Study Protocol
(Epi & non-clinical studies)

"hands4health: Hand hygiene, water quality and sanitation in primary health care not connected to functional water supply system: a cluster-randomized controlled trial in Mali and Burkina Faso"

Type of Research Project	Research projects (HRO) - Research projects – involving measures or sampling of biological material or collection of health-related data from persons.

Study acronym/ID	h4h		
Protocol Version Nr	1	**Date**	17.01.2023
Project Leader / Responsible	PD Dr. Mirko Winkler Swiss Tropical and Public Health Institute Kreuzstrasse 2 4132 Allschwil Phone: +41612848339 mirko.winkler@unibas.ch		
Funding Agency	Swiss Agency for Development and Cooperation (SDC) Freiburgstrasse 130 3003 Bern		

1 GENERAL INFORMATION

I. List of Project Leaders and other key persons involved in the study

Title	Names	Institution	Position	Function in study
Prof. Dr.	Mirko Winkler	Swiss TPH	Group Leader	PI of the present study
Dr.	Maryna Peter	FHNW	Group Leader	Lead of the the h4h project and lead at FHNW
	Bruno Pascual	Terre des hommes Lausanne	WASH Advisor	WASH coordinator at Terre des hommes Lausanne
	Aboubacar Ballo	Terre des hommes Mali	Regional advisor	Lead of Terre des hommes Mali
	Kamboulbé Dah	Terre des hommes Bourkina Faso	WASH Responsable	Lead of Terre des hommes Burkina Faso
Dr.	Anna Gamma	Ranas Ltd.	Senior Behaviour Change Expert	Behaviour Change work package Mali and Burkina Faso
Dr.	Jan Hattendorf	Swiss TPH	Scientific Project Leader	Statistician
	Anaïs Galli	Swiss TPH	PhD Candidate	Investigator
	Meleesa Naughton	Skat Foundation	Water specialist	Knowledge broker

The project leaders are qualified individuals by education and training and responsible for the whole project. All further key persons are also qualified by education and training to perform their assigned tasks and responsibilities.

II. Signatures

Study Title **hands4health: Hand hygiene, water quality and sanitation in primary health care not connected to functional water supply system: a cluster-randomized controlled trial in Mali and Burkina Faso**

The following project leaders have approved the protocol version ***[1 (dated 17.01.2023)]***, and confirm hereby to conduct the project according to the current version of the Declaration of Helsinki /, and Essentials of Good Epidemiological Practice issued by Public Health Switzerland (EGEP) / ISO EN 14155 / CIOMS International Ethical Guidelines for epidemiological studies 2009 as well as all national legal requirements and guidelines as applicable.

Project Leader

- I have read this protocol (*version 1, dated 17.01.2023*) and agree that it contains all necessary details for carrying out this study. I will conduct the study as outlined herein and will complete the study within the time designated.
- I will ensure that all individuals and parties contributing to this study are qualified and I will implement procedures to ensure integrity of study tasks and data.
- I will provide copies of the protocol and all pertinent information to all individuals responsible to me who assist in the conduct of this study. I will discuss this material with them to ensure they are fully informed and trained regarding their activities within the study conduct.
- I will use only approved informed consent forms and will fulfil all responsibilities for submitting pertinent information to the Independent Ethics Committees responsible for this study.
- It is understood that this protocol will not be disclosed to others without prior written authorisation from the Project Leader or Sponsor, except where required by applicable local laws

Project Leader (lead center/site)

Signature		
Name	Mirko Winkler	Date of Signature (DD.MM.YYYY)
Title	PD Dr.	
Institution	Swiss Tropical and Public Health Institute	
Address	Kreuzstrasse 2 4123 Allschwil	
Phone	+41612848339	

Local Project Leader at local center/site Mali

Signature		
Name	Aboubacar Ballo	Date of Signature (DD.MM.YYYY)
Title		
Institution	Terre des hommes Mali	
Address	Cité du Niger	
Phone	+ 223 91 57 96 08/ 76471935	

Local Project Leader at local center/site Burkina Faso

Signature		
Name	Kamboulbé Dah	Date of Signature (DD.MM.YYYY)
Title		
Institution	Terre des hommes Burkina Faso	
Address	01 BP 2212 Ouagadougou 01	
Phone	+22676712626	

