



STUDY PROTOCOL

RESEARCH INTEGRITY AND RESEARCH FAIRNESS SURVEY

A survey of questionable and unfair practices in global health research

May 2022

Version control

Version (and date)	Changes from previous version
Version 1 – 17 December 2021	First draft to be reviewed by study team
Version 2 – 14 January 2022	Review by study team
Version 3 – 28 January 2022	Final draft to share with task force members
Version 4 – April 2022	Final version incorporating feedback from task force members
Version 5 – 28 May 2022	Final version incorporating feedback from KEM HRC and KIT
	Research Ethics Committees

Contents

	1.	Sum	mary	3
	2.	Back	ground	4
	3.	Rese	earch Objectives	6
		3.1	Overall and specific objectives	7
		3.2	Research questions	8
		3.3	Hypotheses	8
	4.	Met	hods	8
		4.1	Study Type and Design	8
		4.2	Data Source	9
		4.3	Study Population and Setting	. 10
		4.4	Variable Definition	. 11
		4.5	Sample size	. 13
		4.6	Sampling	. 14
		4.7	Data management plan	. 14
		4.8	Analysis plan	. 15
		4.9	Quality assurance	. 16
		4.10	Ethical review	. 18
		4.11	Confidentiality and GDPR	. 18
	3.	Stud	y implementation	. 19
		3.1	Funding	. 19
		3.2	Study team	. 19
		3.3	Task force	. 20
		3.4	Timeline	. 21
An	ne	x 1: Inf	formed consent form and questionnaire for quantitative data collection	. 22
An	ne	ex 2: Inf	formed consent form and topic guide for qualitative data collection	. 22

1. Summary

Global health research faces two common pitfalls. On one hand, questionable research practices may lead to spurious findings if studies are ill-designed, poorly implemented, inappropriately analysed or selectively reported. On the other hand, and of equal concern in global health, end-users of research and local researchers are too often side-lined from research conducted in their own country. Obtaining approval from weak ethical institutions, bypassing local expert knowledge, ignoring local context, failing to develop in-country capacity are some of the practices which de-value global health epidemiology.

Building on the BRIDGE guidelines, we propose multi-country mixed-methods research integrity and research fairness survey to assess the extent to which research integrity and research fairness are achieved in global health research. It is expected that this survey will reveal the extent of the problems with regards to both integrity and fairness and will identify the barriers and facilitators to research integrity and research fairness.

The overall objective of this study is to provide evidence on the extent to which global health researchers engage in questionable and unfair research practices and identify barriers and facilitators for the fulfillment of research integrity and research fairness principles in research practice.

The specific objectives are:

- 1. To estimate the prevalence of self-reported questionable research practices (QRP) in a sample of global health researchers in Global North and Global South
- 2. To estimate the prevalence of self-reported unfair research practices (URP) in a sample of global health researchers in the Global North and Global South
- 3. To explore differences in the prevalence of self-reported QRP and URP between Global North and Global South researchers
- 4. To identify the individual, institutional and structural factors influencing QRP and URP among Global North and Global South researchers
- 5. To identify promising practices to foster research integrity and research fairness these principles in research practice

Accordingly we propose a mixed methods research study consisting of:

- a quantitative research component with an online **prevalence survey** for objectives 1-3
- a qualitative research component with online in depth interviews and key informant interviews
 for objectives 4-5

This information will be used to identify promising solutions to ensure that the impact of global health research is attained where it is most needed: local research systems and local communities where the research is conducted

2. Background

Research integrity and research fairness have gained considerable momentum in the past decade and have direct implications for global health research. In a recent article¹, we have argued that research integrity and research fairness principles should be equally nurtured by global health researchers who aim to produce high-quality impactful research—but bridging the two can lead to practical and ethical dilemmas.

Research integrity has emerged as a response to the 'reproducibility crisis' (the inability to reproduce research findings), which has shaken the foundations of most scientific disciplines². Findings obtained from ill-designed, badly implemented, inappropriately analysed or selectively reported studies will also lead to irreproducible results. Data fabrication, falsification and plagiarism represent the most extreme case of scientific misconduct and consequently inability to reproduce research findings. Yet, practices in the grey zone between this type of deliberate misconduct and ideal scientific behaviour—denoted as 'questionable research practices' may be more prevalent and ultimately, more damaging. A number of scientific regulatory bodies have issued documents over the past decade to foster research integrity and thereby tackle questionable research practices either in the form of codes of conduct for researchers (such as in the European Union (EU) and in India or guidelines and policies (e.g., in Uganda)⁴.

