

NECS COVID Impacts Tracker sub-study (NECS-cit) Protocol

Table of Contents

Problem Statement:	1
Aims:	1
Research Objectives:	2
Research questions:	2
Study setting	3
Study Design and Sampling Strategy:	3
Sample size	4
Inclusion criteria:	4
Data collection:	4
Ethical issues:	5
Data Processing and Analysis	6
Plan for Communicating Findings of the sub-study	8
Study limitations and risks	8
Management and Organisation of the NECS-cit sub-study	8
Sub-study timeline:	8
Funding:	8
References:	9

Problem Statement:

Young children are especially vulnerable to times of shock, upheaval and adversity. Little is known about the ways that the SARS-CoV-19 (COVID-19) pandemic and its control measures are affecting young children in slums, but they are highly likely to be impacting on all domains of Nurturing Care[1,2], with significant impacts on critical early childhood development. In particular, it is unclear if and how the epidemic is impacting on childcare in slums. In normal times, largely informal childcare is reportedly used by a significant proportion of parents/carers. The informal nature of the childcare market, and lack of effective regulatory/supervisory mechanisms means that the operation of childcare providers is not well tracked.

Aims:

The NECS Covid impact tracker (NECS-cit) sub-study aims to address this important knowledge gap, through a series of computer assisted telephone interview (CATI) surveys. In-person data collection (as planned for the NECS Study) is not currently feasible or desirable due to the risk to both study

participants and to data collectors. Current working assumptions from the Kenyan Ministry of Health/WHO are that the epidemic will peak in Kenya in late August or early September, but there remains considerable uncertainty about these estimates[3,4].

Through documenting, and tracking over time, the childcare situation and parental/carer perceptions, the NECS-cit sub-study will be able to provide timely input into the design and rollout of both epidemic control initiatives and those supporting post-COVID-19 recovery; initiatives which otherwise risk relying on anecdotal evidence alone, and which therefore may neglect or mischaracterise the needs of young children and their carers.

Research Objectives:

1. To understand where preschool-age children who normally live in Nairobi slums are cared for and to document if/how this has changed through the evolution of the Kenyan COVID-19 epidemic, including the emergence of a 'new normal' after the acute phase of COVID-19, (estimating the proportions who are: in paid childcare; cared for at home by a parent, extended family member, or older sibling; left at home alone; or taken to place of work).
2. To explore how COVID-19 may be influencing the health, nutrition and early childhood development of these children, through examining all five domains of nurturing care in the evolving context.
3. To examine how COVID-19 has impacted on parental work and the implications for care of their children.
4. To examine parental/carer perceptions of COVID-19 and how it impacts on preschool children and their care.

Research questions:

- How is COVID-19 impacting on early childhood in slums, across all domains of nurturing care?
 - o Who is currently responsible for day to day care of children under 5 years old in Nairobi slums. How does this compare to pre-COVID-19 and (how) does this change over the next 2-6 months?
 - o How are children under 5 years old spending their time during the COVID-19 epidemic?
 - o How is COVID-19 or associated changes impacting on accessibility, use or perceived safety of healthcare services for children under 5 or their carers?
 - o How is COVID-19 or associated changes impacting on food/nutrition security for children under 5 and their carers
- What factors underly these observed changes?
 - o Parental/carer work, including whether and how this has changed during the COVID-19 epidemic

- Parent/carer perceptions of COVID-19, including the risks it poses to them, and to their children
- The evolution of the COVID-19 epidemiology in Kenya and globally

Study setting

This sub-study will be conducted across three slums in Nairobi, Kibera, Kawangware and Mukuru-Viwandani. These have been selected for three reasons. Firstly, they are collectively typical of the larger and longer established slums across Nairobi. Secondly, inclusion of Mukuru-Viwandani overlaps with the setting of the wider Nairobi Early Childcare in Slums Study which will allow useful deeper exploration of emerging insights when field data collection is feasible. Thirdly, our data collection partner (BUSARA[5]) has an existing database of low-income household contacts who have been consented to be invited to take part in future studies.

All three slums are characterised by high levels of poverty, poor sanitation, inadequate shelter, poor infrastructure, high levels of insecurity and low rates of formal employment[6,7] which may have an impact on the childcare options that families have available.

Study Design and Sampling Strategy:

Remote data collection methods will be used, specifically a series of monthly computer assisted telephone interview (CATI) surveys[8] of parents/guardians of children under age 5 who live in Nairobi slums. A sample of 600 parents/guardians will be selected randomly from the BUSARAdatabase of around 48,000 low-income household contacts living in the three Nairobi slums described above (Kibera (about 25,000 contacts), Kawangware (about 13,000 contacts) and Mukuru-Viwandani (about 10,000 contacts).