Statistician

Signature		
Name	Jan Hattendorf	Date of Signature (DD.MM.YYYY)
Title	Dr.	
Institution	Swiss TPH	
Address	Kreuzstrasse 2 4123 Allschwil	
Phone	+41612848193	

Table of contents

III. Abbreviations / Glossary of terms

CFU	Colony-Forming Unit
COVID-19	Coronavirus Disease 2019
cRCT	Cluster-Randomized Controlled Trial
CRF	Case Report Form
DAG	Directed Acyclic Graph
DALY	Disability-Adjusted Life Year
Eawag	Swiss Federal Institute of Aquatic Science and Technology
EPFL	Ecole Polythechnique Fédérale de Lausanne
FACET	Facility and Evaluation Tool for WASH in Institutions
FGD	Focus Group Discussion
FHNW	Fachhochschule Nordwestschweiz
HAI	Health Care-Associated Infection
HCF	Health care facilities
HCW	Health Care Worker
HRO	Ordinance of Human Research with the Exception of Clinical Trial (Switzerland)
ICF	Informed Consent Form
IDP	Internally Displaced People
IEC	Independent Ethics Committee
IoT	Internet of Things
IPC	Infection Prevention and Control
JMP	Joint Monitoring Programme
KII	Key Informant Interview
LMIC	Low and Middle-Income Country
LoRaWAN	Low-Power, Wide Area Networking Protocol
NGO	Non-Governmental Organization
Kofam	Koordinationsstelle Forschung am Menschen (Federal Office of Public Health's (FOPH) portal for human research in Switzerland)
ODK	Open Data Kit
PHCF	Primary Health Care Facility
RANAS	Risk, Attitude, Norm, Ability and Self-regulation
SDC	Swiss Agency for Development and Cooperation

SDG	Sustainable Development Goal
Swiss TPH	Swiss Tropical and Public Health Institute
Tdh	Terre Des Hommes
ToA	Theory Of Action
ToC	Theory Of Change
UNICEF	United Nations Children's Fund
WASH	Water, Sanitation and Hygiene
WASH FIT	Water and Sanitation for Health Facility Improvement Tool
WHO	World Health Organization

IV. Synopsis

Project Leader	PD Dr. Mirko Winkler
Study Title	hands4health: Hand hygiene, water quality and sanitation in primary health care not connected to functional water supply system: a cluster-randomized controlled trial in Mali and Burkina Faso
Short Title/Study ID	Hand hygiene intervention in primary health care
Protocol Version and Date	Version 1, 17.01.2023
Study Category with Rationale	Non-clinical study, risk category A: no drugs are being tested, and only hand-rinse samples are being taken
Background and Rationale	On the African continent, more than half of the population does not have access to a handwashing facility with water and soap at home. This inaccessibility contributes to the spread of communicable diseases, such as diarrhea. Countries affected by humanitarian emergencies are particularly vulnerable to water shortages and a lack of hygiene. This lack is particularly problematic in health care settings to avoid health care associated infections. Data about hand hygiene or the success of hygiene interventions in primary health care facilities (PHCFs) in conflict settings is scarce. Therefore, the “hands4health” project will collect data about hand hygiene in PHCFs and then administer a hand hygiene intervention package containing handwashing stations and behaviour change in PHCFs bordering conflict regions in Mali and Burkina Faso.
Objective(s)	**Primary objective:** Evaluate the effects of the comprehensive h4h handwashing intervention on hand hygiene in PHCFs in Mali and Burkina Faso. **Secondary objectives:** 1) Assess hygiene-related risks, attitudes, norms, abilities and self-regulation (RANAS) behavioural factors of health care providers 2) Assess the impact of the h4h intervention package on hygiene-related RANAS behavioural factors of health care providers 3) Explore perceived effects on health and wellbeing of the hands4health intervention package in PHCFs
Primary Endpoint Secondary Endpoints	The **primary endpoint** of this study will be good handwashing practice defined as health care workers (HCWs) who wash their hands with water and soap almost always in the five critical moments of the World Health Organization assessed by structured handwashing observations. Critical moments are: i) Before touching a patient ii) Before clean/aseptic procedures iii) After risk/exposure to body fluids iv) After touching a patient v) After touching a patient’s surroundings The **secondary endpoints** in the survey are: A) Self reported handwashing practice answered for each critical moment on a Likert scale ranging from almost never to almost always.