As a result of global health's emphasis on transnational issues and health equity, we believe that research integrity needs to be expanded to also include research fairness principles. Strictly speaking, the transnational nature of global health refers to the study of determinants and solutions that cross national boundaries, such as climate change or urbanisation. But in practice—for a host of historical reasons—

¹ Alba S, Verdonck K, Lenglet A, et al. Bridging research integrity and global health epidemiology (BRIDGE) statement: guidelines for good epidemiological practice. BMJ Global Health 2020;5:e003236

² Challenges in irreproducible research, 2020. Available: https://www.nature.com/collections/prbfkwmwvz

³ Steneck NH . Fostering integrity in research: definitions, current knowledge, and future directions. Sci Eng Ethics 2006:

⁴ ALLEA - All European Academies. The European code of conduct for research integrity. ⁴Indian Council of Medical Research. Guidelines on code of conduct for research scientists engaged in field of life sciences. Uganda National Council for Science and Technology. Research registration and clearance policy and guidelines, 2016.

transnational research often implies transnational research collaborations and more specifically partnerships between Global North and Global South institutions. The power imbalances potentially arising in such partnerships are at the centre of research fairness concerns and are broadly aligned with calls to decolonise global health⁵. More specifically, research fairness aims at redressing some of the power imbalances in global health, which prevent local stakeholders from shaping the research agenda and competing on a level playing field in scientific arenas. In doing so, research fairness seeks to maximise the positive impact of global health research both on local researchers and on local communities.

In the light of these reflections, we developed the BRIDGE guidelines for epidemiological studies targeted at stakeholders involved in the commissioning, conduct, appraisal and publication of global health research. These guidelines consist of 6 standards and 42 accompanying criteria covering all stages of implementation of a research study (Figure 1). A total of 45 experts provided input on the first round of e-Delphi consultation and 40 in the second. Respondents covered a range of organisations (including for example academia, ministries, NGOs, research funders, technical agencies) involved in epidemiological studies from countries around the world. The final guidelines consist of a set of 6 standards and 42 accompanying criteria including study preparation, protocol development, data collection, data management, data analysis, dissemination and communication.

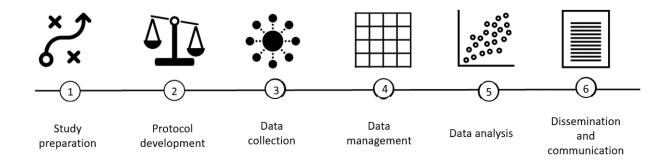


Figure 1. Overview of BRIDGE standards

While the BRIDGE guidelines were specifically developed for epidemiological studies many criteria are applicable to global health research more broadly. Building on the BRIDGE guidelines, we propose multi-

⁵ Abimbola S, Pai Madhukar. Will global health survive its decolonisation? Lancet 2020

country mixed-methods research integrity and research fairness survey to assess the extent to which research integrity and research fairness are achieved in global health research more broadly.

The only systematic review available on scientific research misconduct to date6 pooled 21 surveys mostly in biomedical, medical and clinical sciences from the UK, USA and Australia. The review suggested that 2%–14% of scientists may have fabricated or falsified data, with nearly three-quarters admitting other questionable research practices. There is little research into the quality of global health research, but what it reveals is very sobering. A recent review of 121 randomised control trials performed in sub-Saharan Africa suggests that many studies suffer from inadequate methods and incomplete reporting7. For example, a description of adequate randomisation sequence generation was present in only 62% of reports, intervention allocation concealment in 39% and adjustments for incomplete outcome data in 64%. Interventions were completely reported in only 60% of studies. The most worrying data come from two recent Nigerian studies, which suggest staggering levels of scientific misconduct: nearly 70% of interviewed researchers admitted to some form of personal scientific misconduct8 while 96% believed that one or more forms of scientific misconduct had occurred in their workplace9. To the best of our knowledge, there has been no research assessing the prevalence of fair or unfair research practices.

