


International Sexual Health And REproductive health (I-SHARE) survey during COVID-19: study protocol for online national surveys and global comparative analyses

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► Additional material is published online only. To view please visit the journal online (<http://dx.doi.org/10.1136/sextrans-2020-054664>).

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Received 24 June 2020

Revised 14 September 2020

Accepted 27 September 2020

Published Online First

20 October 2020

ABSTRACT

Background COVID-19 may have a profound impact on sexual health, reproductive health and social life across the world. Shelter in place regulations that have extended across the globe may influence condomless sex, exacerbate intimate partner violence and reduce access to essential reproductive health services. Population representative research is challenging during shelter in place, leaving major gaps in our understanding of sexual and reproductive health during COVID-19. This International Sexual Health And Reproductive health (I-SHARE) study protocol manuscript describes a common plan for online national surveys and global comparative analyses.

Methods The purpose of this cross-sectional study is to better understand sexual and reproductive health in selected countries during the COVID-19 pandemic and facilitate multinational comparisons. Participants will be recruited through an online survey link disseminated through local, regional and national networks. In each country, a lead organisation will be responsible for organising ethical review, translation and survey administration. The consortium network provides support for national studies, coordination and multinational comparison. We will use multilevel modelling to determine the relationship between COVID-19 and condomless sex, intimate partner violence, access to reproductive health services, HIV testing and other key items. This study protocol defines primary outcomes, prespecified subanalyses and analysis plans.

Conclusion The I-SHARE study examines sexual and reproductive health at the national and global level during the COVID-19 pandemic. We will use multilevel modelling to investigate country-level variables associated with outcomes of interest. This will provide a foundation for subsequent online multicountry comparison using more robust sampling methodologies.

INTRODUCTION

The global COVID-19 pandemic has ushered in restrictive social measures that are important for its control. However, shelter in place, self-isolation, quarantine and cordon sanitaire measures could each have a profound influence on sexual and

reproductive health. For example, COVID-19 measures may decrease the number of pregnant women delivering in hospitals,¹ delay care-seeking² and increase intimate partner violence.³ Restrictions in movement, social isolation and increased social and economic pressures will likely increase the risk of intimate partner violence in the COVID-19 era.³ Evidence from other public health emergencies (eg, infectious disease epidemics, wars and humanitarian disasters)^{4–6} suggests that many women are unable to obtain family planning services in order to avoid unwanted pregnancies. The Guttmacher Institute has noted that several countries have reduced or stopped provision of sexual and reproductive health services due to COVID-19, interrupting supply chains for condoms and other contraceptives.^{7,8} Women who do become pregnant during this period may be at greater risk of adverse outcomes, including stillbirth, spontaneous abortion (miscarriage) and small for gestational age.⁹ In addition, the reorientation of health systems towards COVID-19 will have unintended consequences for other health services.² For example, the 2014–2015 Ebola epidemic reduced access to healthcare services and may have exacerbated HIV mortality rates in Guinea, Liberia and Sierra Leone.¹⁰

COVID-19 also creates unique challenges for population-based behavioural research.¹¹ Many research institutes are closed, and both national and international travels are restricted. While some single-country studies of COVID-19 focused on sexual and reproductive health have been organised, none have been coordinated in a way that allows for multicountry analyses. Multicountry analyses are important for the following reasons: single-country studies are unable to provide insight about regional and higher level trends in sexual and reproductive health; country-level variation in shelter in place policies between countries can be empirically examined; and multicountry data allow an examination of whether cross-national variation in sexual and reproductive health results from differences in the composition of the populations or from differences in the context (eg, COVID-19 measures).



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To cite: Michielsen K, Larrson EC, Kågesten A, et al. *Sex Transm Infect* 2021;**97**:88–92.

