32nd WHO Regulatory Update on COVID-19

02 April 2021

World Health Organization

Key Messages

There are now just 5 days left before the WHO and Director-General Tedros Adhanom Ghebreyesus' 100-day challenge, a movement under the banner of vaccine equity. Yet 28 countries are still waiting for vaccines so they can start vaccinating health workers and older people. Of those, 11 might be able to start vaccinating before World Health day, April 7th. WHO is asking countries with doses of vaccines that have WHO emergency use listing to donate as many doses as they can to help protecting health workers and at-risk communities, to reach the goal and to race against the virus.

Highlights and main issues

- Using COVID-19 vaccines as an example, WHO held its first global consultation on a proposed decision framework for assessing the impact of SARS-CoV-2 variants of concern (VOCs) on public health interventions on 29 March 2021. WHO will continue working with various stakeholders to determine global framework with clear standards, roles and responsibilities and mechanisms to issue comprehensive policies to prevent and control COVID-19.
- Approximately 33.3 million doses of vaccines from three manufacturers, SII/AZ/Pfizer, have been shipped through COVAX Facility to 74 of 92 AMC participants as of 29th March. Shipment dates of an additional 1.35 million doses to 7 AMC participants have been confirmed.
- To facilitate the clear identification of pharmaceutical substances included in COVID-19 vaccines, the WHO International Nonproprietary Names Programme encourages vaccine developers to submit INN requests for well-defined vaccine ingredients.
- The scientific and regulatory assessment of very rare cases of unusual blood clots, associated with low numbers of platelets in people vaccinated with AstraZeneca's COVID-19 vaccine, continues. The WHO Global Advisory Committee on Vaccine Safety's sub-committee on COVID-19 vaccines has been actively reviewing the emerging evidence, in collaboration with European Medicines Agency and other regulatory agencies, and will update its advice, if needed.
- WHO Living guideline on therapeutics and COVID-19 has been published. It includes advice on ivermectin which should be used to treat COVID-19 only within clinical trials.
- WHO guidance on assessing vaccine effectiveness (VE) has been published. This guidance is targeted mostly for evaluations undertaken in low- and middle-income countries but most of the concepts also apply to VE evaluations in high-income settings.
- A WHO Medical Product Alert has been issued that refers to falsified COVID-19 Vaccine identified as "BNT162b2" originally detected in Mexico in February 2021 and recently confirmed as falsified to the WHO.

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Contents

Key Messages 1
Highlights and main issues 1
Virus variants 3
- First Global Consultation: Risk Monitoring Framework 3
- Global Workshop: Enhancing Sequencing for SARS-CoV-2 3
- Meeting Report: Knowledge Gaps and Research 4
- COVAX Workshop: SARS-CoV-2 Variants 4
- Call for Partners: Development of Antibody Working Standards & Reference Panels 5

Update on the ACT-Accelerator 5
- United Action Needed for Robust International Health Architecture 5
- Meeting: ACT-A Facilitation Council 6
- COVAX 6
- Delivery Delays: COVISHIELD 6
- Joint Statement: Prioritization of COVID-19 Vaccination for Seafarers and Aircrew 7

WHO's other COVID-19-related work 7
- Origin of SARS-CoV-2 virus: Need for further studies 7
- Report: WHO COVID-19 Infection, Prevention and Control 8
- Guidance: Expedite Genomic Sequencing Component of GISRS Surveillance 8
- WHO Weekly Operational Update 8
- Global COVID-19 Clinical Data Platform 9
- EPI-Win Update: Clinical Long-Term Effects of COVID-19 9
- WHO COVID-19 Vaccines Dashboard 9
- Training Materials for Health Care Workers 9

Alignment of approaches by regulators 10
- WHO Expert Committee on Biological Standardization (ECBS) 10
- WHO Expert Committee on Specification for Pharmaceutical Preparations (ECSPP) 10
- Draft WHO Guidance for Comments 10

In vitro diagnostics 11
- WHO EUL and Listing Update 11

Therapeutics 11
- Updated: Living Therapeutics Guideline with Advice on Ivermectin 11
- Clinical Trials 12

Vaccines 12
- Call for Developers: Naming of COVID-19 Vaccines 12
- AstraZeneca COVID-19 Vaccine 13
- Safety of COVID-19 Vaccines 13
  - Safety Surveillance of COVID-19 Vaccines in Pregnant and Breastfeeding Women 13
  - Support Materials for Safety of COVID-19 Vaccines 13
- Guidance: Assessing Vaccine Effectiveness 14
  - Draft Landscape of Observational Studies on VE 14
- Draft Guidance for Comments: Smart Vaccination Certificate 15
- Status Update: EMA approved and candidate COVID-19 vaccines 15
- Status Update: WHO EUL/PQ evaluation 15
- Support materials: 16
  - WHO Vaccine explainer 16
  - Living mapping and living systematic review of COVID-19 studies 16
  - Landscape and tracker of COVID-19 candidate vaccines 17

WHO Assays Working Group 17
Substandard and falsified products 17
- Falsified COVID-19 Vaccine BNT162b2 17

Supply Chain 18
Transportation backlogs 18
Upcoming events 18
R&D Blueprint Monthly meeting 18
COVAX Webinars 19
World Health Day 2021: Building a Fairer, Healthier World 19

Virus variants

First Global Consultation: Risk Monitoring Framework

WHO is a developing a Risk Monitoring Framework to identify, monitor and assess SARS-CoV-2 variants of interest (VOI) and variants of concern (VOC). It will be a holistic approach including surveillance (through epidemiological studies, molecular testing, genomic sequencing); research on variants of concern (modelling, laboratory and epidemiological studies) and evaluation of the impact on diagnostics, therapeutics and vaccines. On 29th March, WHO held its first global consultation on the proposed decision framework for assessing the impact of SARS-CoV-2 VOCs on public health interventions, attended by nearly 1'000 participants from around the world. Using COVID-19 vaccines as an example, the consultation reviewed how a decision-making process could look with respect to analyzing the impact of VOCs and issuing policy recommendations.

Regulators and product developers engaged with the consultation to outline information needs on variants from their perspectives. A summary was provided of guidance that has already been developed on evaluation of changes, if needed, to COVID-19 vaccines with established vaccine efficacy. For this scenario, neutralizing immune responses may be used to bridge responses from the original efficacy trials to the modified vaccine. Safety and other immune responses should also be studied. The primary immunization series will need to be tested, as well as the effect of a booster dose. Immune responses with modified vaccines will likely need to be evaluated against several different SARS-CoV-2 variants, as well as the original virus against which the parent vaccine was developed. Current regulatory guidance does not address authorization of completely new vaccines against SARS-CoV-2 variants. As reliable information on vaccine safety and efficacy will be important to support confidence in such vaccines, randomized clinical endpoint strategies are likely to be required to allow direct evaluation of vaccine protection against variants.