Given the dearth of data on research integrity and research fairness in global health, our research is aims to fit an important information gap. Indeed, it is expected that this survey will reveal the extent of the problems with regards to both integrity and fairness and will identify the individual, institutional and structural factors influencing research integrity and research fairness. This information will be used to identify promising practices to ensure that the impact of global health research is attained where it is most needed: local research systems and local communities where the research is conducted

3. Research Objectives

-

⁶ Fanelli D . How many scientists fabricate and falsify research? A systematic review and meta-analysis of survey data. PLoS One 2009;4:e5738.doi:10.1371/journal.pone.0005738

⁷ Ndounga Diakou LA , Ntoumi F , Ravaud P , et al . Avoidable waste related to inadequate methods and incomplete reporting of interventions: a systematic review of randomized trials performed in Sub-Saharan Africa. Trials 2017:18:291

⁸ Okonta P , Rossouw T . Prevalence of scientific misconduct among a group of researchers in Nigeria. Dev World Bioeth 2013;13:149–57

⁹ Okonta PI, Rossouw T. Misconduct in research: a descriptive survey of attitudes, perceptions and associated factors in a developing country. BMC Med Ethics 2014;15:25

3.1 Overall and specific objectives

The following definitions apply:

- Questionable research practices (QRP): QRPs are defined in the field of research integrity as
 'misbhaviours'¹⁰ in the grey zone between fabrication, falsification, and plagiarism (FFP) and
 responsible conduct of research (RCR) that "violate traditional values of the research enterprise
 and that may be detrimental to the research process"¹¹. The term describes practices such as
 describing a hypothesis after finding significant results, selective publication of results, concealing
 of conflicts of interests etc. ¹²
- Unfair research practices (URP): URPs derive from the field of research fairness and refer to practices that where there is unfair treatment of research partners in the planning, execution and dissemination of the research. Of particular concern in global health are practices that prevent local actors from shaping the research agenda in their country and curb their ability to reap scientific rewards for their contributions. URPs include bypassing local expertise and expert knowledge, avoiding local ethical institutions, failing to develop in-country capacity etc.¹³

Accordingly, the overall objective of this study is to provide evidence on the extent to which global health researchers engage in questionable and unfair research practices and identify barriers and facilitators for the fulfillment of research integrity and research fairness principles in research practice.

The specific objectives are:

- To estimate the prevalence of self-reported questionable research practices (QRP) in a sample of global health researchers in Global North and Global South
- 2. To estimate the prevalence of self-reported unfair research practices (URP) in a sample of global health researchers in the Global North and Global South
- To explore differences in the prevalence of self-reported QRP and URP between Global North and Global South researchers

¹⁰ Fanelli D (2009) How Many Scientists Fabricate and Falsify Research? A Systematic Review and Meta-Analysis of Survey Data. PLoS ONE 4(5): e5738. doi:10.1371/journal.pone.0005738

¹¹ Steneck NH. Fostering integrity in research: definitions, current knowledge, and future directions. Sci Eng Ethics. 2006 Jan;12(1):53-74. doi: 10.1007/pl00022268. PMID: 16501647

¹² Gerrits RG, Jansen T, Mulyanto J, et al Occurrence and nature of questionable research practices in the reporting of messages and conclusions in international scientific Health Services Research publications: a structured assessment of publications authored by researchers in the Netherlands BMJ Open 2019;9:e027903. doi: 10.1136/bmjopen-2018-027903

¹³ http://rfi.cohred.org/origin-of-the-rfi/

- 4. To identify the individual, institutional and structural factors influencing QRP and URP among Global North and Global South researchers
- 5. To identify promising practices to foster research integrity and research fairness these principles in research practice

3.2 Research questions

In line with the objective, the research questions are as follows:

- 1. What is the prevalence of self-reported QRPs in a representative sample of researchers working in institutes belonging to international global health research networks, overall and stratified by geographic location (Global North, Global South)
- 2. What is the prevalence of self-reported URPs in a representative sample of researchers working in institutes belonging to international global health research networks, overall and stratified by geographic location (Global North, Global South)
- 3. Is there a statistically significant difference in self-reported QRPs and URPs between researchers based in the Global and in the Global South
- 4. What are the individual, institutional and structural determinants of QRP and URPs for researchers from Global North and Global South?
- 5. Which practices do researchers perceive as being effective to prevent themselves or their colleagues from engaging in QRPs and URPs?

3.3 Hypotheses

The following null hypothesis will be tested for research objective/question 3: there is no difference in QRP/URP between Global North and Global South researchers. Sample size calculations are based on research question/objective 1 and 2 (prevalence of QRPs and URPs) as explained in the section on sample size calculations.

