Key Messages

The COVID-19 pandemic has revealed the importance of data to support academics, researchers and industry in developing vaccines and therapeutics; to support regulators and health authorities in their decision-making; to support healthcare professionals in their treatment decisions; and to support public confidence in the vaccines and therapeutics being deployed. More than 50% of clinical trials are generally unreported by academics, researchers and industry, often because the results are negative. These unreported trial results have potential to hinder the design of best-suited trials, cause unnecessary testing and delay the development of innovative safe and efficacious treatments and vaccines. ICMRA and WHO call on the pharmaceutical industry to commit, within short timelines, and without waiting for legal changes, to provide voluntary access to trial results data for the benefit of public health, while personal data and individual patient data should be redacted.

Highlights and main issues

- B.1.617 is a variant has recently been designated as a WHO Variant of Concern. Preliminary evidence suggests potential reduced effectiveness of Bamlanivimab, a monoclonal antibody used for COVID-19 treatment, and potentially slightly reduced susceptibility to neutralization antibodies.
- A new WHO report provides a summary of global research initiatives and achievements to tackle COVID-19 agreed at the outset of the pandemic. The impact of regulatory science is acknowledged and priority areas for future regulatory science are highlighted.
- The International Nonproprietary Name (INN) Expert Group has adopted a nomenclature for COVID-19 vaccine substances dedicated to SARS-CoV-2 variants of concern (VOCs). The WHO INN Programme encourages vaccine developers to submit INN requests for COVID-19 vaccine substances, including those directed against SARS-CoV-2 VOCs and urges regulatory authorities to facilitate their implementation.
- WHO has issued an Emergency Use Listing EUL for the Moderna COVID-19 vaccine (mRNA 1273), named as ‘elasomeran’ by INN.
- WHO has recommended listing of the BIBP inactivated COVID-19 vaccine for EUL.
- Additional production sites of Vaxzevria, the AstraZeneca COVID-19 vaccine, in Europe have been listed for the WHO EUL, based on oversight of the EMA.
- Several countries, starting with France, New Zealand and Sweden, have made commitments to donate doses from their stocks to boost vaccine supplies to COVAX. Such support will ensure that people in vulnerable countries, especially in Africa, will be able to receive their second doses through the COVAX initiative.
- A WHO Expert Group has been established to prepare WHO Emergency Interim Guidance on the clinical diagnosis and management of Thrombotic
Thrombocytopenic Syndrome (TTS), a rare event reported after vaccination with Vaxzevria, Covishield and the Janssen COVID-19 vaccines.

- WHO has commended countries that have announced support for a temporary waiver on intellectual property rights for COVID-19 vaccines.
- WHO has published posters intended for health workers and other personnel on the safety and mitigation measures that need to be adhered to when dealing with medical oxygen.

Contents

Key Messages .............................................................................................................. 1
Highlights and main issues ........................................................................................... 1
Virus variants ................................................................................................................... 3
  Designation of a new WHO Variant of Concern .......................................................... 3
  Epidemiological Update ............................................................................................... 4
  Integrated surveillance of influenza and SARS CoV-2 .................................................. 4
  Multivalent COVID-19 vaccines to help address emergence of variants .................... 4
  Global and local approaches to detect and interpret SARS-CoV-2 variants .................. 5
Update on the ACT-Accelerator ....................................................................................... 5
  Temporary waiver on intellectual property rights for COVID-19 vaccines .................... 5
  ACT now, ACT together 2020-2021 Impact Report .................................................... 5
  ACT-A Facilitation Council meeting ............................................................................ 5
COVAX ......................................................................................................................... 6
  Sharing of vaccine doses with COVAX ........................................................................ 6
WHO’s other COVID-19-related work ............................................................................. 6
  COVID-19 Research and Innovation Achievements ..................................................... 6
  IHR Emergency Committee on new coronavirus COVID-19 outbreak ....................... 7
  COVID-19 vaccines: National deployment and vaccination plans ................................. 7
Alignment of approaches by regulators ........................................................................... 7
  Transparency and data sharing .................................................................................... 7
  Draft WHO Guidance for Comments .......................................................................... 8
    WHO guidelines on evaluation of similar biological products ...................................... 8
    WHO guidelines on the transfer of technology in pharmaceutical manufacturing ...... 8
In vitro diagnostics ........................................................................................................ 8
  WHO EUL and Listing Update ..................................................................................... 8
    IVDs listed by National Regulatory Authorities in IMDRF jurisdictions ..................... 9
Therapeutics .................................................................................................................. 9
  Clinical Trials ............................................................................................................. 9
  Support materials ...................................................................................................... 9
    COVID-19 therapeutics: Knowledge gaps and research priorities .............................. 9
Blood products .............................................................................................................. 10
  Assessing national regulatory systems for blood products .......................................... 10
  Advancing Access to Safe, Effective and Quality-Assured Blood Products .................. 10
Vaccines ....................................................................................................................... 10
  WHO COVID-19 Vaccines Dashboard ...................................................................... 10
  Beijing Institute of Biological Products ....................................................................... 10
    Listed for WHO EUL ................................................................................................. 10
    WHO SAGE interim recommendations .................................................................... 11
  Moderna COVID-19 vaccine (mRNA 1273) elasomeran ............................................. 11
    WHO EUL and SAGE interim recommendations ...................................................... 11
  Pfizer-BioNTech COVID-19 Vaccine tozinameran ...................................................... 12
  Health Canada ......................................................................................................... 12
Designation of a new WHO Variant of Concern

B.1.617 is a variant which include mutations of E484Q, L452R and P681R, was reported initially from India and recently been designated as a Variant Of Concern by WHO. B.1.617 contains three sub-lineages, which differ by few but potentially relevant mutations in the spike protein as well as prevalence of detection globally. As of 11 May, over 4’500 sequences have been uploaded to GISAID and assigned to B.1.617 from 44 countries in all six WHO regions, and WHO has received reports of detections from five additional countries. Though there may be important differences among the three sublineages, currently available evidence is too limited for VOI/VOC characterization by sublineage. Future delineation of sublineages as VOIs/VOCs may be possible as our understanding by sublineage and relative importance of their epidemiology increases.

