WHO O2COV2:
Oxygen requirements and approaches to respiratory support in patients with COVID-19 in low- and middle-income countries: a WHO study
Information sheet for potential implementing sites

Background
The World Health Organization (WHO) is coordinating an observational study of low- and middle-income country (LMIC) sites to examine baseline practices and resources for respiratory care for patients with COVID-19. This study will stand alone in its results, and also provide baseline data for a subsequent platform trial of advanced respiratory support interventions intended to improve outcomes and prevent the need for mechanical ventilation for patients with COVID-19. We are seeking LMIC sites with a broad range of resources and experience to participate in the observational study.

Study aims
To further inform an upcoming WHO supported platform trial of respiratory support strategies by:
1. Characterizing the type and duration of different modalities of respiratory support delivered to patients with severe and critical COVID-19 in LMICs.
2. To quantify the amount (m³ and L/min.) of oxygen delivered to patients with severe and critical COVID-19 in LMICs.
3. To describe the process of escalation and de-escalation of oxygen therapy in COVID-19 in LMICs.
4. To describe facility-level characteristics for oxygen delivery.
5. To report baseline demographics and hospital outcomes of hospitalized patients with COVID-19 in specific centres.

Study population
- Patients with confirmed SARS-CoV-2 infection confirmed virologically in the lab by RT-PCR via nasopharyngeal or oropharyngeal sample or by SARS-CoV-2 Ag-RDTs that meet the minimum performance requirements of ≥ 80% sensitivity and ≥ 97% specificity compared with a NAAT reference assay.

Study timing
- The expected period within which data can be collected is approximately 7 days or fewer if hospital outcome reached before day 7. In cases, where hospitalization is longer, study participants will be followed daily until hospital discharge.

Site expectations
- Expected time commitment of a site coordinator: full-time supervision of data collectors for 2 weeks; part-time coordination activities pre- and post-data collection.
- Expected time of research assistants at sites: full time (day only) data collection over 2 weeks.
- No target sample size.

Site lead expectations
- Obtaining ethical approvals required for each site, leveraging support from WHO as needed (see below).
- Providing oversight for data collection and entry, using quality assurance protocols provided by WHO.
- Engaging and overseeing data collectors.
- Liaising with WHO on issues that arise during study preparation, data collection, and follow up through established consortium of site leads.
**Site potential benefits**
- Sites which participate in the observational trial will be eligible to be included in the platform intervention trial.
- Research capacity building.
- Experience and learning about data collection, patient outcome, building databases, international collaborations.
- Detailed knowledge about patient cohort and care processes, quality of care, outcomes that can be used for internal audits and quality improvement.
- Involvement in research is known to lead to improved outcomes for patients.
- Morale boosting and compensation for health workers.
- Pulse oximeters and other capacity building of involved facilities.

**Resources available to sites where needed**
While international studies of this nature are often done without resources provided to individual sites in high-income countries, we understand that many sites will only be able to participate if the costs incurred by the study are covered. We also understand that logistical support may be needed. The following areas of support will be made available to participating sites as needed; additional areas may be proposed by individual sites.

**Study oversight and authorship**
- WHO is able to compensate site leaders for their time in obtaining ethical approvals, identifying data collectors, overseeing data collection, assuring quality data collection, and liaising with WHO leadership. This compensation will be individually determined with each site.
- WHO will provide full detailed protocol for the study’s operation.
- WHO invites all site leaders to be considered for authorship in the final manuscripts, with requirements for authorship outlined prior to beginning data collection and authorship commensurate to contributions made.
- Sites will own their own data. No identifying information will be available to any party other than the site investigators, as per site investigator discretion and local regulations.
- Joint publications with multiple sites will be coordinated by WHO.

**Ethical approvals**
- WHO requested and received approval from the WHO ERC for waiver of consent because it was determined that the master protocol met the CIOMS criteria justifying a waiver of consent. However, when this protocol is adopted at specific country sites, national ERCs may make a different determination regarding consent in accordance with their respective national research ethics guidelines, for example, requiring modified consent or full individual consent as appropriate.
- An information note made easily available to all potential recruitments at site of screening
- WHO will provide technical support to site leaders as questions arise on the ERC applications.

**Budget**
- Fees relating to ethical approvals and research permissions may be considered in budget requests.
- Fees relating to data collection, including staff costs and material costs (tablets/phones, printing, internet) may be considered in budget requests.
  - Stipends for data collectors may be provided on a per hour or per form basis, but the maximum available compensation from WHO is based on payment per accurate completed form.
  - Costs for other incidentals, such as transport, may be considered in budget requests.
  - Costs for PPE for data collectors may be considered in budget requests.
- WHO can provide pulse oximeters necessary for conduct of the study. The oximeters will be donated to the site at the end of the study.

WHO will support translation and back-translation of study documents as required.

For expression of interest, please see website: [https://www.who.int/initiatives/oxygen-access-scale-up](https://www.who.int/initiatives/oxygen-access-scale-up)
For questions contact: covidrespstudy@who.int