4. Methods

4.1 Study Type and Design

This is a mixed methods research study consisting of:

- a quantitative research component with an online prevalence survey for research questions 1, 2
 and 3
- a qualitative research component with online in depth interviews and key informant interviews for research questions 3 and 4

4.2 Data Source

The questionnaire for the online survey can be found in <u>Annex 1</u>. This tool lists 20 responsible/questionable practices related to research integrity with a selection of questions developed by the Dutch National Survey on Research Integrity (NSRI)¹⁴ which are in line with the BRIDGE criteria for research integrity. We chose to align ourselves with this survey to enable comparisons with this survey's results and because the questions have undergone prior psychometric validation. For research fairness there are 20 fair/unfair research practices derived from the BRIDGE guidelines. These were formulated similarly to the NSRI survey (statements in the first person, three-year recall period, 7-point Likert scale ranging from strongly disagree to strongly agree). For both integrity and fairness questionnaires, in order to keep respondents alert and to avoid that they fill in the form mechanically with a 'strongly agree' or 'strongly disagree' some statements are phrased as a questionable/unfair practice and some are phrased as responsible/fair.

An exploratory approach will be followed, whereby the research tools/ guides for the qualitative component will be developed based on preliminary analyses of the quantitative component. While quantitative will help us understand the existing practices at individual level, the qualitative component will investigate the root causes, and more specifically it will attempt to disentangle between individual determinants (career progression), structural issues (related to research funding) and institutional issues (related to institutions norms and policies). As a consequence the following questions may be asked in relation to whether they promote or disincentive fairness or integrity in research, and what respondents see as viable alternatives:

- Individual issues: Is career progression in your field dependent on academic output?
- Institutional issues: Do your institution have guidelines on how to agree on authorship / sharing
 IP / etc? Does your institution require publications to be sent to your institution's legal
 department before publication (especially in trials, etc)? Is there a requirement that your

.

¹⁴ https://www.nsri2020.nl/

- institution needs to be PI or Co-PI on a grant? Does your institution require certain 'overheads' / F&A costs irrespective of service provided to your study?
- Structural issues: As PI have you ever challenged or refused funding because you felt donorimposed timelines or deliverable requirements were 'unfair' to partners or encouraged 'compromising your research integrity'

In addition the qualitative component will seek to understand 'confounders' that are not investigated in the quantitative component, such as those at structural level (type of donor,. e.g. government, philanthropy, business, etc) or institutional level (e.g. US vs. EU, north-south vs. south-south collaborations).

4.3 Study Population and Setting

The study population consists of researchers currently involved in global health research and working in institutes that are part of the following research networks: tropED (Network for Education in International Health), INDEPTH Network, Asian Health and Demographic Surveillance System (HDSS), Astra South Asia, AIMS (African Institute of Mathematical Science), CUGH (Consortium of Universities for Global Health), Humanitarian Health Ethics Network, Collaboration for Evidence Based Health Care in Africa (CEBHA+), Trials of Excellence in Southern Africa, West African and Central African Network for TB, HIV/AIDS and Malaria, East African Consortium for Clinical Sciences, Bill and Melinda Gates Foundation Global Health Grantees, Southeast Asia One Health University Network (SEAOHUN), COVID-19 Clinical Research Coalition, and the European and Developing Countries Trial Partnership (EDCTP).

The algorithm in Figure 2 below will be used to assess the eligibility of institutions within the sample framework. The following definitions apply:

- Appropriate Type of Institution An institution that has a focus on research in global health,
 which is either a university, non-profit non-government research/knowledge centre (like KIT),
 a government research institute, or a funding institution that plays an active role in research
 protocol development.
- Appropriate Type of Research Research that is focused on global health (international) or public health (national) in which it involves interactions with communities, patients, public, or other local actors. (ie: not laboratory based or document based).