Preliminary evidence suggests potential reduced effectiveness of Bamlanivimab, a monoclonal
In India, heterogeneity in B.1.617 geographic distribution is observed across regions, with co-circulation of other VOCs (including VOC 202012/01 and 501Y.V2) and other variants (e.g., B.1.618), which collectively may be playing a role in the current resurgence in this country. Indeed, studies have highlighted that the spread of the second wave has been much faster than the first. Preliminary modelling by WHO based on sequences submitted to GISAID suggest that B.1.617 has a higher growth rate than other circulating variants in India, suggesting potential increased transmissibility, with other co-circulating variants also demonstrating increased transmissibility. Other drivers may include challenges around the implementation and adherence to public health and social measures (PHSM), and social gatherings (including mass gatherings during cultural and religious celebrations, and elections). Further investigation is needed to understand the relative contribution of these factors.

Epidemiological Update

WHO, in collaboration with national authorities, institutions and researchers, routinely assesses if variants of SARS-CoV-2 result in changes in transmissibility, clinical presentation and severity, or if they result in changes in public health and social measures (PHSM) implementation by national health authorities. Systems have been established to detect “signals” of potential VOCs or VOIs and assess these based on the risk posed to global public health.

Information on the newly designated VOC within lineage B.1.617, and an update on the geographical distribution, and emerging evidence surrounding phenotypic characteristics of all designated VOIs and VOCs is provided in the latest edition of the WHO Weekly Epidemiological Update.

Integrated surveillance of influenza and SARS CoV-2

The WHO Global Influenza Programme is organizing a series of e-workshops on “Integrated surveillance of influenza and SARS-CoV-2” to strengthen capacities towards building an agile Global Influenza Surveillance and Response System (GISRS) capable of addressing the threats from influenza as well as other respiratory emergencies. Its first e-workshop on 5th May provided a comparative overview of the virology of SARS CoV-2 and influenza viruses and also addressed the understanding of the use of bioinformatics for SARS-CoV-2, influenza and RSV surveillance.

Multivalent COVID-19 vaccines to help address emergence of variants

The meeting report of a COVAX Workshop on “multivalent COVID-19 vaccines: Chemistry, manufacturing and control (CMC) and clinical implications” is now available. The meeting focused on multivalent vaccines (containing for example an antigen against the prototype strain as well as an antigen directed against a variant) and the lessons learned when developing such multivalent vaccines.
Global and local approaches to detect and interpret SARS-CoV-2 variants

A COVAX workshop held on 16th April shared information on how to efficiently connect local pathogen genomic sequencing, epidemiology, virology and immunology to rapidly generate actionable information on the immunological consequences of emerging SARS-CoV-2 variants. There was discussion of how knowledge gained in one country or region can feed into, and benefit from, large international efforts and inform global and local decision making. Ideas were discussed for best practices for assessing virus neutralization activity, and approaches to standardizing assays and protocols to improve interpretation of results generated in different laboratories and geographies.

Presentations for ‘Global and local approaches to detect and interpret SARS-CoV-2 variants’

Update on the ACT-Accelerator

Temporary waiver on intellectual property rights for COVID-19 vaccines

Throughout the COVID-19 pandemic, WHO has been working with partners to scale up the development and distribution of vaccines, diagnostics and treatments through the Access to COVID-19 Tools Accelerator, a pillar of which is the COVAX Facility for the equitable sharing of vaccines to at-risk people worldwide. On 5th May, US Trade Representative, Ambassador Katherine Tai, issued a statement saying the extraordinary circumstances caused by the COVID-19 pandemic required extraordinary measures to respond and that the waiving of intellectual property protections on vaccines was needed to help end the pandemic. The United States would, the statement continued, participate in World Trade Organization negotiations to support the temporary waiving of protections, and work with the private sector and other partners to expand vaccine manufacturing and distribution. The EU has also indicated their intention to engage in these discussions.

WHO Director-General commends United States decision to support temporary waiver on intellectual property rights for COVID-19 vaccines (05 May 2021)

ACT now, ACT together 2020-2021 Impact Report

To coincide with the first anniversary of the ACT-Accelerator, the partners released a progress report. The 2020-2021 Impact Report looks back at the challenges and progress of the ACT-Accelerator over the last year. It highlights the accelerated actions taken by each of the ACT-Accelerator pillars to ensure low- and middle-income countries are not left behind in the race to protect their health workers, test their populations, and ensure appropriate treatments, medical supplies and more recently vaccines, are delivered to where they are needed most.

The report describes the partnerships built with these countries to identify gaps in their health systems and jointly find solutions. It illustrates the solidarity underpinning the collaboration to find new tools, conduct vaccine trials, recruit volunteer patients to test existing treatments and support financing facilities to guarantee procurement of COVID-19 tools. Countries and communities where ACT-Accelerator has made a difference are showcased.

ACT now, ACT together 2020-2021 Impact Report (28 Apr 2021)

ACT-Accelerator Impact Report: Summary (English, French, Arab)

ACT-A Facilitation Council meeting

6th Access to COVID-19 Tools Accelerator Facilitation Council meeting was held on 12 May 2021. Primary objectives of the meeting were to:

- Identify barriers and strategies for increasing uptake and use of COVID-19 tools at country level
34th WHO Regulatory Update on COVID-19

- Guide COVAX Task Force on strategies to expand COVID-19 vaccine production

Event was co-hosted by Dr Tedros, Director General, WHO and Ms Stella Kyriakides, Commissioner for Health and Food Safety, European Commission and co-chaired by Dr Zwelini Mkhize, Minister of Health, South Africa and Mr Dag Ulstein, Minister of International Development, Norway.

Recording (12 May 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.

**Sharing of vaccine doses with COVAX**

COVAX urgently needs 20 million doses during the second quarter of 2021 to cover interruptions in supply triggered by increased demands for vaccines in India where COVAX’s main supplier of the AstraZeneca product is based. Dr Tedros commented that “Such support will ensure that people in vulnerable countries, especially, in Africa, will be able to receive their second doses through the COVAX initiative.” WHO and its partners are advocating for countries to make contributions to donate doses from their stocks to boost vaccine supplies to COVAX to deepen vaccination coverage in low income countries and to ensure populations in such places receive needed second doses.