Responding to this gap in the literature, our team designed an online, multicountry sexual and reproductive health research study. This study is part of a project called the *International Sexual Health And REproductive Health in the times of COVID-19 (I-SHARE)*. The purpose of this open science project is to bring together a diverse group of sexual health researchers in order to harmonise sexual and reproductive health survey instruments and facilitate global comparison. The project includes interdisciplinary working groups focused on coordination, data analysis, survey development, digital technology and survey promotion. The I-SHARE project will allow us to examine whether measures implemented by the government will have an effect on sexual health outcomes above and beyond individual characteristics. This study protocol manuscript describes a common plan for online national surveys and global comparative analyses.

METHODS

Goal and aims

The overall goal of this global study is to better understand sexual and reproductive health among adults during the COVID-19 pandemic using an online convenience sample from selected countries. The primary study aims are :

1. To examine changes in sexual risk behaviours (especially condomless sex) related to the initiation and resolution of COVID-19 measures using a multicountry analysis.
2. To examine changes in intimate partner violence related to the initiation and resolution of COVID-19 measures using a multicountry analysis.
3. To examine changes in access to essential reproductive health commodities and services (eg, contraceptives and abortion services) related to the initiation and resolution of COVID-19 measures using a multicountry analysis.

Secondary study aims include the following:

1. To examine changes in HIV/STI testing related to the initiation and resolution of COVID-19 measures using a multicountry analysis.
2. To examine changes in harmful cultural practices (eg, female genital mutilation and child marriage) related to the initiation and resolution of COVID-19 measures using a multicountry analysis.
3. To examine changes in mental health and other optional secondary outcomes (eg, nutrition) related to the initiation and resolution of COVID-19 measures using a multicountry analysis.

We will use a cross-sectional online survey with convenience sampling in each country. National sample sizes will be calculated based on national priorities and analyses.

Our collaborative research team brings together two groups: the Academic Network for Sexual and Reproductive Health and Rights Policy (ANSER) led by the University of Ghent and partner institutions; and a team within the London School of Hygiene & Tropical Medicine who worked in partnership with the Human Reproduction Programme at the World Health

Organisation to develop a standardised sexual health survey instrument for use in diverse global settings. Investigators in the following countries are piloting online surveys in their respective countries: Armenia, Argentina, Australia, Botswana, Czech Republic, Canada, China, Colombia, Denmark, Ecuador, Egypt, Ethiopia, France, Germany, Italy, Kenya, Latvia, Lebanon, Luxembourg, Malaysia, Mexico, Moldova, Mozambique, Nigeria, Panama, Portugal, Republic of Moldova, Singapore, South Africa, Spain, Sweden, Uganda, Uruguay and the USA. A full list of research institutes is available online.¹² The in-country

lead in each country will have first access to national data and make final decisions about data sharing. Each in-country lead will make preparations for dissemination. The survey link will be available for between 2 and 4 weeks. People from outside of selected countries will be excluded.

Survey development

The survey instrument has the following sections: sociodemographics; compliance with COVID-19 social distancing measures; couple and family relationships; sexual behaviour; access to contraceptives; access to maternal healthcare; abortion; sexual and intimate partner violence; HIV/STI female genital mutilation/cutting and early/forced marriage (optional domain); mental health (optional domain); and nutrition (optional domain).

In each country, the lead organisation will select networks through which to disseminate the link to the survey. The survey link will be distributed through email listservs, local partner organisations affiliated with ANSER, other sexual and reproductive health networks and social media links. Final decisions about incentives will be made by the in-country lead, and the survey will take approximately 15–20 min to complete.

The survey development was a collaborative effort of all partners in the project and was partly based on existing questions and scales and partly on newly developed questions. The full survey instrument is included as online supplemental 1. The network will centrally programme the online survey questionnaire using Open Data Kit software (V.1.16). This will be an online survey self-administered through smartphones, tablets or computers.

In each country, the in-country lead will organise translation, local field testing and ethical review. Translation will ensure that the survey is available in the national language of the country and other relevant languages. Field testing will provide the survey instrument in a print form to at least 10 individuals and have them provide feedback about translations, covering sensitive topics and preambles. Further field testing in digital form among 5–10 potential participants per country will be used to iteratively examine errors in skip logic. We estimate between 1 and 4 rounds of iteration per country survey to finalise content. We anticipate that paper-based field testing will finalise the core survey instrument structure and digital field testing will finalise each country survey instrument. Details of the digital field testing are available as online supplemental material.

