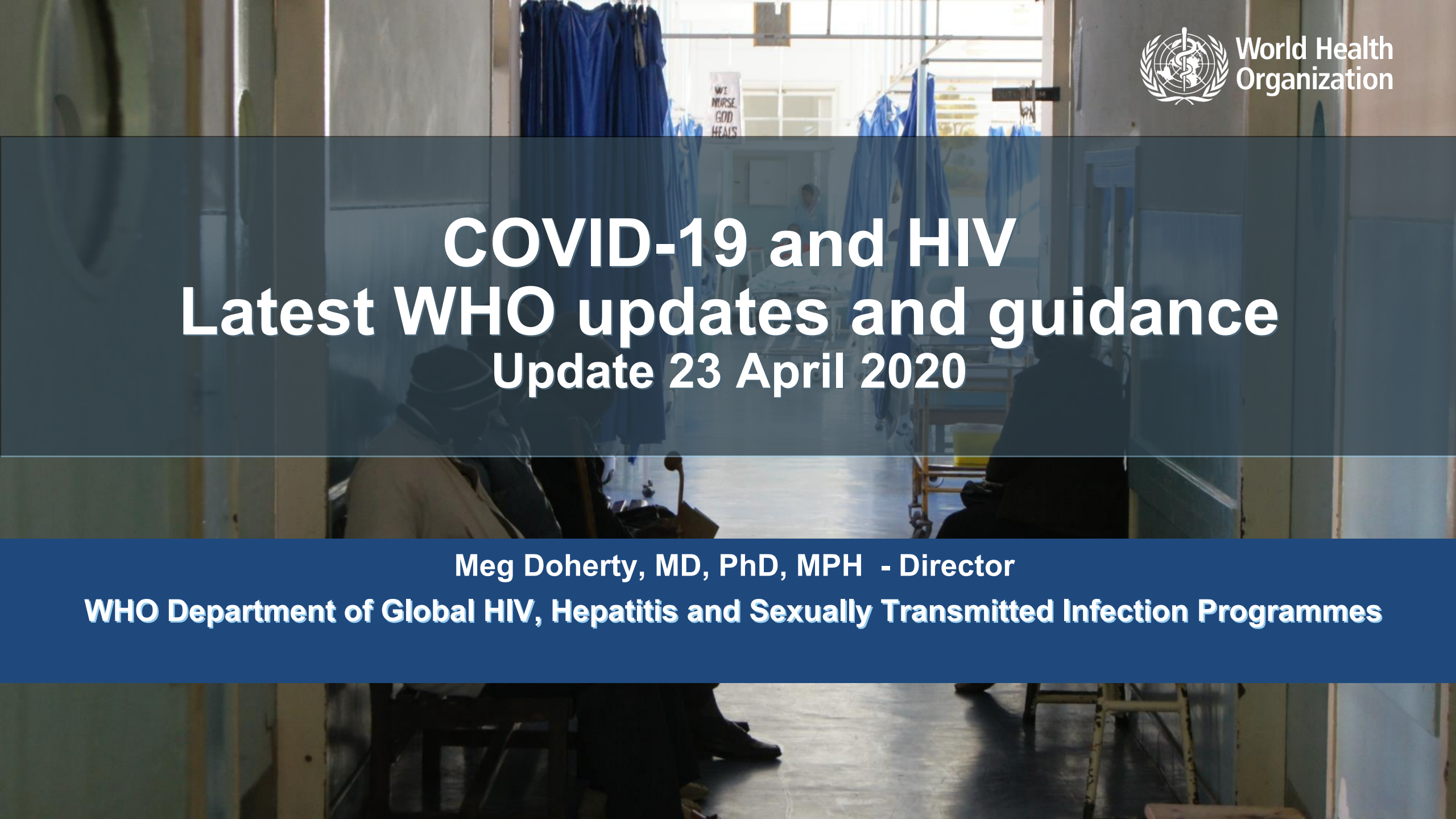


World Health Organization

COVID-19 and HIV
Latest WHO updates and guidance
Update 23 April 2020

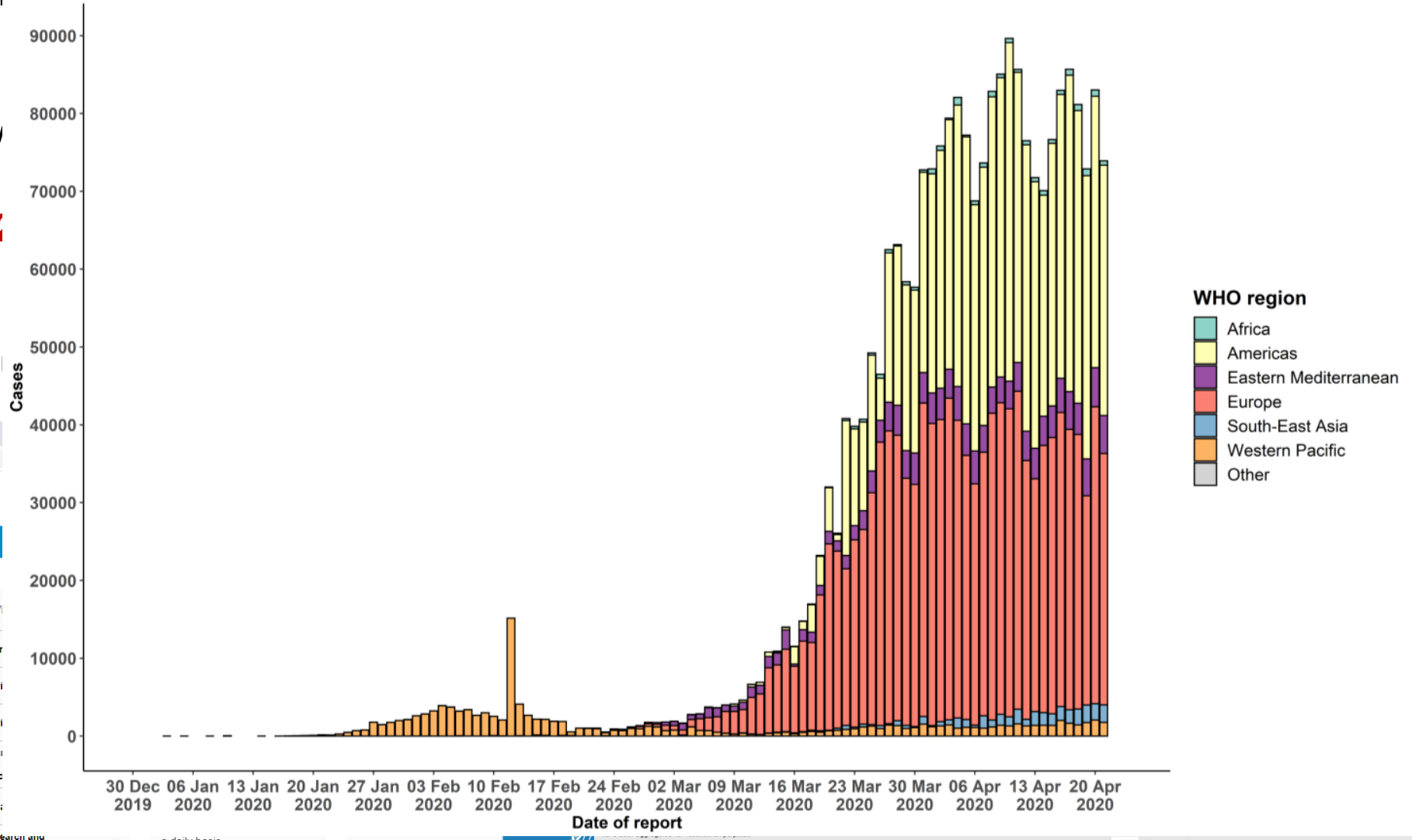