Vaccine development in 300 days, as happened with the currently authorized COVID-19 vaccines, was unprecedented. However, this may need to be further accelerated if control of the exponential spread of the disease is to be achieved. Experience from the influenza vaccine strain change model was cited as providing useful learnings. For example, the WHO's biweekly technical calls throughout the year with developers and manufacturers ensure full transparency and flow of intelligence that enables at-risk-work to be initiated by developers in a timely manner. Real-time surveillance and analytics with continuous sharing of information with regard to SARS-CoV-2 VOI and VOC with developers is a solution that will enable developers to initiate work at-risk well before a VOC is declared.

The consultation reiterated the need of global framework with clear standards, roles and responsibilities and mechanisms to issue comprehensive policies to prevent and control COVID-19 with emphasis on WHO's leadership in coordinating and ensuring timely sharing of information on SARS-CoV-2 variants with relevant stakeholders, including regulators and with developers.

The report of the meeting and presentations will be made available shorlty.

Global Workshop: Enhancing Sequencing for SARS-CoV-2

On 19 March 2021, WHO hosted a global workshop on enhancing sequencing to monitor SARS-CoV-2 evolution, bringing together stakeholders in a high level discussion to agree on a common vision and a global, coordinated plan to increase SARS-CoV-2 sequencing capacity, in order to

strengthen detection of VOIs and VOCs. Over 800 participants, including representatives from Ministries of Health, academia and donors, engaged in discussions on the international sequencing landscape, available capacities and opportunities for network-driven strengthening of SARS-CoV-2 variant detection. The workshop highlighted to leverage existing surveillance systems and structures, such as SARS-CoV-2 reference network, the Global Influenza Surveillance and Response System (GISRS), HIV, TB and Polio laboratory networks, to strengthen existing regional networks, and to build new sustainable capacity to generate and process sequencing data for SARS-CoV-2 and other infectious pathogens. Sequence and supporting meta-data sharing is critical to better understand virus evaluation and to inform the COVID-19 response.

The workshop outcomes include:

- A situational overview of national and regional sequencing and data analysis capacities around the world and demonstration of ongoing support from Member States with capacities to support others.
- An agreement from participants on the importance of timely data sharing and a need to build capacity for sequencing, data processing leading to informed action.
- An agreement toward a global plan to enhance sequencing and analysis capacities and linking results with public health actions.

WHO will provide the coordination role by providing a platform, leadership and coordination for future discussions, capacity building and network-based knowledge sharing.

The workshop outcomes were reported to the first Global Consultation on a Decision Framework for Assessing the Impact of SARS-CoV-2 VOC on 29 March 2021.

> COVID-19 Weekly Epidemiological Update 32 with special focus on SARS-CoV-2 VOC (pages 5-12) (23 Mar 2021)

Meeting Report: Knowledge Gaps and Research

In light of the potential risk posed by SARS-CoV-2 variants, in January 2021 WHO organized an ad-hoc consultation to discuss the development of an R&D agenda in response to existing and emerging SARS-CoV-2 variants. The key objectives were to identify the critical research questions related to variants and agree on a research approach to address them. Six breakout groups covered a range of specific issues related to COVID-19 variants: Epidemiology and mathematical modelling; evolutionary biology; animal models; assays and diagnostics; clinical management and therapeutics; and vaccines.

The meeting report provides a summary of presentations and panel discussions.

> COVID-19 new variants: Knowledge gaps and research (25 Mar 2021)

COVAX Workshop: SARS-CoV-2 Variants

The COVAX Clinical Development & Operations SWAT Team and the Enabling Sciences SWAT Team co-organized a workshop on 25 March on “SARS-CoV-2 variants: Practical considerations for accelerated clinical development in light of current regulatory guidance”.

The meeting was convened in the light of current models that predict that there will not be enough vaccines to cover the world's population until 2023 or 2024. Manufacturing capacity for existing vaccines has expansion limits and the world needs more, and possibly, different vaccines. In addition, evolving variants are a concern. The meeting considered the clinical development pathways for two scenarios: 1) to evaluate adaptions of existing vaccines and 2) to evaluate new vaccines.

> SARS-CoV-2 variants - Practical considerations for accelerated clinical development in light of current regulatory guidance (23 Mar 2021)

Call for Partners: Development of Antibody Working Standards & Reference Panels

Through a joint effort in 2020, the Coalition for Epidemic Preparedness Innovations (CEPI), the National Institute for Biological Standards and Control (NIBSC: WHO Collaborating Centre for biological standardization) and the WHO provided COVID-19 vaccine developers and the entire scientific community with a research reagent for an anti-SARS-CoV-2 antibody, an International Reference Panel and the first WHO International Antibody Standard for assay calibration. These materials are constituted of plasma samples sourced from SARS-CoV-2 convalescent patients.

The emergence of SARS-CoV-2 variants which appear to be serologically diverse from the original VIC-01 isolate has raised questions on the suitability of current assays, the efficacy of candidate vaccines, and the suitability of WHO-endorsed International Standard established in December 2020.

To address these questions, NIBSC, with the support of CEPI and WHO, is looking for partners for sourcing serum or plasma from vaccinated individuals and / or recovered patients for the development of working standards for each of the SARS-CoV-2 variants of concern. Such material will be evaluated in a multi-center collaborative study in parallel with the first WHO International Antibody Standard. This will bridge between the WHO International Antibody Standard and a possible replacement should one be needed.

This initial outreach is focusing on the collection of B.1.1.7, B.1.351 and P1 variant serum collection, but partners interested in supporting collection of other emerging variant-specific serum/plasma are also welcome. Partners will be selected on a rolling basis in 2021.

> NIBSC is seeking partners for sourcing serum or plasma from individuals vaccinated against and/or recovered from infection with SARS-CoV-2 variants for the development of antibody working standards and reference panels (29 Mar 2021)
>
> For question, contact Giada.Mattiuzzo@nibsc.org
>
> Standardization of vaccines for coronavirus disease (COVID-19) (29 Mar 2021)
>
> Establishment of the WHO International Standard and Reference Panel for anti-SARS-CoV-2 antibody WHO/BS/2020.2403 (Nov 2020)

Update on the ACT-Accelerator

United Action Needed for Robust International Health Architecture

The COVID-19 pandemic is the biggest challenge to the global community since the 1940s. At that time, following the devastation of two world wars, political leaders came together to address the challenges that could only be achieved together in the spirit of solidarity and cooperation, namely peace, prosperity, health and security.

Today, leaders gather, aiming to take united actions to overcome the COVID-19 pandemic and to build a more robust international health architecture that will protect future generations. There will be other pandemics and other major health emergencies. No single government or multilateral agency can address this threat alone. The question is not if, but when. Together, the world must be better prepared to predict, prevent, detect, assess and effectively respond to pandemics in a highly coordinated fashion. The COVID-19 pandemic has been a stark and painful reminder that nobody is safe until everyone is safe.

