Advancing the COVID-19 clinical care pathway for acute COVID-19 and post COVID-19 condition: Patient centered clinical research

Prof. Wangari Waweru-Siika, Department of Anaesthesia Aga Khan University, Kenya
Advancing the COVID-19 clinical care pathway
Effective therapeutics and evidence based clinical interventions

• Bringing evidence generation to global clinical management guidelines in real time to save lives.

  • **Corticosteroids** prioritized early 2020, tested in multiple trials, including large platform trial (RECOVERY); simultaneous prospective meta-analysis (WHO REACT) leading to 1st WHO Living guideline: Therapeutics and COVID-19 in Sept 2020.

  • To date 8 versions of the living guideline; including **corticosteroids, IL6 RB, baricitinib, casirivimab/imdevimab, sotrovimab** in the toolbox for effective COVID-19 treatments. Updating guidelines within **8-10 weeks from data availability.**
Advancing the COVID-19 clinical care pathway

Understanding natural history and spectrum of disease

• Rapid publication of tools for standard patient data collection.
  • Case Record Forms (CRF) for acute COVID-19, MISC, pregnant woman and post COVID-19 condition, minimal common data set, core outcome set (COS) and COVID-19 severity classification system (published by May 2020).

• Simultaneous large data registries available to pool individual patient level data.
  • WHO Global Clinical Data Platform and Dashboard (launched April 2020) now with 570,172 individual patient records and ISARIC includes > 500,000 entries.

• Ongoing prospective data collection for:
  • Severity study in children with COVID-19, post COVID-19 condition and maternal, pregnancy and neonatal outcomes for women and neonates infected with SARS-CoV-2.
Advancing the COVID-19 clinical care pathway

Improving access to oxygen therapy

• Global inequities in oxygen, advanced respiratory support devices and basic emergency and critical care

  • WHO launched O2COV2 study to assess availability and use of oxygen for COVID-19 (September 2021) and will serve to launch a platform study to assess non-invasive interventions for those with severe or critical COVID-19. Currently is onboarding 36 study sites across 24 LMIC.

• WHO is leading the development of Global Oxygen investment KPIs that capture oxygen from procurement to patient care to inform research, clinical operations and advocacy using delphi methodology.
Patient Centred Clinical Research
Clinical interventions and treatments

Research Tools

Evidence Ecosystem

Access

Pharmacovigilance

Clinical Assessment

Symptoms

Individual benefit of participating in RCT

Rehabilitation and recovery

Side effects

Symptoms

Rehabilitation and recovery

Side effects

Individual benefit of participating in RCT

Clinical assessment
Outstanding Clinical Research Priorities
Advancing the COVID-19 clinical care pathway

Outstanding research priorities

• Post COVID-19 condition (long covid)—from burden of disease, symptom, natural history, recognition, pathophysiology, clinical management, therapeutics and service delivery.

• Evaluation of supportive care and clinical management interventions, to improve outcomes in severe or critical COVID-19 in LMIC.

• Develop and validate prognostic models to better describe high risk patients.

• Establish reliable approach to update severity classification and define disease severity with VOCs.

• Prospective antiviral resistance and safety monitoring with introduction of new therapeutics.
Standardized tools and data registries
COVID-19 lessons for the future response

Standardized tools and global data registries to inform clinical guidelines for all disease of outbreak potential

• Establish **standardized patient data toolkit** for COVID-19 and beyond; including mid- and long-term impacts. Minimal core outcome set, case record forms.

• Sustain **global clinical data registries** that allow IPDA aggregation.

• Sustain **WHO global clinical data platform and dashboard** for rapid analysis to inform clinical and public health interventions; such as severity, clinical interventions and uptake, resource requirements, effectiveness.
Knowledge uptake
Knowledge Uptake
Taking guidelines to the bedside

• Sustain innovations for trustworthy rapid evidence synthesis and guideline development (LNMA, PMA, and living guidelines).

• Establish methodology of rapid country implementation of evidence-based guidelines.

• Conduct operational research on effectiveness of therapeutics, post guideline monitoring, safety and resistance monitoring, access.
Strengthen research capacity in LMIC
Priorities to expand research capabilities

Strengthen research capacity in LMIC

• **Funding** for research in LMIC.

• Building partnerships in **platform trials** at sites in LMIC.

• Identifying/engaging local researchers/research networks in LMIC sites.

• Expanding **WHO collaborating centers** in LMIC to include **clinical research**.

• **Strategic partnerships** to create an agile evidence ecosystem to ensure patient impact.
Future steps

• WHO to invest in maintaining and expanding strategic clinical research networks globally.

• WHO to establish priority clinical research tools, questions and protocols that are part of outbreak readiness package to allow rapid scale up of research during next emergency.

• Expand patient-led and community-based participatory research, including qualitative research methodology.
Many thanks to the over 300 experts involved our working group and its subgroups

Clinical characterization & management working group & sub-working groups

• WHO REACT (Heparin, IL6 RB, steroids)
• Respiratory studies, O2COV2 study and International SC
• Post COVID-19 steering committee (case definition, COS)
• Severity classification in COVID-19
• Severe COVID-19 in children study
• MISC expert working group
• A prospective cohort study investigating maternal, pregnancy and neonatal outcomes for women and neonates infected with SARS-CoV-2
• Neurology and COVID-19 forum
• COVID-19 Therapeutic guideline development group
• Methods-MAGIC collaboration group
Thank you

Global research and Innovation Forum
24th-25th February 2022

Health Care Readiness (who.int)
Therapeutics and COVID-19 (who.int)
The WHO Global Clinical Platform for COVID-19
COVID-19 Clinical Care Pathway (who.int)
A living WHO guideline on drugs for covid-19 | The BMJ
Therapeutics and COVID-19: living guideline (magicapp.org)