Inclusion criteria for the survey include 18 years or older (or younger if country IRBs and ethical regulations permit and the in-country lead can ensure appropriate procedures), currently residing in one of the participating countries, and able to provide online informed consent. We will include standard fraud protection methods, including CAPTCHA and measure to prevent more than one response from a single IP address (in countries where this is available).

Safety considerations

This research study will present no greater than minimal risk to participants. At the same time, this survey will include several questions that are sensitive in many local settings, including questions about sexuality, sexual behaviour, abortion, and intimate partner violence. The participant will be allowed to stop the survey at any point and leave out questions that they do not wish to answer. We will not collect participant names or any other identifiers. Country-level data will only be able to be accessed by in-country leaders who have final decisions about use of data. Data sharing agreements will be signed between

participating country institutions for cross-country analyses. National resources for intimate partner violence, sexual health services and reproductive health services will be provided at the end of the survey.

Data analysis plan

This statistical analysis plan focuses on the multicountry comparison component of the analysis. Only survey data that meet the following criteria will be included in the multicountry comparison: at least 200 participants, Institutional Review Board (IRB) approval from the local authority, description of sampling methodology, local instrument translated and field tested.

Primary analysis

Sociodemographics will be summarised using descriptive statistics. The multicountry analysis will use multilevel modelling to examine individual-level and country-level variables associated with primary outcomes, including sexual behaviours, intimate partner violence and access to reproductive health services. Primary outcomes are further specified in online supplemental material. We will use MLwiN 3.05, a software program used in multilevel modelling (<http://www.cmm.bristol.ac.uk/MLwiN/>). The general form of the two-level random intercepts model used to predict the proportion of participants with condomless sex (specific aim #1) will be of the form:

$$\text{logit}(\pi_i) = \log[\pi_i/(1 - \pi_i)] = \beta_0j + \beta_1x_{ij} \quad \beta_0j = \beta_0 + u_{0j}$$

This is a binomial logistic multilevel model with random intercepts, and the binary response y_{ij} equals 1 if the individual i in country j had condomless sex. There is a single explanatory variable in this example, x_{ij} . The intercept consists of a fixed component β_0 and a country-specific component, the random effect u_{0j} . Similar models will be created to estimate intimate partner violence and access to reproductive health services. Data on country-level indicators will be collected from the WHO and publicly available databases.¹³ Several of our country-level data come from the Oxford COVID-19 Government Response Tracker (OxCGRT), an open access database with detailed data on 17 COVID-19 indicators in 180 countries.¹⁴ The OxCGRT has created several indices derived from 17 indicators and report a number between 1 and 100 to reflect the level of government action. We will focus on the following country-level factors: overall government response (OxCGRT), containment and health index (OxCGRT), economic support index (OxCGRT), stringency of lockdown index (OxCGRT), number of COVID-19 per 100 000 population, public insurance and estimated excessive mortality when compared with the year prior.

When level 2 sample size is insufficient (eg, female genital mutilation and early marriage) to perform a multilevel analysis, cross-country differences will be determined through a fixed effects model with country as a covariate.

Given that online sampling has its own inherent biases,¹⁵ we will use propensity score matching in some cases. Propensity score methods can be used to reduce coverage error and make web survey samples more closely approximate population representative samples.^{16 17} Propensity score methods have been used to make groups more comparable based on covariates.¹⁸ Given that we also cannot randomly assign study participants to the stringency of lockdown measures, a key covariate, propensity score methods can help us to make more accurate estimation of the associations between COVID-19 and our primary outcomes. We will also provide more detailed descriptions of the specific country context and COVID-19 response where appropriate.