The Access to COVID-19 Tools Accelerator (ACT-A) was set up to promote equal access to tests, treatments and vaccines and support health systems across the globe, committed to ensuring universal and equitable access to safe, efficacious and affordable vaccines, medicines and diagnostics for this and future pandemics.

ACT-A has delivered on many aspects but more effort is required to achieve equitable access. Furthermore collaborative effort must continue to strengthen national, regional and global capacities and resilience to future pandemics, enhancing international cooperation to improve, for example, alert systems, data-sharing, research, and local, regional and global production and

distribution of medical and public health counter measures, such as vaccines, medicines, diagnostics and personal protective equipment.

On 31st March, Mr Carl Bildt was appointed as WHO Special Envoy for the ACT-Accelerator to help lead the collective advocacy for the ACT-A, mobilizing support and resources so it can deliver against its strategy for 2021.

> Carl Bildt, former Prime Minister of Sweden, appointed WHO Special Envoy for the ACT-Accelerator (31 Mar 2021)
>
> Science in 5: Equity in vaccines, treatment and tests by Dr Mariângela Simão (01 Apr 2021)

Meeting: ACT-A Facilitation Council

The 5th ACT-A Facilitation Council meeting was held on 23rd March, co-hosted by Dr Tedros and Ms Stella Kyriakides, Commissioner for Health and Food Safety, European Commission and co-chaired by Dr Zweli Mkhize, Minister of Health, South Africa and Mr Dag-Inge Ulstein, Minister of International Development, Norway. The meeting focused on bottlenecks in achieving ACT-A diagnostics & therapeutics goals for 2021 and key areas to rapidly scale-up vaccine supply to COVAX. ACT-A is continuing to hold discussions with manufacturers and countries at all income levels about how to ramp up production, solve bottlenecks and continue to explore options for technology transfer, including through the C-TAP mechanism.

> Recording - ACT-A Facilitation Council (23 Mar 2021)

COVAX

COVAX, the vaccines pillar of the ACT-Accelerator, is convened by CEPI, GAVI and WHO, with the ambition of contracting enough volumes to equitably deliver 2 billion doses of safe, effective and quality vaccines by the end of 2021. Vaccines included in the COVAX Facility portfolio have been selected from the COVAX R&D portfolio and other clinical candidates.

Approximately 33.3 million doses of vaccines from three manufacturers, SII/AZ/Pfizer, have been shipped through COVAX Facility to 74 of 92 AMC participants as of 29th March. Shipment dates of an additional 1.35 million doses to 7 AMC participants have been confirmed.

Delivery Delays: COVISHIELD

Deliveries of COVID-19 vaccines produced by the Serum Institute of India (SII) to lower-income economies participating in the COVAX Facility will face delays during March and April as the Government of India battles a new wave of COVID-19 infections. COVAX and the Government of India remain in discussions to ensure some supplies are completed during March and April.

Following the agreement between Gavi and SII, which included funding to support an increase in manufacturing capacity, SII is contracted to provide COVAX with COVISHIELD (the SII-licensed and manufactured AstraZeneca (AZ)-Oxford vaccine) to 64 lower-income economies participating in the COVAX AMC (including India), alongside its commitments to the Government of India. In this early phase of COVID-19 vaccine roll-out, vaccine manufacturers require time to scale up and optimize their production processes.

To date, COVAX has been supplied with 28 million COVISHIELD doses and was expecting an additional 40 million doses to be available in March, and up to 50 million doses in April. COVAX has notified all affected economies of potential delays. SII has pledged that, alongside supplying India, it will prioritize the COVAX multilateral solution for equitable distribution.

> COVAX updates participants on delivery delays for vaccines from Serum Institute of India (SII) and AstraZeneca (25 Mar 2021)
>
> Considerations for optimizing deployment of AstraZeneca/AZD1222 and SII/Covishield vaccines in a time-limited constrained supply situation (17 Mar 2021)

Joint Statement: Prioritization of COVID-19 Vaccination for Seafarers and Aircrew

Maritime and air transport are two essential activities that underpin global trade and mobility and are key to a sustainable socio-economic recovery. More than 80% of global trade by volume is moved by maritime transport, supported by the world's 2 million seafarers who operate the global fleet of merchant ships. As of January 2021, it is estimated that some 400,000 seafarers are stranded on board commercial vessels, long past the expiry of their contracts and unable to be repatriated. A similar number of seafarers urgently need to join ships to replace them.

Passenger air transport carried about 5.7 billion passengers in 2019 while airfreight represents 35% of the value of goods shipped in all modes combined. The total number of licensed aviation professionals, which include pilots, air traffic controllers and licensed maintenance technicians, was 887,000 in 2019, according to ICAO personnel statistics.

Maritime and air transport rely on seafarers and aircrew, as key workers required to travel across borders at all times, which may result in the need for them to present proof of a COVID-19 vaccination as a condition for entry in some countries. This is despite WHO recommendation[1] that, at the present time, countries should not introduce requirements of proof of vaccination for international travel as a condition of entry, as there are still critical unknowns regarding the efficacy of vaccination in reducing transmission and limited availability of vaccines.

To facilitate seafarers and aircrew's safe movement across borders, on 26 March, International Civil Aviation Organization (ICAO), International Labour Organization (ILO), International Maritime Organization (IMO), International Organization for Migration (IOM) and WHO issued a joint statement to call governments to prioritize seafarers and aircrew in their national COVID-19 vaccination programmes, together with other essential workers, in accordance with the WHO SAGE Roadmap[2] for prioritizing the use of COVID-19 vaccines in the context of limited supply.

> ICAO-ILO-IMO-IOM-WHO Joint Statement on prioritization of COVID-19 vaccination for seafarers and aircrew (26 Mar 2021)

[1] Statement on the sixth meeting of the International Health Regulations (2005) Emergency Committee regarding the coronavirus disease (COVID-19) pandemic (15 Jan 2021)

[2] WHO SAGE Roadmap For Prioritizing Uses Of COVID-19 Vaccines In The Context Of Limited Supply (13 Nov 2020)

WHO's other COVID-19-related work

Origin of SARS-CoV-2 virus: Need for further studies

Following the May 2020 World Health Assembly resolution WHA73.1, WHO, working closely with the World Organisation for Animal Health, the Food and Agriculture Organization of the United Nations and countries, to identify the zoonotic source of the virus and the route of introduction to the human population, including the possible role of intermediate hosts, aiming to prevent both reinfection with the virus in animals and humans and the establishment of new zoonotic reservoirs, thereby reducing further risks of the emergence and transmission of zoonotic diseases.

The report published on 30th March calls for further studies, including testing wildlife samples for SARS-CoV-2 related viral sequence and antibodies; continuing surveys of Rhinolophus bats in southern provinces of China and countries around East Asia, South-East Asia and any other regions where Rhinolophus bats are distributed; tracing the cold chain product supplier countries where SARS-CoV-2 positive testing was preliminarily reported before the end of 2019, and where evidence of more distantly related SARS-CoV in bats outside Asia were reported, if there are credible links. It also calls for a global expert group to support future joint traceability research studies in countries and regions with initial reports of positive results in sewage, serum, human or animal tissues/swab and other SARS-CoV-2 test by the end of 2019.

