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

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

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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

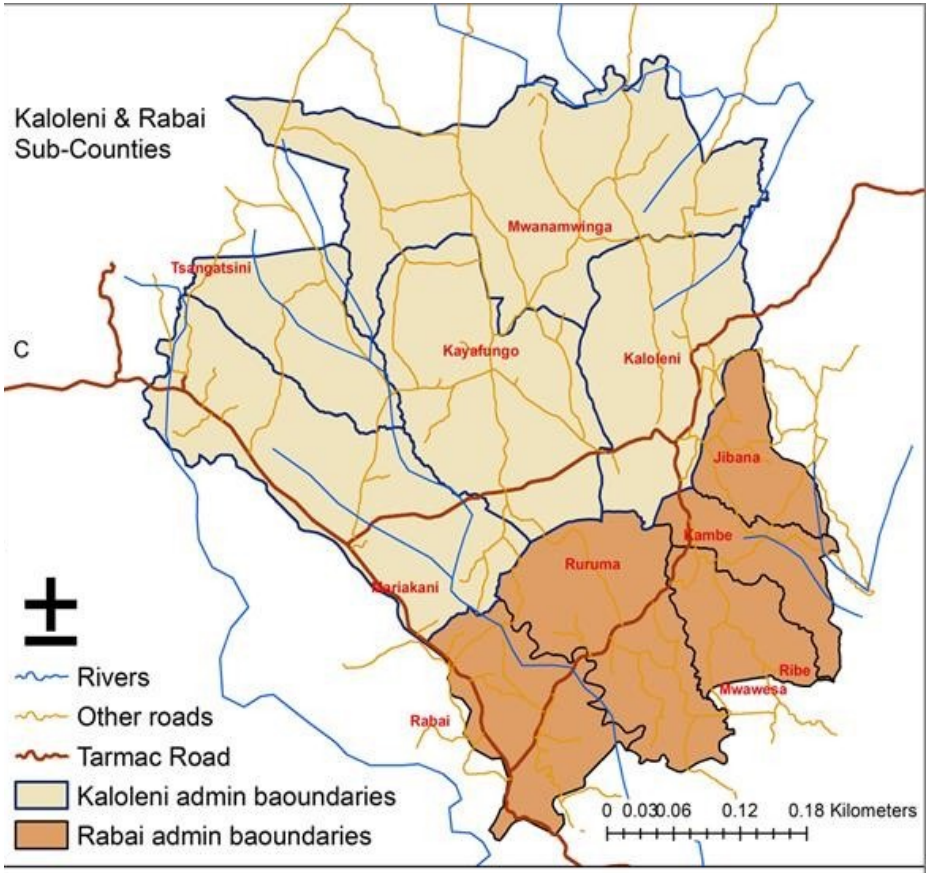
2. Identify the burden of COVID-19 disease in rural areas of sub-Saharan Africa, and risk factors for infection and transmission

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.

Study methods (I)

- 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 <12years) – 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

