There is grave concern for the impacts of COVID-19 in humanitarian and resource-poor settings, where prevention measures such as physical distancing and lockdowns have limited feasibility, and where health system capacity is limited. Available evidence is largely from upper-middle and upper-income countries where the types and prevalence of co-morbidities and clinical management capacities differ greatly as compared to resource-poor settings such as low-income humanitarian contexts in Africa. The objectives of this study are to assess risk factors for poor outcomes (hospitalization, death) and characterize clinical disease progression of COVID-19 cases in Juba, South Sudan and North and South Kivu, Eastern DRC. Specifically, the study aims to:

1. Characterize risk factors for poor COVID-19 outcomes, including both comorbidities with evidence from high income settings, as well as prevalent conditions in humanitarian settings for which data is not yet available.
2. Determine how the progression of confirmed COVID-19 cases in resource-poor African settings may differ from other settings where data are available.

**STUDY PURPOSE AND AIMS**

A prospective cohort design is being used to follow 1) confirmed COVID-19 cases being managed at home via mobile teams; and 2) probable or confirmed cases admitted to participating health facilities (three hospitals in Eastern DRC and the IMC Infectious Disease Unit in Juba). At enrollment, data is collected on sociodemographic characteristics and potential risk factors for poor outcomes. Participants are followed until COVID-19 recovery, death, or loss to follow-up. Analyses will examine which risk factors (nutritional status, anemia, and co-morbidities) and patient characteristics (age, gender, smoking status, clinical symptoms) are significantly associated with poor COVID-19 outcomes, including hospitalization and ultimate disease outcome (recovered/deceased).

In addition, health facility assessments and qualitative interviews with COVID-19 providers were conducted to understand perceptions of risk factors and clinical management as well as contextual and operational challenges. Study implementation challenges include limited testing availability, inability to enroll all confirmed cases, high numbers of refusals and inability to enroll late presenting hospital cases due to severity of condition or death which biased the sample; delays in receiving equipment also limited HbA1C and anemia testing.

Study enrollment began on December 1, 2020 and will continue through the end of June 2021 (7 months) with final results expected in September 2021. The clinicaltrials.gov study registration number is NCT04568499; the study is also registered with the Johns Hopkins Bloomberg School of Public Health Institutional Review Board.

The preliminary results include descriptive statistics by demographic and enrollment characteristics and co-morbidities in the study population, as of June 1, 2021. It is important to note that the sample of COVID-19 cases enrolled is not representative of all COVID-19 cases, rather it is a convenience sample from catchment areas of participating health facilities. Enrollment preference was given to hospitalized cases to enable understanding of clinical progression of severe disease thus hospitalized cases are over-represented in the sample where almost all cases in both countries are managed on an outpatient basis. The table at right presents preliminary data for 473 (87.1%) laboratory confirmed COVID-19 cases (by either PCR or rapid antigen test) that have enrolled in the study. Preliminary take-away messages include:

- Most cases were among males (67.7%) and travelers represented a larger than anticipated number of cases (44%) due to pre-flight testing requirements for many international destinations.
- Chronic conditions were more frequently reported as co-morbidities than infectious conditions (malaria, TB, HIV) which were rare. Obesity/overweight was prevalent (54%) while anemia figures are difficult to interpret due to missingness. History of diabetes and hypertension were more frequent among hospitalized patients than those managed as outpatients.
- High blood pressure (41%) was common overall, as was low oxygen levels (15%) and respiratory distress. Overall, 26% of confirmed cases were hospitalized and 4.3% died, including 16% of patients admitted for in-patient care at a hospital.

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