> WHO calls for further studies, data on origin of SARS-CoV-2 virus, reiterates that all hypotheses remain open (30 Mar 2021)

Report: WHO COVID-19 Infection, Prevention and Control

As part of WHO's response to the COVID-19 pandemic, the WHO Research and Development (R&D) Blueprint was activated to improve coordination between scientists and global health professionals, accelerate the research and development process, and develop new norms and standards to learn from and improve upon the global response.

Three primary objectives for Infection prevention and control (IPC) research were identified in February 2020 and a global research roadmap was developed to accelerate research that can contribute to containing the spread of this epidemic and to facilitate receipt of optimal care.

The In July 2020, the WHO COVID-19 IPC R&D Expert Group reviewed the progress of the previously identified priorities within the global research roadmap, and agreed on ongoing and newly identified research needs.

In addition, on 14 January 2021 the WHO COVID-19 IPC R&D Expert Group, the WHO COVID-19 IPC Guideline Development Group and the WHO Secretariat discussed the implications of the SARS-CoV-2 variants of concern for current IPC recommendations.

This report provides the summary of the IPC pillar progress made between February 2020 to January 2021 with respect to the following 3 objectives and the implications of the SARS-CoV-2 variants of concern.

1) Understand effectiveness of movement control and other public health strategies to prevent secondary transmission in health care and community settings
2) Optimize the effectiveness of PPE and its usefulness to reduce risk of transmission in health care and community settings
3) Minimize the role of the environment in transmission

WHO COVID-19 infection prevention and control (IPC) pillar achievements. February 2020 – January 2021 (01 Apr 2021)

Guidance: Expedite Genomic Sequencing Component of GISRS Surveillance

Representative, quality, timely and continuous genetic surveillance of SARS-CoV-2 is critical to the COVID-19 outbreak response. This document provides practical guidance to Global Influenza Surveillance and Response System (GISRS) laboratories and other relevant national laboratories to move beyond virus detection to genomic sequencing of SARS-CoV-2 PCR positive materials obtained from sentinel surveillance of influenza-like illness (ILI), acute respiratory infection (ARI) and severe acute respiratory infection (SARI).

It contains considerations on sample selection for sequencing, numbers of viruses to be sequenced, metadata and timeliness for sharing genetic sequence data (GSD) and opportunities for technical support.

Operational considerations to expedite genomic sequencing component of GISRS surveillance of SARS-CoV-2 (30 Mar 2021)

WHO Weekly Operational Update

The 29th March issue of the WHO Weekly Operational Update highlights the continued roll-out of COVID-19 vaccines through the COVAX Facility to Lao People's Democratic Republic (132,000 doses) on 20th March and Afghanistan, Djibouti, Jordan, Tunisia, Somalia, Sudan and the occupied Palestinian territory including east Jerusalem with a total of more than 1.9 million doses delivered as of 21st March. The PAHO sub-regional Caribbean office has launched a survey to gauge acceptance of COVID-19 vaccines among Caribbean health care workers.

To support ongoing efforts in expanding testing strategies and capacity in Indonesia, WHO provided one million antigen-detecting rapid diagnostic tests (Ag-RDTs) on 13th March for community health centres (puskesmas) and other points of care across the country. The procurement was made possible among others by the Government of Japan.

Weekly operational update on COVID-19 (29 Mar 2021)

Global COVID-19 Clinical Data Platform

To increase global understanding of clinical characterization and management of patients with suspected or confirmed COVID-19 in different settings and populations, WHO invites Member States, health facilities and other entities to participate in a global effort to collect anonymized clinical data related to hospitalized suspected or confirmed cases of COVID-19 and contribute data to the Global COVID-19 Clinical Data Platform. WHO will use the information to inform:

- Characterization of the key clinical features and prognostic factors of cases of suspected or confirmed COVID-19, thereby increase understanding of the severity, spectrum, and impact of the disease in the hospitalized population globally, in different countries.
- Characterization of clinical interventions, thereby facilitating global and national operational planning during the COVID-19 pandemic.

To date, 81 countries have stated their intention to contribute data to the clinical platform and 40 countries have started sharing data.

COVID-19 Clinical Data Platform

For any questions, contact COVID_ClinPlatform@who.int

EPI-Win Update: Clinical Long-Term Effects of COVID-19

While most people with COVID-19 recover and return to normal health, some people can have symptoms that last for weeks or even months after recovery from acute illness. Even people who are not hospitalized and who have mild illness can experience persistent or late symptoms. People are not infectious to others during this time.

This persistent state of ill health is known as ‘post COVID condition’, but other names are also used to describe the condition. However, there is no internationally agreed definition of post COVID condition yet.

WHO has designed a post-COVID case report form to collect standardized clinical data from individuals after hospital discharge or after acute illness to examine the medium- and long-term consequences of COVID-19 and is working with experts to develop a clinical case definition of post-COVID condition. Scientific studies are underway to understand the health challenges and implications of post-COVID condition.

EPI-WIN: Clinical long-term effects of COVID-19 (26 Mar 2021)

WHO COVID-19 Vaccines Dashboard

In March 2021, the WHO Coronavirus (COVID-19) Dashboard started publishing data on the global vaccine rollout that are useful to tracking the global rollout of COVID-19 vaccines, including total doses administered, persons vaccinated with at least one dose, and start date of vaccinations, by country, territory and area. As of 31 March 2021, a total of 520,540,106 vaccine doses have been administered.

To see the data, choose “Vaccination” from the dropdown menu on the left-hand side of the map.

WHO Coronavirus (COVID-19) Dashboard

Training Materials for Health Care Workers

Based on the most up-to-date clinical guidance, WHO develops training materials via the WHO Academy and OpenWHO platforms. Training is open to anyone interested.

WHO Academy COVID-19 app on Apple store

WHO Academy COVID-19 app on Google Play

OpenWHO Clinical management of COVID-19 course series

The Public Health Emergency Operations Centre (PHEOC)

Alignment of approaches by regulators

WHO Expert Committee on Biological Standardization (ECBS)

ECBS provides recommendations and guidelines for the manufacturing, licensing and control of blood products and related in vitro diagnostic tests, biotechnology products and vaccines along with the establishment of WHO Biological Reference Materials. The 71st report covers overview of the WHO response to COVID-19, the work of the R&D Blueprint and priorities for the Coalition for Epidemic Preparedness and Innovations (CEPI). The report also summarizes WHO COVID-19 vaccine-related and blood product-related standards activities, as well as guidelines on plasmid DNA vaccines. A proposal to develop a WHO guidance document on regulatory considerations in the evaluation of mRNA vaccines is outlined. Work on this document has progressed rapidly and the document will be published online for public comments from July to September and considered by the ECBS in October 2021.