These contacts have previously participated in BUSARA surveys/field experiments and were predominantly recruited door-to-door in informal areas by field assistants. BUSARA has pre-existing consent to approach them for future studies.

The initial survey will be conducted in September and October 2020. Depending on the evolution of the COVID-19 epidemic in Kenya, and how instructive these initial results are felt to be, a further four rounds of surveys will be conducted in November, December, January and February.

Survey questions will explore:

- Parent/guardian and household characteristics including work and socio-economic status;
- Use of different childcare strategies/approaches (with a particular focus on use of paid childcare);
- Child interaction/early learning;
- The impacts of covid on all of these and on healthcare/perceptions of community safety and COVID-19 risk

A draft consent script and survey instrument is appended to this protocol.

A sub-set of 15-25 respondents who live in Mukuru will be invited to take part by telephone in in-depth interviews. These will explore the same themes as the questionnaire, but will attempt to understand the respondents own childcare challenges/strategies in more detail. A draft telephone consent script and interview guide is appended to this protocol.

Sample size

The main NECS Study Household Survey includes a sample size of 480 households, which has been calculated to allow for estimates of the proportion of households using different childcare strategies with precisions of +/-5%.

For the NECS-cit sub-study, we aim to follow up an initial sample of 600 participants, allowing for a 20% loss to follow up, we expect to result in 480 participants followed throughout the study. This is the same number proposed for the household survey in the main NECS study, which has been calculated to allow for estimates on the proportion of households using different childcare strategies with a precision of +/-5%. In addition, new respondents may be randomly selected to replace those lost to follow up between rounds should this number be higher than expected.

Telephone in-depth interviews will be conducted with 15-20 participants (depending on when saturation is reached on key emerging themes), to include both users and non-users of paid childcare, and those who report more and less significant impacts of COVID-19 on the care of their children.

Inclusion criteria:

Respondent:

1. Has given consent (within the last 5 years) to being contacted with invitations to participate in future research.
2. Is aged 18 years or older
3. Has child under 5 years, who has lived with them at some point this year (2020)
4. Lives in informal settlement/slum area of Nairobi

Data collection:

Survey data collection will be through computer assisted telephone interviewing (CATI), where a call centre operator works through a set script to initially gain informed consent from participants, and then to ask a pre-set list of largely closed-ended questions. In-depth interviews will be conducted by either BUSARA or APHRC staff and will be digitally audio-recorded. Due to COVID-19, these call centre operators are largely working from home. SurveyCTO[9] data collection platform will be used for all data collection.

Training of data collectors and piloting: All data collectors will have conducted similar surveys in the past, and are employees of BUSARA or APHRC. They will participate in a 2-3 day training session in advance of data collection starting. A Senior Lab Officer/Manager, involved in the initial planning phases, will be in charge of this training and will be creating all relevant training content for data collectors.

Pre-testing of the CATI instrument will be conducted with at least 14 respondents and will be used to clarify the survey instrument.

Data quality will be managed through a combination of:

- Training and pre-testing described above
- Automated range and constancy check embedded into the SurveyCTO software
- Checks on 10% of the sample (contacting respondents and/or reviewing audio recordings of consent discussions)
- Daily debriefings amongst data collectors, led by supervisors
- Refresher training (before each round of survey)

Qualitative data collection will be carried out by interviewers with college-level education in a relevant or related field, and with experience in conducting qualitative interviews. Data quality for all qualitative work will be ensured by in depth training of interviewers, encouraging reflexivity during data collection and regular review and feedback by supervisors.

Ethical issues:

Ethics approval will be sought in parallel from both LSHTM Research Ethics Committee and the AMREF Africa Ethics and Scientific Review Committee (ESRC). Data collection will not begin until ethics approval in both the UK and Kenya has been granted. Major revisions to the study procedures and tools will result in re-submission to the LSHTM and Amref Health Africa ESRC for re-review.

Informed consent will be sought from all respondents. Study participants will receive a SMS message in advance explaining the purpose of the research before they are called. Following this, A clear and explicit consent process will be conducted, where verbal consent, if given, will be audio-recorded, and their right to withdraw consent at any time will be explained.

The appended draft instruments include: (1) The consent script that will be read out; (2) Anticipated 'Frequently Asked Questions' and responses; and (3) and the draft survey questions/topic guide.

This consent script includes:

- Why the study is being conducted
- Confidentiality and how data will be used and shared
- What results of the research will be used for
- Participants right to withdraw consent at any point

Participants will, once consented, be invited to either respond at this time, or to schedule a call back at a more convenient time for both questionnaires and in-depth interviews.

Confidentiality: Survey responses will be anonymized before being securely transferred to LSHTM/APHRC (see *Data Processing and Analysis* below). Audio recordings of the consent process for surveys will be retained by BUSARA, and will be available for audit purposes only.