	B) Number of total coliforms and E.coli colony-forming units (CFUs) per hand before handwashing. C) Hygiene-related health outcomes which are summarized in table 3. The health outcomes will be reassessed with local experts of the respective countries to assure feasibility before the start of the intervention.
Study Design	**Overall project:** Multi-center cluster-randomized controlled trial (cRCT) design. Module 1-3 will be repeated three times within the cRCT at baseline, two months post-intervention and at endline. Module 4 data collection will take place in both study arms longitudinally starting after the intervention has been implemented. Module 5 and 6 are qualitative focus group discussions (FGDs) and interviews and will take place after the second round of data collection in Modules 1-3. For Module 2, only a maximum of 10 HCWs per facility will be observed.
Inclusion/Exclusion Criteria	Study participants will be HCWs of the PHCFs which were chosen to be included in this study. **Inclusion criteria Modules 1-3:** PHCFs were chosen based on accessibility for the study teams, not having a water source directly connected to the building of the facility, having a maternity ward, having at least five employees and being impacted by conflict. All of the HCWs who are present in the PHCFs of the day of data collection will be invited to participate in the project for Modules 1 and 3. HCWs must fulfil all the inclusion criteria: - Minimum age of 18 years - HCWs, men and women, who are in direct (body) contact with the patients **Exclusion criteria Modules 1-3:** HCW participants must not fulfil any of the following exclusion criteria: - HCWs, whose primary occupation is not in the PHCF of the h4h project - Suffering from any skin conditions not allowing the HCW to use soap or alcoholic hand rub - Refusals to participate **Inclusion/Exclusion criteria Module 4:** As the data will be collected on the health care facility level, all facilities in the project will be included. **Inclusion criteria Module 5:** - HCWs of the intervention facilities - Minimum age of 18 years **Exclusion criteria Module 5:** Refusals to participate. **Inclusion criteria Module 6:** - The participant needs to be: a) a stakeholder within the community, state, region or country of the intervention who's position is related in any way to WASH in HCFs b) working in one of the intervention PHCFs. They do not need to be HCWs, they can also be hygiene technicians or in a leading position of the facilities.

	- Minimum age of 18 years **Exclusion criteria Module 6:** Refusals to participate
Measurements and Procedures	Different methods across modules will be used to achieve the objectives of this project. These modules will include qualitative and quantitative data approaches in order to enable a triangulation of the overall project results. The following modules will be used in the cRCT and the overall project: (i) Module 1: Combined RANAS and knowledge, attitudes and practice (KAP) survey, (ii) Module 2: Structured handwashing observations, (iii) Module 3: Microbiological analysis of hand rinse samples, (iv) Module 4: Diary approach for pre-defined health outcomes, (v) Module 5:FGDs and (vi) Module 6: Key informant interviews (KIIs). Endpoints of Modules 1-3 will be assessed at baseline, at follow-up and endline of the cRCT. Module 4 will be used to collect data longitudinally over the course of 9 months. Module 5 and 6 will be used in the middle of the intervention phase in the intervention groups.
Number of Participants with Rationale (if no Power Analysis conducted)	The sample size calculation yielded a minimum of 20 health care facilities per country. With political instability and other factors which might lead to a loss of follow-up, we increased the sample size to 24 health care facilities per country. This will lead to 48 health care facilities in total. We estimate a median of 6 HCWs working in the facilities and a mean number of 5 observed handwashings per person. This would lead to about 384 participants in the entire study. For Modules 1 and 3, all HCWs who are present during data collection and eligible will be asked to participate in the study. For Module 2, the observations a maximum of 10 HCWs per PHCF will be followed in order to avoid disturbing the daily routines of the PHCF too much. Module 4 follows the sample size calculation of the cRCT design, hence 24 PHCFs will be monitored. For Module 5, 6-10 FGDs will be administered and for Module 6, 10-20 interviews.
Study Duration	14 months
Study Schedule	January 2023 of First-Participant-In (planned) March 2024 of Last-Participant-Out (planned)
Investigator(s)	Prof. Dr. Mirko Winkler and Anaïs Galli Swiss Tropical and Public Health Institute Kreuzstrasse 2 4132 Allschwil Phone: +41612848339 mirko.winkler@unibas.ch and anais.galli@swisstph.ch Aboubacar Ballo Terre des hommes Mali Cité du Niger Rue 24, Porte 118 BP 1311 Bamako, Mali Phone: + 223 91 57 96 08/ 76471935 aboubacar.ballo@tdh.ch Kamboulbé Dah Terre des hommes Burkina Faso 01 BP 2212 Ouagadougou 01 Phone : kamboulbe.dah@tdh.ch Meleesa Naughton Skat Foundation St. Leonhard-Strasse 45 Benevolpark