Section 2: Strategic directions in biological standardization: impact of COVID-19

Section 3: International Recommendations, Guidelines and other matters related to the manufacture, quality control and evaluation of biological products

Section 4: International reference materials – blood products and related substances

Section 7: International reference materials – standards for use in public health emergencies

Annex 2: Guidelines on the quality, safety and efficacy of plasmid DNA vaccines: Replacement of Annex 1 of WHO Technical Report Series, No. 941

WHO Expert Committee on Biological Standardization: WHO TRS N°1028 (12 Mar 2021)

WHO Expert Committee on Specification for Pharmaceutical Preparations (ECSPP)

The 55th ECSPP report contains a number of important WHO Guidance documents for regulators that are particularly relevant to COVID products, including:

Section 7: Good manufacturing practice and inspection

Section 8: Distribution and supply chain

Section 9: Regulatory guidance and model schemes

Section 9.4 Update on WHO-listed authorities (WLA), including the definition

Section 10: Update on activities related to COVID-19

Annex 4: Guideline on data integrity

Annex 9: Guidelines on the implementation of the WHO Certification Scheme on the quality of pharmaceutical products moving in international commerce

Annex 10: Good reliance practices in the regulation of medical products: high level principles and considerations

Annex 11: Good regulatory practices in the regulation of medical products

TRS 1033 - 55th report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations: WHO TRS N° 1033 (25 Mar 2021)

Draft WHO Guidance for Comments

Guidance on setting remaining shelf life for the supply and procurement of Emergency Health Kits (Comments by **15 Apr 2021)**

In vitro diagnostics

WHO EUL and Listing Update

The WHO Prequalification Unit is assessing products for Emergency Use Listing (EUL) for candidate in vitro diagnostics (IVDs) to detect SARS-CoV-2. The following IVDs are eligible for EUL submission:

- Assays for the detection of SARS-CoV-2 nucleic acid;
- Rapid diagnostic tests and enzyme immunoassays for the detection of IgM/IgG to SARS-CoV-2; and
- Rapid diagnostic tests for the detection of SARS-CoV-2 antigens.

WHO EUL submissions

Applicants are asked to submit their applications for assessment based on WHO instructions and requirements for NAT and Ag detection RDTs and IVDs detecting antibodies to SARS-CoV-2 virus.

Manufacturers who are interested in an EUL submission for assays to detect SARS-CoV-2 are invited to contact diagnostics@who.int, to arrange a pre-submission meeting/videoconference/phone conversation.

As of 31 March, 28 products have been listed as eligible for WHO procurement among a total of 133 expressions of interest (60 for NAT assays, 41 for antibody detection assays and 32 for antigen detection RDTs) have been received.

EUL listed IVDs (18 Mar 2021)

Status of each EUL application (23 Mar 2021)

Therapeutics

Updated: Living Therapeutics Guideline with Advice on Ivermectin

Vaccination is beginning to have an impact on case numbers and hospitalizations in a few countries, but limitations in global access to vaccines mean that many populations remain vulnerable. Even in vaccinated individuals, uncertainties remain about duration of protection and efficacy of current vaccines against emerging SARS-CoV-2 variants. Taken together, there remains a need for more effective treatments for COVID-19.

The COVID-19 pandemic – and the explosion of both research and misinformation – has highlighted the need for trustworthy, accessible and regularly updated living guidance to place emerging findings into context and provide clear recommendations for clinical practice. This living guideline responds to emerging evidence from randomized controlled trials (RCTs) on existing and new drug treatments for COVID-19.

More than 3,800 trials investigating interventions for COVID-19 have been registered or are ongoing. Among these are national and international platform trials (e.g. RECOVERY, WHO SOLIDARITY, DISCOVERY, REMAP-CAP and ACTIV) that recruit large numbers of patients in many countries, with a pragmatic and adaptive design. These platform trials are currently investigating and reporting on interventions, including antiviral monoclonal antibodies and immunomodulators. This rapidly evolving evidence landscape requires trustworthy interpretation and expedited clinical practice guidelines to inform clinicians and health care decision-makers.

This fourth version of the WHO living guideline addresses the use of ivermectin in patients with COVID-19, following the increased international attention on ivermectin as a potential therapeutic option. While ivermectin, an antiparasitic agent that interferes with nerve and muscle function of helminths through binding glutamate-gated chloride channels, is also being investigated for prophylaxis, this guideline only addresses its role in the treatment of COVID-19. Ivermectin is relatively inexpensive and accessible, and some countries have already witnessed its widespread

use in the treatment of COVID-19; in other countries, there is increasing pressure to do so.

WHO confirmed that currently lack persuasive evidence of a mechanism of action for ivermectin in COVID-19, and any observed clinical benefit would be unexplained, consequently advising ivermectin to be used only within the structured clinical trial setting.

> Therapeutics and COVID-19: living guideline (31 Mar 2021)
>
> WHO advises that ivermectin only be used to treat COVID-19 within clinical trials (31 Mar 2021)

Clinical Trials

International Clinical Trials Registry Platform (ICTRP)

> Information on clinical trials and trial registration. Clinical trials registered with the ICTRP platform can be searched and details of COVID-19 clinical trials can be downloaded in csv and xml formats.

Mapping and systematic review of Covid-19 trials (COVID-19 - living NMA initiative)

> A real-time monitoring and mapping of new evidence for treating and preventing COVID-19, with living mapping of trials and living synthesis of published trials.

Global Coronavirus COVID-19 Clinical Trial Tracker (Cytel)

> An interactive dashboard of clinical trials on COVID-19 that can be explored by type of product, trial status and country.

Vaccines

Call for Developers: Naming of COVID-19 Vaccines

International non-proprietary names (INN) serve to identify pharmaceutical substances or APIs. WHO collaborates with INN experts and national nomenclature committees in choosing a single name that is acceptable worldwide for each active substance to be marketed as a pharmaceutical. Since the turn of the century, increasing globalization and rapid scientific and technical development have fueled a rapid rise in the number of new biological products that are developed and approved for use. This trend, which is expected to continue, is reflected in the growing number of INN requests received each year, which rose from around 150 in 2000 to nearly 350 in 2020.

INNs are also assigned to vaccines based on DNA, RNA, recombinant protein, recombinant virus, and peptides. As of April 2021, several INNs have been assigned to mRNA-based vaccines and one plasmid-based DNA vaccine, including the anti-severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) mRNAs *zorecimeran* and *tozinameran*, and the anti-SARS-CoV-2 DNA plasmid *reluscovtogene ralaplasmid.*

Currently new mRNA vaccines are being developed against variant SARS-CoV-2 viruses, presenting new structures. The INN Expert Group will discuss nomenclature schemes to address this issue during the forthcoming INN Consultation on 13 to 16 April 2021.

For the safety of vaccine recipients and the global recognition of vaccine ingredients, the WHO INN Programme encourages vaccine developers to submit INN requests for well-defined vaccine ingredients through its online system.