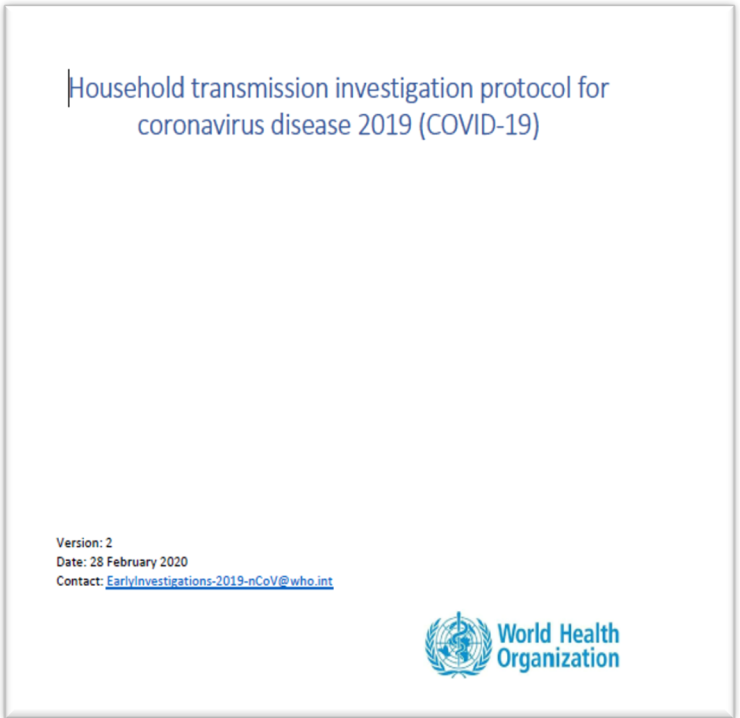
- Data collected will be used to:
  - Calculate the length of the period of transmissibility
  - Calculate the reproductive number
  - Investigate the disease spectrum, especially rates of asymptomatic infections
  - Assess risk groups for infection and for disease.
  - Estimate the understanding and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

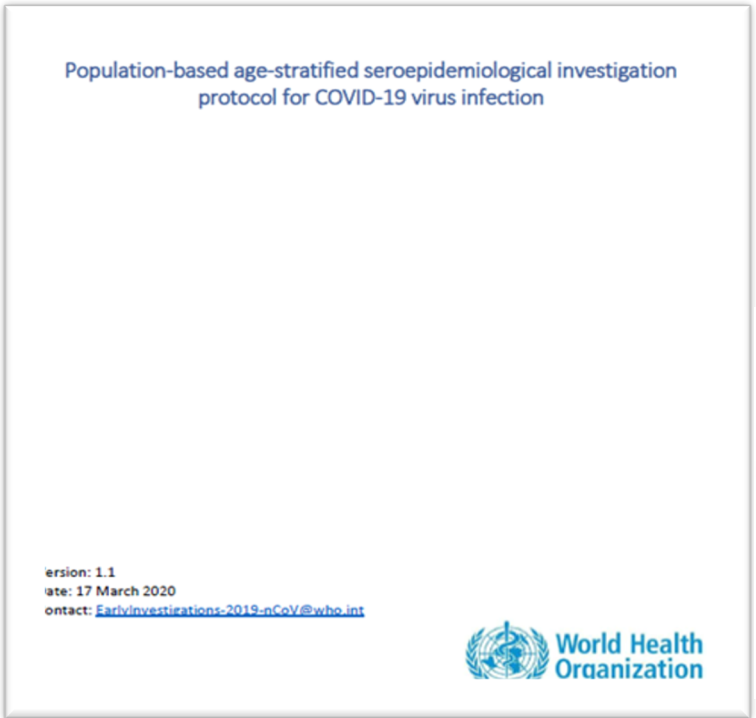
Study milestones

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

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

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Principal Investigator

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Co-Investigator

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Fieldworker

Shobna Sawry
Epidemiologist

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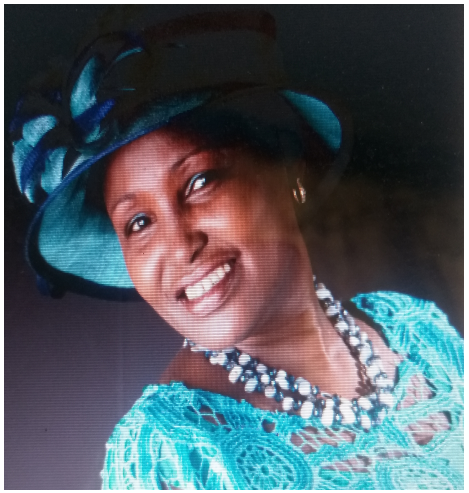
Data Manager

Team – Kenya Study Site

Stanley Lutchers
Principal Investigator



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Other Partners

ISGlobal Barcelona Institute for Global Health

Burnet Institute
Medical Research. Practical Action.

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