

ISO 9001:2015 certified



POPULATION-BASED AGE-STRATIFIED SEROEPIDEMIOLOGICAL INVESTIGATION FOR COVID-19 INFECTION IN ZANZIBAR (COVID-ZANZ)

Protocol

DPG-H Meeting

July 14, 2021

Solomon Mwakasungula (MSc)



ISO 9001:2015 certified



Protocol outline

Introduction

Methods

Data management and Reporting of findings

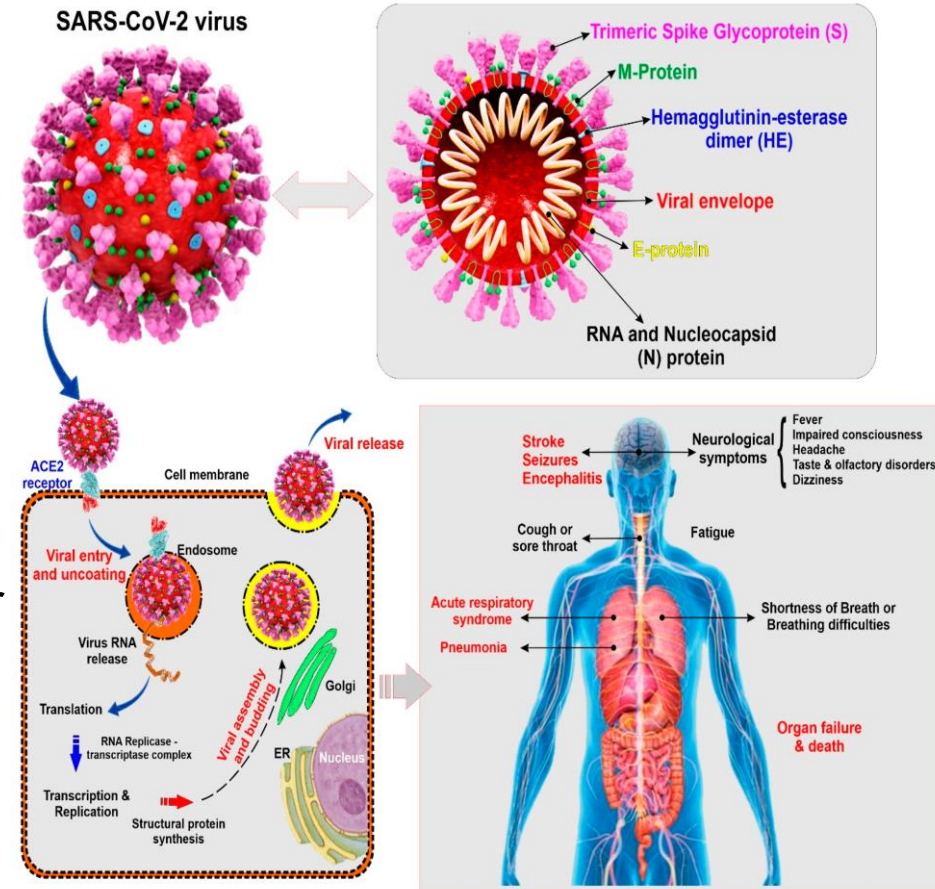
Financing



Introduction

- Detection and spread of an emerging respiratory pathogen is accompanied by uncertainty over epi & serologic indicators
 - ❖ transmissibility
 - ❖ its virulence
- SARS-CoV-2 initial surveillance focused on *patients with symptoms or severe disease*
 - ❖ full spectrum of the disease become unclear
 - ❖ fraction of mild or asymptomatic infections not captured
 - ❖ Estimates of the case fatality ratio is affected

Hence: Underestimation of disease burden



Archie, S.R.; Cucullo, L. 2020



Introduction

qRT-PCR remain to be the gold standard for virus detection

RDT detects antigen

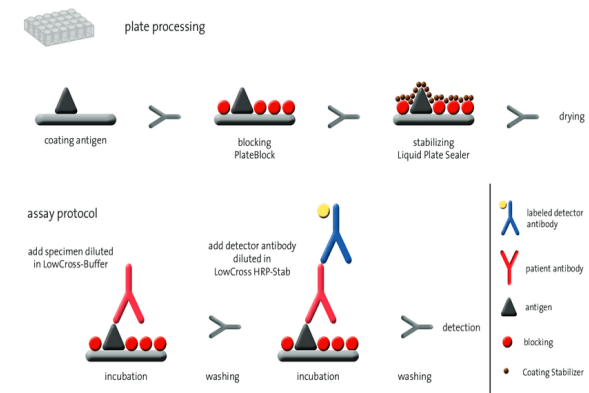
- ❖ confirm proportion of population infected
- ❖ false-negative results
- ❖ Mildly affected or asymptomatic individuals are not screened

Statistics on confirmed cases and deaths are not ideal estimator of the proportion of the population infected

Detection of antibodies to SARS-CoV-2 in a person's blood likely indicates that they were infected at some point since the start of the pandemic.

Seroprevalence surveys identify people in a population or community that have antibodies against an infectious disease

Seroprevalence surveys are of utmost importance to assess the proportion of the population that has already developed antibodies against the virus and might potentially be protected against subsequent infection



Objectives

General Objectives

To measure the seroprevalence of SARS-CoV-2 antibodies in the general population in Zanzibar in order to ascertain cumulative immunity and antibody dynamics.

