

Epidemic Response and Transmission Dynamics of Coronavirus Disease (COVID-19) in Khartoum State-Sudan 2020: Study Protocol

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Study Protocol

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Abstract

Background: A novel Coronavirus was identified as severe acute respiratory syndrome Coronavirus 2 (SARS-CoV-2), and the syndrome of clinical manifestation was named (COVID-19). Consequently, on Jan 30, 2020, the World Health Organization (WHO) declared the outbreak as a pandemic and a public health emergency of international concern. The objectives of this research are to investigate the response of the health system at different levels towards the control of the COVID-19 epidemic and to explore the COVID-19 transmission dynamics among Sudanese community.

Methods: A community and institutional-based cross sectional based study will be conducted in Khartoum State include all the seven localities. The sample size of participant is estimated at 920 using the population formula ($n=N/1+ (n*d^2)$) and considering the response rate. The sample will be drawn using multistage cluster sampling.

Data will be collected using interview with key informant and concerned bodies/institutes involved in the response at both the federal and Khartoum State levels. Administered pre-coded, pretested closed ended questionnaire will be developed to collect data from community participants. Data will be managed and analyzed using Statistical Package for Social Sciences version 21. Analysis is mostly univariate descriptive and bi-variate with Chi Square & Fischer Exact tests analysis to find associations between variables of interest.

Discussion: This study is expected to evaluate the extent and magnitude of the epidemic response at different levels in addition to the adequacy of the epidemic response. The study participants will be screened to estimate proportion of individuals per age strata who show sero-positivity for virus infection, thus it will estimate the percentages of individuals reporting symptoms/signs of infection and asymptomatic fraction.

The results of this study will strengthen the current interventional approaches of COVID-19 epidemic control and will provide set of database for better planning and implementation of COVID-19 control across the country. It will contribute to in-depth understanding of the COVID-19 transmission dynamics among Sudanese community and will improve the community awareness about COVID-19.

Background

As of December 31, 2019 when the Chinese health authorities reported a cluster of 27 pneumonia cases of unknown etiology in Wuhan City, Hubei Province. A novel coronavirus was identified as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), and the syndrome of clinical manifestation was named (COVID-19). Consequently, on Jan 30, 2020, the World Health Organization (WHO) declared the outbreak as a pandemic and a public health emergency of international concern [1].

In the first 7 days of the year 2020, cases were reported outside of China; and by February 11, 2020, there were 42 708 cases reported in China and spread to 25 countries which reported a total of 395 cases.

Africa confirmed its first case in Egypt on Feb 14, 2020, and on March 6, 2020 89 192 confirmed cases and 3380 deaths were reported globally [2].

Low- and middle-income countries, with suboptimal health system are requested to plan for a one health strategic approach to stop COVID-19 pandemic. As one health approach is mandatory, all the challenges related to COVID-19 must be considered and addressed globally to ensure rapid and effective response measures are taken [3].

An observed phenomena of low-level endemic transmissions of SARS-1,MERS, and SARS-CoV-2 in part of Africa has grasp the attention of epidemiologists while they were drawing and comparing epidemic curves across the continents. An open claim of the role of environmental or climate factors on limiting the transmissibility has been hypothesized and a recommendation on the need for sero-epidemiological studies to address transmission and viability of Coronavirus across African countries is requested [4].

Currently, it is valuable to shed some light on the current response by health ministries in different contexts outside China and in Sudan in particular. Definitely, analyzing the response in one area is expected to create some sort of lesson learning by enhancing active surveillance to prevent community transmission.

The emerging pandemic of a new deadly SARS-CoV-2 Virus that sourced in China and affecting more than 102 countries has rang the bell for health ministries all over the world. As a result, the concept of investing more time and effort planning for how to control and how to prevent future epidemic has now became more clearly important than ever before. This is more evident in the mainland China report on the epidemic trend [5, 6].

Reporting the efforts of combating COVID-19 is extremely valuable especially, when the intention is to support positive actions and to find implementation gap in the other ones. For sure, this not only should provide guidance for planning and advising current health intervention and response. Nevertheless, it is expected to find a solid ground by generating materials and policies to inform similar health intervention in the short term and long term future [7].