> INN online application
>
> INN Request form
>
> Selection process of INNs: For any questions, contact innprogramme@who.int
>
> Proposed INN: List 124 –COVID-19 (special edition) WHO Drug Information, Vol. 34, No. 3, 2020

AstraZeneca COVID-19 Vaccine

European Medicines Agency (EMA) convened its Pharmacovigilance Risk Assessment Committee (PRAC) met on 31st March in the context of its ongoing review of very rare cases of unusual blood clots associated with low numbers of platelets, in people vaccinated with AstraZeneca's COVID-19 vaccine (now called Vaxzevria). The PRAC meeting was a follow up to the EMA's ad-hoc expert group meeting held on 29th March where they discussed with independent external experts with a range of medical specialities, including hematologists, neurologists and epidemiologists, possible mechanisms, whether underlying risk factors could be identified and what additional data are needed to further characterize the observed events and the potential risk.

The review has not identified any specific risk factors, such as age, gender or a previous medical history of clotting disorders, for these very rare events. A causal link with the vaccine is not yet proven but is possible and further analysis is continuing.

The EMA is of the view that the benefits of the AstraZeneca vaccine in preventing COVID-19, with its associated risk of hospitalization and death, outweigh the risks of side effects. PRAC is continuing its assessment of the reported cases and will meet from 6th to 9th April.

EMA's recommendations are the foundation upon which individual EU Member States will design and implement their own national vaccination campaigns. These may differ from country to country depending on their national needs and circumstances, such as infection rates, priority populations, vaccine availability and hospitalization rates.

> EMA press briefing on the update on the investigation of AstraZeneca's COVID-19 vaccine and thromboembolic events (31 Mar 2021)
>
> COVID-19 vaccines safety monitoring: Update on emerging data since EU authorisations by Dr. Peter Arlett, Head of Data Analytics and Methods, EMA (31 Mar 2021)

WHO is carefully monitoring the rollout of all COVID-19 vaccines and will continue to work closely with countries to manage potential risks, and to use science and data to drive safety recommendations. The WHO Global Advisory Committee on Vaccine Safety's sub-committee on COVID-19 vaccines is actively and rapidly reviewing the emerging evidence, working in collaboration with EMA and other agencies, and, if needed, will update its advice.

Safety of COVID-19 Vaccines

Safety Surveillance of COVID-19 Vaccines in Pregnant and Breastfeeding Women

While there is no indication that pregnant women have an increased susceptibility to infection with SARS-CoV-2, there is evidence that pregnancy may increase the risk of severe illness and mortality from COVID-19 disease in comparison with non-pregnant women of reproductive age. As seen with non-pregnant women, a high proportion of pregnant women have asymptomatic SARS-CoV-2 infection and severe disease is associated with recognized medical (e.g., high body-mass index (BMI), diabetes, pre-existing pulmonary or cardiac conditions) and social (e.g., social deprivation, ethnicity) risk factors. Pregnant women with symptomatic COVID-19 appear to have an increased risk of intensive care unit admission, mechanical ventilation and death in comparison with non-pregnant women of reproductive age, although the absolute risks remain low. COVID-19 may increase the risk of preterm birth, compared with pregnant women without COVID-19, although the evidence is inconclusive.

> Safety surveillance of COVID-19 vaccines in pregnant and breastfeeding women (01 Apr 2021)

Support Materials for Safety of COVID-19 Vaccines

Countries around the world are rolling out COVID-19 vaccines, and a key topic of interest is their safety. Vaccine safety is one of WHO's highest priorities, and WHO is working closely with national authorities to develop and implement standards to ensure that COVID-19 vaccines are safe and effective.

Safety of COVID-19 Vaccines (31 Mar 2021)

Side Effects of COVID-19 Vaccines (31 Mar 2021)

How to monitor and report COVID-19 vaccine side effects (15 Mar 2021)

WHO-ECHO Webinar on Reporting on COVID-19 vaccines

On 30th March, WHO-ECHO webinar on Reporting on COVID-19 vaccines "Monitoring and Adverse Events Following Immunization (AEFI)" was held to describe mechanisms for reporting and monitoring of AEFI.

Recording in English, French, Spanish

Guidance: Assessing Vaccine Effectiveness

The Vaccine effectiveness and impact interim guidance outlines how to assess COVID-19 vaccine effectiveness (VE) using observational study designs. It discusses critical considerations in the design, analysis and interpretation of COVID-19 VE evaluations, as biased results may be produced even in settings where data completeness and quality are high. This guidance is targeted mostly for evaluations undertaken in low- and middle-income countries but most of the concepts also apply to VE evaluations in high-income settings.

Objectives of VE evaluations are to evaluate real-world performance of vaccines, to address gaps in evidence from clinical trials (including effectiveness in subgroups, effectiveness against variants of concern and duration of protection), to provide input into impact models, and to provide post-authorization confirmation of effectiveness of conditionally approved products.

The most feasible outcomes to evaluate in VE evaluations in most settings are symptomatic disease and severe disease. VE studies of death, infection and transmission, while of great public health importance, generally require targeted special studies with more resources.

Due to lack of randomization of vaccination in real-world settings, all observational study designs are subject to bias because vaccinated persons often differ from unvaccinated persons in their disease risk, independent of vaccination. Important biases include: confounding by health care seeking, exposure risk, misclassification of outcomes due to diagnostic errors, prior SARS-CoV-2 infection, and spurious inferences of waning. Collection of key covariates to control for confounding bias in the analysis is important.

The primary analysis should compare persons receiving the recommended number of doses of the same vaccine with unvaccinated individuals. Secondary analyses include partially vaccinated persons, persons receiving doses of two different vaccines, targeted subgroups, viral variants, and history of prior SARS-CoV-2 infection or disease if available. Even though partial vaccination and the use of different vaccines to complete a course are not currently recommended by WHO, these might happen in the real world and findings could inform future policy.

We recommend standardized reporting of the results of studies based on the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidance, as well as suggested additional COVID-19 specific elements.

Evaluation of COVID-19 vaccine effectiveness (17 Mar 2021)

Sample size calculator for evaluation of COVID-19 vaccine effectiveness (Excel)

Draft Landscape of Observational Studies on VE

WHO has published a new landscape document that provides an overview of the different observational studies that are being conducted to assess the effectiveness of COVID-19 vaccination, including key features in terms of study design, sample size, study population, key outcomes measured and location of study.

These landscape documents have been prepared by WHO for information purposes only

concerning the 2019-2020 global of the novel coronavirus. Inclusion of any particular product or entity in any of these landscape documents does not constitute, and shall not be deemed or construed as, any approval or endorsement by WHO of such product or entity (or any of its businesses or activities).

