STUDY PROTOCOL

Social, ethical and behavioural aspects of COVID-19 [version 1; peer review: awaiting peer review]

Wirichada Pan-ngum¹,², Tassawan Poomchaichote¹,³, Giulia Cuman⁴, Phee-Kheng Cheah⁵, Naomi Waithira¹,⁶, Mavuto Mukaka¹,⁶, Bhensri Naemiratch¹, Natinee Kulpijit¹, Rita Chanviriavuth¹, Supa-at Asarath¹, Supanat Ruangkajorn¹, Margherita Silan⁷, Silvia Stoppa⁸, Gianpiero Della Zuanna⁷, Darlene Ongkili⁹, Phaik Kin Cheah¹⁰, Anne Osterrieder¹,⁶, Mira Schneider¹,⁶, Constance R.S. Mackworth-Young¹¹, Phaik Yeong Cheah¹,³,⁶

¹Mahidol Oxford Tropical Medicine Research Unit, Faculty of Tropical Medicine, Mahidol University, Bangkok, 10400, Thailand
²Department of Tropical Hygiene, Faculty of Tropical Medicine, Mahidol University, Bangkok, 10400, Thailand
³The SoNAR-Global Network, Mahidol University, Bangkok, 10400, Thailand
⁴Paediatric Ethics Committee; Research Ethics Committee, University Hospital of Padua, Padua, Italy
⁵Sabah Women & Children's Hospital, Ministry of Health, Malaysia, Kota Kinabalu, Sabah, Malaysia
⁶Centre for Tropical Medicine & Global Health, Nuffield Department of Medicine, University of Oxford, Oxford, UK
⁷Department of Statistical Sciences, University of Padua, Padua, Italy
⁸Luoghi di Prevenzione, Reggio Emilia, Italy
⁹Queen Elizabeth Hospital, Ministry of Health, Kota Kinabalu, Sabah, Malaysia
¹⁰Faculty of Arts & Social Science, Universiti Tunku Abdul Rahman, Kampar, Malaysia
¹¹Department of Global Health and Development, London School of Hygiene and Tropical Medicine, London, UK

Abstract

Introduction: Vaccines and drugs for the treatment and prevention of COVID-19 require robust evidence generated from clinical trials before they can be used. Decisions on how to apply non-pharmaceutical interventions such as quarantine, self-isolation, social distancing and travel restrictions should also be based on evidence. There are some experiential and mathematical modelling data for these interventions, but there is a lack of data on the social, ethical and behavioural aspects of these interventions in the literature.

Therefore, our study aims to produce evidence to inform (non-pharmaceutical) interventions such as communications, quarantine, self-isolation, social distancing, travel restrictions and other public health measures for the COVID-19 pandemic.

Methods: The study will be conducted in the United Kingdom, Italy, Malaysia and Thailand. We propose to conduct 600-1000 quantitative surveys and 25-35 qualitative interviews per country. Data collection will follow the following four themes: (1) Quarantine and self-isolation (2) social
distancing and travel restrictions (3) wellbeing and mental health (4) information, misinformation and rumours. In light of limitations of travel and holding in-person meetings, we will use online/remote methods for collecting data. Study participant will be adults who have provided informed consent from different demographic, socio-economic and risk groups.

**Discussion:** At the time of writing, United Kingdom, Italy, Malaysia and Thailand have initiated strict public health measures and varying degrees of “lockdowns” to curb the pandemic. It is anticipated that these public health measures will continue in some countries (e.g. Italy, Malaysia) or be tightened further in other countries (e.g. Thailand, UK) to control the spread of the disease in the coming weeks and months. The data generated from our study could inform these strategies in real time.

**Keywords**
COVID-19, social, ethics, qualitative, Thailand, Malaysia, United Kingdom, Italy

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**Corresponding author:** Phaik Yeong Cheah (phaikyeong@tropmedres.ac)

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**Introduction**
COVID-19 is a respiratory disease caused by a novel coronavirus (SARS-CoV-2) and causes substantial morbidity and mortality. At the time of writing, there are no vaccines to prevent COVID-19 or infection with SARS-CoV-2 or therapeutic agents to treat COVID-19. Outbreak forecasting and mathematical modelling suggest that case numbers will continue to rise.1

Managing the COVID-19 pandemic poses a considerable challenge for global and public health actors. Responding institutions and organizations have to utilise non-pharmaceutical interventions such as quarantine, self-isolation, social distancing, travel restrictions and other public health measures.2

In the current situation of expanding transmission and uncertainty, it is important to have evidence to inform such public health interventions to ensure maximum public acceptance, success, and minimum disruption to the lives of those affected. It is also necessary to understand how people acquire, interpret and act upon diverse information about COVID-19. This will help public health authorities with approaches to communication, and choice of communication channels and messaging.