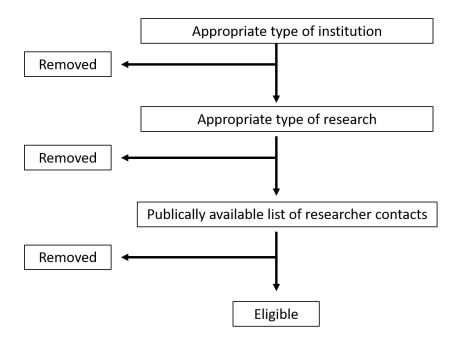


Figure 2. Algorithm to assess the eligibility of institutions

4.4 Variable Definition

Outcome

For objectives/question 1 and 2, there are two main outcome variables: 1) the prevalence of questionable research practices (QRP) and: 2) the prevalence of unfair research practices (URP). The questionnaire presented in **Annex 1** provides a list of questionable and unfair research practices. The questionnaire includes questions are formulated as 'positive' behaviours ('responsible' research practices as opposed to 'questionable' and 'fair' as opposed to 'unfair'). For each study participant 6 binary variables will be derived to calculate the prevalence of QRPs and URPs depending on various thresholds, and therefore levels of severity, as shown in Table 1. In addition one continuous variable will also be created

For objective/question 3, the primary outcome variable will be QRPc and URPc as described in Table 1. Comparisons based on QRP1/URP1, QRP3/URP3, QRP10/URP10 will also be done for exploratory purposes.

Table 1. Definition of variables to estimate the prevalence of questionable and unfair research practices

Threshold	Variable name and definition					
At least one	QRP1: participant has engaged in 1 or more QRPs (out of 20) in the past 3 years					
(binary variable)	(having responded to at least 1 QRP related question with either always, very					
	frequently, frequently with a questionable practice or having responded with never,					
	very rarely, rarely with a responsible research practice)					
	URP1: as above for URPs					
3 or more	QRP3: as above for 3 or more QRPs in the past 3 years					
(binary variable)	URP3 : as above for 3 or more URPs in the past 3 years					
10 or more	QRP10: as above for 10 or more QRPs in the past 3 years					
(binary variable)	URP10: as above for 10 or more URPs in the past 3 years					
No threshold	QRPc: a score will be calculate for each person as the weighted sum of all responses					
(continuous	to the 20 QRP questions. Responses to 'negatively worded' QRP questions will be as					
variable)	follows: 3=always; 2=very frequently; 1=frequently. Response to 'positively worded'					
	questions will be weighted as follows: 3=never, 2=very rarely 1=rarely					
	URPc: as above for URPs					

Exposure

For objective/question 3, the main exposure variable is whether participants work in institutes located in the Global South or in the Global North. In the absence of a consensus or objective measurement to classify countries as Global North or Global South, we will as participants to identify themselves as either global north or global south researchers.

Confounders and effect modifiers

For objective/question 3, we anticipate the main confounders and effect modifiers to pertain to the researchers age, gender, seniority (highest attained degree), discipline, place of origin (Global South researcher working for Global North institutions or vice versa, years of involvement in research and role of the researcher). These variables are indirect identifiers, and as such participants will be given the option not to provide this information should they feel uncomfortable about revealing it.

4.5 Sample size

Prevalence survey

The following equation was used for the calculation of sample size for each stratum, where N is the sample size, Z is the Z-Score, p is proportion set for the selected indicator, Deff is the design effect, C is precision, R is response rate

$$N = \frac{Z^2 * p * (1 - p) * Deff}{C^2 * R}$$

The sample size calculation was based on a Z-score of 1.96 (corresponding to an alpha level of 5%), a hypothesised prevalence (p) of 0.5 for the prevalence of QRPs/URPs, a precision (C) of 10% on each side, a design effect (Deff) of 3 and a 50% response rate (R). The samples are stratified across two strata: the Global North and the Global South. The resulting sample size per stratum is 437. In order to reach this sample size we will recruit 15 individuals per sampled institute, and thus there will be 30 institutions per strata.

Qualitative study

We will initially select 6-7 willing participants per strata to conduct in-depth interviews making a total of approx. 12-14 in-depth interviews. It is expected that will reach saturation sampling with this sample size, but should that not the case, we will continue conducting interviews until we are certain that all issues have been explored fully and present a complete and consistent picture. Similarly if the researchers identify data saturation, we will conduct fewer interviews than decided. Invited participants for the indepth interviews will be selected from the list of participants invited to the prevalence survey. we will aim to achieve a balance in terms of disciplines, seniority (see Section C of the survey questionnaire in Annex 1. To ensure anonymity of survey responses, there will be no possibility to link the in-depth interview respondents to the survey respondents and responses.