Draft landscape of observational study designs on the effectiveness of COVID-19 vaccination (29 Mar 2021)

Draft Guidance for Comments: Smart Vaccination Certificate

In response to the need for WHO to support Member States to deliver COVID-19 vaccines, at scale, with digital tools, WHO has developed a guidance and technical specifications document, in collaboration with a multi-disciplinary group of experts, on adopting interoperability standards for digital documentation of vaccination status (i.e. Smart Vaccination Certificates).

It is critical to reiterate that the Smart Vaccination Certificate (SVC) is not intended to serve as an "immunity passport". Further, proof of COVID-19 vaccination is not recommended as a condition of departure or entry for international travel. Additionally, along with the digital implementation of SVCs, it is recommended that the COVID-19 vaccination status should still be recorded through the paper-based International Certificate for Vaccination.

Due to the constantly evolving context of the COVID-19 pandemic, this document is intended to have three releases prior to the release of the final version, with public feedback and input considered for all three releases. This document contains the key business requirements for an SVC for national adoption that includes the prioritized scenarios of use, use cases, key workflows, a core data set with preferred terminology code sets, and an initial Implementation Guide for the content in Release Candidate 1. This document also begins to outline the international trust framework and a high-level overview of a governance mechanism.

Call for public comments: Interim guidance for developing a Smart Vaccination Certificate – Release Candidate 1 (Comments by **12 Apr 2021**)

WHO Smart Vaccination Certificate Working Group

Status Update: EMA approved and candidate COVID-19 vaccines

EMA update on approved and candidate vaccines (31 Mar 2021)

Status Update: WHO EUL/PQ evaluation

WHO has placed into the public domain the status of COVID-19 vaccines for which an expression of interest has been received by WHO/PQ. The information shared includes the National Regulatory Authority (NRA) of record for each vaccine; whether the expression of interest has been accepted; if a pre-submission meeting has been held; if the dossier has been accepted for review; the status of the assessment; and the anticipated decision date.

Please visit the site regularly for the latest updated version.

Below is version 01 April 2021.

32nd WHO Regulatory Update on COVID-19

	Manufacturer	Name of Vaccine	NRA of Record	Platform	EOI accepted	Pre-submission meeting held	Dossier accepted for review*	Status of assessment**	Anticipated decision date***
1.	Pfizer BIONTECH	BNT162b2/COMIRNATY Tozinameran (INN)	EMA	Nucleoside modified mNRA	✓	✓	✓	Finalized	31/12/20
2.	EU Nodes AstraZeneca COVAX	AZD1222	Core – EMA Non-COVAX	Recombinant ChAdOx1 adenoviral vector encoding the Spike protein antigen of the SARS-CoV-2.	✓	✓	Accepted core data of AZ – non-Covax	Core data – now as donation for COVAX.	1st wk April 2021
							Data for Covax sites expected in April 2021 onwards	Awaited	April 2021 onwards
3.	SK BIO AstraZeneca COVAX	AZD1222	MFDS KOREA	Recombinant ChAdOx1 adenoviral vector encoding the Spike protein antigen of the SARS-CoV-2.	✓	✓	✓	Finalized	15 Feb 2021
4.	**Serum Institute of India**	Covishield (ChAdOx1_nCoV-19)	DCGI	Recombinant ChAdOx1 adenoviral vector encoding the Spike protein antigen of the SARS-CoV-2.	✓	✓	✓	Finalized	15 Feb 2021
5.	janssen Infectious Diseases & Vaccines	Ad26.COV2.S	EMA	Recombinant, replication-incompetent adenovirus type 26 (Ad26) vectored vaccine encoding the (SARS-CoV-2) Spike (S) protein	✓	✓	Core data (US +NL sites) ✓	Finalized	12 March 2021
							Additional sites awaited	Awaited	To be fixed after data submission
6.	Sinopharm / BIBP[1]	SARS-CoV-2 Vaccine (Vero Cell), Inactivated (InCoV)	NMPA	Inactivated, produced in Vero cells	✓	✓	✓	In progress	Mid. April 2021
7.	sinovac	SARS-CoV-2 Vaccine (Vero Cell), Inactivated	NMPA	Inactivated, produced in Vero cells	✓	✓	✓	In progress	Mid. April 2021
8.	moderna	mRNA-1273	EMA	mNRA-based vaccine encapsulated in lipid nanoparticle (LNP)	✓	✓	✓	In progress using the abridged procedure (EMA).	Mid. April 2021
9.	THE GAMALEYA NATIONAL CENTER	Sputnik V	Russian NRA	Human Adenovirus Vector-based Covid-19 vaccine	Additional information submitted	Several meetings held.	"Rolling" submission of clinical and CMC data has started.	Additional data (Non-CLIN, CLIN, CMC) Required. Inspections in May and June 2021	Will be fixed after all data is submitted and inspections completed.
10.	康希诺生物 CanSinoBIO	Ad5-nCoV	NMPA	Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector)	✓	✓	Rolling data starting April 2021		
11.	NOVAVAX		EMA	No pre-submission meeting yet.	Submitted EOI on 23 Feb	To be planned in April based on company request.			
12.	Vector State Research Centre of Virology and Biotechnology	EpiVacCorona	Russian NRA	Peptide antigen	Letter received not EOI. Reply sent on 15/01/2021				
13.	Zhifei Longcom, China	Recombinant Novel Coronavirus Vaccine (CHO Cell)	NMPA	Recombinant protein subunit	Response to 2nd EOI sent 29 Jan 2021. Additional information requested.				

	Manufacturer	Name of Vaccine	NRA of Record	Platform	EOI accepted	Pre-submission meeting held	Dossier accepted for review*	Status of assessment**	Anticipated decision date***
14.	IMBCAMS, China	SARS-CoV-2 Vaccine, Inactivated (Vero Cell)	NMPA	Inactivated	Not accepted, still under initial development				
15.	Sinopharm / WIBP[2]	Inactivated SARS-CoV-2 Vaccine (Vero Cell)	NMPA	Inactivated, produced in Vero cells					
16.	Bharat Biotech, India	COVAXIN	DCGI	SARS-CoV-2 Vaccine, Inactivated (Vero Cell)	Requested meeting to discuss details of submission/timelines				
17.	Clover Biopharmaceuticals	SCB-2019	EMA	Novel recombinant SARS-CoV-2 Spike (S)-Trimer fusion protein	In discussion on submission strategy and timelines				
18.	BioCubaFarma - Cuba	Soberana 01, Soberana 02 Soberana Plus	CECMED	SARS-CoV-2 spike protein conjugated chemically to meningococcal B or tetanus toxoid or Aluminum	In discussion on submission strategy and timelines				

1. Beijing Bio-Institute of Biological Products Co-Ltd
2. Wuhan Institute of Biological Products Co Ltd

* Dossier Submission dates: more than one date is possible because of the rolling submission approach. Dossier is accepted after screening of received submission.
**Status of assessment: 1. Under screening; 2. Under assessment; 3. Waiting responses from the applicant. 4. Risk-benefit decision 5. Final decision made
*** Anticipated decision date: this is only an estimate because it depends on when all the data is submitted under rolling submission and when all the responses to the assessors' questions are submitted.