	9000 St.Gallen Phone meleesa.naughton@skat-foundation.ch
Study Centre(s)	Multinational: Mali, Burkina Faso
Statistical Analysis incl. Power Analysis	To determine the required sample size, we run a series of simulations using the software R. Assuming a mean number of six staff members (range two to nine) per health facility and a mean number of five times a person was supposed to wash their hands (SD=5) and an intra cluster correlation coefficient of 0.15, we need to enrol 10 health facilities in each trial arm to detect difference of 15%-points (30% control versus 45% intervention) with 81% power at a two-sided 5% significance level. To account for potential loss to follow-up we aim to enrol in total 24 health facilities. Baseline characteristics will be summarized using descriptive statistics. The difference between two study arms at follow-up will be investigated using mixed effect logistic regression models with random intercepts for health care facilities using the available case population analysed according to the intention-to-treat principles. In the primary analysis only the intervention will be included as predictor.
Ethical consideration	This project will be carried out in accordance with the research plan outlined in this protocol and with principles enunciated in the current version of the Declaration of Helsinki / Essentials of Good Epidemiological Practice issued by Public Health Switzerland (EGEP) / ISO EN 14155 / CIOMS International Ethical Guidelines for epidemiological studies 2009 as well as all national legal requirements and guidelines as applicable. This protocol will be reviewed by the Ethikkommission Nordwest- und Zentralschweiz (EKNZ, Ethics Committee of Northern and Central Switzerland) and also be reviewed and approved by the National Institute of Public Health (INSP) in Mali, and the Comité d'Ethique pour la Recherche en Santé (CERS) in Burkina Faso. This trial will be registered at the U.S. National Library of Medicine under ttps://www.clinicaltrials.gov.

2 BACKGROUND INFORMATION

2.1 The effects of hand hygiene on health

Globally, about 3.3% of deaths are attributable to effects of insufficient water, sanitation, and hygiene (WASH), of which 53% occur in sub-Saharan Africa (1). Similarly, 4.6% of the global disability-adjusted life years (DALYs) can be attributed to inadequate WASH (1). These numbers are likely to be underestimating the true effects of WASH on the global burden of diseases, as they only stem from quantifiable effects. Examples are malaria, diarrheal diseases, soil-transmitted helminthiasis, and Schistosomiasis, which are often neglected or not representatively reported (1). Moreover, important health outcomes such as mental health or maternal and neonatal adverse health effects are not included in the calculations for the health effects attributable to insufficient WASH.

Despite recent efforts to increase hygiene during the coronavirus disease 2019 (COVID-19) pandemic, one third of the global population lacked access to basic hygiene in 2020 (2). Basic hygiene is defined as having a handwashing facility on premises with water and soap (3). On the African continent, more than half of the population did not have access to basic hygiene and 28% did not have any handwashing facility (3). When considering the regions of Africa, West African countries have the worst access to basic hygiene services, with 35% of the population not having any handwashing facility. Within the countries, inequalities persist between geographic regions and urban and rural areas (3).
Hand hygiene is crucial to sustain individual and community health. Without proper hand hygiene, pathogens can be easily transmitted from faecally contaminated hands (e.g. after using the toilet, changing diapers, handling animal products) to other people's hands, eyes, and mouths (4). Hence, inadequate hand hygiene can increase the risk for transmission of diarrheal, respiratory, and skin diseases (5-7). Scientific literature reviews report that handwashing education can reduce diarrheal disease prevalence by 23-40% (4-6), respiratory disease prevalence by 16-21% (4, 7), and school absenteeism due to gastrointestinal diseases by 29-57% (8).