At the end of each in-depth interview we will enquire of any probable key informant who would provide more insights in the subject to each participants, thus snowballing the key informants. During snowballing we will seek 'outliers' (people who dropped out from their institute because they could not confirm to institutional policies and regulations) and other important research stakeholders (e.g. funders, commissioners, publishers) who may be known to be knowledgeable about the topics investigated but

are not part of our sampling frame (e.g. funders, publishers etc).. In addition to the 12-14 respondents drawn from our sampling frame, we will seek an additional 3-4 of these snowballed key informants for conducting the key informant interviews.

4.6 Sampling

Prevalence survey

Survey participants will be sampled by two-stage cluster sampling. In the first sampling stage we will randomly select institutes from our sampling frame—list of global health research institutes derived from the global health networks listed in section 4.3 (Study population). In the absence of a consensus or objective measurement to classify countries as Global North or Global South, we will refer to the World Bank 2021 country income classifications¹⁵ in low, lower-middle, upper-middle, and high-income countries. More specifically, countries that are low, lower-middle and upper middle will be considered Global South, and high-income countries will be considered Global North.

In the second stage we will compile a lists of all researchers listed in publicly available websites as working in the selected research institutes. We will then randomly select researchers from these lists and invite them to participate in our online survey.

Qualitative study

Participants for the in-depth interviews will be equally selected from both strata. Convenient sampling will be done based on the time availability of willing participants to participate in the interview process. We will use snowballing approach to identify the key informants during the in-depth interviews.

4.7 Data management plan

The online survey will be programmed in Survey Monkey, a secure online survey platform that adheres to stringent data safety and protection practices. Surveys will be collected through Survey Monkey's anonymous response collector, limiting the respondent information and deleting identifiable information in backend logs like email and IP addresses after 13 months. Numerous other advantages to using survey

¹⁵ https://blogs.worldbank.org/opendata/new-world-bank-country-classifications-income-level-2021-2022

platforms like Survey Monkey include advanced quality assurance and analytical tools like automatic data checking to avoid irrelevant data entries, and professionally managed security features.

Some indirect identifiers (but no direct identifiers) will be requested during the survey (see confounders in section 4.4). Participants will be given the option to skip all indirect identifiers should they feel uncomfortable sharing this information. Collected identifiers will be made available to the analysts. The Survey Monkey account will be password protected and only accessible by the data manager and principal investigator. Once all survey responses have been completed, anonymised survey data will be migrated from the protected Survey Monkey server to the KIT servers, which are compliant with general data protection regulation (GDPR) for further data analysis. All staff that will be handling data will be adhering to institutional guidelines for backing up, storing and archiving data.

Numerous mechanisms will remain in place to ensure that data quality is sustained throughout every step of the data collection, cleaning and analysis process. This includes exhaustive trialing of data collection tools, validation of sample data, and the creation of comprehensive codebooks for the dataset.

Data collection will be conducted over the course of four weeks. Participants will be sent two reminders two and three weeks after receiving the first email invitation.

4.8 Analysis plan

Statistical analyses

Participants will be described in terms of their personal characteristics. The average Likert scale response per QRP and URP will be reported for each question. The prevalence of QRP and URP will be calculated using the outcome definition described in Section 4.4. Confidence intervals will be calculated by taking into account survey clustering and weights using the survey package in R or Stata. The test of significance between the prevalence of QRPs and URPs in Global North and Global South researchers will be done by fitting a logistic or linear regression models.

If possible, we will account for all survey settings, and adjusting for the effect of potential confounders listed in section 4.4. However, this is dependent on participants' willingness to share these indirect identifiers with us. Given that these are not-compulsory and that participants are openly offered the possibility to skip these questions due to the sensitivity of the information they provided regarding QRPs and URPs, it is possible that there will be too many missing responses to enable survey settings and adjustments of confounders. If that is the case, we will attempt to account for clustering using robust

standard errors wht post-hoc adjustment (after analyses) with a scale factor that will be estimated based on the estimated number of institutes and participants in the study¹⁶.

Qualitative analyses

We will conduct inductive analysis of the data. We will use the BRIDGE checklist to guide the analysis process by creating preexisting codes and later adding new codes arising from the data. The coding will be line-to line coding using a standard software for qualitative data management. Relevant and similar codes will be merged into categories and categories will be analyse to assess if any themes arise from the data.

We will conduct the qualitative analysis at two levels, within cases/ participants and between cases/ participants which will help us understand the depth of information shared by each respondent and also possible relationships between the preexisting and new codes. We will aim to create a framework from the data if relevant themes arise from the data.