Vaccines and drugs for the treatment and prevention of COVID-19 require robust evidence generated from clinical trials before they can be used. Decisions on how to apply non-pharmaceutical interventions such as quarantine, self-isolation, social distancing and travel restrictions should also be based on evidence. There are some experimental and mathematical modelling data for these interventions3,4, but there is a lack of data on the social, ethical and behavioural aspects of these interventions in the literature5,6.

Therefore, our study aims to produce evidence to inform (non-pharmaceutical) interventions such as communications, quarantine, self-isolation, social distancing, travel restrictions and other public health measures for the COVID-19 pandemic. We propose to conduct a mixture of quantitative surveys and qualitative interviews to answer our research questions.

**Description and rationale of study sites**
At the time of writing, governments in Italy, UK, Malaysia and Thailand have initiated strict public health measures and varying degrees of “lockdowns” to curb the pandemic.

*Italy* has recorded one of the highest number of COVID-19 cases in the world and has been restricting the movements of its residents since 9 March 2020. On 22 March, the Italian government ordered the shutdown of all non-necessary activities and movement between cities. In the *United Kingdom*, as of 23 March 2020, people have been requested to stay at home except to shop for basic necessities, attend to medical needs, travel to and from work (if they cannot work from home) and exercise once a day.

Malaysia and Thailand have recorded some of the highest numbers of COVID-19 cases in Southeast Asia. The Malaysian government declared a “Movement Control Order” on 16 March 2020 which prohibits mass movements and gathering, closure of non-essential businesses and closing its borders. On 25 March 2020, the Thai Prime Minister declared a state of emergency in *Thailand*.

It is anticipated that these public health measures will continue in some countries (e.g. Italy, Malaysia) or be tightened further in other countries (e.g. Thailand, UK) to control the spread of the disease in the coming weeks and months. The data generated from our study could inform these strategies in real time.

**Master protocol**
**Overarching objective**
To produce evidence to inform (non-pharmaceutical) interventions such as communications, quarantine, self-isolation, travel restrictions and other public health measures for the COVID-19 epidemic.

**Specific objectives**
1. To understand the factors that impede and facilitate the compliance of quarantine, self-isolation, social distancing and travel restrictions at different phases of the epidemic;
2. To explore people’s understanding about quarantine, self-isolation, social distancing and travel restrictions;
3. To identify information sources and investigate any rumours/ misinformation and to reverse and correct any rumours/ misinformation about COVID-19

**Research questions**
1. What are the perceptions and experiences regarding quarantine, self-isolation, social distancing, and travel restrictions?
2. What are the economic, social and ethical impacts (e.g. lost wages, challenges in child care, food and household supplies, loneliness) of quarantine, self-isolation, social distancing, and travel restrictions?
3. How do people understand and define these terms (quarantine, self-isolation, social distancing and travel restrictions)? What are the barriers and enablers for complying with these measures? How do people cope?
4. What are individuals from various communities (e.g. parents, caretakers, people from different occupations) most fearful of (e.g. loss of wages, dying, spreading to others; being unable to care for children/older people/other family members; self-isolation; being unable to get care)?
5. What are the rumours circulating in social media, conversations and discussions? To what extent has public information been clear? How do people obtain information?

**Project timeline**
The duration of data collection is three months. It is expected that the primary analyses will be completed by December 2020. The secondary, more in-depth analyses will take another year.
Study design
We will conduct a mixed methods study using quantitative surveys and qualitative interviews to obtain contextual information from communities on the following four themes:
(1) Quarantine and self-isolation
(2) Social distancing and travel restrictions
(3) Wellbeing and mental health
(4) Information, misinformation and rumours

Study sites
The study will be conducted in the UK, Italy, Malaysia and Thailand. In light of limitations of travel and holding in-person meetings, we will use online/remote methods for collecting data.

Study participants
The study participant will be adults who have provided informed consent.