2.2 Hand hygiene in health care settings

2.2.1 WASH in health care facilities

One fourth of health care facilities in the world do not have access to basic water services (9). The global baseline report of the United Children's Fund (UNICEF) and the WHO Joint Monitoring Programme (JMP) in 2019 stated that from the 55 mostly low-and middle-income countries (LMICs) which offered data about handwashing facilities at the point of care, only 43% had fully functional stations with soap (10). The likelihood of not having a handwashing facility doubles if the health care facility is a PHCF (9). A study conducted in 14 LMICs found that 37% of sampled health care facilities had water with *E.coli* contaminations, exceeding the WHO guidelines (11).

2.2.2 Health care-associated infections

Health care-associated infections (HAIs) are the most common adverse health effect occurring in health care settings (12). These infections lead to prolongation of hospital stays, disability, the spread of anti-microbial resistant bacteria, excess deaths generating high individual and societal costs (13). LMICs are disproportionately affected by HAIs with a prevalence ranging from 5.7-19% in mixed patient populations of hospitals (12, 14).

Beyond improving community health, proper hand hygiene is also crucially important in health care settings. A systematic literature review reports that multi-component hand hygiene campaigns resulted in a median effect of 49% (12.7-100%) reduction of HAIs (15). The World Health Organization (WHO) strongly promotes good hand hygiene practices in health care with guidelines, toolkits, and the WHO Multimodal Hand Hygiene Improvement Strategy (16). There is a lack of

studies investigating single-component interventions, rendering it difficult to estimate the true effect of hand hygiene alone (15, 17).

2.2.3 Hand hygiene of HCWs (HCWs)

Global estimates about hand hygiene of HCWs are scarce. The WHO estimates that in high-income countries hand hygiene compliance in health care settings hardly surpasses 70% (18). In LMICs, only 9% of critically ill patients are treated with best practices in hand hygiene (18). In sub-Saharan Africa, handwashing prevalence at critical moments differs across countries with about 20% in Burkina Faso (19, 20), 8% in Mali (21), 15% in Uganda (22), and 55% in South Africa (23). The low prevalence in these studies were explained with a lack of knowledge and insufficient infrastructure.

2.3 The hands4health project

This project is funded by the Swiss Development Cooperation (SDC) (https://hands4health.dev/) and aims to increase hygiene in schools and PHCFs without any direct access to water in the context of humanitarian crises. The project has a strong focus on the Sustainable Development Goal (SDG) 6, clean water and sanitation. In addition, the SDG 1 (no poverty), SDG 3 (good health and wellbeing), SDG 4 (quality education), SDG 5 (gender equality), SDG 10 (reduced inequalities), and SDG 11 (sustainable cities and communities) are targeted (24). The project is led by 10 partners from academia, non-governmental organizations (NGOs), and the private sector. To increase the level of hygiene, an intervention package consisting of (i) a handwashing station called Gravit'eau, (ii) a behaviour change intervention from Ranas Ltd., a spin-off company of the Swiss Federal Institute of Aquatic Science and Technology (Eawag), (iii) capacity development and training for chlorination of water storage by Fachhochschule Nordwestschweiz (FHNW), (iv) the low-power, wide area networking protocol (LoRaWan) technology (only for Mali) and (v) the Water and Sanitation for Health Facility Improvement Tool (WASH FIT) and (vi) the management of WASH infrastructure at facilities, including water storage, water distribution, handwashing and sanitation by FHNW. The Gravit'eau is designed by Gravit`eau Association, evaluated by FHNW previously together with Gravit`eau and will be tested by the FHNW with filters supplied from the company Martin Systems. The Ecole Polythechnique Fédérale de Lausanne (EPFL) will test different graywater disinfection methods. The behavioural change intervention will be designed and lead by Ranas Ltd. The NGO Terre des hommes (Tdh) will support the intervention and all data collection with local teams and expertise and cooperates with Green Cityzen to test the LoRaWan technology. The Swiss Tropical and Public Health Institute (Swiss TPH) will lead the efficacy assessment of the project. Skat Foundation will coordinate the development of a systematic approach to facilitate handwashing in institutional settings, as well as develop an overall Theory of Change (ToC) for the intervention and a stakeholder engagement strategy. The ToC process, which will be continued throughout the project duration, and the systematic approach are directly related – both processes provide feedback to each other. One of the main results will be a Theory of Action (ToA), which will help the field and project teams to plan and implement their activities in a strategic and targeted way. The ToC aims to help local teams and the researchers to understand how the local WASH system works in PHCFs of the project countries, and to identify the interplay of actors and factors that shape the overall system dynamic.

