Regulation of in vitro diagnostics, therapeutics, and vaccines
WHO Update – 9
Coronavirus disease 2019 (COVID-19)
15 May 2020

World Health Organization

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Key Messages

Regulatory evaluations of candidate diagnostics, therapeutics and vaccines are proceeding rapidly. However, this is raising questions of trust in the quality of the evaluations.

It is important to communicate to stakeholders that any positive regulatory decisions will be based, as always, on a favourable benefit-risk analysis. Transparency will be key to ensuring stakeholders trust the regulatory processes and decisions.

Highlights and main issues

- 2300 vials of an antibody research reagent, intended to be used as a positive control for the development and evaluation of serological assays that detect the presence of antibodies against SARS-CoV-2, specifically neutralization assays and ELISAs, is now available from NIBSC, UK, a WHO Collaborating Center.
- Six NAT assays are now listed under the WHO EUL for IVDs
- WHO continues to receive reports of FS products in relation to the Covid19 outbreak, either because demand has increased or because supply has been constrained. Vigilance is requested from all regulators.
- A new Scientific Brief from WHO, based on a rapid review, concluded that there is low-certainty evidence that patients on long-term therapy with angiotensin-converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs) are not at higher risk of poor outcomes from COVID-19.
- Draft WHO Guidelines for the evaluation of quality, safety and efficacy of DNA vaccines for human use have been published for comment.

Steps towards a new technology platform announced

WHO and the president of Costa Rica announced progress on a technology platform that aims is to lift access barriers to effective vaccines, medicines and other health products against COVID-19. Costa Rica proposed the idea at the beginning of the COVID-19 outbreak and several countries are now backing the proposal.

The platform will pool data, knowledge and intellectual property for existing or new COVID-19 health products to deliver 'global public goods' for all people and all countries. Through the open sharing of science

and data, numerous companies will be able to access the information they need to produce the technologies, thereby scaling up availability worldwide, lowering costs and increasing access.

The platform acknowledges the importance of international collaboration on regulatory practices to ensure availability, affordability and assured quality of therapeutics, diagnostics and vaccines. WHO and Costa Rica will officially launch the platform on 29 May.

73rd World Health Assembly: Covid-19 Response

In light of the current global situation, the WHA will be held virtually, using video conferencing technologies starting at 12:00 on 18th May and closing on 19th May.

73rd WHA site

The assembly will review a draft resolution addressing the COVID-19 response. Amongst a range of measures in this resolution are calls for equitable access to and fair distribution to all countries of personal protective equipment, other materials required for the response to the COVID-19 pandemic, in particular quality, safe, efficacious and affordable medicines and vaccines, and the urgent removal of obstacles to achieve this.

Alignment of approaches by regulatory groups

The International Coalition of Medicines Regulatory Authorities (ICMRA) met on 14 May to discuss therapeutics under investigation for treatment or prevention of COVID-19, and the availability of medicines, especially shortages. ICMRA were also provided with an update of WHO-led activities to support regulators.

An overview was presented of the therapeutics in trials which regulators consider will be actionable for regulatory purposes, and the expected dates trial data will become available. Actionable trials were defined as randomized controlled trials in Phase 2 or beyond with expected enrollment of 250 or above per arm. Currently only about 20% of trials in progress are considered likely to result in evidence that could be used for regulatory action.

Many countries reported shortages of medicines, and regulatory activities to anticipate and trouble-shoot medicines supply issues were discussed and shared.

In vitro diagnostics

WHO EUL for SARS-CoV-2 virus IVDs

The WHO Prequalification Unit is assessing products for Emergency Use Listing (EUL) for candidate in vitro diagnostics (IVDs) to detect SARS-CoV-2. Applicants submit their applications for assessment based on WHO instructions for NAT and antibody detection rapid tests (RDTs) submissions.

35 submissions for NAT assays have been received so far and 5 more are expected.

The status of each application is presented here (14 May)

Six products have been listed as eligible for WHO procurement based on their compliance with WHO EUL requirements:

Date Listed	Product name	Product code(s)	Manufacturer
14 May 2020	Detection Kit for 2019 Novel Coronavirus (2019-nCoV) RNA, (PCR- Fluorescence Probing)	DA0930, DA0931 and DA0932	Da An Gene Co., Ltd. Of Sun Yat-sen University
07 May 2020	Real-time fluorescent RT-PCR kit for detecting 2019-nCoV	MFG030010	BGI Europe A/S
24 April 2020	PerkinElmer® SARS-CoV-2 Real-time RT-PCR Assay	SY580	SYM-BIO LiveScience Co., Ltd
09 April 2020	Abbott Realtime SARS-CoV-2	09N77-090 and 09N77-080	Abbott Molecular Inc.
07 April 2020	Primerdesign Ltd COVID-19 genesig Real-Time PCR assay	Z-Path-COVID-19-CE	Primerdesign Ltd.
03 April 2020	cobas SARS-CoV-2 Qualitative assay for use on the cobas 6800/8800 Systems	09175431190 and 09175440190	Roche Molecular Systems, Inc.