4.9 Quality assurance

Following the Open Quality¹⁷ approach to quality assurance for epidemiological studies, we propose the following preventive and control strategies

Study phase	What can go wrong	Preventive/control measure
Study	The research does not fill	Extensive literature review and formation of study team
preparation	a knowledge gap	with lived experience of challenges in global health
		research (completed in Jan 2022 during development of
		draft protocol)
Protocol	The methods are flawed	Protocol review by a task force comprising of experts in
development		the field of research integrity and research fairness
		(completed in Feb 2022).

¹⁶ https://www.stata.com/support/faqs/statistics/robust-standard-errors/

¹⁷ Alba, S., Straetemans, M. Whatever can go wrong, need not go wrong: Open Quality approach for epidemiology. *Emerg Themes Epidemiol* **18**, 8 (2021). https://doi.org/10.1186/s12982-021-00098-0

Study phase	What can go wrong	Preventive/control measure
Data	Email invitation ends up	Email will be sent by gep@kit.nl but will be forwarded
collection	in recipients spam	personally by the PI
	folders	
	Participants ignore email	Reminders will be sent. In addition an introductory letter
	and do not respond	will be sent to heads of institutes/departments
		personally by PI to encourage staff to participate.
	Questions are not clear	Questionnaire will be pilot tested by colleagues not
	to respondents	involved in the research
Data	The data is incomplete	We will allow for 'don't know' or 'don't want to disclose'
management	The data is incomplete	Features will be put in place in Survey Monkey to ensure
management		that all questions are answered (no blanks).
		that an questions are answered (no stantes).
	Data management	No direct personal identifiers will be requested during the
	procedures do not	survey (questions relating to indirect identifiers will be
	guarantee confidentiality	optional). Survey Monkey account will be password
	of respondents	protected and only accessible by the data manager and
		principal investigator. Once all survey responses have
		been completed, survey data will be migrated from the
		protected Survey Monkey server to the KIT servers, which
		are compliant with general data protection regulation
		(GDPR) for further data analysis.
		In-depth interviews will be recorded with a handheld
		recorder and participants will be asked not to divulge any
		personally identifying information in the interview. After
		transcription, recordings will be deleted and saved
		anonymously.
		anonymousiy.
Data analysis	Data is not analysed	Analyses will be documented in a statistical
	correctly	programming file (Stata do file or R script) which will be
		reviewed and re-run by an independent analyst

Study phase	What can go wrong	Preventive/control measure					
		Qualitative analyses will be reviewed by an independent					
		analyst after review of the transcripts					
Reporting and	Scientific publication is	Develop other modes of dissemination for various target					
dissemination	too technical and has	groups (e.g. donors) such as webinars, short videos and					
	little reach	summary briefs					

4.10 Ethical review

Ethical review has been requested by two lead implementing institutes involved in the study: the KIT Research Ethics Committee, KEM Hospital Research Centre Ethics Committee. Permission was granted by both committees. While the study statistician is currently employed at the University of the Free State in South Africa (see Section 3.2), he is contributing to this study in his personal capacity and therefore ethical review was not requested from his institute. Given the high number of participating institutes and countries (up to 24) it was not be feasible to request permission from all research institutes and countries.

4.11 Confidentiality and GDPR

No direct personal identifiers will be requested during the survey. We will ask for some indirect identifiers (e.g. institution name, region of resident, gender, seniority, years of involvement research and discipline), which, combined, may enable to reveal the identity of respondents. However, participants are free to not provide this information. We will also ask participants to name the institute in which they work so that we can check our progress towards our sampling targets and appropriately account for clustering in our statistical analyses. Should participants feel uncomfortable disclosing this information, they may leave it blank and submit they survey without entering this information.

Survey Monkey account will be password protected and only accessible by the data manager and principal investigator. Once all survey responses have been completed, anonymised survey data will be migrated from the protected Survey Monkey server to the KIT servers, which are compliant with general data protection regulation (GDPR) for further data analysis.

In-depth interviews will be recorded with a handheld recorder and participants will be asked not to divulge any personally identifying information in the interview. After transcription, recordings will be deleted and saved anonymously.

3. Study implementation

3.1 Funding

This study is funded by KIT Royal Tropical Institute (Amsterdam, Netherlands) and KEMHRC (Pune, India).