Several countries have made commitments recently, including France, New Zealand and Sweden. Such support will ensure that people in vulnerable countries, especially, in Africa, will be able to receive their second doses through the COVAX initiative.

WHO welcomes Sweden’s announcement to share COVID-19 vaccine doses with COVAX (03 May 2021)

**WHO’s other COVID-19-related work**

**COVID-19 Research and Innovation Achievements**

A new report provides a summary of global research initiatives and achievements to tackle COVID-19 agreed at the outset of the pandemic. Within a few weeks of declaring COVID-19 to be a public health emergency of international concern (PHEIC), WHO published a coordinated global research roadmap, identifying the knowledge gaps the world urgently needed scientists to fill to find solutions to tackle the COVID-19 pandemic. Fourteen months later, research on most of the knowledge gaps has been initiated, is progressing and has provided answers to several of the knowledge gaps identified in the roadmap. Most notably, Research and Development (R&D) has delivered safe and efficacious COVID-19 vaccines at an unprecedented speed. In the new report, research progress is measured on all the knowledge gaps, key R&D achievements are identified and the gaps that still exist highlighted.

Progress and challenges in regulatory science are summarized in the report which highlights the importance of regulatory engagement with the R&D agenda. The result has been that procurement agencies and WHO Member States have been provided rapidly with authoritative and trusted guidance on urgently needed quality-assured diagnostics, treatments, vaccines and other health products to address COVID-19. Practical, collaborative ways of working with regulators around the world have been developed that have enabled timely regulatory decision-making without compromising the independent evaluation of quality, safety and efficacy of these essential COVID tools. This has enabled these products to be used in populations worldwide and continues
in gathering post-approval clinical and safety data in a standardized manner.

COVID-19 vaccines development has been unique. However, there is still a need for rapid results in the context of major public health needs around the world. Reliable results are needed to support vaccine confidence and, importantly, equitable results that respect the rights and values of all people are needed. Important and critical investigation is being coordinated by WHO to advance our understanding for safe and effective COVID-19 vaccines and to accelerate and coordinate the research, development and evaluation of candidate products.

Recording available in 6 languages (13-14 May 2021)
COVID-19 Research and Innovation Achievements (13 May 2021)

IHR Emergency Committee on new coronavirus COVID-19 outbreak

The seventh meeting of the Emergency Committee convened by the WHO Director-General under the International Health Regulations (2005) (IHR) regarding the coronavirus disease (COVID-19) took place on 15th April 2021. On the basis of recommendations from the Committee, the Director-General determined that the COVID-19 pandemic continues to constitute a Public Health Emergency of International Concern (PHEIC). He accepted the advice of the Committee to WHO and issued the Committee’s advice to States Parties as Temporary Recommendations under the IHR. WHO were requested to promote global solidarity and equitable vaccine access by encouraging States Parties and manufacturers to support the COVAX Facility, including by sharing vaccine doses, and to conduct technology transfer for local production of COVID-19 vaccines and ancillary supplies, including in low- and middle-income countries with scalable capacities. Furthermore, regulatory agencies were encouraged to use reliance mechanisms, and WHO was requested to support States Parties in strengthening their regulatory agencies to facilitate supply of vaccines with assured quality, efficacy, and safety.


COVID-19 vaccines: National deployment and vaccination plans

WHO developed this guide to support national governments developing their national deployment and vaccination plans (NDVPs) for COVID-19 vaccines by outlining the roles, needs and opportunities for community health workers (CHWs) to contribute. It builds on and is structured to align with the Guidance on developing a national deployment and vaccination plan for COVID-19 vaccines.

The role of community health workers in COVID-19 vaccination: implementation support guide (26 Apr 2021)

Alignment of approaches by regulators

Transparency and data sharing

Transparency and data sharing strengthens the validity and value of the scientific evidence base. To succeed, initiatives need multi-stakeholder engagement aimed at finding solutions that deliver benefits for public health. Through transparency, regulators are opening their decisions to public scrutiny demonstrating, confidence in their work. Approximately 50% of clinical trials are generally unreported by academics, researchers and industry, often because the results are negative. These unreported trial results have potential to hinder the design of best-suited trials, cause unnecessary testing and delay the development of innovative safe and efficacious treatments and vaccines. Regulators also continue to spend considerable resources negotiating transparency with sponsors. In a joint statement, International Coalition of Medicines regulatory Authorities (ICMRA) and WHO call on the pharmaceutical industry to commit, within short timelines, and without waiting for legal changes, to provide voluntary unrestricted access to trial results data for the benefit of
public health. Both positive and negative clinically relevant data should be made available, while only personal data and individual patient data should be redacted.

Joint Statement on transparency and data integrity International Coalition of Medicines Regulatory Authorities (ICMRA) and WHO (07 May 2021)

Draft WHO Guidance for Comments

WHO guidelines on evaluation of similar biological products – comments by 24 May 2021

The WHO guidelines on evaluation of similar biological products, published in 2013, is in a process of revision and the proposed revised version, based on a review of current scientific evidence and experience, is released for public comment.

The opportunity allowed a review of new developments and to identify areas where the current guidance could be more flexible without compromising its basic principles, providing additional explanation regarding the possibility of further tailoring the amount of data needed for regulatory approval. The intent is that a revision of the WHO Guidelines would result in greater flexibility and reduced regulatory burden, while continuing to ensure the quality, safety and efficacy of such products.


Please use Comment form

WHO guidelines on the transfer of technology in pharmaceutical manufacturing - comments by 01 Jun 2021

The current WHO guidelines on the transfer of technology in pharmaceutical manufacturing was published in 2011. Numerous regulatory changes have been made since then. Transfer of technology is considered an integral part of the product life cycle management and is subject to regulatory expectations. This includes a risk-based and science-based process and method design (such as a quality by design approach), achieving a “state of control” and data governance. The original document thus requires updating, not least to support the consistent supply of therapies for critical needs, including public health emergencies.

WHO guidelines on the transfer of technology in pharmaceutical manufacturing (comments by 01 Jun 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 7 May, 28 products have been listed as eligible for WHO procurement among a total of 138 expressions of interest (61 for NAT assays, 41 for antibody detection assays and 36 for antigen detection RDTs) have been received.