Statement of the problem:

Interventional approaches and efforts have been exerted by the FMOH and other concerned bodies towards to control and slow down the epidemic across the country. The strengths and weaknesses of the adopted interventional approaches are to be documented and assessed systematically. This will facilitate generation of quality-evidence for strengthening the overall interventional approaches and to expand the database of epidemic control. The transmission dynamics of COVID-19 among Sudanese population need to be recognized and identified to generate evidence for prevention and control. The acceptability of the adopted interventional approaches by the Sudanese population and prevailing stigmatization are ill understood.

Research questions:

1. What is the overall response of the health system at national and Khartoum State level to control the epidemic situation?
2. What is peculiar about the COVID-19 transmission among Sudanese patients and their contacts?
3. What is the role of asymptomatic infection in transmission?
4. What is the level of acceptability and adherence of the community towards current interventions to control and prevention of COVID-19?

Rationale:

- It is of utmost importance to recognize the COVID-19 transmission dynamics among Sudanese population and the generated data is expected to provide evidence about the determinants of transmission, risk groups, susceptibility and magnitude of asymptomatic infections.
- It is necessary to document the response of the health system towards COVID-19 at different levels in terms of adequacy, effectiveness, mobilization of resources and approaches to control the situation.
- The generated data about COVID-19 immune response and immunospecificity can be used to improve interventional approaches, clinical management and better understanding of the transmission.

The study is planned to address the issues of acceptability, adherence, satisfaction with the control measures and stigmatization towards COVID-19. Such data can help strengthening the current efforts to combat the community transmission.

General objectives:

The overall objectives of this research are to investigate the response of the health system at different levels towards the control of the COVID-19 epidemic and to explore the COVID-19 transmission dynamics among Sudanese community.

The specific objectives are:

1. To assess the effectiveness of response for controlling the epidemic at the federal, state and community levels.
2. To determine the COVID-19 transmission dynamics and its characteristics
3. To estimate the extent of infection among the study population determined by sero-positivity
4. To identify the acceptability of the community towards the current interventions to control the epidemic

Methods

Study design: A community and institutional-based (at the level of policy makers) cross sectional based study will be conducted in Khartoum State, which is one of the **18** states of Sudan. It has an area of **22,122 km²**. Khartoum, the national capital of Sudan is the capital of the Khartoum State.

Khartoum State is subdivided administratively into seven localities namely; Khartoum, Khartoum North, Omdurman, Jabal Awliya, Sharq Alnīl, Ombadda and Karari Localities. Each locality is subdivided into administrative units and each administrative unit is subdivided into local committees. In addition, the study will include the concerned bodies/institutes involved in the response at both the federal and Khartoum State level.

In addition, the study will include the concerned bodies/institutes involved in the response at both the federal and Khartoum State level. These include:

- The Emergency & Epidemic Control Directorate-Federal Ministry of Health
- The Directorate of Preventive Medicine-Federal Ministry of Health
- Khartoum State Ministry of Health
- The Epidemiology Department-Khartoum State Ministry of Health
- World Health Organization-Sudan

Study population:

For the purpose of the study, the study population will include:

1. The policy, decision makers and other key informants involved in COVID-19 epidemic control. The population is composed of concerned key informants involved in COVID-19 epidemic control including policy-makers, decision makers at the Federal Ministry of Health, Khartoum State Ministry of Health, health insurance, NGOs, civil society organizations, women, youth and community leaders.
2. Population of Khartoum State: According to 2008 population census, projection 2018, the population of Khartoum State is estimated to **be 7, 993, 852** million people who are a mixture of tribes and ethnic groups of Sudan.

Sample size & sampling technique:

For the purpose of the study, the sample size will be estimated based on the total population of Khartoum State using the following formula:

$$n = N / 1 + (N * D^2)$$

Where n: sample size, N: Total population = 7, 993, 852, D: degree of precision= 0.05. Thus the estimated sample size (n) = 399.99.

Since the sampling technique planned to be used is multi-stage sampling technique rather than simple random technique; then it is necessary to multiply the estimated sample size by the design effect, which

is approximately equal to 2 in order to improve representation.

Thus the sample size= $399.99 \times 2 = 799.98 \approx 800$

On the assumption that the non-response rate is 15%, then the final estimated sample size= 920

Sampling technique:

A multi-stage cluster sampling technique will be used to draw the sample. The sample is drawn through the following steps:

Step (1): The study will be conducted in 50% of the localities, which are selected using simple random sampling technique.

