

Title	Post-COVID-19 condition in low-and-middle-income countries: pilot study
Working group	Clinical epidemiology
Study aim	To conduct a pilot study on post-COVID-19 condition in centers of low-and-middle-income countries to test the feasibility of data collection in multiple countries, generating a preliminary estimate of the burden of COVID-19 as well as contributing to inform a full-scale study proposal.
Study population	Patients tested for SARS-CoV-2 infection with PCR [+/-] and diverse clinical severity [severe/mild/asymptomatic].
Methods	<p><u>Screening</u> For efficiency, we will use clinical registries, both in hospitals and diagnostic labs, to identify patients tested for SARS-CoV-2 infection with PCR (positive and negative) varying clinical severity (1. Severe or critical disease; 2. Mild disease; 3. Asymptomatic).</p> <p>Participant centers will identify a representative sample of <i>index cases</i> with severe/critical disease. Based on their case density, centers must choose an <i>index case</i> around the peak of admissions within 6-12 months of starting the data collection, seeking the following admissions, consecutively. Each index case will be paired with similar number of cases of different characteristics (age, sex, and disease severity) diagnosed around the same date (± 1 week), assembling the following groups:</p> <ol style="list-style-type: none"> 1. Severe/critical disease: patients <u>admitted to the hospital</u> with a clinical and laboratory diagnosis (COVID-19) or neither laboratory test indicating nor clinical suspicion of SARS-CoV-2 infection (Non COVID-19). May or may not be admitted to ICU or received non-invasive ventilation. 2. Mild disease: patients <u>seen but not admitted</u> to the hospital after clinical and laboratory diagnosis (COVID-19) or neither laboratory test nor clinical suspicion of SARS-CoV-2 infection (Non COVID-19) or that sought outpatient medical care. Their clinical condition did not warrant hospitalization/referral. 3. Asymptomatic: patients seen around the same time of severe/critical or mild disease with a sample taken for PCR, either for surveillance/research or as contact of a positive case (SARS-CoV-2 asymptomatic infection, SARS-CoV-2 negative controls) <p>Each participant center may decide to include groups 2 or 3 according to their access to PCR information for outpatients. However, all centers must collect at least 1 paired case for each participant of groups severe/critical disease.</p> <p><u>Sample size</u> Each center will contribute with 100-150 patients, 25 per 4-6 groups. We expect to include at least 600 patients from at least 3 LMICs.</p> <p><u>Data collection</u></p>

	<p>Data will be collected retrospectively, based on patient’s charts. Additional information will be gathered by remote contact (telephone/virtual interview), to include missing data on the index event and clinical status afterwards. In the meantime, participants may or may not be included in clinical trials of PCC.</p> <p><u>Participant centers</u> We expect to include centers from Asia, Africa, and Latin America. Potential centers are the ones part of the working group such as Health Professions Institute (Bangladesh), Ramathibodi Hospital (Bangkok), Saint Paul's Hospital Millennium Medical College (Ethiopia), Kibong’oto infectious diseases Hospital (Tanzania), Fundación Cardioinfantil (Colombia), Instituto de Medicina Tropical Alexander von Humboldt (Perú).</p>
Exposures	<p>Exposures of interest will be socio-demographic variables including access to information related to COVID-19, vaccination status/willingness, patient’s relevant medical history and medical issues around the <i>index event</i>.</p>
Outcomes	<p>The primary outcome will be a composite of hospitalization, absence from work for at least two days or getting medical care for medical reasons.</p>
Study procedures and organization	<p>The study will be overseen by the clinical epidemiology working group of the CRC, as steering committee. Every participating center must identify a principal site investigator (PI), responsible for conducting the study locally. The PI also holds responsibility for submission before the ethics committee/IRB when it applies. For this pilot, centers will be responsible for gathering the resources necessary to complete the expected data collection. The study coordination will provide technical support to administer the study CRFs and will be monitoring the completeness and integrity of data submitted.</p> <p><u>Case Report Form</u> Available in English and Spanish</p>