- EUL listed IVDs (30 Apr 2021)
- IVDs not accepted for EUL listing (27 Apr 2021)
- Status of each EUL application (04 May 2021)

**IVDs listed by National Regulatory Authorities in IMDRF jurisdictions**

To help countries, WHO publishes links to emergency lists, together with contact details, on IVDs authorized for use in the International Medical Device Regulators Forum (IMDRF) jurisdictions along with other useful information on policies and guidance.

- IVDs listed by IMDRF NRAs (03 May 2021)

*Note: WHO does not endorse any of the lists provided by NRAs. The information is provided exclusively to assist stakeholders with identifying the links to the various lists.*

**Therapeutics**

**Clinical Trials**

- [International Clinical Trials Registry Platform (ICTRP)](https://www.who.int/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](https://www.covid19 trials.org/)
  
  (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](https://www.covid19-trialtracker.org/)
  
  (Cytel)

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

**Support materials**

**COVID-19 therapeutics: Knowledge gaps and research priorities**

Over the past year, management of COVID-19 has greatly improved and mortality has been markedly reduced. Platforms have been rapidly established to evaluate potential therapeutics, initially focusing on repurposing of existing medicines. Some effective treatments have been identified and widely introduced. Despite these successes and the recent rollout of COVID-19 vaccines, new and improved therapeutics are still required. A WHO ad hoc consultation on 3rd March 2021, held under the umbrella of the WHO R&D Blueprint, sought to take stock of the current status of therapeutic development and to explore potential future directions of travel.

- [WHO ad hoc consultation COVID-19 therapeutics: Knowledge gaps and research priorities](https://www.who.int/)
  
  (13 May 2021)
**Blood products**

Assessing national regulatory systems for blood products

Introductory webinar on the Global Benchmarking Tool plus blood (GBT+blood) was held on 19th April. The GBT+blood was developed to ensure policy coherence and reduce the unnecessary burden of benchmarking, costs and duplications for Member States.

Topics covered:
- WHO Regulatory Systems Strengthening program, benchmarking and overview of the WHO GBT+blood;
- WHO GBT+blood, indicators and factsheets;
- Experience with pilot assessments during development of the GBT+blood;
- Promoting the use of the GBT+blood for capacity building in the WHO Regions.

Webinar presentations and recordings (available in 6 languages)

**Advancing Access to Safe, Effective and Quality-Assured Blood Products**

WHO held a webinar on 11 May introduce and promote the WHO Guidance on Centralization of blood donation testing and processing and WHO Guidance on increasing supplies of plasma-derived medicinal products in low-and middle-income countries through fractionation of domestic plasma.

Introduction to recent WHO publications on advancing access to safe, effective and quality-assured blood products Webinar (11 May 2021)

Webinar presentations available in 5 languages (11 May 2021)

**Vaccines**

**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 12th May, more than 1.26 billion vaccine doses administered in 206 countries and economies out of 220, but with an imbalance of over 87% of doses delivered to high income or upper middle-income countries while only 0.2% of doses delivered to low-income countries. As of 10th May, COVAX has shipped 59.2 million doses to 122 participants. 14 countries, economies & territories have not started vaccination (7 in African region, 2 Latin America, 1 South-East Asia and 4 Western Pacific).

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

WHO Coronavirus (COVID-19) Dashboard

**Beijing Institute of Biological Products**

Listed for WHO EUL

WHO has recommended the Sinopharm inactivated SARS-CoV-2 Vaccine (Vero Cell) produced by Beijing Insatiate of Biological Products Co Ltd for Emergency Use Listing (EUL). The WHO assessment included on-site inspections of the production facility, a review of clinical practices as part of the overall assessment the quality, safety and efficacy of the vaccine, as well as risk management plans and programmatic suitability, such as cold chain requirements. The data supported the shelf-life of 24 months at 2 to 8 °C, more suitable for low resource settings.
WHO EUL Recommendation COVID-19 Vaccine BIBP
WHO lists additional COVID-19 vaccine for emergency use and issues interim policy recommendations (07 May 2021)

WHO SAGE interim recommendations

WHO’s Strategic Advisory Group of Experts on Immunization (SAGE) has also completed its review of the vaccine. On the basis of all available evidence, WHO recommends the vaccine for adults 18 years and older, in a two-dose schedule with a spacing of three to four weeks. Vaccine efficacy for symptomatic and hospitalized disease was estimated to be 79%, all age groups combined.

Few older adults (over 60 years) were enrolled in clinical trials, so efficacy could not be estimated in this age group. Nevertheless, WHO is not recommending an upper age limit for the vaccine because preliminary data and supportive immunogenicity data suggest the vaccine is likely to have a protective effect in older persons. There is no theoretical reason to believe that the vaccine has a different safety profile in older and younger populations. WHO therefore recommends that countries using the vaccine in older age groups conduct safety and effectiveness monitoring to make the recommendation more robust.

Interim recommendations for use of the inactivated COVID-19 vaccine BIBP developed by China National Biotec Group (CNBG), Sinopharm - Interim guidance (07 May 2021)
Annexes to WHO interim recommendations for use of the COVID-19 vaccine BIBP: GRADE and Evidence to Recommendations tables (07 May 2021)
Background document on the inactivated COVID-19 vaccine BIBP developed by China National Biotec Group (CNBG) (06 May 2021)

Moderna COVID-19 vaccine (mRNA 1273) elasomeran

WHO EUL and SAGE interim recommendations

WHO has recommended the Moderna COVID-19 vaccine (mRNA 1273) for EUL. This vaccine has the International Nonproprietary Name of elasomeran. WHO’s EUL assesses the quality, safety and efficacy of COVID-19 vaccines and is a prerequisite for COVAX Facility vaccine supply. It also enables countries to expedite their own regulatory approval to import and administer COVID-19 vaccines.

The vaccine has already been reviewed by WHO SAGE, which makes recommendations for vaccines’ use in populations (i.e. recommended age groups, intervals between shots, advice for specific groups such as pregnant and lactating women). The SAGE recommended the vaccine for all age groups 18 and above in its interim recommendations (25 January 2021).