Meg Doherty, MD, PhD, MPH - Director

WHO Department of Global HIV, Hepatitis and Sexually Transmitted Infection Programmes

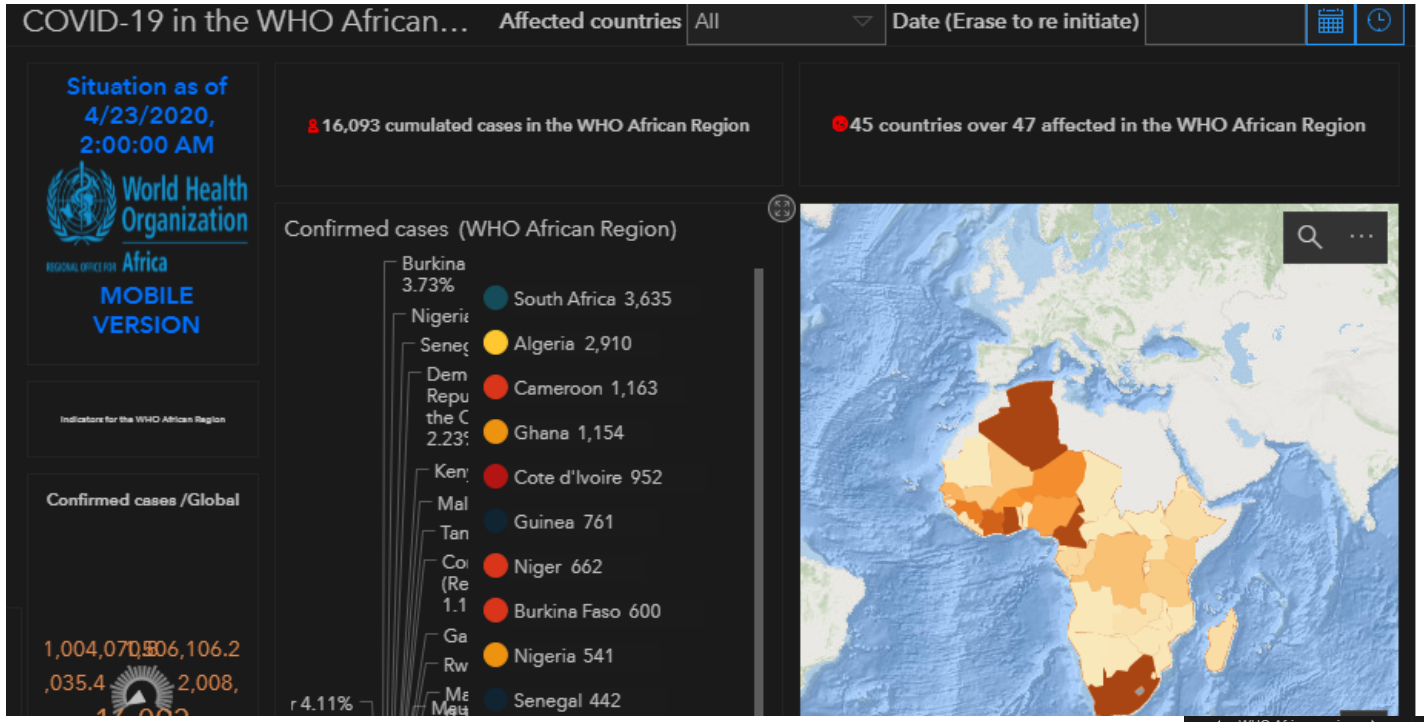
Recapping the last 4 months ….