Support materials:

WHO Vaccine explainer

	Pfizer	Moderna	AstraZeneca	J&J
What you need to know	AR EN ES FR RU ZH	AR EN ES FR RU ZH	EN ES FR RU ZH	EN[NEW] RU[NEW]
Vaccine overview	AR[NEW] EN RU ZH ES FR PT	EN AR[NEW] FR PT RU ZH	AR EN ES FR PT RU ZH	EN[NEW]
Instructional training video	EN FR[NEW]	EN[NEW]	EN [NEW]	EN[NEW]
SAGE Interim recommendations	EN	EN		

Living mapping and living systematic review of COVID-19 studies

Living mapping and living systematic reviews are available based on daily searches of the literature for candidate vaccines against COVID-19. As of 23 March 2021, the Covid-19 - living NMA initiative collected 191 RCTs and 63 non-randomized studies of vaccines from the ICTRP. 111 of these trials are recruiting patients. The tool allows vaccine comparisons where data are available as well as a table with the general characteristics of each trial. For each vaccine comparison, forest plots for all the outcomes of interest are available as well as the Summary of Findings table.

The mapping tool

Landscape and tracker of COVID-19 candidate vaccines

The COVID-19 candidate vaccine landscape database compiles detailed information on COVID-19 vaccine candidates in development. The landscape is updated regularly.

> Update (02 Apr 2021)

WHO Assays Working Group

An update on the Agility project was presented at the 31 March meeting. This is a collaboration between WHO / CEPI / Public Health England and the UKs National Institute for Biological Standards and Control. The project involves propagation and quality control of viral stock from SARS-CoV-2 variants for use by the research and development community; assessment of the comparative neutralization sensitivity of the variants using a standard panel of plasma; and, if needed, assessment of the variants in an hamster model. The standard convalescent panel was obtained in the UK before July 2020. The panel therefor predates the emergence of the current variants of concern. Neutralization of wild type virus for the B.1.1.7, B.1.351 and P1 variants was found to be reduced by 8-fold, 66-fold and 13-fold respectively compared to the B (Vic01) strain. When data were normalized by expressing neutralizing antibody titres in International Units/ml, by calibration with the WHO International Standard, only the B 1.351 strain was found to be significantly less susceptible to neutralization by the convalescent panel than the B(Vic01) strain.

Substandard and falsified products

Falsified COVID-19 Vaccine BNT162b2

A WHO Medical Product Alert has been issued that refers to falsified vaccine identified as "BNT162b2" detected in Mexico in February 2021 and recently confirmed as falsified to the WHO. The falsified product was supplied and administered to patients outside authorized vaccination programs. This falsified COVID-19 Vaccine may still be in circulation in the region and may continue to be offered to patients outside authorized vaccination programs.

Laboratory analysis of the contents of the falsified products is pending and the Alert will be updated as soon as results are available.

> Medical Product Alert N°2/2021: Falsified COVID-19 Vaccine BNT162b2: Falsified COVID-19 Vaccine BNT162b2 identified in the WHO region of the Americas (26 Mar 2021)

Reports of substandard/falsified medicines, vaccines and IVDs for COVID-19:

A number of ministries of health, national regulatory authorities and public procurement organizations have received suspicious offers to supply COVID-19 vaccines. WHO is also aware of vaccines being diverted and reintroduced into the supply chain, with no guarantee that cold chain has been maintained. Some falsified products are also being sold as vaccines on the internet, especially on the dark web, and WHO is aware of other reports of corruption and re-use of empty vaccine vials.

WHO urges the secure disposal or destruction of used and empty vaccine vials to prevent them from being reused by criminal groups. People are urged not to buy vaccines outside government-run vaccination programmes. Any vaccine bought outside these programmes may be substandard or falsified, with the potential to cause serious harm. Any harm caused by a falsified product does not reflect a safety failure of the genuine vaccine.

WHO urges all countries and individuals to pay careful attention to this issue. Any suspicious sale of vaccines should be reported to national authorities, who will report it to WHO. Information flow is essential to map global threats and protect confidence in vaccines.

If you have any information concerning the manufacture, distribution, or supply of these products, please contact rapidalert@who.int.

Supply Chain

Transportation backlogs

Backlogs of transportation are reported from several regions. A review across UN agencies is underway to understand the magnitude of the problem and potential diplomatic solution options.

Important reminder on traceability

Products should be traced to the batch number level from the manufacturer to all points up to the point of care.

Newly added shortages:

- Atracurium Injection
- Oxygen
- Morphine granules

Atracurium is important for intubated patients and has been reported in shortage by multiple countries. Oxygen is in critical shortage, especially in LMICs. An important discontinuation of morphine granules is compounding the ongoing shortage of morphine, particularly for paediatric patients.

Shortage watch list

The following medicines are showing signals of imminent shortage and should be watched carefully. Hording and speculative procurement should be avoided. Care should be used to ensure the best use of available national inventories. These shortages are reported in Western European and South American countries:

- Antibiotics: azithromycin, levofloxacin, metronidazole, amoxiclav, piperacillin, tazobactam
- Atracurium Injection
- epinephrine and norepinephrine
- Benzodiazepine sedatives: midazolam and lorazepam
- Nonbenzodiazepine sedatives: propofol
- Antipsychotics: haloperidol
- Neuromuscular relaxants: succinylcholine, atracurium, or vecuronium.
- Opioids: morphine and fentanyl
- Malaria treatments: hydroxychloroquine, chloroquine, artemether-lumafantrine, artemisinin-based combination therapies, sulfadoxine-pyrimethamine + amodiaquine)
- NCD: Metformin and insulin
- Anticoagulants: heparin, porcine based in countries with limited access to new generation anticoagulants
- Antipyretics: paracetamol (aka acetaminophen)
- PPE
- Oxygen and related equipment
- Ventilators

Upcoming events

R&D Blueprint Monthly meeting: 06 April 14:00 – 16:00 CET

The second monthly WHO COVID-19 Vaccine research forum will be held with the goals of these ongoing meetings to encourage and facilitate the rapid dissemination of research protocols and emerging results and to provide regular updates against R&D Blueprint roadmap priorities with the ability to pivot given dynamic research needs.

Please Register

COVAX Webinars

13 Apr 2021, 17:00 – 20:30 CET

Challenges of vaccinating pregnant and lactating women during the COVID-19 pandemic

14 Apr 2021, 15:00 - 18:00 CET

Multivalent COVID-19 vaccines to help address emergence of variants: CMC and Clinical implications

16 Apr 2021, 15:00 – 18:00 CET

Global and local approaches to detect and interpret SARS-CoV-2 variants

World Health Day 2021: Building a Fairer, Healthier World

World Health day Campaign site

07 April 2021 14:00 – 15:30 CET

Webinar - An urgent call to work together to tackle health inequities

Webinar agenda