On 14 May 2020 WHO listed the sixth NAT assay under the emergency use listing procedure. The **Detection Kit for 2019 Novel Coronavirus (2019-nCoV) RNA (PCR- Fluorescence Probing) manufactured by Da An Gene Co., Ltd. Of Sun Yat-sen University** is intended for the in vitro qualitative detection of novel coronavirus (2019-nCoV) ORFlab and N genes in the throat swabs, sputum specimens of suspected pneumonia patients infected by novel coronavirus, suspected clustering cases and others needing diagnosis or differential diagnosis for novel coronavirus. This kit is based on one-step RT-PCR technique. The assay should be used in combination with the following products:

Product name	Intended use	Manufacturer
Nucleic Acid Extraction Kit(DA0623)	Extract RNA	Da An Gene Co., Ltd. of Sun Yat-sen University
Nucleic Acid Extraction Kit(Cat.#DA-250)	Extract RNA	Da An Gene Co., Ltd. of Sun Yat-sen University
QIAamp Viral RNA Mini Kit(52904)	Extract RNA	QIAGENE
Automatic Nucleic Acid Extractor(Smart32)	Combine with the DA0623	Da An Gene Co., Ltd. of

and the Applied Biosystems™ Real time PCR system 7500 (V2.4), or the Roche Diagnostics LightCycle480 II (V1.5).

Antibody detection rapid tests have been eligible for WHO emergency use assessment since 17 April. WHO recently received the first expression of interest for an antibody detection RDT and several pre-submission calls have been held with manufacturers interested in submitting for EUL assessment. WHO is currently working on the development of instructions for submission of antibody detection enzyme immunoassays (EIAs) and antigen detection RDTs. These will be published soon on the WHO website and the EUL eligibility expanded to such products.

COVID-19 in vitro diagnostics 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.

This information is updated on a weekly basis. The most recent update was published here.

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.

Assay comparison studies

FIND as conducted independent evaluations at the University Hospitals of Geneva (HUG), to verify the limit of detection (LOD) and the clinical performance (as reported by the manufacturers) of molecular test kits.

The LOD analysis was performed using cultured viral stocks from a clinical isolate from Switzerland and quantified using an E gene standard. The clinical performance analysis was conducted on extracted samples from individuals suspected to have COVID-19 that were tested using an in-house PCR protocol that was optimized based on the Tib Molbiol assay.

Summary of the evaluation (12 May)

Initial results of the multi-centre performance evaluations on the SARS-CoV-2 immunoassays that FIND is independently evaluating will be posted by the end of May 2020, with additional results released as they become available.

Therapeutics

WHO Solidarity Clinical Trial

More than 100 countries have now joined the Solidarity trial, and more than 2 500 patients have been randomized from 15 countries, to evaluate the safety and efficacy of four drugs and drug combinations.

For additional details please see Regulatory update 7.

Solidarity Trial: Informal consultation on the dose of chloroquine and hydroxychloroquine

The report of a meeting held on 8 April to discuss the dose of chloroquine (CQ) and hydroxychloroquine (HCQ) for the SOLIDARITY trial was published on 8 May. The CQ or HDQ schedule selected for the trial includes two oral loading doses (250 mg per tablet CQ or 200mg per tablet HCQ), then oral twice-daily maintenance doses for ten days. The meeting was convened to discuss the appropriateness of the selected doses for the trial.

The activity of CQ and HCQ against the SAR-CoV-2 virus is seen only at high concentrations, so if there is any benefit from the drugs, it is likely to require high concentrations of free drug in plasma to produce high concentrations in the infected respiratory epithelium. It is assumed that the cytosolic concentrations of the drugs in the respiratory epithelium will be in dynamic equilibrium with the plasma. These drugs are hypotensive in high concentrations and have a multichannel effect on the heart. Also, sometimes they may cause bradycardia without hypotension and they may also cause prolonged QT intervals.