Risks:

The anticipated risks associated with this observational study are modest. No clinical procedures or other interventions will be received by study participants. The primary impact of the study on participants will be through the time they give, but there is also potential for some psychological discomfort or distress due to the nature of the issues being explored, especially if concerns around inadequacy of current childcare options or provision emerge.

One additional risk arising from telephone (rather than face to face) data collection is any discomfort/disruption arising from receiving one or more unsolicited telephone calls from unknown numbers.

This risk will be mitigated by the following:

- (1) Recruitment for telephone interviews will be from an existing pool of potential participants who have given consent (within the last 5 years) to being contacted with invitations to participate in future research.
- (2) Study participants will receive a SMS message in advance explaining the purpose of the research before they are called.
- (3) A clear and explicit consent process will be conducted, where verbal consent will be audio-recorded, and their right to withdraw consent at any time will be explained.
- (4) Participants will, once consented, be invited to either respond at this time, or to schedule a call back at a more convenient time.
- (5) Following the call, participants will also receive, alongside a 'Thank you' message, more information about how the data will be used and alongside contact details for any questions. They will also receive a small financial incentive (equivalent to US\$1.5) to compensate for the time and battery charging costs associated with participation. This will be provided instantly through electronic transfer of talktime credit.

Benefits: Through understanding how the COVID-19 epidemic in Kenya is affecting parents/guardians of children in Nairobi Slums and communicating this in a timely way to key stakeholders (including all of Government, Donors, and Multilateral agencies) programme and policy interventions can better address the problems study participants are facing.

Data Processing and Analysis

This project will generate:

1. Quantitative survey data CATI surveys;
2. Qualitative data in the form of interview and focus group audio recordings, transcripts and notes

In addition, audio recordings of consent will be generated.

Data handling: Data collected through CATI surveys will be encrypted and anonymised by the data collection partner. These anonymised data will be electronically transferred to APHRC and LSHTM using encrypted data transfer, with encryption keys shared via a different, also encrypted, secure message service.

Qualitative interviews and focus group discussions will be audio-recorded on password protected digital audio recorders. Interviewers will be trained to only record code names of people and places

in notes and transcript. A separate, encrypted excel sheet will store these codes. The password for this sheet will only be shared via encrypted mobile messages. All audio files will be stored in encrypted laptops. In addition, a clear system for storage and deletion of files and notebooks will be established.

Analysis:

CATI surveys: Descriptive statistics will show changes from ‘pre-covid’ to the current situation and then monthly over time. In addition, regression methods will be used to explore any associations between these changes and the evolving COVID-19 epidemiology (drawing predominantly on Kenyan Ministry of Health Daily Sitrep data [10]) and COVID-19 control measures (drawing on the Coronavirus Government Response Tracker dataset [11]). Household socio-economic status will be recorded in order to enable comparisons between the NECS-cit sample and existing slum population survey data to inform analysis/interpretation.

In-depth interviews: Thematic analysis of the IDIs will be carried out using NVivo[12]. Transcripts and field notes will be coded to iteratively identify emerging themes and concepts. The emerging themes and concepts will also be used to update the IDI topic guides and to develop conceptual or explanatory frameworks. Regular (at least weekly during data collection) debriefing meetings will be conducted amongst data collectors to encourage reflexivity.

Data archiving and sharing

All data collection tools, anonymised raw data and data analysis code will be archived in the APHRC Microdata portal (http://aphrc.org/?page_id=3081) and the NECS LSHTM Data Compass Site[13] in accordance with ethical and regulatory requirements. The data will also be mirrored on Figshare (<http://www.figshare.com>), a widely used online repository where users can make research outputs available in a shareable and discoverable manner.

All published papers will include links to the repository, with access to the relevant analytic data sets and analysis scripts, to ensure transparency and reproducibility. The datasets will be assigned unique DataCite DOIs. Audio data from qualitative interviews, where anonymisation is either not possible or there is a high risk of individuals being identified, will not be made available in the repository. However, suitably qualified researchers will be able to access these data under strict collaboration agreements.

As per APHRC procedures, data and all appropriate documentation will be stored in a data repository for a minimum of 5 years after the completion of the study, including the follow-up period. After this period, a review will be made on whether to retain for a further period of ongoing research or in the case where the write-ups from the data have not yet been completed. After we have established that the data are no longer required for any purpose, they will be deleted or rendered unusable.