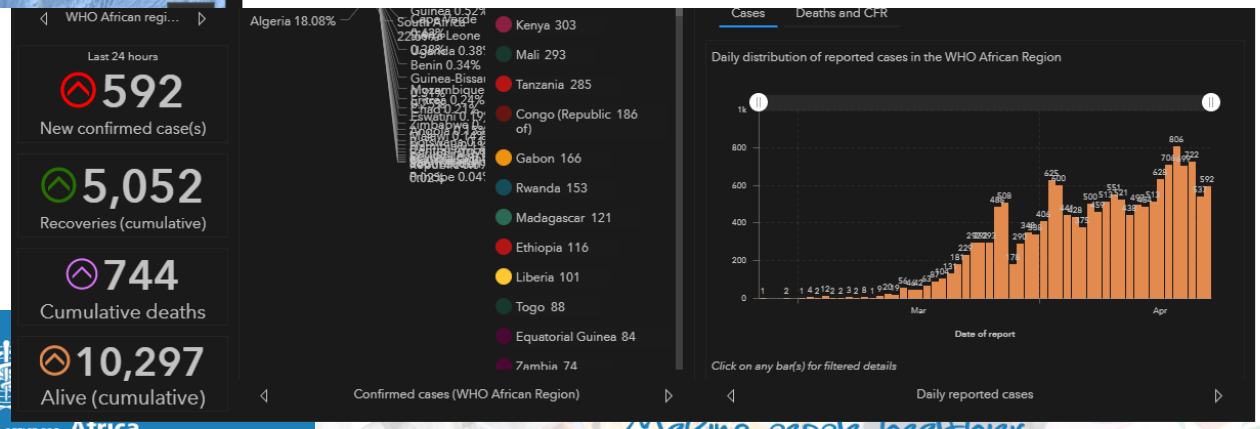
- A pneumonia of unknown cause detected in Wuhan, China was first reported to the WHO Country Office in China
- The outbreak w 2020
- **By 23 April 202 es**

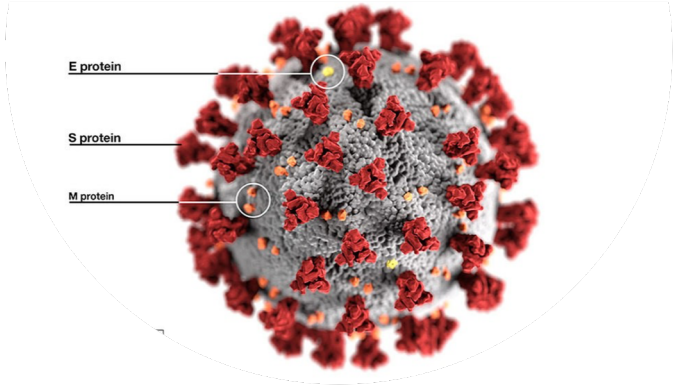
Sharing real-time u
www.who.int And g

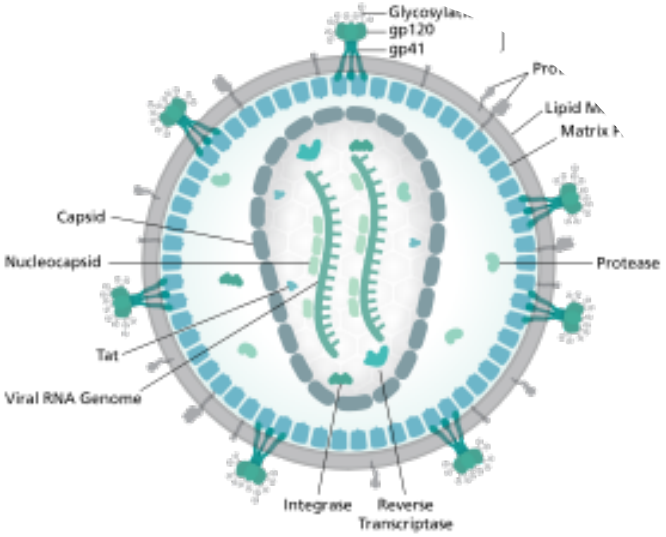


WHO AFRO COVID-19 Dashboard









COVID-19 and HIV & TB

World Health Organization

- Patients with severe immunodeficiency usually have high risk of complications with any infectious disease
- Several reports of HIV-CoVs co-infections **(HIV/SARS - Wong, 2004; HIV/MERS - Salahoub, 2015; HIV/COVID19 - Zhu, 2020; Guo, 2020; Joob, 2020); Spain with 56 PLHIV;** Mild moderate CoV disease despite severe immunodeficiency; most recover
- PLHIV low CD4 & COVID similar outcomes to non-PLHIV **(Guo, 2020**)
- TB and comorbidities DM, malnutrition may increase risk of COVID-19
- **Children and COVID-19:**
- Predominantly Asymptomatic/Mild/Moderate Disease
- Case reports of infant deaths and children < 14 yo
- Challenge to maintain clinics, MMD, and transition to new paediatric ARVs
- Unknown number & outcomes of HIV/TB/COVID coinfections among < 5 yo

Efficacy and safety of ARVs for the treatment and prevention of SARS, MERS or COVID-19

JIAS JOURNAL OF THE INTERNATIONAL AIDS SOCIETY Open Access

REVIEW | Open Access |

Systematic review of the efficacy and safety of antiretroviral drugs against SARS, MERS, or COVID-19: initial assessment

Nathan Ford, Marco Vitoria, Ajay Rangaraj, Susan L Norris, Alexandra Calmy, Meg Doherty

First published:26 March 2020 | https://doi.org/10.1002/jia2.25489

This article has been accepted for publication and undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the Version of Record. Please cite this article as doi:10.1002/jia2.25489

Use of ARV as treatment for CoV infections

- 433 titles, two randomized trials and 24 observational studies reported outcomes using LPV/r as treatment.
- 21 observational studies reporting treatment outcomes,
  - 3 with SARS, 6 with MERS, 12 with COVID-19.
- 1 RCT of 99 patients with severe COVID-19
  - LPV/r was not associated with a statistically significant difference in time to clinical improvement, although LPV/r given within 12 days of symptoms was associated with shorter time to clinical improvement;
  - 28 day mortality was numerically lower in the LPV/r group (14/99) compared to the control group (25/100), but not statistically significant.
- Other RCT found no benefit.
- In the observational studies 3 out of 361 patients who received LPV/r died;

Use of ARV as Prevention (PEP) for CoV infections

- 2 studies reported a possible protective effect of LPV/r as post-exposure prophylaxis (SARS and MERS). The certainty of the evidence was very low due to uncertainty and limited sample size.

25 registered trials planning to assess the safety and efficacy of ARVs for the treatment of coronavirus infection (23 for the treatment of COVID-19).

