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

Kristien Michielsen,[1,2] Elin C. Larsson,[3,4] Anna Kågesten,[5] Jennifer T. Erausquin, [6] Sally Griffin,[7] Sarah Van de Velde,[8] Joseph D. Tucker,[9,10,11] for the I-SHARE Team*

[1] International Centre for Reproductive Health, Department of Public Health and Primary Care, Faculty of Medicine and Health Sciences, Ghent University, Ghent, Belgium

[2] Academic Network for Sexual and Reproductive Health and Rights Policy (ANSER), Ghent, Belgium

[3] Department of Womens and Childrens Health, Karolinska Institutet, Stockholm, Sweden

[4] Department of Womens and Childrens Health, Uppsala University, Stockholm, Sweden

[5] Department of Global Public Health, Karolinska Institutet, Stockholm, Sweden

[6] Department of Public Health Education, University of North Carolina Greensboro, Greensboro, USA

[7] Centro Internacional para Saúde Reprodutiva, Maputo, Mozambique

[8] Department of Sociology, University of Antwerp, Antwerp, Belgium

[9] Institute of Global Health and Infectious Diseases, University of North Carolina at Chapel Hill, Chapel Hill, USA

[10] Faculty of Infectious and Tropical Diseases, London School of Hygiene and Tropical Medicine, London, UK

[11] UNC Project-China, 2 Lujing Road, Guangzhou, China

*The I-SHARE Team includes the following in-country leads: 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 (Univeristy of Witwatersrand), Amanda Gabster (Instituto Conmemorativo Gorgas de Estudios de la Salud), Peter Gichangi (Technical University of Mombasa), Wanzahun Godana (Arba Minch University), Alejandra 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 Kenya), 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 Morroni (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 (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 (Universiry of Cuenca). Other members of the I-SHARE team are included here: https://ishare.web.unc.edu/team-members/.

Abstract

Background: COVID-19 may have a profound impact on sexual behaviors, 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 (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 COVID-19 and facilitate multi-national comparisons. Participants will be recruited in selected countries through an online survey. The survey link will be disseminated through local, regional, and national networks. In each country, a lead organization will be responsible for organizing ethical review, translation, and survey administration. The consortium network provides support for national studies, coordination, and multi-national comparison. We will use multi-level modelling to determine the relationship between COVID-19 and condomless sex, gender-based violence, access to reproductive health services, HIV testing, and other key items. This study protocol defines primary outcomes, pre-specified subanalyses, and analysis plans.

Discussion: The I-SHARE study examines sexual and reproductive health at the national and global level. We will use multi-level modelling to examine country-level variables associated with outcomes of interest. This will provide a foundation for subsequent online multi-country comparison using more robust sampling methodologies.

Key words: online, COVID-19, sexual health, reproductive health, HIV, global

Introduction

The global COVID-19 pandemic has ushered in restrictive social measures that are important for COVID-19 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-seeking,[2] 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 (e.g., 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 many countries have reduced or stopped provision of sexual and reproductive health services, 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, and small for gestational age.[9] In addition, the re-orientation 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 behavioral research.[11] Many research institutes are closed and travel is restricted. Many single country studies of COVID-19 focused on sexual and reproductive health have been organized, but none are focused on multi-country analyses. Responding to this gap in the literature, our team designed an online, multi-country sexual and reproductive health research study. 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 COVID-19 using an online convenience sample from selected countries. The primary study aims are listed below:

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

Secondary study aims including the following:

1) To examine changes in HIV/STI testing related to the initiation and resolution of COVID-19 measures using a multi-country analysis.
2) To examine changes in harmful cultural practices (e.g., female genital mutilation, child marriage) related to the initiation and resolution of COVID-19 measures using a multi-country analysis.
3) To examine changes in mental health related to the initiation and resolution of COVID-19 measures using a multi-country analysis.

We will use a cross-sectional online survey with convenience sampling. National sample sizes will be calculated based on national priorities and national-level 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 and Tropical Medicine who worked in partnership with the Human Reproduction Programme at the World Health Organization to develop a standardized sexual health survey instrument for use in diverse global settings. Investigators in the following countries are piloting online surveys in their respective countries: Argentina, Australia, Belgium, Botswana, Cambodia, Cezch Republic, Canada, China, Colombia, Denmark, Ecuador, Egypt, Ethiopia, France, Germany, Italy, Kenya, Latvia, Lebanon, Malaysia, Mexico, Moldova, Mozambique, Nigeria, Panama, Portugal, Republic of Moldova, Singapore, South Africa, Spain, Sweden, Uganda, Uruguay, and the United States. 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 two and four weeks. People from outside of selected countries will be excluded.