Elasomeran is an mRNA-based vaccine. It was found by the SAGE to have an efficacy of efficacy of 94.1%, based on a median follow-up of two months. Although the vaccine is provided as a frozen suspension at −25 °C to −15 °C in a multidose vial, vials can be stored refrigerated at 2 °C to 8 °C for up to 30 days prior to withdrawal of the first dose, meaning that ultra-cold chain equipment may not always be necessary to deploy the vaccine.

The US Food and Drug Administration issued an emergency use authorization for the Moderna vaccine on 18 December 2020 and a marketing authorization valid throughout the European Union was granted by the European Medicines Agency on 6 January 2021.

WHO EUL Recommendation COVID-19 mRNA Vaccine (nucleoside modified)
WHO lists Moderna vaccine for emergency use (30 Apr 2021)
Background document on the mRNA-1273 vaccine (Moderna) against COVID-19 (03 Feb 2021)
Interim recommendations for use of the Moderna mRNA-1273 vaccine against COVID-19 (25
Pfizer-BioNTech COVID-19 Vaccine tozinameran

Health Canada

Health Canada have extended the indication for Pfizer-BioNTech COVID-19 Vaccine tozinameran for active immunization in adolescents 12 to 15 years of age. The decision was based on an analysis of the efficacy, immunogenicity and safety of tozinameran in 2,260 adolescents 12 to 15 years of age (in the ongoing Study C4591001). In that study, participants were treated with two doses of the vaccine (n=1,131) or placebo (n=1,129), 21 days apart.

The vaccine efficacy (VE) in adolescents 12 to 15 years of age was consistent with the VE previously demonstrated in the adult population. The observed adverse events did not suggest any serious safety concerns for this age group. Generally, reactogenicity profiles and unsolicited safety results in this age group were comparable to that in young adults 16 to 25 years of age. The Phase 3 study is ongoing and will continue to collect information on the long-term safety and efficacy of the vaccine. There are post-authorization commitments for monitoring the long-term safety and efficacy of Pfizer-BioNTech COVID-19 vaccine tozinameran for immunization in this age group.

Regulatory Decision Summary - Pfizer-BioNTech COVID-19 Vaccine - Health Canada (05 May 2021)

US FDA

The U.S. Food and Drug Administration expanded the emergency use authorization (EUA) for the Pfizer-BioNTech COVID-19 Vaccine for the prevention of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) to include adolescents 12 through 15 years of age. The FDA amended the EUA originally issued on Dec. 11, 2020 for administration in individuals 16 years of age and older.

The FDA has determined that Pfizer-BioNTech COVID-19 Vaccine has met the statutory criteria to amend the EUA, and that the known and potential benefits of this vaccine in individuals 12 years of age and older outweigh the known and potential risks, supporting the vaccine’s use in this population.


ACIP meeting presentations: 12 May 2021

Safety, immunogenicity and efficacy of BNT162b2 in persons aged 12-15 years pdf Dr. J Perez

GRADE: Pfizer-BioNTech COVID-19 vaccine pdf Dr. M Wallace

Evidence to Recommendation Framework: Pfizer-BioNTech COVID-19 vaccine in adolescents aged 12-15 years pdf Dr. S Oliver

Clinical considerations for Pfizer-BioNTech COVID-19 vaccination in adolescents pdf Dr. K Woodworth
AstraZeneca COVID-19 Vaccine

WHO EUL

Additional sites for the production of the AstraZeneca COVID-19 vaccine in Europe have been added to the WHO EUL, based on oversight by the EMA.

WHO EUL COVID-19 Vaccine (ChAdOx1-S) [recombinant]) (15 Apr 2021)

WHO SAGE interim recommendations

An updated SAGE statement was published on 22 April without substantial change in policy, but to provide more precision in recommendation language and characterization of risks. SAGE confirmed that benefits of these vaccines largely outweigh the risks.

Key highlights of the update are as follows:

- Pursuant to the latest data, further clarification of precautions and types of risk (i.e., Thrombosis with Thrombocytopenia Syndrome) has been added.
- More data have been obtained on the effectiveness of the vaccines in different population groups, such as older adults, making the evidence base more robust.
- Clarifications and specifications have been added as to the vaccination of specific population groups (pregnant and lactating women, person with previous SARS-CoV2 infection and others).


Annexes to the interim recommendations for use of the ChAdOx1-S [recombinant] vaccine against COVID-19 (AstraZeneca COVID-19 vaccine AZD1222, SII Covishield, SK Bioscience) (20 Apr 2021)

Background document on the AZD1222 vaccine against COVID-19 developed by Oxford University and AstraZeneca (05 Mar 2021)

EMA

To support national authorities making decisions on how to best use the vaccine in their territories, EMA’s Committee for Medicinal Products for Human use (CHMP) has further analyzed available data to put the risk of these very rare blood clots in the context of the vaccine’s benefits for different age groups and different rates of infection. The analysis will inform national decisions on the roll out of the vaccine, taking into account the pandemic situation as it evolves and other factors, such as vaccine availability. The analysis could change as new data become available.

The Committee recommended to continue giving a second dose of Vaxzevria between 4 and 12 weeks after giving the first one in line with the product information.

Annex to Vaxzevria Art.5.3 - Visual risk contextualization (23 Apr 2021)

EMA Vaxzevria (previously COVID-19 Vaccine AstraZeneca) (authorization details, product information, safety updates)

Janssen vaccine

EMA

At its meeting of 20 April 2021, EMA’s safety committee (PRAC) concluded that a warning about unusual blood clots with low blood platelets should be added to the product information for COVID-19 Vaccine Janssen. Healthcare professionals and people who will receive the vaccine should be aware of the possibility of very rare cases of blood clots combined with low levels of blood platelets occurring within three weeks of vaccination. Thrombosis in combination with thrombocytopenia...
requires specialized clinical management. The EMA reiterated COVID-19 is associated with a risk of hospitalization and death. The reported combination of blood clots and low blood platelets is very rare, and the overall benefits of COVID-19 Vaccine Janssen in preventing COVID-19 outweigh the risks of side effects.