The dose of CQ or HCQ employed in the SOLIDARITY protocol was intended to exploit the maximum chance of therapeutic efficacy. The SOLIDARITY protocol is using the highest dose of CQ of any COVID 19 study or expanded access protocol. Hence, it is crucial to proceed with caution. It was suggested that cardiac monitoring be considered in the SOLIDARITY protocol. It was stressed that the study is in hospitalized patients and is not a community study. Respective countries are free to include additional safety monitoring clauses in their protocols, as already seen in some EU countries.

The meeting concluded that the study should continue with the selected doses in sites where the protocol is approved, especially where there is the clinical ability to ensure safety monitoring of patients.

The report on the dose of CQ and HCQ (published on 08 May)

Informal consultation on the potential inclusion of immunomodulators in a clinical trial

There are several ongoing studies in China, Italy and Spain using immunomodulatory therapies. The rational to use these therapies is to reduce the proinflammatory immune response as a complement to antiviral therapy. Clinical data suggest that in severe cases of COVID-19 pneumonia the level of cytokines is very high - the "cytokines storm"- in particular pro-inflammatory tumor necrosis factor alpha (TNF-α), and interleukin-1 (IL-1), IL-6 and IL-18. On the contrary, patients with severe COVID-19 demonstrate remarkably impaired interferon (IFN)-I signatures as compared to mild or moderate cases.

Unfortunately, most of the evidence that is available today for immunomodulators is not from randomized controlled trials (RCT), but from compassionate use, case reports and observational studies. As there are some safety concerns about the use of immunomodulators there is a need to study the role of immunomodulators in a RCT to generate strong evidence of their efficacy for treatment of COVID-19. There are many potential immunomodulators that could be studied. The WHO Therapeutics Working Group was therefore convened on 6 May 2020 to start a process to prioritize candidates for eventual inclusion in the WHO SOLIDARITY trial.

The WHO secretariat had prepared an initial list of candidate products and members of the group were invited to suggest other candidates to be added. Both biological and chemical drugs were listed.

The biologicals included anti-cytokine/cytokine receptor monoclonal antibodies (mAbs) (ant-IL-6 receptor mAbs e.g. tocilzumab, siltuximab; anti-IL6 mAb e.g sarilumab); IL-1 receptor antagonist e.g. anakinra); anti-IFNY mAbs; anti-complement (C5/C5a or C6) mAbs. There are many anti-TNFa mAbs, including biosimilars, as potential candidates and more than 20 years' experience using anti-TNFa mAbs in autoimmune inflammatory disease such as rheumatoid arthritis, inflammatory bowel disease, psoriasis or ankylosing spondylitis.

The chemical drugs included inhibitors of protein kinases e.g. Janus kinases (JAK), Bruton´s tyrosine kinase (BTK), mTor. Several protein kinase inhibitors are licensed or are under development for a broad spectrum of conditions, including inflammatory diseases (rheumatoid arthritis, Crohn´s), hematologic malignancies, or as immunosuppressants. One Janus kinase inhibitor, batricinib, has been included as an arm in the US NIAID's Phase III Adaptive Covid-19 Treatment Trial.

Other potential candidates include inhibitors of dihydroxyorotate dehydrogenase (DHODH), which are claimed to exhibit both host-targeting antiviral activity and suppression of immuno-inflammatory reactions; inhibitors of phospholipase A2; and a potentially bioactive peptide being developed as an aerosolized solution to specifically treat acute respiratory distress syndrome in severely/critically ill patients.

Potential advantages of chemical drugs over biologicals include that they are easier to produce and scale up production; usually do not require a cold chain; usually cost less; and administration is generally oral. These are characteristics that are particularly relevant for LMIC.

It was recognized by the group that there are some safety concerns about the use of immunomodulators, especially in the context of severe pneumonia. However, the main objective of the meeting was not to make any choice at this stage, but, rather, a preliminary step to develop a landscape of potential immunomodulatory therapies. Members of the group were invited to provide feedback in writing to the secretariat on what products would be the most suitable to further investigate/discussion, and also what products should not be considered, with a rationale for the feedback provided.