- 19 assessing LPV/r, 1 assessing upboosted LPV, 1 assessing ritonavir, 1 darunavir and cobicistat, 1 assessing TAF

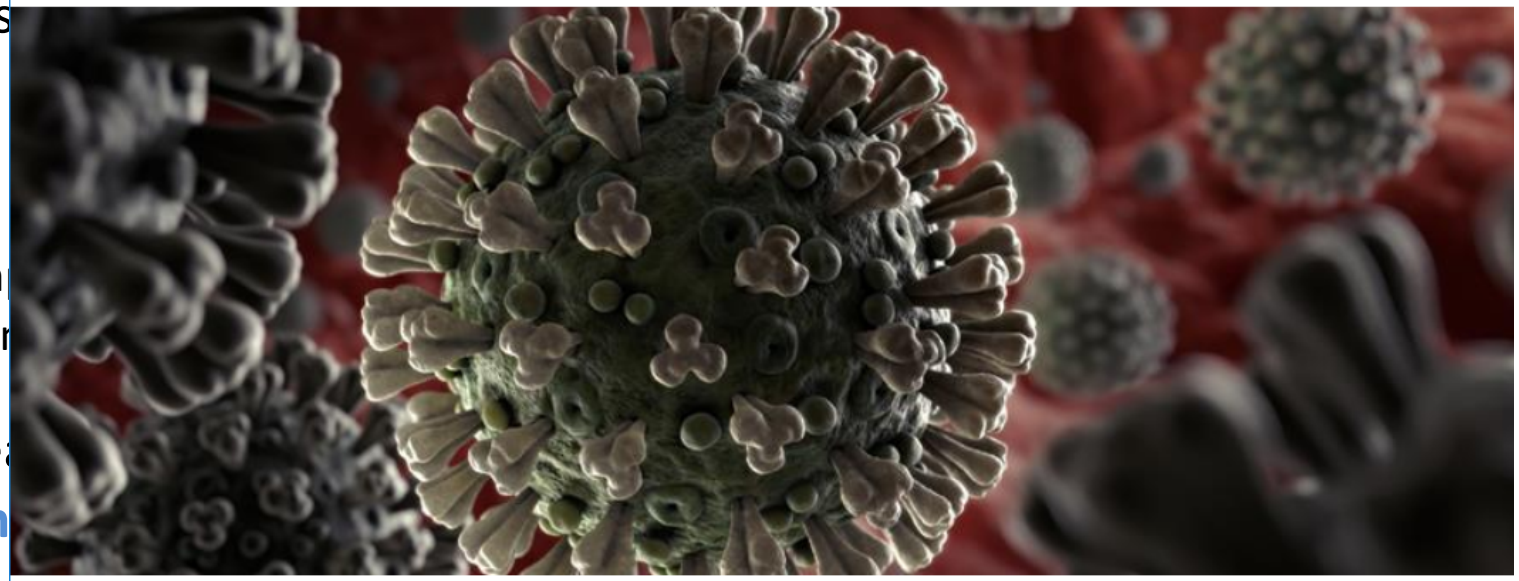
SOLIDARITY Tr

- **WHO launched** the **SOLIDARI**
- The **SOLIDARITY** trial provides
  overloaded to participate.
- The trial entails:
  - an experimental antiviral com
    hydroxychloroquine; a combi
- >90 Many countries have alre
  Bahrain, Canada, France, Iran
- The **COVID-19 Solidarity Resp**
  individuals and organizations

World Health Organization

Health Topics | Countries | Newsroom | Emergencies | About Us

Home / Emergencies / Diseases / Coronavirus disease 2019 / Global research on coronavirus disease (COVID-19)



Update on research activities for novel coronavirus

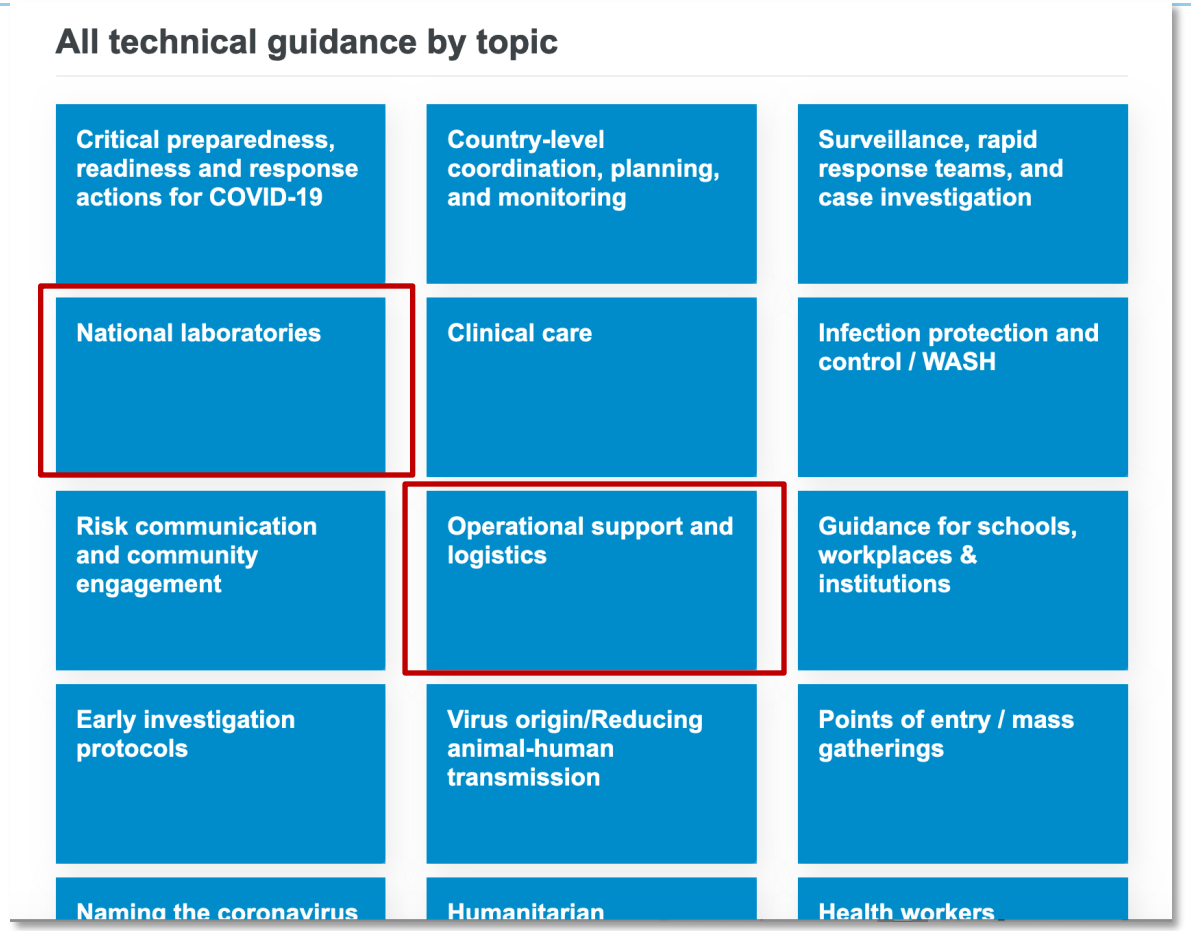
International Clinical Trials Registry Platform