2.3.1 Gravit'eau handwashing station

Gravit'eau is a handwashing station which recycles water with gravity (25). The station does not need to be connected to an electricity source as it is activated by a foot pump. The design of the station is adaptable to the context of use and can hold up to 90 litres of water. The used water is collected and is treated using gravity in a grease trap and by the gravity-driven membrane filtration. The membrane module contains ultrafiltration membrane that removes pathogenic microorganisms. In health care facilities, chlorine can be added as a second barrier. The then pathogen-free water is stored in a storage tank until its next use (http://www.graviteau.ch). To keep an acceptable water quality also in terms of color, the water needs to be replaced about once a month and the filter needs to be replaced every five to eight years (25).

In contrast to pre-existing handwashing stations using a bucket with a tap, Gravit'eau can save time and water resources by reducing the frequency of refilling the water tank from once a day to once a month. Consequently, more water can be saved for other purposes such as drinking or sanitation and the time efforts of the staff of the facility is reduced as well. Moreover, the station is built by local contractors using local materials, which enhances durability, facilitates maintenance and offers an opportunity to adapt the design to the needs of the facility and the context (like the size of the doors in facility, inside or outside, etc.). So far, the station has been tested in a laboratory at FHNW, in a German Music Festival, in mobile health clinics in Palestine, in child-friendly spaces and schools in Nigeria, and in health clinics in Mali. However, these tests did not involve long-term data collection. In order to scale up the use of Gravit'eau, the station needs to be tested in the field for at least nine months to take into account daily use, seasonal water shortages, local adaptation, and climate conditions.

2.3.2 Behavioural change intervention

The risks, attitudes, norms, abilities, and self-regulation (RANAS) model was developed based on theories from environmental and health psychology in order to systematically change behaviour (Figure 1). To change behaviour effectively, the underlying behavioural factors need to be addressed and changed (26). According to the developers of the RANAS approach, "[RANAS] is an easily applied method for measuring behavioural factors, assessing their relevance for the target behaviour, designing tailored strategies that change the target behaviour, and measuring the effectiveness of these" (Mosler and Contzen, 2016: 5) (26). The RANAS approach consists of four phases: (i) identification of potential behavioural factors through an explorative phase with qulitative data collection tools; (ii) measurement of these factors with a questionnaire and determination of the relevant factors steering the behaviour (i.e. hand washing with soap) through statistical analyses; (iii) selection of behaviour change techniques from a standardized catalogue of Behaviour Change Techniques and development of campaign activities; and (iv) implementation and evaluation of these behaviour change activities. The RANAS approach is always tailored to the local context and takes into account a wide range of potential behavioural barriers and motivators based on the RANAS model, namely risk factors, attitude factors, norm factors, ability factors and self-regulation factors as well as social, physical and personal context. Ranas trains local "Ranas experts" and supports them in developing their own behaviour change activity catalogue which will be thoroughly piloted before implementation. The RANAS approach has been applied successfully in a variety of settings to change hygiene behaviour (27-30).