The report on the potential inclusion of immunomodulators in Solidarity Trial (published on 08 May)

Research mapping of candidate therapeutics for COVID-19

A living research mapping of candidate COVID-19 therapeutics, displaying studies per country, showing study design, disease severity in study participants, and type of treatment being studied, as well as network maps of these studies, has been made available at: https://www.covid-nma.com/dataviz/

Living synthesis of Covid-19 study results

A list of treatment comparisons, a summary of the evidence for that comparison, and a detailed description of primary studies, including a risk of bias assessment is at: https://covid-nma.com/living_data/index.php

COVID-19 and the use of angiotensin-converting enzyme inhibitors and receptor blockers

Concerns exists that angiotensin-converting enzyme inhibitors (ACE inhibitors) and angiotensin receptor blockers (ARBs) increase susceptibility to coronavirus SARS CoV-2 and the likelihood of severe COVID-19 illness. These concerns are based on considerations of biological plausibility, and the observation that there is an overrepresentation of patients with hypertension and other cardiovascular comorbidities among patients with COVID-19 who have poor outcomes.

Millions of people around the world are on treatment with ACE-Is and ARBs for hypertension, heart failure, coronary artery disease, or kidney disease. Speculation about worse outcomes among patients on these medications during the COVID-19 pandemic has caused widespread anxiety among patients and their care providers. On the other hand, the harms of indiscriminate withdrawal of these medications on cardiovascular outcomes are well documented. There is also widespread speculation about the potential benefits of ACE-Is and ARBs, based on biological plausibility arguments and animal data and small clinical studies on patients with other viral respiratory infections.

WHO has published a scientific brief to summarize the current evidence, on the basis of a rapid review, on the impact of ACE inhibitors or angiotensin receptor blockers on severe acute respiratory illness due to SARS CoV-2. After adjustment for confounders, history of ACE inhibitor or ARB use was not found to be associated with increased severity of COVID-19 illness.

There were no studies that address the potential benefits and harms of initiating ACE inhibitors or ARBs as treatment for patients with COVID-19. No studies were found that were designed to directly assess whether ACE inhibitors or ARBs increase the risk of acquiring COVID-19. The rapid review concluded that there is low-certainty evidence that patients on long-term therapy with ACE inhibitors or ARBs are not at higher risk of poor outcomes from COVID-19.

WHO Science brief on COVID-19 and the use of ACE inhibitors and ARB (07 May)

Adverse drug reactions

Since the last analysis (summarised in WHO Regulatory Update No. 7), **686 new case safety reports** were reported, between 20th April and 3rd May, to VigiBase, the WHO Global database of Individual Case Safety Reports. Most of the reports describe at least one drug or substance in the WHO Solidarity trial as either suspected or interacting.

Cumulatively, there are now a total of 1146 reports on these drugs, from five WHO regions, with most of the reports coming from the European region (71.5 %). 57.7 % of the reports were classified as "serious" (not all reporting standards include 'seriousness' as a reporting field (e.g. INTDIS)). Males accounted for 59% of the reports.

The database also includes a smaller number of case safety reports with non-Solidarity trial drugs in the treatment of COVID-19 disease.

Descriptive analysis of spontaneous report from VigiBase: (04 May)

Vaccines

Landscape of candidate vaccines for SARS-CoV-2

A landscape analysis of candidate SARS-CoV-2 vaccines is regularly published by WHO.

Landscape of COVID-19 candidate vaccines (11 May)

WHO Guidelines for assuring the quality, safety, and efficacy of plasmid DNA vaccines

Given the potential of DNA vaccination as a platform technology to address priority pathogens of public health emergencies, such as SARS-CoV-2, the need for international regulatory convergence for DNA vaccines is clear.

WHO is revising its guidance to regulators, product developers and manufacturers to facilitate such convergence. A draft document, based on extensive consultation with experts, has been published for public comment. The document provides up- to-date guiding principles for evaluation of quality, safety and efficacy of DNA vaccines for human use.

The draft has been published to obtain feedback from a broad audience of relevant government authorities, manufacturers, and other experts prior to submission to the Expert Committee on Biological Standardization.

Written comments proposing modifications to the draft text are requested by 13 June 2020 using a Comment Form

Draft Guidelines for assuring the quality, safety, and efficacy of plasmid DNA vaccines

Enabling research: Animal models, clinical trial protocols, assay development, standards

WHO Working Group on Assays and Reference Preparations

At the 13 May meeting of the group, the National Institutes for Food and Drug Control (NIFDC), WHO Collaborating Centre (Cc) for standardization and evaluation of Biologicals in China, presented work on development of pseudovirus-based neutralization assays (PBNA) for SARS-CoV-2 and development of a national standard of antibody to SARS-CoV-2. NIFDC has established the PBNA and completed validation of the assay including optimization of assay conditions/reagents, pseudovirus (PsV) yield, and validation against wild virus-based neutralization assay.