COVID-19 Emergency Use Listing Procedure (EUL)

COVID-19 Updates/New technical guidance

World Health Organization

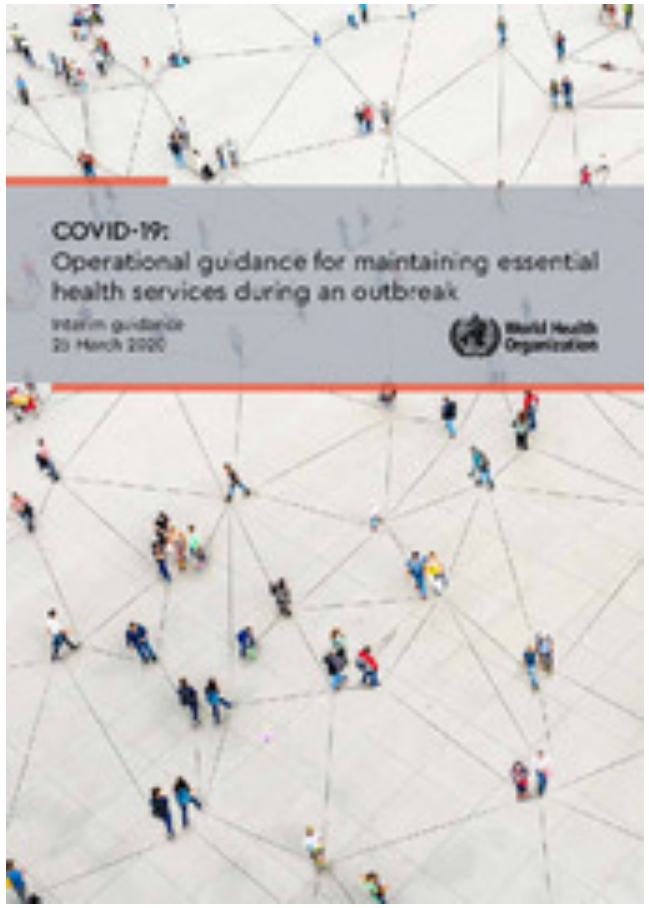
- **New Guidance**
  - **Surveillance:** Operational considerations for surveillance of COVID-19 using GISRS
  - **Clinical care:** Severe Acute Respiratory Infections Treatment Centre: Practical manual (section on women and children)
  - **Lab:** Guidance for laboratories shipping specimens to WHO reference laboratories that provide confirmatory testing for COVID-19 virus
  - **Logistics:** Essential Supplies Forecasting Tool



https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance

Maintaining Essential Health Services- Umbrella Document

World Health Organization



https://www.who.int/publications-detail/covid-19-operational-guidance-for-maintaining-essential-health-services-during-an-outbreak

When health systems are overwhelmed, both direct mortality from an outbreak and indirect mortality from vaccine-preventable and treatable conditions increase dramatically. **This provides guidance on a set of targeted immediate actions that countries should consider at national, regional, and local level to reorganize and maintain access to high-quality essential health services for all.**

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COVID-19 and HIV, Malaria Q&A

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Q&A on COVID-19, HIV and antiretrovirals

24 March 2020 | Q&A

- Are people living with HIV at increased risk of being infected with the virus that causes COVID-19?
- Can antiretrovirals be used to treat COVID-19?
- Can antiretrovirals be used to prevent COVID-19 infection?
- What studies on treatment and prevention of COVID-19 with antiretrovirals are being planned?
- What is WHO's position on the use of antiretrovirals for the treatment of COVID-19?

Health Topics | Countries | Newsroom | Emerger

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Malaria and the COVID-19 pandemic

27 March 2020 | Q&A

WHO is continuously monitoring and responding to the COVID-19 pandemic. This Q&A will be updated as more is known about the novel coronavirus, how it spreads and how it is affecting malaria responses worldwide.

- How many malaria-affected countries have reported cases of COVID-19?
- Should core malaria vector control interventions be maintained in view of the rapid global spread of COVID-19?
- Should WHO-recommended preventive therapies be maintained in sub-Saharan Africa?
- Are there any changes to WHO guidance with respect to malaria diagnosis and treatment?
- What additional special measures may be needed in the context of COVID-19?

https://www.who.int/news-room/q-a-detail/q-a-on-covid-19-hiv-and-antiretrovirals

World Health Organization REGIONAL OFFICE FOR Africa

Community distribution of ARVs in time of COVID-19

People living with HIV who are on treatment should ensure that they have at **least 30 days of ARVs** with them and, where possible, 3 to 6 months supply of ARVs.