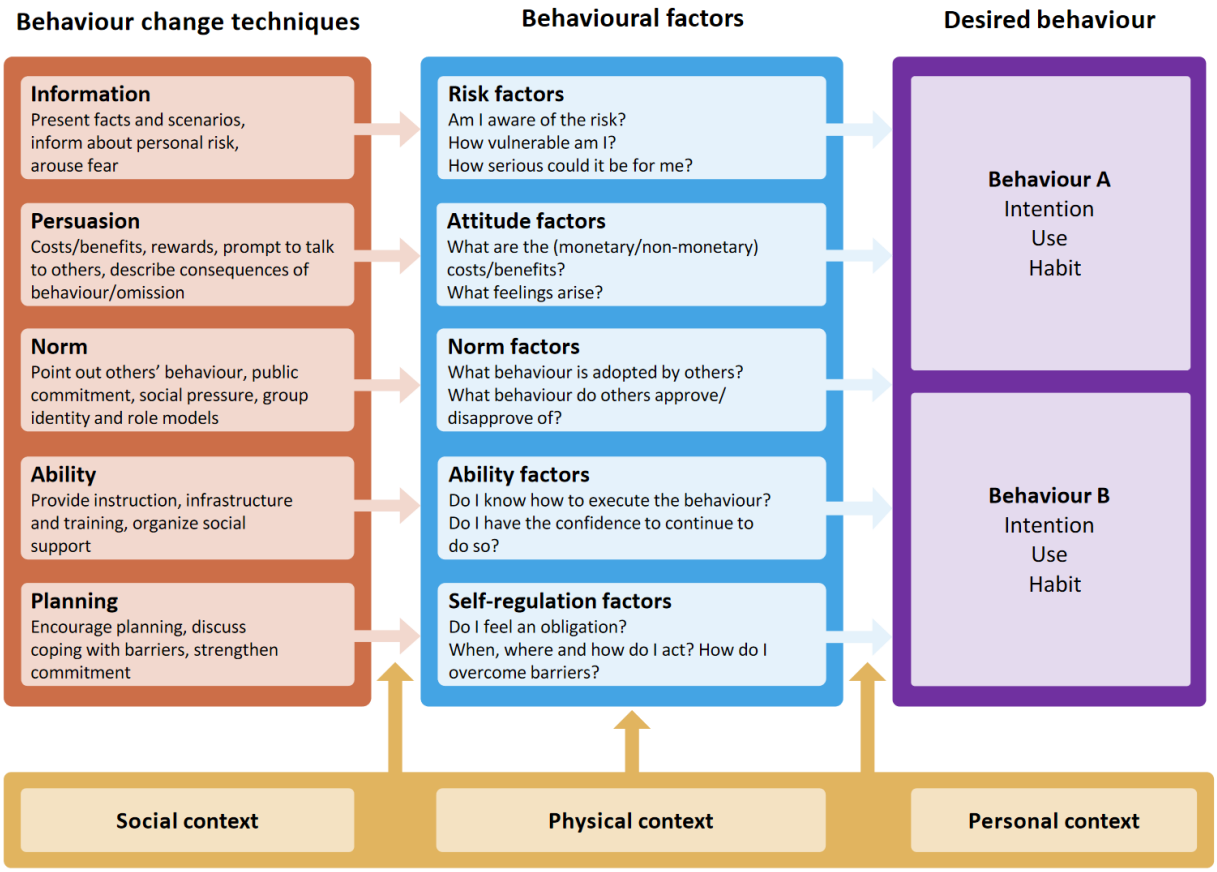


Figure 1: RANAS model for systematic behaviour change (26)

2.3.3 Capacity development and training for chlorination of water storage

Chlorination of drinking water and handwashing water is mandatory in the health care facilities. However, the staff does not always have an understanding of the procedure of chlorination and the monitoring of the concentrations of residual chlorine in the water. Additionally, HCFs might be missing tools for the chlorination and monitoring processes. The staff needs to be able to ensure water is chlorinated regularly and properly and require:

- hardware to dose and monitor chlorine to be available
- existing and functional supply chain for chlorine products
- knowledge on how to dose the chlorine, measure concentrations and
- knowledge on how to dose the chlorine.

FHNW support the Tdh team to choose the equipment to dose and monitor chlorine concentration considering the forms of chlorine available on the local market. During the training of trainers workshop we will train the teams and representatives of the health authorities on these aspects and discuss with them the possibility of training the staff of the facilities and supporting the overall maintenance of infrastructure to introduce controlled chlorination. The Tdh and Cesvi teams will train the staff of the facilities afterwards and review the management systems to ensure the long term supply chains are functional and there is quality control and monitoring in place.

2.3.4 LoRaWAN technology

The Graviteau project is looking for a solution to monitor the Gravit'eau handwashing station to ensure that the service is provided. Greencityzen is supporting us to deploy Internet of Things (IoT) solutions in health centres to secure the water supply. The LoRa-based solution has proven to be a viable concept. The Greencityzen HummBox IoT platform also allows the integration of third-party sensor information (https://www.greencityzen.fr/home/).