Step (2): The administrative units within the selected localities are subdivided into clusters based on the geographical locations. Then 50% of the administrative units within the selected localities are selected using simple random sampling technique.

Step (3): The public committees within the selected administrative units are subdivided into clusters based on the geographical locations. Then 50% of the local committees within the selected administrative units will be selected.

Step (4): Each of the selected local committees is subdivided into clusters of households and then 50% of the clusters will be selected. The estimated sample size will be distributed proportional to size of the population in each of the selected local committees.

Step (5): The households within the selected clusters will be identified and then adults within the households will be interviewed.

Data collection instruments:

1. Interview guidance: Interview guidance will be developed pre-tested using pilot survey across five candidates with insuring they will not be included in the study. Data will be collected from concerned key informants. The guidance will be composed of 12-15 open-ended questions that include the personal data, magnitude and extent of response towards COVID-19 epidemic at different levels. The interview will focus as well on the adequacy & effectiveness of the response in addition to the adopted control measures and their impact. The channels of coordination and the lessons learned will also be highlighted.

2. A standardized administered questionnaire: It will be developed, pre-tested using pilot survey across five candidates with insuring they will not be included in the study. The questionnaire will be used for quantitative data collection from interviewed community members. The questionnaire will be composed of about 40 close-ended questions covering the study variables. The questionnaire is composed of five chapters; the back ground characteristics, history of exposure, determinants of transmission, acceptability of the current control measures and the serological investigations.

List of study variables:

- The response towards epidemic of Federal ministry of Health i.e. political, organizational , resource mobilization, capacity building, communication
- The response towards epidemic Khartoum State Ministry of Health i.e. political support, resource mobilization
- The response of other governmental bodies towards epidemic i.e. mobilization of resources
- The response of WHO and other UN agencies i.e. coordination, technical support, allocation of resources
- The response of NGOs towards the epidemic i.e. mobilization of resources, delivery of supplies and IEC messages.
- The response towards epidemic at the community level
- The adequacy/effectiveness of response towards epidemic at different levels.
- The establishment of coordination channels at different levels.
- The adopted control measures and their effectiveness
- Personal and family characteristics of the sampled community members.
- History of exposure and symptoms
- History of expanded immunization during childhood
- Occurrence of pre-symptomatic/asymptomatic transmission
- Prevalence rate of asymptomatic/sub-clinical infection
- Determinants of transmission.
- Identified risk groups and susceptible individuals
- Estimates of COVID-19 sero-prevalence rate
- Acceptability of the current interventional measures by the community i.e. hand hygiene, respiratory etiquette, use of masks, isolation, avoidance of crowding, workplace and school closures
- Prevalence of stigmatization at the community level.

Plan of data management and analysis:

The data collectors in the field will employ portable handheld computers (tablet PC) for data collection and the data will be directly fed in to the electronic data management system. The data manager will design a data entry template using the Statistical Package for Social Sciences (SPSS) version 21. Then the data manager who is a qualified statistician with adequate knowledge and skills in using SPSS performs data cleaning and ensures correctness and consistency of responses. Inconsistent responses will be omitted from the data set and treated as missing values. SPSS version 23 will be used for analyzing the quantitative data set and generating outputs. Analysis is mostly univariate descriptive in order to generate indicators of interest. In addition, bi-variate analysis will be conducted to find associations between variables of interest. Since most of the variables are categorical, associations

between variables are determined using non-parametric tests such as Chi Square & Fischer Exact tests. Analysis outputs will be displayed as tabular and graphic formats. The collected qualitative data will be validated and content analysis will be held.

Ethical considerations

An ethical approval was obtained from Alneelain Institutional Review Board. Permissions will be obtained from the authorities of the selected localities, administrative units and popular committees. An informed written consent will be obtained from each study participant prior to the interview. In this study anonymity will be of utmost importance. All necessary measures will be taken to ensure confidentiality of the collected information. Data will be directly entered into a password protected electronic database.