Good results were obtained to show the robustness of the PBNA. The PBNA protocol and PsV reagent have been shared with over 50 labs that develop COVID-19 vaccines or therapeutics in China. The PBNA has been used to evaluate the immunogenicity of COVID-19 vaccines, by testing the serological response in clinical trials of vaccines; the in vitro efficacy of monoclonal antibodies; and the screening of antiviral drugs. NIFDC published the assay development and validation in Emerging Microbes and Infections.

NIFDC is also developing a national neutralizing antibody standard for SARS-CoV-2. A total of 1000 vials have been prepared and are stored at -30 degree C. A collaborative study is ongoing in China, involving by 11 laboratories, to validate the reagent.

The Assays WG also discussed the need for assays to differentiate the immune response from vaccination and from natural infection, which will be followed-up in subsequent calls.

Antibody research reagent now available for coronavirus (COVID-19)

An anti-SARS-CoV-2 antibody research reagent is now available from the National Institute for Biological Standards and Control (NIBSC), WHO Collaborating Centre in UK. This follows previous work by the Institute to develop a SARS-CoV-2 RNA research reagent.

The new antibody reagent is plasma that has been treated to inactivate enveloped viruses and is derived from a donor that has recovered from COVID-19.

It is intended to be used as a positive control for the development and evaluation of serological assays that detect the presence of antibodies against SARS-CoV-2, specifically neutralisation assays and ELISAs.

NIBSC COVID-19 site

WHO Working Group on Animal Models

The 14 May meeting was presented with results from one group of an infection/reinfection experiment in rhesus macaques. The animals were protected against re-challenge with the same SARS-CoV-2 virus as used for the initial infection. Of note, complete protection of the lower respiratory tract was documented and there was significantly reduced virus load in nasal swabs.

Another group reported results of immunization/challenge experiments in rhesus macaques. In one experiment, animals had been immunized with the priming dose only of ChAd1Ox vaccine candidate. The immunized animals showed protection against virus infection of the lower respiratory, but virus replication was seen in the upper respiratory tract. It was noted by the group that the SARS-CoV-2 challenge dose used in this experiment was very high. A follow-up experiment is underway using the full prime/boost immunization regimen.

Substandard and Falsified products

WHO continues to receive reports of SF products in relation to the Covid19 outbreak, either because demand has increased or because supply has been constrained. Vigilance is requested from all regulators.

Supply chain updates from WHO HQ and Reginal Offices

Customs and trade

A list of priority items has been developed and transmitted to customs authorities, including a request to expedite or not delay the movement of a critical list of medicines. The letter will be reproduced and provided to partners who are moving humanitarian deliveries to ensure that this global policy document is provided with each shipment.

Shipments from UN partners:

Challenges with transportation continue to affect shipments in many regions. Reports are the availability of flights for transporting goods has improved in North America, Europe, and to some extent into and out of India. Other regions continue to experience problems with transportation.

Laboratory specimens for patient testing are a challenge for several countries who either do not have local testing capacity or whose testing capacity has been diverted. The implication is that some critical diseases

are not being diagnosed in a timely manner, including polio and others. Solutions are underway to include the specimens with other cold chain shipments to countries that have available laboratory capacity.

Over 105 countries have received shipments of PPE from the UN consortium. Additional products that have been procured include PPE and oxygen concentrators. Procurement of diagnostics is imminent, pending information on production and availability of products. Procurement is implemented across systems of multiple agencies, including WHO, UNICEF and the World Bank.

Shortages:

WHO continues to monitor shortages across regional networks, industry associations and regulatory networks.

Supplies levels are showing signs of correcting in North America and Western Europe, where monitoring is strong and where caseloads are starting to plateau or decline. In other regions, however, shortage reports continue.

Most countries are considering reserve stock as a preventative measure, either for a second wave or to increase current treatment capacity.

Many countries are developing internal allocation approaches to ensure that medicines are moving to the regions and facilities where they can be used. Specifically, as care shifts up and down across levels in the system, logistics information needs to be available to estimate needs at existing and repurposed facilities.

WHO is developing preparedness survey tools that address both service delivery capacity and preparing for medicines availability.

