COREP

Determining the epidemiological parameters of COVID-19 through sero-surveillance with Dried Plasma Spots and nested household transmission studies in rural Kenya and South Africa

RIA2020EF- 3026

Webinar - 18.03.2021.

EDCTP COVID-19 Emergency Funding Mechanism: Collaborative clinical research studies in sub-Saharan Africa

Joy Mauti and Till Bärnighausen

Rationale and objectives

FOCUS ON POPULATION EPIDEMIOLOGY AND SCREENING APPROACHES

1. Define epidemiological parameters of COVID-19 infection in rural Kenya and South Africa, including the reproductive number, transmissibility, clinical disease spectrum and population-level incidence

2. Identify the burden of COVID-19 disease in rural areas of sub-Saharan Africa, and risk factors for infection and transmission

3. Establish the diagnostic performance, feasibility, usability and cost-effectiveness of Dried Plasma Spot samples collected at community level through fingerpricks by community health workers, followed by centralised serological testing
Study communities

SOUTH AFRICA SITE

KENYA SITE
Study populations

- Assumed primary COVID-19 cases (confirmed through NHLS).
- Consenting household members (15 – 20 households, ~120 participants).
- Cases will be contacted telephonically and invited to participate.
- Informed consent will be obtained from:
  - Primary cases,
  - Household members,
  - Parents or guardians in the case of children under 18 years.
Enrolled household cases and their household contacts will complete data and specimen collection at enrolment (day 1) and for 28 days of follow-up, with four household visits in total.

Semi-structured questionnaire:
- Primary case and adult household members day 1, 7, 14 and 28.

Symptom diaries:
- Daily, day 1 – 28.

Offer of HIV testing and counselling (but not a requirement)
Study methods (II)

- Molecular and serology assessments
- Household members day 1, 7, 14 and 28
- Serum sample (DBS in children <12 years) – SARS-CoV-2 antibody test
- Respiratory sample – molecular PCR for SARS-CoV-2
Study methods (III)

- Specimen will be collected at the household
- If no suitable testing room, patient to be transported to nearest facility where study team will collect specimens
- Laboratory testing to be undertaken by BARC laboratory
- Full PPE provided for study team
Study data and analysis

• Data collected will be used to:
  • Calculate the length of the period of transmissibility
  • Calculate the reproductive number
  • Investigate the disease spectrum, especially rates of asymptomatic infections
  • Assess risk groups for infection and for disease.
  • Estimate the understanding and implementation of preventative behaviours
  • Estimate potential vaccine uptake and hesitancy
# Study milestones

<table>
<thead>
<tr>
<th>Activity</th>
<th>Sites and Dates</th>
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<tbody>
<tr>
<td>Obtaining Ethical Approval &amp; Research permits at national and local level.</td>
<td>• South Africa (10.2020, 01.2021, 03.2021)</td>
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<td>• Germany (11.2020, 01.2021)</td>
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<td>• Kenya (11.2020, 01.2021, 03.2020)</td>
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<td>Establishment of the Laboratory Teams</td>
<td>• Both Sites (10.2020)</td>
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<td>Establishment of the Data Management Team</td>
<td>• Joint Team (11.2020)</td>
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<td>Recruitment &amp; Training of Study Teams</td>
<td>• Kenya (01.2021 -02.2021)</td>
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<td></td>
<td>• South Africa (02.2021 -03.2021)</td>
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<td>Establishments of Community Advisory Boards</td>
<td>• Both Sites – 03.2021</td>
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<td>Preparing to publish the Study Protocols</td>
<td>• Kenya – 02.2021</td>
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<td>Development of a preliminary Statistical Analysis Plan</td>
<td>• Germany -01.2021</td>
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<td>Onset of Fieldwork</td>
<td>• Both Sites – 04.2021</td>
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<td>Incorporated in the WHO Unity studies</td>
<td>• 02.2021</td>
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**WHO Unity Studies**

- The UNITY Studies promote standardized methods that enable the global community to collectively address knowledge gaps and inform an evidence-based COVID-19 response

- Unity studies are a valuable tool for research equity
Team – South Africa Site

Gloria Mailema
Principal Investigator

Catherine Martin
Principal Investigator

Matthew Chersich
Co-Investigator

Modiehi Mopeli
Research Nurse

Emly Lekitlane
Fieldworker

Shobna Sawry
Epidemiologist

Nkululeko Mngomezulu
Data Manager
Team – Kenya Study Site

Stanley Lutchers
Principal Investigator

Eunice Irungu
Study Co-ordinator

Anthony Ngugi
Co-Investigator

Claire Otieno
Research Nurse

Ben Kitole
Co-Investigator