Inclusion criteria:
• Adults (age may vary by country)
• Residing in Thailand, Italy, Malaysia or the UK
• Provided consent to participate in the study
• Able to use a computer or smart phone

Exclusion Criteria:
• Individuals who are illiterate (because the data collection is online and the survey is self-administered)

Note: Individuals who are tested positive for coronavirus will not be excluded unless they meet the exclusion criterion

Study procedures
Recruitment:
Invitation to join the survey will be sent through professional and personal contacts via email, other online media, and recruitment posters.

There will be two ways of recruiting people to participate in the qualitative interviews:
1) Via quantitative survey – at the end of the online survey, participants will be asked if they wish to take part in the qualitative research. They will be asked to click on a link that will take them to a different webpage that will enable them to provide their email address if they are interested to participate in the qualitative interview. The email address will not be linked to the survey answers. The study team will email the people who provided their email address to seek invite them to join the qualitative interview.

2) Via recruitment posters advertised on partner websites and social media. Interested participants can contact the study team directly. The study team will email the people who provided their email address to join the qualitative interview.

Participants in the qualitative study will be selected with the aim to recruit a maximum variation sample, based on characteristics including participant age, gender, risk and socio-economic status.

Informed consent:
In light of the limitations of holding in-person meetings, participants will be asked to provide consent online. Consent will be taken separately for participation in the quantitative survey and the qualitative interviews.

Data collection methods, study participants, sample size and topics for discussion
We will conduct the following:
Quantitative method: About 600 online surveys per country. No formal sample size calculation has been performed. This number is more than what is recommended for a mixed methods study. Furthermore, it is feasible for data collection within three months. Surveys will be self-administered. The online survey will be available in English, Thai and Italian (see extended data).

Qualitative method: Online (via MS Teams, telephone, or other approved platforms) interviews and focus group discussions with 25–35 participants per country. Actual numbers will depend on context, changes in epidemic, and data saturation. Qualitative data collection will be conducted by in-country interviewers in the language (English, Malay, Thai or Italian) preferred by the participant. A pre-prepared topic guide will be used to direct conversations (extended data).

Questions for both quantitative and qualitative will be guided by the following themes:
(1) Quarantine and self-isolation
(2) Social distancing and travel restrictions
(3) Wellbeing and mental health
(4) Information, misinformation and rumours

We will target different communities (based on age, gender, risk and socio-economic status) within Thailand, Italy, Malaysia and the UK. Potential communities include those working in the healthcare sector, tourism industry, taxi drivers, market vendors, university students and public advisory groups.

Data analysis and management
Quantitative data: Quantitative survey data will be entered and analysed using SPSS software. Data may also be analysed using Stata 15.0 (or later) software. The quantitative data will be retrieved from the online survey platform. The data can be accessed real time to monitor the response rate to boost the sharing of the link to reach the target sample size. Once the data have been collected we will review the data and bring together the related responses. Frequency counts and percentages will be used to summarise categorical data. Associations between categorical variables will be assessed using the Pearson Chi-Square tests or Fisher’s exact tests as appropriate. Data will be presented in
Qualitative and quantitative data will be analysed by country and pooled for comparison between countries.

Direct access will be granted to authorised representatives from the sponsor, ethics committees, and regulatory authorities to ensure compliance with regulations.

De-identified data will be stored digitally and indefinitely. De-identified data may also be shared with other research groups. All applications for data sharing will be reviewed by the MORU Data Access Committee in consultation with country Principal Investigators. All researchers accessing the data need to adhere to a set of terms and conditions that aim to protect the interests of research participants and other relevant stakeholders.

Data generated from this study will adhere to the 2016 “Statement on data sharing in public health emergencies”.

Quality control and quality assurance procedures
The study will adhere to the relevant guidelines for surveys and qualitative research. All interviewers, and transcribers will be trained prior to the study.

The study will be conducted in accordance with relevant national and international guidance and regulations.

Survey questions have been pilot-tested and have undergone pilot testing in accordance with established cognitive interviewing and questionnaire design methodology.

Discontinuation/withdrawal of participants from study
Each participant has the right to withdraw from the study at any time. Withdrawal of consent to participate from this study will result in exclusion of the data for that participant from analysis. Withdrawn participants will not be replaced. If identified, the reason for withdrawal will be recorded.