COVID-19 vaccine safety update COVID-19 VACCINE JANSSEN (11 May 2021)
COVID-19 Vaccine Janssen COVID-19 vaccine (Ad26.COV2-S [recombinant]) (authorization details, product information, safety updates)

US CDC Clinician Outreach and Communication Activity
Clinician Outreach and Communication Activity (COCA) presented the latest evidence on TTS after administration of the Janssen COVID-19 vaccines. Speakers discuss information on TTS and updated vaccine recommendations.

Johnson & Johnson/Janssen COVID-19 Vaccine and Thrombosis with Thrombocytopenia Syndrome (TTS): Update for Clinicians (27 Apr 2021)
Presentation (27 Apr 2021)

US Advisory Committee on Immunization Practices (ACIP)
23 April 2021: ACIP meeting materials Coronavirus Disease 2019 (COVID-19) Vaccines
Introduction.pdf Dr. B Bell
Pathogenesis and Management of Thrombosis with Thrombocytopenia Syndrome (TTS).pdf Dr. M Streiff
Thrombosis with thrombocytopenia syndrome (TTS) following Janssen COVID-19 vaccine.pdf Dr. T Shimabukuro
Update on Janssen COVID-19 vaccine.pdf Dr. M Mammen
VaST assessment.pdf Dr. G Lee

During the ACIP meeting, the numbers presented were risks and benefits per two million vaccine doses; numbers have been updated here to reflect risks and benefits per one million vaccine doses. Dr. S Oliver

INN for variant COVID-19 vaccine active substances
The International Nonproprietary Names (INN) Expert Group has adopted a nomenclature for COVID-19 vaccine substances dedicated to SARS-CoV-2 variants of concern (VOCs). Any change to the structure of a medicinal active substance will trigger a requirement for a new INN to be assigned. To highlight the close relationship of a variant COVID-19 vaccine substance to the original vaccine active substance, the INN of the variant active substance will be linked to the original INN (where one exists) by the addition of a short, random, two or three-letter syllable as a prefix to the original INN. This approach will be applied only to COVID-19 vaccine substances in which changes have been made to an original substance in order to direct the immune response to a VOC, i.e., a strain change, and where regulators are likely to authorize the variant vaccine by an abbreviated procedure. Any other change to the structure of the active substance, e.g., a change that alters the structure for other reasons such as improved antigen stability, or a change that improves expression or otherwise of a nucleic acid or vector, will be assigned a new unique alternative INN, not necessarily related to any preceding INN (where one exists). It is highlighted further that each active substance of a multivalent COVID-19 vaccine requires its own INN.

The WHO INN Programme encourages vaccine developers to submit INN requests for COVID-19 vaccine substances including those directed against SARS-CoV-2 VOCs and urges regulatory
WHO Regulatory Update on COVID-19

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 11 May 2021.

### Status of COVID-19 Vaccines within WHO EUL/PQ evaluation process

<table>
<thead>
<tr>
<th>Manufacturer/INN主持召开</th>
<th>Name of holder</th>
<th>NRA</th>
<th>Status</th>
<th>Pre-submission meeting held?</th>
<th>Status of assessment</th>
<th>Anticipated decision date</th>
</tr>
</thead>
<tbody>
<tr>
<td>AstraZeneca (UK)</td>
<td>AstraZeneca</td>
<td>UKRA</td>
<td>Finished</td>
<td>Yes</td>
<td>Finalised</td>
<td>06 April 2021</td>
</tr>
<tr>
<td>BDP</td>
<td>BDP</td>
<td>DGM</td>
<td>Accepted for review</td>
<td>Data for these cases submitted in April 2021 onwards</td>
<td>Finalised</td>
<td>08 April 2021</td>
</tr>
<tr>
<td>GlaxoSmithKline</td>
<td>GlaxoSmithKline</td>
<td>DGM</td>
<td>Pre-submission meeting held</td>
<td>Data for these cases submitted in April 2021 onwards</td>
<td>Finalised</td>
<td>09 April 2021</td>
</tr>
<tr>
<td>Moderna</td>
<td>Moderna</td>
<td>DGM</td>
<td>Pre-submission meeting held</td>
<td>Data for these cases submitted in April 2021 onwards</td>
<td>Finalised</td>
<td>09 April 2021</td>
</tr>
<tr>
<td>Sabin Vaccine Institute</td>
<td>Sabin Vaccine Institute</td>
<td>DGM</td>
<td>Pre-submission meeting held</td>
<td>Data for these cases submitted in April 2021 onwards</td>
<td>Finalised</td>
<td>09 April 2021</td>
</tr>
<tr>
<td>Sinovac Biotech</td>
<td>Sinovac Biotech</td>
<td>DGM</td>
<td>Pre-submission meeting held</td>
<td>Data for these cases submitted in April 2021 onwards</td>
<td>Finalised</td>
<td>09 April 2021</td>
</tr>
</tbody>
</table>

Saftey of COVID-19 Vaccines

Clinical diagnosis and management of Thrombosis with Thrombocytopenia Syndrome

A WHO Expert Group has been established to prepare WHO Emergency Interim Guidance on the clinical diagnosis and management of Thrombotic Thrombocytopenic Syndrome (TTS), a rare event reported after vaccination with Vaxzevria, Covishield and the Janssen COVID-19 vaccines.

Covid-19 Vaccines Risk Management Planning

The WHO Safety Surveillance Manual encourages developers to adopt existing formats of risk management strategies such as the EU risk management plan (RMP). All national regulatory authorities (NRAs) are encouraged to follow ICH guidelines and to provide clear guidance and directives to vaccine developers.
Recently EMA has provided guidance on core requirements for RMPs of COVID-19 vaccines (coreRMP19). Core RMPs that meet the requirements summarized in the WHO Safety Surveillance Manual will contain a Pharmacovigilance Plan consisting of “routine pharmacovigilance” and, where applicable, a list of global commitments on additional PV activities, including enhanced safety surveillance, post-marketing safety and effectiveness.


**EMA Consideration on core requirements for RMPs of COVID19 vaccines coreRMP19 guidance**

### COVAX workshop

A COVAX Clinical Development and Operations held its first workshop on COVID-19 vaccines risk management planning on 28 April, highlighting stakeholders’ experiences in receiving RMP approved in different countries and their post-approval challenges in implementation. The Workshop also developed consensus on how to bridge expectations and “real world experience”, and how to improve efficiency and effectiveness of pharmacovigilance activities in the context of a pandemic.