A partial list of medicines reported to be in shortage include the following:

- Antibiotics: azithromycin, levofloxacin, metronidazole, amoxiclav, piperacillin, tazobactam
- Renal replacement fluids
- paracetamol
- 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)
- HIV: Lopinavir/ritonavir
- NCD: Metformin
- GI: Nizatidine (use in COVID-19 treatment and a spike in demand due to the recall of ranitidine)

Other products:

- Blood and plasma: *In some countries, particularly in areas where clinical trials of convalescent plasma are underway, there are reports of shortages in blood and plasma supply. The shortage is in part due to the unavailability of donors in lockdown measures and also an increase in use.*
- PPE: *supplies remain strained*
- Oxygen and ventilators: *remain in shortage for a number of countries.*

Solutions continue to include:

- alternative supply sources and the regulatory flexibilities to facilitate the implementation
- global labeling to facilitate broader releases to markets
- shifting patients to alternative therapies (relevant to lopinavir/ritonavir)
- allocation models that allow for optimized distribution of medicines within a given country
- allocation models for eventual new medicines, pending outcomes of clinical trials
- special controls on over-the-counter sales, especially through on-line pharmacies (relevant for CQ and paracetamol)
- local production for PPEs and other products where manufacturing capacity can be increased or repurposed.

Manufacturing capacity:

While manufacturing capacity in India is reported to have increased to up to 70% for export products and 80% for domestic products. Nonetheless, reports of shortages of API and finished pharmaceutical products are continuing, and WHO is working with industry associations to identify particular problems.

The confinement measures in India continue, but have shifted to a "hot zone" approach that eases restrictions in some areas with low numbers of cases. This is expected to improve production capacity as well as warehousing and intra-country transportation.

Export restrictions

Export restrictions have been reduced, including restrictions from European countries.

Medical Devices

The COVID-19 Supply Chain System is available at:

https://www.who.int/emergencies/diseases/novel-coronavirus-2019/covid-19-operations

It provides a centralized supply system for personal protective equipment, medical devices for clinical management and for diagnostics.

These products are procured by WHO using the technical specifications published in

https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/covid-19-critical-items

and https://www.who.int/medical_devices/priority/COVID-19/en/

WHO HQ has established a technical advisory group of experts for personal protective equipment and for medical equipment required for clinical management to support assessments of innovative technologies, and technical specifications among other requirements.

The COVID-19 Biomedical Equipment Inventory Tool can be found below. Of note, WHO is in full support of such initiatives and encourages data sharing to HQ to ensure appropriate allocation.

This page will include the 5 subtopics:

- Personal protective equipment
- In vitro diagnostics
- Medical equipment and consumables to manage the patient
- For innovative technologies for COVID

- Global collaboration for medical devices for COVID

COVID-19 Biomedical Equipment Inventory Tool

WHO has developed a COVID-19 Biomedical Equipment Inventory Tool (survey) whose aim is to collect facility data on the availability of biomedical equipment (oxygen, accessories and consumables) and ventilators at the country level. These data can serve to inform planning and readiness, at facilities and in-country, as well as to inform WHO's global COVID-19 Supply Chain System of existing capacity so that appropriate equipment is sent to where it can be absorbed, and in an equitable manner.

WHO has a team assembled at HQ to support countries and participants to conduct the survey at facilities in-country, which can be completed electronically via the web or by using a free "app" (SurveyCTO platform), or using a paper survey with an excel spreadsheet "roll-up". We are encouraging countries to complete this survey in order help inform country-level planning, as well as to reduce burden on incredibly stretched global supply chain systems, which are in a current shift towards a WHO-led consortium.

The COVID-19 Biomedical Equipment Inventory Tool can be found at the links below. Of note, WHO is in full support of initiatives already under way to this effect and encourages data sharing to HQ to ensure appropriate allocation.

- WHO Biomedical Equipment Inventory Tool. Quick start guide
- Biomedical Equipment for COVID-19 Case Management Interim guidance Inventory tool for facility readiness and equipment re-allocation (06 May)
- Biomedical Equipment for COVID-19 Case Management (excel, 06 May)

Please contact COVID-MED-DEVICES@who.int for support in implementing the survey, including leveraging existing survey initiatives, as well as if you are willing to participate. Access to the Survey CTO

Regulatory Flexibility initiatives

Regulatory flexibilities are being widely used to facilitate access to products and avoid shortages during the public health emergency. Many regulatory evaluations of candidate diagnostics, therapeutics and vaccines are proceeding very rapidly.

However, this is raising questions of trust in the quality of the evaluations. It is important to communicate to stakeholders that any positive regulatory decisions will be based, as always, on a favourable benefit-risk analysis. Transparency remains key to ensuring stakeholders trust the regulatory processes and decisions.

Access to regulatory updates by WHO staff

All WHO staff have access to the Regulatory Updates at the following location:

P:\PubPersons\RPQ\COVID_Regulatory_Updates