine candidates are targeting the SARS-CoV spike (S) protein,[6,7] displayed on the virus surface, which is composed of two subunits [6,7]. The S1 subunit contains a receptor-binding domain (RBD) that binds with the host cell receptor angiotensin-converting enzyme 2 (ACE2), S protein priming occurs through the serine protease TMPRSS2 (to cleave S protein at S1/S2) and fusing of the viral and host membranes occurs through the S2 subunit. The S protein induces neutralizing-antibody and T-cell responses, as well as protective immunity, during infection with SARS-CoV [7]. The vaccine formulation and delivery are being developed to induce strong neutralizing antibodies, predominant $CD4^+$ T helper 1 cell (Th1) immune response, and balanced CD4/CD8 and polyfunctional T cell responses, which have favorable antiviral properties [7].

The traditional timeline to develop a vaccine is 15–20 years. For COVID-19, the hope is to have a vaccine available in 12–18 months.

## 1. Safety surveillance

There are accelerated timelines for vaccine development to achieve WHO Emergency Use Listing, while using regulatory pathways through national regulatory authorities. Common adverse events that occur shortly after vaccination may be detected in the clinical trials, but rare adverse events, and those with delayed onset, are likely to be detected only once large populations are immunized. In addition, no DNA or RNA vaccines have been licensed in humans to date. Safety surveillance accompanying deployment will be critical. Historic example of real adverse reactions that are only detected after widespread vaccine use (Guillain-Barré syndrome (GBS) following the 1976 swine flu vaccine program and enhanced disease post infection after vaccination with the Dengue vaccine) and coincidental events later found not be

**Table 2**
COVID-19 Vaccine Candidates in Pre-Clinical Development (estimated to be 182 as of June 29, 2020).

| Vaccine Platform | Examples of Types of Vaccines | Estimated Number of Vaccine Candidates |
|---|---|---|
| Live-attenuated vaccines | • Codon deoptimized<br>• Measles Virus (S, N targets) | 3 |
| Inactivated | • Inactivated<br>• Inactivate whole virus<br>• Inactivated + CpG 1018 | 6 |
| Non-replicating viral vectors | • Modified Vaccinia Ankara (MVA) encoded Virus Like Particles (VLP)<br>• MVA expressing structural proteins<br>• MVA-S<br>• MVA-S encoded<br>• Adenovirus-based NasoVAX expressing SARS2-CoV spike protein<br>• Adenovirus 26 (Ad26) (alone or with MVA boost)<br>• Adeno-associated virus vector (AAVCOVID)<br>• Adeno-associated virus<br>• Ad5 S (GREVAXplatform)<br>• Oral Ad5 S<br>• Adenovirus-based + HLA-matched peptides<br>• Replication defective Simian Adenovirus (GRAd) encoding SARS-CoV-2 S<br>• Influenza A H1N1 vector<br>• Parainfluenza virus 5 (PIV5)-based vaccine expressing the spike protein<br>• Recombinant deactivated rabies virus containing S1<br>• [E1-, E2b-, E3-] hAd5- COVID19- Spike/Nucleocapsid<br>• Inactivated Flu-based SARS-CoV2 vaccine + Adjuvant<br>• Dendritic cell-based<br>• Oral vaccine in tablet formulation | 21 |
| Replicating viral vectors | • Measles<br>• Measles (S, N targets)<br>• Horsepox vector expressing S protein<br>• YF17D<br>• Live viral vectored vaccine based on attenuated influenza virus backbone (intranasal)<br>• Recombinant vaccine based on Influenza A virus, for the prevention of COVID19 (intranasal)<br>• Attenuated Influenza expressing an antigenic portion of the Spike protein<br>• Influenza vector expressing RBD<br>• M2-deficient single replication (M2SR) influenza vector<br>• Vesicular Stomatitis Virus (VSV)<br>• VSV-S<br>• Replication competent VSV chimeric virus technology (VSVΔG) delivering the SARSCoV-2 Spike (S) glycoprotein<br>• Newcastle disease virus vector (NDVSARS-CoV-2/Spike)<br>• Avian paramyxovirus vector (APMV) | 17 |
| Protein Subunit | • Protein Subunit<br>• Protein Subunit S,N,M and S1 protein<br>• RBD protein fused with Fc of IgG + Adj<br>• S1 or RBD protein<br>• RBD based<br>• RBD protein fused with Fc of IgG with Adjuvant<br>• Capsid-like Particle<br>• Drosophila S2 insect cell expression system VLPs<br>• Peptide antigens formulated in LNP<br>• Peptides derived from Spike protein<br>• Peptide<br>• S protein<br>• S protein with adjuvant<br>• Microneedle arrays S1 subunit<br>• Spike-based<br>• Spike-based (epitope screening)<br>• Adjuvanted protein subunit (RBD)<br>• Ii-Key peptide<br>• Protein Subunit EPVCoV-19<br>• gp-96 backbone<br>• Molecular clamp stabilized Spike protein<br>• Subunit<br>• Subunit protein, plant produced<br>• Subunit protein, baculovirus produced<br>• Recombinant protein, nanoparticles (based on S-protein and other epitopes)<br>• COVID-19 XWG-03 truncated S (spike) proteins<br>• Adjuvanted microsphere peptide<br>• Synthetic Long Peptide Vaccine candidate for S and M proteins<br>• Oral E. coli-based protein expression system of S and N proteins<br>• Nanoparticle<br>• Recombinant spike protein with Advaxadjuvant<br>• VLP-recombinant protein with adjuvant<br>• Plant-based subunit (RBD-Fc + Adjuvant)<br>• Structurally modified spherical particles of the tobacco mosaic virus (TMV) | 59 |