In addition, investigators may discontinue participation of any individual from this study at any time if the investigator considers it necessary for any reason.

Audio recordings will be deleted if a participant decides to withdraw mid-interview. For those participating in a focus group discussion, if a participant withdraws mid-focus group, those portions of the audio recording that capture their views will be deleted.

Ethical and regulatory considerations
Risk and harm:
This is a minimal risk study posing minimal risk and harm to the participants.

The main ethical issues in this study relate to privacy and confidentiality. Care will be taken to maintain privacy during the audio recording of interviews and interactions with individual participants.

Approvals:
The protocol, informed consent form, participant information sheet and any associated materials have been approved by the following ethics committees:

Oxford Tropical Research Ethics Committee (OxTREC, 520-20); University Tunku Abdul Rahman Scientific and Ethical Review Committee (USERC/63/2020); Ministry of Health Malaysia Medical Research and Ethics Committee (NMRR-20-595-54437-IIR) and the Ethics Committee of the Faculty of Tropical Medicine, Mahidol University (MUTM 2020-031-01). Ethics committee approval is not required for the study to be conducted in Italy as OxTREC covers it.

The Chief and country Principal Investigators will submit and, where necessary, obtain approval from the above parties for all amendments to the original approved documents.

Participant confidentiality:
The study team members will ensure that the participants’ confidentiality is maintained. The participants will be identified only by a participant identification number on all study documents and any electronic database. All documents will be stored securely and only accessible by study staff and authorised personnel. The study will comply with the EU General Data Protection Regulation (GDPR) and country specific data protection regulations.

Compensation:
Participants will not be offered any payment to complete the online survey. Participants who take part in the interviews and
focus groups will be compensated in kind according to country guidelines for their time.

Benefits:
There will be no immediate benefits for any of the study participants. The chief benefit to participation in this study is that participants will be afforded the opportunity to contribute to the generation of new knowledge.

Public engagement and involvement:
As part of the development of our study and data collection tools, we have conducted a series of public engagement or public involvement activities e.g. with the existing community advisory boards\(^{12,13}\) and Bangkok Health Research Interest Group. We believe that public engagement and involvement is necessary for ethical research\(^{14}\). The INVOLVE group, the UK’s national advisory group for public involvement defines public involvement as research that is actively carried out ‘with’ or ‘by’ members of the public rather than ‘to’, ‘about’, or ‘for’ them.

Reporting:
The country Principal Investigators shall submit progress reports and end-of-study reports to the relevant ethics committees.

Publication policy
The Chief Investigator will lead writing and reviewing of drafts of the manuscripts, abstracts and any other publications arising from the overall study. The country Principal Investigators will lead the writing of country publications in collaboration with the Chief Investigator. Authorship will be based on the set of criteria outlined by the International Committee of Medical Journal Ethics. The study results will also be published as regular short reports, and an evaluation report of the online data collection approach.

Dissemination of information
Regular short reports will be made available in real time to public health authorities and researchers, including:
- WHO COVID-19 Research Roadmap Social Science Research Working Group (the Chief Investigator, PYC is a member of the group)
- UK Emergency Preparedness and Response Health Protection Research Unit
- Health professionals and healthcare staff from the Department of Disease Control, Thailand Ministry of Public Health, e.g. Division of Communicable Diseases, Bureau of Epidemiology, Health Intervention and Technology Assessment Program (HITAP)
- Italian Ministry of Health
- Italian Ministry of Innovation Technologies and Digitalisation
- Ministry of Health, Malaysia
- Network of research ethics committees in participating countries
- Research networks for pandemics and infectious diseases e.g. SoNAR-Global Network, Public Health Emergency Preparedness and Response Ethics Network (PHEPREN)
- University researchers and other organisations working on COVID-19 response

Results of the will be published as academic publications and presented at academic conferences. They will also be available in lay language for dissemination to the wider public.

Details of the study are available from the study website: https://www.tropmedres.ac/covid-19/sebcov

Study status
Ethics approvals have been obtained. Data collection will commence soon.

Data availability
Underlying data
No data are associated with this article

Extended data

This project contain the following extended data:
- SEBCOV_Survey_AllVersions_V1.0_24Apr2020.pdf (Study survey questions in English, Thai and Italian)


This project contains the following extended data:

Data are available under the terms of the Creative Commons Attribution 4.0 International license (CC-BY 4.0).

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References