Specific project objective

1. To collect serum specimens in population for the purpose of measuring SARS-CoV-2 antibodies
2. To use the WANTAI ELISA kit in order to measure the seroprevalence of COVID-19 total antibodies by sex and age group, occupation, geographical location (urban and rural) in order to ascertain the population immunity in Zanzibar
3. To estimate the proportion of asymptomatic, pre-symptomatic or subclinical infections in the population



RELEVANCE

- ❖ Improve fundamental understanding of population immunity against COVID 19 in Zanzibar
- ❖ Contribute to the body of knowledge the role of mild or asymptomatic infection on COVID 19 transmission
- ❖ Strengthen collaborative research capacity in Zanzibar



Methods

Study area and population

Community based surveillance involving the two main islands

- ❑ Unguja
- ❑ Pemba

Study design

- ❖ population-based repeated cross-sectional study
- ❖ Entail 2 serial sampling at time 0, and at 6 months

Sampling methods

Three stage cluster sampling method to select the district, shehias and household

Samples size

Assuming a prevalence of 50% for unknown disease prevalence, confidence level of 95% , margin error of +/- 5% and a design effect of 2 Total of 792 approximated to **800 participants** will be recruited

- 33 urban and rural clusters (shehias) will be selected
- ~25 people/household will be sampled per shehia



Methods

Eligibility criteria

A: Inclusion criteria

- ❖ All individuals irrespective of age, sex, acute or prior COVID-19 infection

B: Exclusion criteria

- ❖ Refusal to give informed consent, or contraindication to venipuncture.
- ❖ Participants to have reported of being vaccinated against COVID-19

Data collection

Questionnaire will be administered

- Demographic,
- clinical information
- perception toward COVID-19 Vaccines



Laboratory evaluations

- ❖ 10ml blood collected in tubes with clotting factors
- ❖ Serum sample will be harvested from each tubes
- ❖ shipped at 4 °C or frozen to -20 °C or lower (at -80 °C) and shipped on dry ice.
- ❖ **Wantai kits (detects total antibody IgM, IgA IgG) will be used for ELISA**
- ❖ Samples will be analysed and stored at the IHI's Bagamoyo research laboratory.

Ethical considerations

- ❖ Participation will be voluntary
- ❖ Informed consent will be obtained from participants
- ❖ study will be conducted according to the local laws, GCP and GLP
- ❖ **ZAHREC and IHI-IRB** will approve the protocol prior to study commencement
- ❖ All research team will be trained on COVID 19 IPC, face masks, portable hand sanitizer ,social distancing

Data management and Reporting of findings

Data management

- ❖ Data will be collected by electronic data capture using Tablets
- ❖ The ReCap open source software will be programmed and database stored in servers at IHI ICT infrastructure
- ❖ Data will be de-identified and only study participant (ID#) used for data analysis purposes.
- ❖ Access to data will be via a secure password and only authorized research team members will be given access

Reporting of findings

- ❖ Data analysed will be used to develop reports for MoHZ, WHO and other stakeholders.
- ❖ Community education materials (household-targeted materials, posters, and animated educational videos) will be developed
- ❖ At least two peer-reviewed manuscripts are expected in total from the proposed research project

Statistical analysis

- ❖ Prevalence of human exposure to COVID-19
- ❖ Bivariate analyses and logistic regression models will be used to evaluate demographic, seasonal, and social-ecological risk factors for exposure in humans.
- ❖ Spatial analyses for clusters of viral exposure to identify most affected clusters
- ❖ Data will be analyzed by R-programming or STATA



Financing

S/No.	Item	1 st Round	2 nd Round
	Personnel IHI & ZAHRI)	US \$	US \$
1	Salaries and fringe benefits	59,985.0911	59,985.0911
	Sub-Total	59,985.0911	59,985.0911
	Program Support		
2	Field and laboratory supplies	7,621.05	2,078.05
3	Ethical clearance	2,753	
4	Office supplies & stationary	1,030.10	1,030.10
5	Communications (Internet and mobile phone)	725	725
6	Project administration	12,600.	
7	Operations (fuel and vehicle use, per diem, training, community sensitization, data management, report writing etc.)	47315.82	40903.82
	Sub-Total	72,052.97	44,736.97
	Total	132037.06	104722.06
9	Indirect Costs (15%)	19,805.559	15708.309
	Grand Total	151,843.61	120,430.369

Budget justification

- Salaries for ZAHRI & IHI researchers
- Sub contract for research assistants
- Expedited ethical clearance
- Participants incentives
- Lab and field supplies
- Samples shipment & storage
- Transport, refreshment during training & sensitization
- Stationeries
- Data management and storage
- Development of community dissemination materials
- Vehicle fuels, per diem,

Project time frame = 18 months

Sources of funding

Description	1 st round (US \$)	2 nd round (US \$)
Total amount required	151,843.61	120,430.369
WHO contribution	90,254	0
Other development Partners	? ??	????
Deficit	61,589.61	120,430.369
Deficit Total	182,019.979	



*Thank you
for Listening!*



ISO 9001:2015 certified