Survey development

The survey instrument has the following sections: socio-demographics; compliance with COVID-19 social distancing measures; couple and family relationships; sexual behavior; access to contraceptives; access to maternal healthcare; abortion; sexual and gender-based 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 organization will select networks through which to disseminate the link to the survey. The survey link will be distributed through email listservs, local partner organizations 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 minutes 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 supplemental material. The network will centrally program the online survey questionnaire using Open Data Kit software (version 1.16). This will be an online survey self-administered through smartphones, tablets or computers.

In each country, the in-country lead will organize 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 related issues.

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 a

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 behavior, 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 multi-country comparison component of the analysis. Only survey data that meet the following criteria will be included in the multi-country comparison: at least 200 participants, IRB approval from the local authority, description of sampling methodology, local instrument translated and field tested.

Primary Analysis

Socio-demographics will be summarized using descriptive statistics. The multi-country analysis will use multi-level modelling to examine individual-level and country-level

variables associated with key outcomes of interest, including condomless sex, intimate partner violence, and access to reproductive health services. 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:

$$\text{logit}(\boldsymbol{\pi i}) = \log[\boldsymbol{\pi i} / (1 - \boldsymbol{\pi i})] = \beta 0j +$$

$$\beta 1 x_{ij}\ \beta 0j = \beta 0 + u0j$$

This is a binomial logistic multilevel model with random intercepts, and the binary response yij equals 1 if the individual i in country j had condomless sex. There is a single explanatory variable in this example, xij. The intercept consists of a fixed component $\beta 0$ and a country-specific component, the random effect $u0j$. 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 publically available databases.[13] We will focus on the following country-level indicators: extent of COVID-19 lockdown, types of restrictive social measures (high, medium, low), public responsiveness to restrictive measures (high, medium, low) number of COVID-19 cases, public insurance, and estimated excessive mortality when compared to the year prior. Categories for the degree of restriction and responsiveness will be assessed based on publically available data at the time the survey was administered.

When level-2 sample size is insufficient (e.g., female genital mutilation, early marriage) to perform a multilevel analysis, cross-country differences will be determined through a country-dummy-set. Multi-group confirmatory factor analysis will be used to determine if constructs are valid across different contexts.

Given that online sampling has its own inherent biases,[14] 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.[15 16] Propensity score methods have been used in multi-country research to make groups more comparable based on covariarates.[17] Given that we also cannot randomly assign study participants to the primary exposure or to country of residence, a key covariate, propensity score methods can help us to make more accurate estimation of the associations between COVID-19 and our primary outcomes of interest. 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, 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 to not single people, gender (men compared to women), and socio-economic status.

Field testing

To inform the development of this behavioral survey, in-country leaders organized field testing in respective countries. Field testing was based on the local context in order to identify potential translation problems and estimate the length of the survey.

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 multi-country comparisons, de-identified and unlinkable data for multi-country 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 organized 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, statistical analyses. In each participating country, there will be one lead institution responsible for the implementation of the study.

Ethics

In each country where the study will be implemented, the local partner will request approval of the appropriate ethical committee or review board. Furthermore, ethical approval for cross-country comparisons will be sought after de-identified data is available. Before starting the survey, each participant will be asked to read an informed consent form (supplemental material) 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.

Discussion

This multi-country behavioral survey will examine sexual risk behaviors, 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, middle, and high-income countries, and extending out of two complementary global networks (ANSER and the response to a WHO open call). The pre-specified subanalyses and analytical plans outlined here will increase the rigor of this research, in marked contrast to many of the behavioral COVID-19 studies now underway.

COVID-19 has led to unprecedented uncertainty in our social world, with important implications for sexual and reproductive health. The pandemic presents unique

opporunities and challenge. Some have hypothesized that social restriction measures and decreased travel would decrease the frequency of sexual behaviors. 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.[18 19]

This study has several limitations. First, the sample will be a convenience sample which precludes causal inferences and necessitates caution when making inferences. Second, we exclude offline people, a diverse and hetergenous group of individuals. Third, the online nature of the survey will exclude individuals who do not have internet access. Finally, studies will gather limited information about youth 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 sub-group analyses will provide insights on need, access, and equity issues in sexual and reproductive health during a pandemic. Multi-country 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.