MMS approach should also be considered for concomitant used medicines in comorbidities

Testing Considerations for HIV in the context of COVID-19

Lara Vojnov
WHO HIV, hepatitis and STI department

ASLM Webinar "*Maintaining HIV & TB Testing in the context of COVID-19*"

23 April 2020

World Health Organization

Differentiated HIV testing services (HTS) in COVID-19 Context

- It is important to **support undiagnosed PLHIV to get tested and linked to ART**
  - PLHIV, who do not know their status and are not ART and those with known risk factors (e.g. diabetes), who acquire a COVID-19 infection may be at risk of COVID-19 complications
- **Safety of HTS providers needs to be ensured** during testing procedures
  - practices including PPE, hand hygiene, respiratory hygiene, and physical distancing measures.
  - adaptations such as increased use of phone calls, digital tools (e.g. videos, websites, social media, text messages) and approaches like self-testing
- **Considerations for prioritizing and adapting HTS programmes**
  - Continuing ongoing critical clinical services (e.g. ANC, individuals with symptoms or conditions indicative of HIV or with related co-infections or other co-morbidities (e.g. TB , STIs, malnutrition), and EID of HIV-exposed children).
  - Partner/index/family testing to reach the partners of PLHIV presenting at facilities, as well ongoing key populations programmes; increasingly using phone calls
  - Increasing use of HIV self-testing (HIVST) and restricting/pausing community outreach in some settings
  - Maintain linkage and referrals to ART and condoms.
  - Key populations and other vulnerable groups who need HTS, as well as other comprehensive sexual health services, and social protection.
  - Monitor supply chain management as there may be increased risks of disruptions.

Considerations for HIVST

- HIVST may be an acceptable alternative to maintain services while adhering to physical distancing guidance.
- It is important to strategically implement HIVST **prioritizing areas and populations** with the greatest needs and gaps in testing coverage.
- **HIVST approaches include:**
  - distribution for personal use and/or sexual and/or drug injecting partners of PLHIV and social contacts of key populations
  - In some high HIV burden settings, pregnant women may also provide HIVST kits to their male partners.
- **Priority settings to consider**
  - Pick up at facilities or community sites
  - Online platforms (e.g. websites, social media, digital platforms) and distribution through mail
  - Pharmacies, retail vendors, vending machines

HIV and COVID-19 Diagnostics considerations

WHO encourages collaboration and sharing of currently existing molecular diagnostic platforms to support the COVID-19 preparedness response.

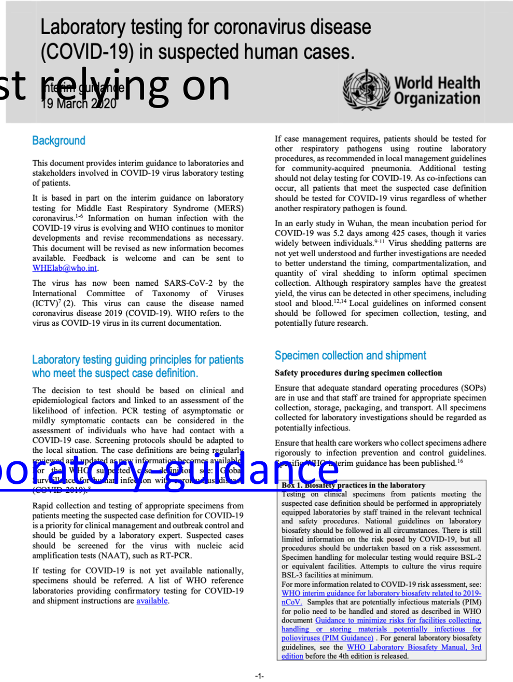
- Diagnostic technologies and systems developed through disease programs can be considered to support the COVID-19 response; however, established systems should not be disrupted.
- It is not recommended to move equipment from their currently designated laboratories or health care facilities to different or central settings to respond to the COVID-19 demand. This will cause significant disruptions to the current networks and to critical testing for HIV and TB.
- Maintain other critical molecular diagnostics, particularly:
  - Early infant diagnosis
  - Viral load testing for people living with advanced HIV disease; those suspected of failing treatment, including pregnant and breastfeeding women; infants, children, and adolescents.
  - Tuberculosis testing for all patient groups

COVID-19 Diagnostics considerations

- Three molecular technologies have US FDA emergency use authorization that are commonly used by HIV and TB programmes – Abbott m2000, Cepheid Xpert, Roche cobas 6800/8800; two have received WHO emergency use listing.

- **A Diagnostics Supply Consortium has been developed that includes WHO, Unicef, Global Fund, World Bank, Unitaid, Gates Foundation, FIND, and CHAI**
  - This consortium is working with suppliers, particularly Abbott, Cepheid, Hologic, Roche, and ThermoFisher, to negotiate access to tests as well as pricing considerations.
  - Discussions have progressed well and final numbers from each supplier are being finalized.
  - Countries and partners are encouraged to consider a multi-pronged testing approach, not just relying on one technology or solely on automated technologies, due to limited test availability.
  - Additional technologies will be brought into the consortium as available.

- **Several guidance documents exist & operational guidance documents to support COVID-19 testing with practical and programmatic guidance are in development**
  - https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/laboratory-guidance



Laboratory testing for coronavirus disease (COVID-19) in suspected human cases.

Interim guidance
19 March 2020

World Health Organization

Background

This document provides interim guidance to laboratories and stakeholders involved in COVID-19 virus laboratory testing of patients.

It is based in part on the interim guidance on laboratory testing for Middle East Respiratory Syndrome (MERS) coronavirus.[1-6] Information on human infection with the COVID-19 virus is evolving and WHO continues to monitor developments and revise recommendations as necessary. This document will be revised as new information becomes available. Feedback is welcome and can be sent to WHElab@who.int.

The virus has now been named SARS-CoV-2 by the International Committee of Taxonomy of Viruses (ICTV)[7] (2). This virus can cause the disease named coronavirus disease 2019 (COVID-19). WHO refers to the virus as COVID-19 virus in its current documentation.

Laboratory testing guiding principles for patients who meet the suspect case definition.