Subgroup analyses

We will combine data from different countries in order to conduct subanalyses on the following groups of individuals: people living with HIV infection, pregnant women, younger individuals (under 25 years old), individuals under 18 years old (if possible), people living in low-income countries compared with people in middle-income or high-income countries, people living in middle-income countries and people who report an income below the median in their country, rural people versus urban people, single people compared with not single people, sex, and socioeconomic status.

Quality assurance

In-country survey leads will be responsible for quality assurance mechanisms. All data collected will be stored on a password-protected secure server. Encryption keys will be given to the in-country leads so that each country's data will only be available to the in-country lead and people that they designate. Among countries willing to share their data for multicountry comparisons, deidentified and unlinkable data for multicountry comparisons will be stored at the University of Ghent and the University of North Carolina at Chapel Hill.

Dissemination of results

Results will be disseminated in scientific papers and also made available to a public audience. All participating countries will be encouraged to develop a policy brief and communicate research findings to relevant policy makers. The ANSER consortium will take a lead in providing policy briefs for selected countries.

Project management

General coordination of the multi-country study will be organised by researchers at the ANSER consortium represented by Ghent University and the University of North Carolina at Chapel Hill. There are international working groups on: survey development, technical support, survey implementation and statistical analyses. In each participating country, there will be one lead institution responsible for the implementation of the study. The network has agreed on a single data management plan (online supplemental file 4).

Ethics

In each country where the study will be implemented, the local partner will request approval of the appropriate ethical committee or review board. Before starting the survey, each participant will be asked to read an informed consent form (online supplemental material 1) and provide consent through checking a box. The informed consent form will include a link to more detailed information on privacy regulations and management of data. At the end of the survey, the participants will be informed about country-specific organisations where they can seek help.

DISCUSSION

This multicountry behavioural survey will examine sexual risk behaviours, intimate partner violence and access to reproductive health services during the COVID-19 era. Several structural factors increase the importance of understanding sexual and reproductive health during this period of time. The I-SHARE study breaks new ground by focusing on sexual and reproductive health during COVID-19, including a range of low-income, middle-income and high-income countries, and extending out of two complementary global networks (ANSER and the response

to a WHO open call). The prespecified subanalyses and analytical plans outlined here will increase the rigour of this research.

COVID-19 has led to unprecedented uncertainty in our social world, with important implications for sexual and reproductive health. The pandemic presents unique opportunities and challenge. Some have hypothesised that social restriction measures and decreased travel would decrease the frequency of sexual behaviours. In this light, expanded HIV elimination efforts related to HIV self-testing and digital interventions could work towards eliminating HIV transmission in ways that would have been impossible only a few months ago. However, social restriction measures may also decrease access to HIV testing (among those without HIV) and ART medication (among people living with HIV). Conventional sexual health services, especially those focused on intimate partner violence, may be entirely closed or operating at limited capacity.^{19 20}

This study has several limitations. First, the cross-sectional study will be a convenience sample that precludes causal inferences and necessitates caution when making inferences. Second, the online nature of the survey will exclude individuals who do not have internet access. Studies have shown that people with lower incomes and education are less likely to have internet access.^{21 22} Although there is persistent spatial variation in the digital divide,²³ there is also a growing literature on how to address online sampling bias.^{24 25} Third, COVID-19 control measures differ from country to country. However, there are several policy observatory databases that provide detailed open access information about specific COVID-19 control measures in countries.^{14 26 27} Fourth, as a cross-national survey, harmonising survey questions and responses is not simple. The I-SHARE team benefited from a previous series of Human Reproduction Programme (HRP) consultations to harmonise a sexual and reproductive health survey instrument,²⁸ the literature on creating cross-national surveys²⁹ and local (national level) expertise in sexual and reproductive health from all included countries. Fifth, the extent of field testing was dependent on local personnel and varied from country to country. Finally, studies will gather limited information about adolescents and no information about children.