3.2 Study team

The study team consists of the following:

- Principal Investigator: Sandra Alba, MSc, PhD, is an epidemiologist at KIT Royal Tropical Institute
 with a background in medical statistics. She has 15 years' experience in the application of
 statistical and epidemiological methods in global health research. She led the development of the
 BRIDGE guidelines which serve as the foundation of this survey.
- Senior epidemiologist: Masja Straetemans, MSc, PhD, is an epidemiologist at KIT Royal Tropical Institute. Her background includes environmental health science and public health. Masja is specialised in infectious disease epidemiology and has extensive experience in evidence based healthcare, including systematic reviews and operational/field research
- **Survey statistician**: Joseph B. Sempa, MSc, PhD, is a biostatistician at the University of the Free State. He has 12 years' experience in HIV research. His background includes statistics and public health. Joseph is specialised in infectious diseases epidemiology, with extensive experience in HIV incidence and treatment outcomes modeling, systematic reviews and meta-analysis.
- Qualitative researcher: Rutuja Patil, MSc, is a research scientist at the Vadu Rural Health program (VRHP), KEMHRC Pune, India. She has nearly 12 years of experience working in Health and Demographic Surveillance Systems, Indoor Air-pollution, and Digital health. She is also involved in generating evidence for policymakers using the research activities conducted at VRHP and hence involved in various implementation science studies conducted by the department. She also coordinates communications and related institutional activities.
- **Epidemiologist:** Nima Yaghmaei, MSc in International Health and a MSc in Public Health Nutrition. He has experience in data analysis, project management, and teaching in various environments. Through his international experience, Nima has a strong understanding of the complexities in global health challenges, particularly in unstable settings.

Data manager: Jake Mathewson, MSc is an epidemiologist at KIT with a background in critical care
nursing and a strong foundation in infectious disease control in low-resource and conflict-affected
settings.

3.3 Task force

In order to ensure a high quality and successful implementation of the BRIDGE survey we have selected a small group of experts in global health research to be part of the study's Task Force. We will solicit their assistance with either or both of following tasks:

- 1. Act as a sounding board for the development survey tools and methodologies
- 2. Liaise with members of selected networks to identify participating institutes and participants for the survey

The Task Force consists of the following professionals:

- Senjuti Shah is a Bangladeshi scientist at the Child Health Research Foundation (CHRF), and board member of the Polio Transition Independent Monitoring Board (TIMB) of the World Health Organization (WHO). She is known for her lead on decoding the genome of SARS-CoV2 in Bangladesh. Senjuti is an outspoken critic of unfair research practices in global health through social media platforms
- Gowri Gopalakrishna is an epidemiologist and public health policy scientist interested in mix
 methods studies at the VU. In her previous positions, she was part of the core team involved with
 the control and prevention of the SARS epidemic in 2003 in Singapore. In her current position, she
 is responsible for designing and implementing one of the largest surveys funded by ZonMw to
 study factors that promote or hinder responsible research among academics in The Netherlands.
- Francis Kombe is a South-Africa based research- ethicist and previously project lead of the Council on Health Research for Development (COHRED). He co-founded the African Research Integrity Network and since 2018 he is the CEO of EthiXpert, an organisation which aims to build responsible and ethical research capacity in and for Africa.
- Martijn Wienia is a Senior Programme Manager at NWO-WOTRO Science for Global Development. WOTRO is the division of the Netherlands Research Council (NWO) which funds scientific research for inclusive global development. Martijn's main responsibilities include coordinating research for inclusive global development (e.g. Sustainable Development Goals, Global Health). He is a strong research fairness advocate in the Dutch global health research scene.

3.4 Timeline

TASK	January 2022	February 2022	March 2022	April 2022	May 2022	June 2022	July 2022	August 2022	September 2022
Protocol development and ethical review									
Review with task force & adaptation									
REC application (waiver)									
Prepare list of invited participants									
Prepare topic KIIs									
Data Collection									
Send out online questionnaire + reminders									
Select/invite participants for KIIs									
Conduct KIIs									
Transcribe KIIs									
Data Management									
Develop and pilot online questionnaire									
Analyses									
Quant Analyses + preliminary write up									
Presentation of prel. Survey findings internally									
Finalise quant analyses + triangulation									
Develop coding format for qual data analysis									
Analyse KIIs									
Disseminiation									
Write publication									
Other dissemination material									
7th World Conference on Research Integrity									

Annex 1: Informed consent form and questionnaire for quantitative data collection

Annex 2: Informed consent form and topic guide for qualitative data collection