The decision to test should be based on clinical and epidemiological factors and linked to an assessment of the likelihood of infection. PCR testing of asymptomatic or mildly symptomatic contacts can be considered in the assessment of individuals who have had contact with a COVID-19 case. Screening protocols should be adapted to the local situation. The case definitions are being regularly reviewed and updated as new information becomes available. For the WHO suspected case definition see: Global Surveillance for human infection with coronavirus disease (COVID-2019).[8]

Rapid collection and testing of appropriate specimens from patients meeting the suspected case definition for COVID-19 is a priority for clinical management and outbreak control and should be guided by a laboratory expert. Suspected cases should be screened for the virus with nucleic acid amplification tests (NAAT), such as RT-PCR.

If testing for COVID-19 is not yet available nationally, specimens should be referred. A list of WHO reference laboratories providing confirmatory testing for COVID-19 and shipment instructions are available.

If case management requires, patients should be tested for other respiratory pathogens using routine laboratory procedures, as recommended in local management guidelines for community-acquired pneumonia. Additional testing should not delay testing for COVID-19. As co-infections can occur, all patients that meet the suspected case definition should be tested for COVID-19 virus regardless of whether another respiratory pathogen is found.

In an early study in Wuhan, the mean incubation period for COVID-19 was 5.2 days among 425 cases, though it varies widely between individuals.[9-11] Virus shedding patterns are not yet well understood and further investigations are needed to better understand the timing, compartmentalization, and quantity of viral shedding to inform optimal specimen collection. Although respiratory samples have the greatest yield, the virus can be detected in other specimens, including stool and blood.[12,14] Local guidelines on informed consent should be followed for specimen collection, testing, and potentially future research.

Specimen collection and shipment

Safety procedures during specimen collection

Ensure that adequate standard operating procedures (SOPs) are in use and that staff are trained for appropriate specimen collection, storage, packaging, and transport. All specimens collected for laboratory investigations should be regarded as potentially infectious.

Ensure that health care workers who collect specimens adhere rigorously to infection prevention and control guidelines. Specific WHO interim guidance has been published.[16]

Box 1. Biosafety practices in the laboratory
Testing on clinical specimens from patients meeting the suspected case definition should be performed in appropriately equipped laboratories by staff trained in the relevant technical and safety procedures. National guidelines on laboratory biosafety should be followed in all circumstances. There is still limited information on the risk posed by COVID-19, but all procedures should be undertaken based on a risk assessment. Specimen handling for molecular testing would require BSL-2 or equivalent facilities. Attempts to culture the virus require BSL-3 facilities at minimum.
For more information related to COVID-19 risk assessment, see: WHO interim guidance for laboratory biosafety related to 2019-nCoV. Samples that are potentially infectious materials (PIM) for polio need to be handled and stored as described in WHO document Guidance to minimize risks for facilities collecting, handling or storing materials potentially infectious for polioviruses (PIM Guidance). For general laboratory biosafety guidelines, see the WHO Laboratory Biosafety Manual, 3rd edition before the 4th edition is released.

-1-

Discussion and next steps

- We want to hear about your in-country experiences, needs, questions etc
- Get inputs on draft information notes and documents
- Define next steps and address outstanding questions needs etc.

TB/COVID-19 : considerations in diagnostics

Dennis FALZON
WHO Global TB Programme, Switzerland

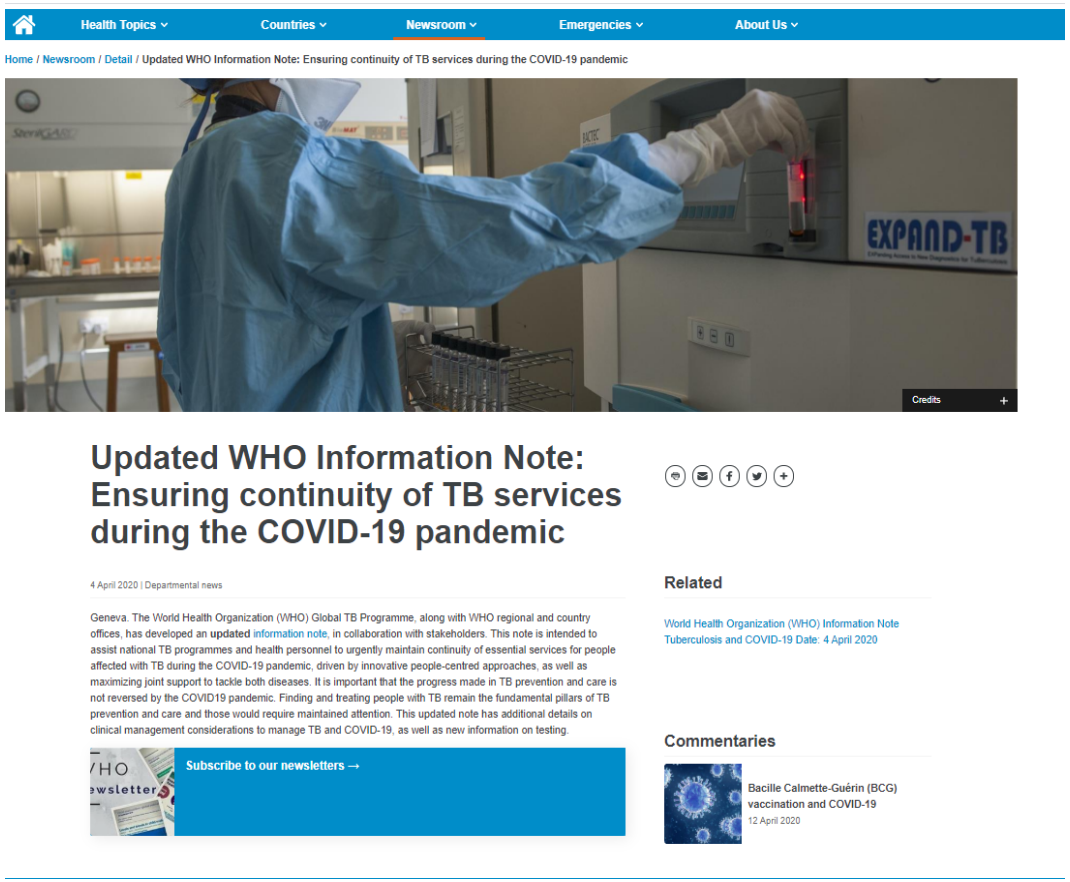
ASLM Webinar *"Maintaining HIV & TB Testing in the context of COVID-19"*

23 April 2020

World Health Organization

END TB

Source



World Health Organization

World Health Organization (WHO) Information Note

Tuberculosis and COVID-19

Date: 4 April 2020

COVID-19: Considerations for tuberculosis (TB) care

As the world comes together to tackle the COVID-19 pandemic, it is important to ensure that essential services and operations for dealing with long-standing health problems continue to protect the lives of people with TB and other diseases or health conditions. Health services, including national programmes to combat TB, need to be actively engaged in ensuring an effective and rapid response to COVID-19 while ensuring that TB services are maintained.