References

1. Grünebaum A, McCullough LB, Bornstein E, et al. Professionally responsible counseling about birth location during the COVID-19 pandemic. *J Perinat Med* 2020 doi: 10.1515/jpm-2020-0183 [published Online First: 2020/05/14]
2. Masroor S. Collateral damage of COVID-19 pandemic: Delayed medical care. *J Card Surg* 2020 doi: 10.1111/jocs.14638 [published Online First: 2020/05/19]
3. Hall B, Tucker JD. Surviving in place: The coronavirus domestic violence syndemic. *Asian Journal of Psychiatry* 2020
4. Curry DW, Rattan J, Huang S, et al. Delivering high-quality family planning services in crisis-affected settings II: results. *Glob Health Sci Pract* 2015;3(1):25-33. doi: 10.9745/ghsp-d-14-00112 [published Online First: 2015/03/07]
5. Barot S. In a state of crisis: Meeting the sexual and reproductive health needs of Women in humanitarian situations. Guttmacher Policy Review: Guttmacher, 2017.
6. McGinn T, Austin J, Anfinson K, et al. Family planning in conflict: results of cross-sectional baseline surveys in three African countries. *Confl Health* 2011;5:11. doi: 10.1186/1752-1505-5-11 [published Online First: 2011/07/15]
7. Purdy C. How will COVID-19 affect global access to contraceptives—and what can we do about it? 2020 [Available from: https://www.devex/com/news/sponsored/opinion-how-will-covid-19-affect-global-access-to-contraceptives-and-what-can-we-do-about-it-96745.
8. Riley T, Sully E, Ahmed A, et al. Estimates of the Potential Impact of the COVID-19 Pandemic on Sexual and Reproductive Health in Low- and Middle-Income Countries, 2020.
9. Kasraeian M, Zare M, Vafaei H, et al. COVID-19 pneumonia and pregnancy; a systematic review and meta-analysis. *J Matern Fetal Neonatal Med* 2020:1-8. doi: 10.1080/14767058.2020.1763952 [published Online First: 2020/05/21]
10. Parpia AS, Ndeffo-Mbah ML, Wenzel NS, et al. Effects of Response to 2014-2015 Ebola Outbreak on Deaths from Malaria, HIV/AIDS, and Tuberculosis, West Africa. *Emerg Infect Dis* 2016;22(3):433-41. doi: 10.3201/eid2203.150977 [published Online First: 2016/02/18]
11. Ali SH, Foreman J, Capasso A, et al. Social media as a recruitment platform for a nationwide online survey of COVID-19 knowledge, beliefs, and practices in the United States: methodology and feasibility analysis. *BMC Med Res Methodol* 2020;20(1):116. doi: 10.1186/s12874-020-01011-0 [published Online First: 2020/05/15]
12. I-SHARE website 2020 [Available from: https://ishare.web.unc.edu/partner-organizations/.
13. #covid19 government measures dataset. 2020
14. Best SJ, Krueger B, Hubbard C, et al. An Assessment of the Generalizability of Internet Surveys. *Social Science Computer Review* 2001;19(2)
15. Schonlau M, van Soest A, Kaptyen A, et al. Selection Bias in Web Surveys and the Use of Propensity Scores. RAND 2006.
16. Propensity-Weighted Web Survey. In: Lavrakas PJ, ed. Encyclopedia of Survey Research Methods, 2008.
17. Arikan S, van de Vijver FJ, Yagmur K. Propensity Score Matching Helps to Understand Sources of DIF and Mathematics Performance Differences of Indonesian, Turkish, Australian, and Dutch Students in PISA. *International Journal of Research in Education and Science* 2018;4:69-81.
18. UNFPA's report COVID-19: A Gender Lens. 2020
19. van Gelder N, Peterman A, Potts A, et al. COVID-19: Reducing the risk of infection might increase the risk of intimate partner violence. *EClinicalMedicine* 2020;21:100348. doi: 10.1016/j.eclinm.2020.100348 [published Online First: 2020/04/16]