**Table 2** (*continued*)

| Vaccine Platform | Examples of Types of Vaccines | Estimated Number of Vaccine Candidates |
|---|---|---|
| | • Recombinant S1-Fc fusion protein<br>• Recombinant protein<br>• Recombinant S protein in IC-BEVS<br>• Orally delivered, heat stable subunit<br>• S-2P protein + CpG 1018<br>• Outer Membrane Vesicle (OMV)-subunit<br>• OMV-based vaccine<br>• Outer Membrane Vesicle(OMV)-peptide | |
| Virus-like Particle (VLP) | • S protein integrated in HIV VLPs<br>• VLP with Adjuvant<br>• VLP, lentivirus and baculovirus vehicles<br>• VLP, based on RBD displayed on VLPs<br>• Enveloped VLP<br>• Plant-derived VLP<br>• ADDomerTM multiepitope display<br>• VLPs peptides/whole virus | 10 |
| DNA | • DNA with electroporation<br>• DNA plasmid vaccine<br>• DNA plasmid vaccine S,S1,S2,RBD and N<br>• DNA<br>• Plasmid DNA, Needle Free Delivery<br>• bacTRL-Spike | 12 |
| RNA | • LNP-encapsulated mRNA<br>• LNP-encapsulated mRNA cocktail encoding VLP<br>• LNP-encapsulated mRNA encoding RBD<br>• Liposome encapsulated mRNA<br>• Replicating Defective SARS-CoV-2 derived RNAs<br>• mRNA<br>• mRNA in an intranasal delivery system | 21 |
| Other/ Unknown | | 43 |

Source- London School of Hygiene and Tropical Medicine [4], WHO [5].

caused by the vaccine (autism following MMR vaccine and sudden infant death syndrome (SIDS) with whole cell pertussis vaccines) that undermine the immunization program, highlight the critical role for robust safety monitoring. CEPI has funded the Brighton Collaboration Safety Platform for Emergency vACcines (SPEAC) project to harmonize the safety of its candidate vaccines, including COVID 19 [8]. The Brighton Collaboration has developed standard templates for benefit risk assessment of vaccine technologies for the main COVID 19 platforms (nucleic acid, protein, viral vector, inactivated viral, and live attenuated viral vaccines) [8,9]. The World Health Organization Global Advisory Committee on Vaccine Safety (GACVS) has recommended that any review of the safety of new vaccines be based on these templates as they offer a structured approach to evaluating safety [10].

Adverse Events of Special Interest (AESIs) (serious or non-serious) are events of significant medical and scientific concern specific to the sponsor's program or product. These require ongoing monitoring and communication by the investigator to the sponsor and might require further investigation to characterize and understand them; and rapid communication by the trial sponsor to regulators. They could be related to vaccines in general, specific vaccine platforms or the disease. AESIs reporting and assessment is done with high priority as they could change the benefit-risk profile of the vaccine or require prompt public communication. For the COVID-19 vaccines, the AESIs could potentially include vaccine-enhanced disease (vaccination could make subsequent infection with SARS-CoV-2 more severe) [7]. Enhanced disease, with a few deaths, was associated with the Dengue vaccine and had been reported with formalin-inactivated respiratory syncytial virus (RSV) vaccine in young children who received the vaccine and were subsequently infected with natural RSV in 1967. Enhanced disease was seen in some preclinical studies with SARS-CoV vaccines and raised questions about other coronavirus vaccines showing a similar AESI. Other AESIs relevant to COVID-19 disease could potentially include respiratory (including pneumonia, acute respiratory distress syndrome), cardiac (including cardiogenic shock, cardiomyopathy, arrhythmia, coronary artery disease, myocarditis and pericarditis), acute renal, and hepatic injury, neurological (including encephalopathy, encephalitis, GBS, anosmia and ageusia), sepsis and septic shock, hypercoagulability, rhabdomyolysis and multisystem inflammatory syndrome in children [11]. AESIs related to novel adjuvants and vaccine platforms (e.g. cardiac AE including myo/pericarditis with MVA, and arthritis with VSV platforms); and vaccination (e.g. anaphylaxis, thrombocytopenia, seizures, GBS) should also be considered.