The World Health Organization (WHO) is advising Member States that are leading the response to the unfolding COVID-19 pandemic (1). The WHO Global TB Programme, along with WHO regional and country offices, has developed an information note, in collaboration with stakeholders. This note is intended to assist national TB programmes and health personnel to **urgently maintain continuity of essential services for people affected with TB during the COVID-19 pandemic**, driven by innovative people-centred approaches, as well as maximizing joint support to tackle both diseases. It is important

https://www.who.int/news-room/detail/04-04-2020-updated-who-information-note-ensuring-continuity-of-tb-services-during-the-covid-19-pandemic

https://www.who.int/tb/COVID_19considerations_tuberculosis_services.pdf

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END TB

What should health authorities do to provide

essential TB services during the COVID-19 pandemic?

What services can be leveraged across both diseases?

TB programme staff: can share expertise and logistical support, such as in active case finding and contact tracing. Capacity building and training may be needed

Community-based care: strongly preferred over hospital treatment where possible and visits to TB treatment centres minimized

Prevention: limit transmission of TB and COVID-19 in congregate settings and health care facilities, basic infection prevention and control, cough etiquette, patient triage. TPT maintained

Diagnosis: TB laboratory networks and platforms could support COVID 19 response

TB treatment: must be ensured and medicines given to patients to take home, including TPT

Digital technologies

Proactive planning, procurement, supply and risk management

World Health Organization

END TB

What measures should be in place to protect staff working in TB laboratories and healthcare facilities, and community health workers, from COVID-19 infection?

TB infection prevention and control measures: many also apply to COVID-19

In diagnostic site: training on universal precautions, consistent use of the N95 respirator, handwashing, gloves, goggles or protection shield, waterproof aprons, regular decontamination of surfaces, staff distancing in the lab, ventilated workplaces and safe transportation.

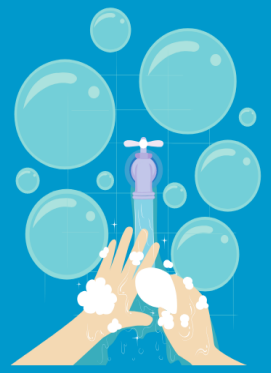
Additional, temporary measures to be considered during the pandemic:

- Reduce visits for TB follow-up
- Fix TB visits on specific days or times
- TB medicines dispensed to the patient or caregiver to last until the next visit
- Sputum collection at home or in open, well-ventilated space, away from health facility

Basic protective measures in COVID-19

Protect yourself and others from getting sick

Wash your hands



- after coughing or sneezing
- when caring for the sick
- before, during and after you prepare food
- before eating
- after toilet use
- when hands are visibly dirty
- after handling animals or animal waste

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Protect others from getting sick

When coughing and sneezing **cover mouth and nose** with flexed elbow or tissue

Throw tissue into closed bin immediately after use

Clean hands with alcohol-based hand rub or soap and water after coughing or sneezing and when caring for the sick

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Protect others from getting sick

Avoid close contact when you are experiencing cough and fever

Avoid spitting in public

If you have fever, cough and difficulty breathing **seek medical care early** and share previous travel history with your health care provider

World Health Organization

World Health Organization
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Should all people being evaluated for TB

also be tested for COVID19 and vice-versa?

As the pandemic advances…

- more people and TB patients will be exposed to COVID-19
- in high TB burden settings a positive result for COVID-19 infection does not exclude concomitant TB, and vice versa
- clinical trajectory can determine need for testing in TB and COVID-19 patients

Simultaneous testing of the same patient for both TB and COVID-19 would generally be indicated in presence of :

1. clinical features common to both diseases
2. simultaneous exposure to both diseases
3. a risk factor for poor outcomes to either disease

Can TB and COVID-19 be tested on the same type of specimen?

- Specimens are usually different – sputum for TB and nasopharyngeal/oropharyngeal swabs for COVID-19
- Diagnostic testing using molecular techniques is currently recommended for both conditions; serology is not recommended for both
- By 23 April 2020, three *in vitro* diagnostic molecular tests were on the WHO Emergency Use Listing for COVID-19

Date Listed	Product name	Product code(s)	Manufacturer
03 April 2020	cobas SARS-CoV-2 Qualitative assay for use on the cobas 6800/8800 Systems	09175431190 and 09175440190	Roche Molecular Systems, Inc.
07 April 2020	Primerdesign Ltd COVID-19 genesig Real-Time PCR assay	Z-Path-COVID-19-CE	Primerdesign Ltd.
09 April 2020	Abbott Realtime SARS-CoV-2	09N77-090 and 09N77-080	Abbott Molecular Inc.

https://www.who.int/diagnostics_laboratory/EUL/en/

Xpert® Xpress SARS-CoV-2 cartridge

- The US FDA granted an Emergency Use Authorization for Xpert® Xpress SARS-CoV-2 cartridge
- This cartridge is meant to be used on GeneXpert machines which have been widely deployed for rapid TB testing. Protecting time to test TB specimens is important if these machines will be involved in COVID-19 testing.
- WHO is currently evaluating this cartridge (below as on 21 April 2020)

World Health Organization

SARS-CoV-2 Nucleic Acid Tests: progress of the active applications in the emergency use listing assessment pipeline

Product name	Product code(s)	Manufacturer name	Dossier review	QMS Desk Assessment
Xpert Xpress SARS-CoV-2	XPRSARSCOV2-10	Cepheid	R	R