Time frame of proposed activities (Gantt chart):

Starting Month: September Year: 2020

W: Weeks

Activity	1 st Quarter			2 nd Quarter			3 rd Quarter			4 th Quarter		
	W 1	W 2	W 3	W 4	W 5	W 6	W 7	W 8	W 9	W 10	W 11	W 12
Preparation of the data collection instruments												
Pre-testing and finalization of the data collection instruments												
Preparations of the training work shop for the field supervisors and data collectors												
Implementation of 3-day training workshop for the field supervisors and data collectors												
Contact and meetings with the concerned bodies at different levels												
Submission of the Progress Report												
Preparations of the field activities												
Data collection												
Data analysis												
Preparation of the final report												
Revision & finalization of the final report												
Submission of the Final technical and Financial Report												
Dissemination workshop												

Discussion

This research is designed to study the epidemic response & the transmission dynamics in Khartoum State- Sudan. This study is expected to evaluate the extent and magnitude of the epidemic response at different levels in addition to the adequacy of the epidemic response.

It will estimate the percentages of individuals reporting symptoms/signs of infection and asymptomatic fraction. The asymptomatic people represent serious hazard as they might spread unseen within the

community and eventually lead to crisis, thus, a considerable attention as in this research is advisable to be paid for this group. Kannan, S. et.al reported that although COVID-19 is a major health problem. However, its symptoms are milder compared to SARS-CoV and MERS-CoV. This is why it is important to apply aggressive protocol for infection control in order to prevent silent person-to-person transmission chain [8].

The study participants will be screened to estimate proportion of individuals per age strata who show sero-positivity for virus infection. As per the control experience of Shenzhen, China, it is important to perform early screening, diagnosis, isolation, and treatment. This is necessary to prevent community transmission. In addition, restriction of public activities and use of personal protective measures should be reinforced [9].

The results of this study will strengthen the current interventional approaches of COVID-19 epidemic control and will provide set of data base for better planning and implementation of COVID-19 control in the country. It will contribute to in-depth understanding of the COVID-19 transmission dynamics among Sudanese community and will improve the community awareness about COVID-19.

The methods of controlling epidemic are easy to be designed if the mechanism is clearly understood and, therefore studying the dynamic of COVID-19 transmission nationally may reveal unique criteria and standards. The current country response assessment is of great importance as it will divulge the facts of how drastically it plays the role in managing this pandemic, and whether it's suiting the dynamic of disease in the country or not. The effective implementation of the enhanced traffic control bundling (TCB) is the most powerful measure to break the community-hospital-community infection. This is more obvious in the successful efforts done by Taiwan in response to COVID-19 outbreak [10].

A modeling study has classified Sudan among countries with moderate importation risk of COVID-19 cases. The status of variable capacity and high vulnerability of these countries to respond to the outbreak should call for urgent financial support to the preparedness and response efforts [11].

Still a lot to be revealed about COVID-19 not only regarding vaccines or specific treatment, but even at the level of countries preparedness and control plans as we notice frequent updates on the prevention, control protocols and guidelines since it is a newly emerged virus. The obvious uncertainty of the progression of COVID-19 infection in the European Union and the European Economic Area (EU/EEA) should grab the global attention to reinforce risk communication efforts and reviewing of pandemic preparedness plans. Therefore, research institutes and public health officials should continue working together to evaluate and guide the updates on the strategies for intervention and control [12]. As the short-term containment is cost-effective than the long-term measures for containment; it is advisable, so far, to focus on the control efforts against COVID-19 by active surveillance and contact tracing. This is expected to delay wide spread community transmission, reduce peak incidence, and lift the pressure on public services. As a result, this will revive health system and give enough time to develop a new vaccine [13].

Abbreviations

SARS-CoV-2: Severe acute respiratory syndrome Coronavirus 2

WHO: World Health Organization

COVID-19: Coronavirus Disease 2019

MERS: *Middle East Respiratory Syndrome*

NGOs: Nongovernmental organizations

rPCR: Real-time polymerase chain reaction

SPSS: Statistical Package for Social Sciences

EU/EEA: European Economic Area

Declarations

Ethics approval and consent to participate

An ethical approval was obtained from Alneelain Institutional Review Board (NU-IRB-16-09-05-2).

Permissions will be obtained from the authorities of the selected localities, administrative units and popular committees.

Consent for publication

Written informed consent will be obtained from the patient and interviewees for publication of this study and any accompanying images. A copy of the written consent will be available for review by the Editor-in-Chief of this journal.

Availability of data and materials

The datasets will be used and/or analyzed during the current study will be available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

ME is the major contributor in writing the protocol.

MI is a major contributor in writing the protocol.

SMS reviewed the protocol and added valuable comments.

All authors read and approved the final manuscript.

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