Plan for Communicating Findings of the sub-study

We will aim to share and analyse data as they are collected, in order to inform National and County Governments in Kenya, and development funders in a timely way. Given these stakeholders are likely to be developing COVID-response and recovery plans over the course of this sub-study, we will disseminate emerging findings through a combination of:

- timely policy briefs
- development of a live data dashboard/tracker
- a set of short webinars/videos
- publication of pre-print(s) and peer reviewed academic publication(s)

Study limitations and risks

Limitations of the study include:

1. The use of an opportunistic sampling frame may mean our sample is not representative of the wider slum population. Mitigation of this will be through comparing the features of our study sample (education, earning, household assets) to what is known about the wider population in analysis.
2. An inability to include younger mothers; all members of the sampling frame are aged 18 or older.
3. Timeliness of data; it is possible that the most significant impacts of the COVID-19 epidemic will have occurred during the main 'lockdown' period before data collection started. To mitigate the risk of not adequately capturing these issues, questions asking about changes 'since COVID started to affect your community' will be included.

Management and Organisation of the NECS-cit sub-study

The PI for this study is Prof Betty Kirkwood at LSHTM. Day to day management will be by Co-Investigator Dr. Robert Hughes (Clinical Research Fellow at LSHTM). Dr Patricia Wekulo will be the Kenya-based lead; she is also a Co-Investigator for the sub-study, as are Dr Zelee Hill (UCL), Dr Sunil Bhopal (Newcastle University) and Dr Elizabeth Kimani (APHRC). Ruth Muendo and Linda Oloo will be Research Assistants for the Study.

The wider NECS Study Technical Advisory Committee (Members: Helen Elsey, Joan Lombardi, Amina Abubakar and Linda Richter) will also be called on to advise on this sub-study.

Sub-study timeline:

Initial data collection will begin in September or October 2020, and will be complete by April 2021. Analysis will begin as soon as the first round of data collection is complete, and will be completed by the end of 2021.

Funding:

The wider NECS study is funded by an award from the British Academy (£293,000), supported by a fellowship to Dr Robert Hughes from the Echnida Giving (£169,000). Echidna Giving are also funding additional data collection costs associated with the NECS-cit Sub-study (£33,275).

References:

- 1 Richter LM, Daelmans B, Lombardi J, *et al.* Investing in the foundation of sustainable development: pathways to scale up for early childhood development. *The Lancet* 2017;**389**:103–18. doi:10.1016/S0140-6736(16)31698-1
- 2 Corburn J, Vlahov D, Mberu B, *et al.* Slum Health: Arresting COVID-19 and Improving Well-Being in Urban Informal Settlements. *J Urban Health* Published Online First: 24 April 2020. doi:10.1007/s11524-020-00438-6
- 3 Reporter C. Kenya projects COVID-19 peak in August or September » Capital News. Capital News. 2020. <https://www.capitalfm.co.ke/news/2020/05/kenya-projects-covid-19-peak-in-august-or-september/> (accessed 10 Jul 2020).
- 4 Diop BZ, Ngom M, Biyong CP, *et al.* The relatively young and rural population may limit the spread and severity of COVID-19 in Africa: a modelling study. *BMJ Global Health* 2020;**5**:e002699. doi:10.1136/bmjgh-2020-002699
- 5 The Busara Center for Behavioral Economics. The Busara Center for Behavioral Economics. <https://www.busaracenter.org> (accessed 10 Jul 2020).
- 6 Chesire EJ, Orago AS, Oteba LP, *et al.* Determinants Of Under Nutrition Among School Age Children In A Nairobi Peri-Urban Slum. *East African Medical Journal* 2008;**85**:471–9. doi:10.4314/eamj.v85i10.9671
- 7 Kibera. Wikipedia. 2020. <https://en.wikipedia.org/w/index.php?title=Kibera&oldid=976073134> (accessed 14 Sep 2020).
- 8 Lamanna C, Hachhethu K, Chesterman S, *et al.* Strengths and limitations of computer assisted telephone interviews (CATI) for nutrition data collection in rural Kenya. *PLOS ONE* 2019;**14**:e0210050. doi:10.1371/journal.pone.0210050
- 9 About. SurveyCTO. <https://www.surveyccto.com/about/> (accessed 6 Sep 2020).
- 10 MINISTRY OF HEALTH – REPUBLIC OF KENYA. <https://www.health.go.ke/> (accessed 10 Jul 2020).
- 11 Coronavirus Government Response Tracker. <https://www.bsg.ox.ac.uk/research/research-projects/coronavirus-government-response-tracker> (accessed 10 Jul 2020).
- 12 Buy NVivo Now | NVivo. <https://www.qsrinternational.com/nvivo/nvivo-products> (accessed 20 May 2019).
- 13 Hughes R, Kitsao-Wekulo P, Bhopal S, *et al.* The Nairobi Early Childcare in Slums (NECS) Study. 2020. <https://datacompass.ishtm.ac.uk/1780/> (accessed 30 Jun 2020).