Our study will generate important research and policy implications. The study outcomes will help guide policy and research related to sexual and reproductive health during emergencies in the selected countries to improve preparedness for future

epidemics and disasters. The subgroup analyses will provide insights on need, access and equity issues in sexual and reproductive health during a pandemic. Several additional recommendations for sexual and reproductive health survey research are included as supplementary material (online supplemental 5). Multicountry analyses will provide preliminary data on the association of COVID-19 response with key sexual and reproductive health outcomes, paving the way for future research.

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Handling editor Jo Gibbs

Acknowledgements We would like to thank the I-SHARE team for assistance. Other members of the I-SHARE team are included here: <https://ishare.web.unc.edu/team-members/>.

Collaborators The I-SHARE Team includes the following in-country leads and working group leaders: Noor Ani Ahmad (Institute of Public Health, Malaysian Ministry of Health), Nathalie Bajos (INSERM), Peer Briken (University Medical Center of Hamburg), Sharyn Burns (Curtin University), Soraya Calvo (University of Oviedo), Pheak Chhoun (Khana Center for Population Health Research), Iliadi-Tulbure Corina (State University of Medicine and Pharmacy Nicolae Testemitanu), Thérèse Delvaux (Institute of Tropical Medicine), Stefano Eleuteri (Sapienza University of Rome), Joel Francis (University of Witwatersrand), Amanda Gabster (Instituto Conmemorativo Gorgas de Estudios de la Salud), Peter Gichangi (Technical University of Mombasa), Wanzahun Godana (Arba Minch University), Alejandra Lopez-Gomex (Universidad de la República, Faculty of Psychology), Sally Griffin (ICRH-Mozambique), Gert M Hald (University of Copenhagen), Devon Hensel (Indiana University), Felipe Hurtado-Murillo (University Hospital Valencia), Elizabeth Kemingisha (Mbarara University of Science and Technology), Samuel Kimani (University of Nairobi), Katerina Klapilova (International Congress of Psychology), Lucia Knight (University of the Western Cape), Gunta Lazdane (Riga Stradins University), Wah Yun Low (University of Malaysia), Ismael Maatouk (Clemeceau Medical Center), Kristen Mark (University of Kentucky), Caroline Moreau (Johns Hopkins University), Chelsea Morrioni (University of Botswana), Filippo Maria Nimbi (Sapienza University of Rome), Pedro Nobre (Porto University), Viola Nilah Nyakato (Mbarara University of Science and Technology), Caitlin Alsandria O'Hara (National University of Singapore), Adesola Olumide (University of Ibadan), Gabriella Perrotta (Buenos Aires University), Rocio Murad Rivera (Profamilia Colombia), Juan Carlos Rivillas (Profamilia Colombia), Eusebio Rubio-Aurioles (Universidad Nexum de México), Osama Shaeer (Kasr El Aini Faculty of Medicine), Simukai Shamu (Foundation for Professional Development, University of the Witwatersrand), Jenna Strizzi (University of Copenhagen), Rayner Kay Jin Tan (National University of Singapore), Kun Tang (Tsinghua University), Weiming Tang (Southern Medical University) and Bernardo Vega (University of Cuenca).

Contributors KM and JDT wrote the first draft of the manuscript. EL, AK, JTE, SG and SVdV all contributed in a substantial way to the writing process. All the authors revised the manuscript. All authors read and approved the final version of the manuscript.

Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests None declared.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement No data are available. This is a study protocol and no data are available.

Key messages

- ▶ Sexual and reproductive health research in the COVID-19 era is essential, but population-based household sampling methods are constrained because of COVID-19 measures.
- ▶ This International Sexual Health And Reproductive health study protocol describes a cross-sectional online study to better understand sexual and reproductive health in selected countries during the COVID-19 pandemic and facilitate multinational comparisons.
- ▶ Global research studies, especially in low-income and middle-income countries, are necessary to understand how COVID-19 measures may influence factors such as condomless sex, access to reproductive health services and intimate partner violence.
- ▶ Further multicountry research may be helpful for enhancing sexual and reproductive health research during COVID-19 measures.

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