Workshop materials will be available shortly.

**Support materials:**

**COVID-19 vaccines: Knowledge gaps and research priorities**

COVID-19 vaccines have been developed, evaluated and licensed at unparalleled speed. They are undoubtedly already saving lives, yet new vaccines are required to increase global manufacturing capacity and to provide products with additional beneficial properties. In January 2021 under the umbrella of the R&D Blueprint initiative, WHO organized an ad hoc consultation to discuss what is currently known about existing COVID-19 vaccines, knowledge gaps and research priorities. Specific objectives were:

- To outline key priority research questions and an agenda for 2021 that identifies knowledge gaps for vaccines in clinical development phase and those being deployed, and research needs for second-generation vaccines.
- To outline additional efforts to ensure further international collaboration contributes to address the knowledge gaps.

A report of the meeting has been published providing a summary of presentations and panel discussions. The report does not necessarily reflect the views of the organizers, participants or panel members.

**WHO R&D Blueprint COVID-19 vaccines: Knowledge gaps and research priorities** (23 Apr 2021)

**COVID-19 Vaccines R&D achievements report**

COVID-19 vaccines development has been unique. However, there is still a need for rapid results in the context of major public health needs around the world. Reliable results are needed to support vaccine confidence and, importantly, equitable results that respect the rights and values of all people are needed. Important and critical investigation is being coordinated by WHO to advance our understanding for safe and effective COVID-19 vaccines and to accelerate and coordinate the research, development and evaluation of candidate products.

Vaccines R&D Achievements Report, February 2020 – May 2021 (13 May 2021)
Guidance on using test negative designs to estimate vaccine effectiveness

Many critical questions remain about the effectiveness of COVID-19 vaccines in real-world settings. These questions can only be answered in post-introduction vaccine effectiveness studies. A WHO guidance document outlines an approach to leverage existing surveillance systems for Severe Acute Respiratory Infection (SARI) to estimate COVID-19 vaccine effectiveness (VE) in preventing SARI associated with laboratory-confirmed SARS-CoV-2 using existing SARI surveillance systems. The approach uses the test-negative design to evaluate VE: cases are SARI patients who tested positive for SARS-CoV-2, and controls are SARI patients who tested negative for SARS-CoV-2.

Estimating COVID-19 vaccine effectiveness against severe acute respiratory infections (SARI) hospitalizations associated with laboratory-confirmed SARS-CoV-2: an evaluation using the test-negative design (06 May 2021)

Research protocols for vaccine effectiveness

- Protocols currently available include retrospective and prospective cohort protocols, retrospective case control, and test negative prospective case control. US Centers for Disease Control and Prevention Vaccine Effectiveness Protocols.
- A test-negative design study aimed at persons with symptomatic COVID-19 seeking primary care. Influenza - Monitoring Vaccine Effectiveness in Europe (I-MOVE): COVID-19 vaccine effectiveness at primary care level in Europe:
- A test-negative design study among hospitalized severe acute respiratory infection (SARI) patients. Influenza - Monitoring Vaccine Effectiveness in Europe (I-MOVE): European study of COVID-19 vaccine effectiveness against hospitalized SARI patients’ laboratory confirmed with SARS-CoV-2:
- Cohort study to measure COVID-19 vaccine effectiveness among health workers in the WHO European Region: guidance document. Cohort study to measure COVID-19 vaccine effectiveness among health workers in the WHO European Region

Additional information
ACIP meeting presentations: 12 May 2021
US ACIP presentation on COVID-19 vaccine effectiveness studies Dr K Fleming-Dutra (12 May 2021)
US ACIP update on emerging SARS-CoV-2 variants and vaccine considerations Dr H. Scobie (12 May 2021)

Evaluation of COVID-19 vaccine introduction

Post introduction evaluation
The mini COVID-19 Post-Introduction Evaluation (mini-cPIE), also called the COVID-19 Vaccination Intra-Action Review (IAR), is a set of tools available to countries to review the early phase(s) of the roll-out of COVID-19 vaccine implementation. The mini-cPIE is a country-led facilitated discussion that aims to identify vaccine delivery challenges needing immediate corrective action and best practices for continual improvement and collective learning. The areas covered follow the National Deployment and Vaccination Plan for COVID-19 Vaccines (NDVP).
WHO Regulatory Update on COVID-19

The mini-cPIE working documents (trigger question database, note taking template, and report template) are available here:


Countries are encouraged to begin using these working drafts for planning and implementation as needed. Given the evolving situation with the COVID-19 vaccine rollout, the trigger questions may be updated frequently based on feedback received. The mini-cPIE is recommended 2 to 6 months following COVID-19 vaccine introduction. Countries may adapt the questions as needed for their context.

This slide set provides an overview of how to conduct a mini COVID-19 Post Introduction Evaluation.

- Mini-cPIE (COVID-19 vaccination IAR): What is it and how to conduct one? (29 Apr 2021)
- Training recording: Mini-cPIE (COVID-19 Vaccination IAR) – What is it and how to conduct one?

COVID-19 and mandatory vaccination: ethical considerations and caveats

Some countries may be considering whether to make COVID-19 vaccination mandatory in order to increase vaccination rates and achieve public health goals and, if so, under what conditions, for whom and in what contexts. A new policy brief has been published. The document does not provide a position that endorses or opposes mandatory COVID-19 vaccination. Rather, it identifies important ethical considerations and caveats that should be explicitly evaluated and discussed through ethical analysis by governments and/or institutional policy-makers who may be considering mandates for COVID-19 vaccination.

https://apps.who.int/iris/handle/10665/340841

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 08 April 2021, the Covid-19 - living NMA initiative collected 208 RCTs and 70 non-randomized studies of vaccines from the ICTRP. 129 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 (11 May 2021)

WHO Assays Working Group

T cells as correlates of protection from Covid-19 were discussed in the 21 April meeting. Data were presented to show that spike-protein reactive T cells and antibodies appear coincidentally with onset of vaccine efficacy. It was suggested that neutralizing antibodies are not absolutely required for immunity against COVID-19. It was further suggested that cellular immunity may play a key role in RNA vaccine-induced protection against COVID-19.
A panel was convened for the 28 April meeting to discuss the information needed on assays to support regulatory decision-making based on clinical immunobridging studies. The panel discussed how to compare the magnitude of a response to a variant virus to the earlier virus strains, given that the assays of necessity must be different for variant vs prototype. Which assays should be used? What is the role of pseudovirus neutralization assay (psVNA) versus wild type neutralization assays (wtVNA)?