An adverse event following immunization (AEFI) is "any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine". AEFIs include the background rate of all diseases post-vaccination and may include excess burden of these diseases if the vaccine causes a vaccine adverse reaction. Safety surveillance must be capable of investigating AEFIs and AESIs as our understanding of the biological mechanisms for adverse reactions has limitations and we must anticipate coincidental events that clinicians, the media and the public may attribute to the vaccine. Safety surveillance must be able to detect and rapidly investigate AESIs and AEFIs to determine if the temporal relationship is causal or coincidental.

Preparations need to be made now in order to ensure that emergency vaccine use in accompanied with robust vaccine safety surveillance and a process for safety assessment which will maintain public confidence in the vaccine. The vaccine will likely be used with COVID-19 widely circulating. Thus safety surveillance will need to distinguish between health outcomes caused by the disease versus those caused by the vaccine. Real or coincidental AESIs and AEFIs have the potential to undermine the vaccine program and exacerbate public fear around the pandemic.

Active and sentinel surveillance systems are necessary to rapidly and rigorously evaluate the safety profile of the vaccines. Many high-income countries have large healthcare administrative databases to conduct such active surveillance and have vaccine experience. However, low-and middle-income countries (LMIC) generally lack the capacity to conduct active safety surveillance and do not have large healthcare administrative databases. As equitable access to the vaccines for people during epidemics is imperative, active safety surveillance in LMIC is critical to ensure that safety surveillance is also equitable.

As was done prior to launch of the 2009–2010 H1N1 vaccines, active surveillance systems should calculate the incidence of background rates of AESI prior to vaccine roll out [12]. Establishing these background rates of disease prior to vaccination allows for a stable rate, based upon multiple years of data, so that the rates of these outcomes after vaccine roll out can be compared. CEPI is developing a comprehensive list of AESIs. The incidence of these outcomes will vary tremendously based upon the region, underlying population, and methods use for case ascertainment which will be highly dependent on the characteristics of the active or sentinel surveillance system. Surveillance in LMIC must be established now, in preparation for vaccine roll out, so that background rates of AESIs can be calculated.

There are several approaches that can be used to establish active surveillance systems in LMIC. There is very limited access to large healthcare administrative databases in LMIC. India and South Africa (the only country in Africa) have such administrative databases though with limited vaccine safety experience. Other LMIC have registries or sentinel site-based surveillance capacity, such as hospital surveillance, that can be very useful for some outcomes. There are a large number of international collaborations with LMIC institutions that have the potential to be used as active vaccine safety surveillance sites. For example, the NIH Fogarty International Center Global Health Program has over 80 partner LMIC institutions and many academic institutions have well established sites in LMIC. Such sites require a defined population and local capacity to collect primary data. Efficiencies can be accomplished by global standards for AESIs and development of harmonized case definitions (as is being done by the Brighton Collaboration under contract with CEPI). However, the time is now to develop these sites for vaccine safety assessment and calculate background rates prior to vaccine introduction.

It is also essential that countries and regions plan for real and coincidental AESIs and AEFIs with a scientifically rigorous and publicly credible process to separate real adverse reactions from coincidental background rates of disease. Safety signals require careful evaluation often involving chart review of potential cases, which can be both time and labor intensive. As recommended by the WHO Global Vaccine Safety Blueprint (GVSB 2.0), "Countries or regions establish either a national expert committee for AEFIs or regional advisory committees or equivalent objective panels with spelled out terms of reference [13]." Public credibility can be optimized by ensuring that these committees are "independent of conflicts of interest with the ministries of health, industry and the immunization program". Vaccine safety communication plans, with clear national and subnational vaccine safety communication roles and responsibilities, should be developed to provide timely, evidence-based messaging to describe what is known, what is not known, and what is being done to fill these gaps.

The COVID-19 pandemic is a global crisis with enormous human and financial costs. Present efforts aimed at curbing the pandemic through social distancing may be helpful. Ultimately, a vaccine is likely the most important long-term tool. However, we must invest in active vaccine safety surveillance globally, and most particularly in LMIC, to ensure the potential of a COVID-19 vaccine is realized. With crisis comes opportunity to expand our global vaccine safety system to meet the needs of COVID-19 and other routine and emergency use vaccines. The WHO Global Vaccine Safety Blueprint 2.0 offers the framework to do so and must be fully funded and implemented.

## Declaration of Competing Interest

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