For vaccines with no efficacy data the panel discussed what general information would be needed to support the authorization of a new vaccine without a clinical endpoint efficacy study? What are the assay considerations?

The considerations of the panel will inform discussion at an upcoming WHO Consultation on Immunobridging.

Note: WHO considers data on correlates of protection for COVID-19 vaccines to be limited and incomplete. Further work is needed.

**WHO Animal Models Working Group**

A panel discussed the role of animal models to support regulatory decision-making based on clinical immunobridging studies in the 6 May meeting. Immunobridging has been proposed to support Emergency Use Authorization of vaccines based on new variant sequences in established platforms. This would entail the performance of an immunogenicity study to compare the immune responses induced by a modified COVID-19 vaccine to those induced by the prototype vaccine, where that prototype vaccine has established efficacy data. Immunobridging has also been proposed for new vaccines that do not have human efficacy data. The panel discussed what considerations should be taken into account regarding animal models used to support these approaches.

The panel considered that meta-analyses of existing animal study data and existing human clinical trial data would support identification of potential correlates of protection for COVID-19 vaccines. The panel proposed that WHO establish a cross-disciplinary group of experts, including biostatisticians, which, if appropriately resourced, could undertake this analysis. The panel also suggested that animal models would be useful to validate candidate correlates of protection through passive transfer experiments in which the correlate was depleted from human sera prior to transfer. The panellists suggested too that studies to investigate whether different correlates of protection are needed for different vaccine platforms would be prudent.

The considerations of the panel will inform discussion at an upcoming WHO Consultation on Immunobridging.

**Supply Chain**

**Transportation backlogs**

In consideration of disruptions in countries with severe impact of COVID19, expect delays with shipments and with availability of air cargo space. Backlogs of transportation have increased in several regions.

**Supply chain of ultracold products**

Care should be taken to avoid transfers of large cold chain shipments through the same airport at the same time due to limited cold chain space. Repacking of cold chain products is not possible in certain connecting airports and transport plans should verify in advance.

**Progress on traceability**

Products should be traced to the batch number level from the manufacturer to all points up to the
point of care. Products should have bar codes on secondary packaging. Partners, including USAID, UNICEF, World Bank, GAVI and WHO are supporting a minimum traceability system to allow validation of vaccines.

**Newly added shortages**

No new shortages have been reported; however, export restrictions are likely and may increase short term medicine shortages.

WHO has developed a portal for collecting shortages information. It is a daily compilation of information from publicly available shortage reporting mechanisms. The information is mainly from high income countries that have publicly available reporting mechanisms and may not be representative of all regions, especially for multi-source products. The current details are below. The portal will be released in the coming weeks.

<table>
<thead>
<tr>
<th>Total # of molecules in shortage</th>
<th>459</th>
</tr>
</thead>
<tbody>
<tr>
<td>Essential Medicines</td>
<td>126</td>
</tr>
<tr>
<td>Other medicines</td>
<td>333</td>
</tr>
<tr>
<td>Multi-country</td>
<td>144</td>
</tr>
<tr>
<td>Multi-country, Essential Medicines</td>
<td>51</td>
</tr>
<tr>
<td>Multi-country, Other Medicines</td>
<td>93</td>
</tr>
</tbody>
</table>

**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-lumefantrine, artemisinin-based combination therapies, sulfadoxine-pyrimethamine + amodiaquine
- NCD: Metformin and insulin
- Anticoagulants: heparin and new generation oral anticoagulants
- Corticosteroids: dexamethasone
- Antipyretics: paracetamol (aka acetaminophen)
- PPE
- Oxygen and related equipment
- Ventilators
- Morphine granules

**Medical Devices**

**WHO Medical Devices Newsletter**

The April and May editions of the newsletter are available with information on oxygen related medical equipment and information on essential *in vitro* diagnostics.

To receive the Newsletter, send an email to: LISTSERV@listserv.who.int with the words:
Oxygen Cylinder Safety

WHO has published posters intended for health workers and other personnel on the safety and mitigation measures that need to be adhered to when dealing with medical oxygen. Medical oxygen, either in liquid or gas form, is an oxidizing agent that can result in a fire or explosion if not handled properly.

See:
https://www.who.int/publications/m/item/oxygen-cylinder-safety
https://www.who.int/publications/m/item/medical-gas-piping-systems-safety
https://www.who.int/publications/m/item/medical-oxygen-fire-risk-mitigation-measures

Upcoming events

AVAREF facilitated options for vaccine access and clinical trials in Africa
03 June 16:00 – 17:30 CET
Since 2006, the African Vaccines Regulatory Forum (AVAREF) has been working with the countries in Africa to facilitate joint reviews of multi country clinical trials, in a harmonized procedure. Recently, in response to the ongoing pandemic and need for accelerated access to quality vaccines, AVAREF is facilitating the emergency use authorization of vaccines by countries in the continent. Using a procedure developed and approved by the 40 sub-Saharan countries in the WHO AFRO region and the 14 countries in the African continent which are under the WHO EMRO region, AVAREF has to date, facilitated approval of several multi country clinical trials and regulatory authorization of products including COVID-19 vaccines.

More information will be made available shortly.

WHO Innovation virtual meeting: Saving Lives by Scaling Innovation in Health
17 May 10:00 – 11:30 CET
Register at https://who.zoom.us/webinar/register/WN_rNXF5RBRyeaz0kNTkb2xQ

Integrated surveillance of influenza and SARS-CoV-2 Workshops 12:00 – 13:30 CET
- 19 May: sentinel surveillance systems
- 02 June: Genomic sequencing and genetic data management
- 16 June: Surveillance data analysis and outputs

For more information, contact: influenza@who.int