2.3.5 WASH FIT

The WASH FIT process is a risk-based approach to improving and sustaining WASH and biomedical waste management infrastructure and services in health facilities in LMICs developed by the WHO and the United Nations Children's Fund (UNICEF) (31). The WASH FIT process is an improvement tool that should be implemented consistently and regularly, with the objective of firstly helping health facility staff and administrators prioritise and improve their services and secondly, supporting national, regional or district level efforts in health care improvement (31).

The Wash FIT methodology includes behavioural changes for infection prevention and control (IPC) such as hand hygiene, biocleaning of equipment and surfaces, medical waste management; changes in infrastructure, and maintenance and repair.

The main goal of the h4h project is to empower the PHCFs covered by this study in the participatory (technical staff, Community health Associations, local authorities, communities) and sustainable management of WASH services in general and in the ownership of the Gravit'eau system by PHCF managers in particular.
The implementation of the WASH Fit approach by Tdh and the health authorities will include the following 5 steps of the classic WASH Fit approach by WHO and UNICEF) (31):

o Setting up the WASH Fit team (technical staff, Community health Associations, local authority, communities);

o Conducting the initial assessment;

o Identification and prioritization of improvement actions;

o Development and implementation of the progressive improvement plan;

o Ongoing monitoring of the effectiveness of the plan and its periodic review.

2.3.6 The management of WASH infrastructure at facilities

The support in the management of the WASH system in each institution will be carried out according to improvement plans resulting from the WASH Fit process led by the PHCFs. In this context, regular visits of a technician, trained and equipped with proper tools under the supervision of the WASH Fit committee could be delivered. The visits aim to provide preventive maintenance to WASH infrastructures and/or support the capacity development of the institutions' staff in daily management. The goal is to treat small issues before they grow in magnitude.

According to the local context and needs, appropriate activities might be the following:

- Providing routine maintenance of WASH infrastructure and equipment
- Providing regular follow-up to the staff in the proper operation of WASH infrastructure, basic maintenance, water treatment methods, and responding to additional training requests from staff as needed
- Build the capacity of facility managers on budget planning for the maintenance of WASH equipment
- Providing timely repairs (e.g. plumbing fixtures and water supplies, latrines, handwashing stations)
- Inspecting and servicing latrines, tanks, sinks, handwashing stations
- Conducting water quality tests to ensure drinking water standards are met
- Reporting on WASH functionality to the relevant stakeholders
- Conducting assessment and identification of further needs

2.4 Study setting: WASH in humanitarian emergencies

This project will take place in Mali and Burkina Faso in rural areas from the year 2021 to 2024. Both countries are located in the West African Sahel zone and are known for their political instabilities (32, 33). In recent years, jihadists and other radical groups have been terrorizing the population leading to a rise in internally displaced people (IDP) (32, 33). Additionally, these countries were affected by the impact of the COVID-19 pandemic threat has swept the world (34). This state of emergency impacts various determinants of health, such as WASH.

The right to water and sanitation is a human right which is expressed as an international law and has to be upheld by affected states during conflict situations (35). Poor WASH has been identified as one of the key risk factors for communicable disease outbreaks in humanitarian emergencies (36). In these situations, sanitation infrastructure is often overburdened, water quality is poor, the water quantity is insufficient, and crowding occurs (37). During acute emergencies, globally 40% of children's deaths in camps are attributable to diarrheal diseases (38).

Hand hygiene promotion is often included in campaigns by NGOs and the United Nations during emergencies. However, these campaigns are mostly administered at community household level and do not target people in health care (39, 40).
In Mali, the project will take place in the region of Ségou in the sanitary districts of Markala, Macina, San, and Tominian (Fig. 2). The official language in Mali is French and in the study regions, most people speak and understand Bambara (32).

In Burkina Faso, the study takes place in the Boucle du Mouhon region and in the provinces of Mouhoun, Nayala, and Sourou. Apart from the official language French, the people in the study provinces mostly speak and understand Moré or Dioula (33). Information about potential project health care facilities assessed in a pilot phase of the h4h project can be seen in Table 1.

In both countries, the areas studied are affected by armed extremist groups, but humanitarians are not targeted and Tdh has security and humanitarian access experts who ensure adequate security standards are met based on a localised risk analysis. Security management is ensured by focusing on the accessibility and acceptance of interventions including this project. In addition, the potential of armed groups moving further into the study regions provokes worries about maintaining access to water sources, which are already scarce.

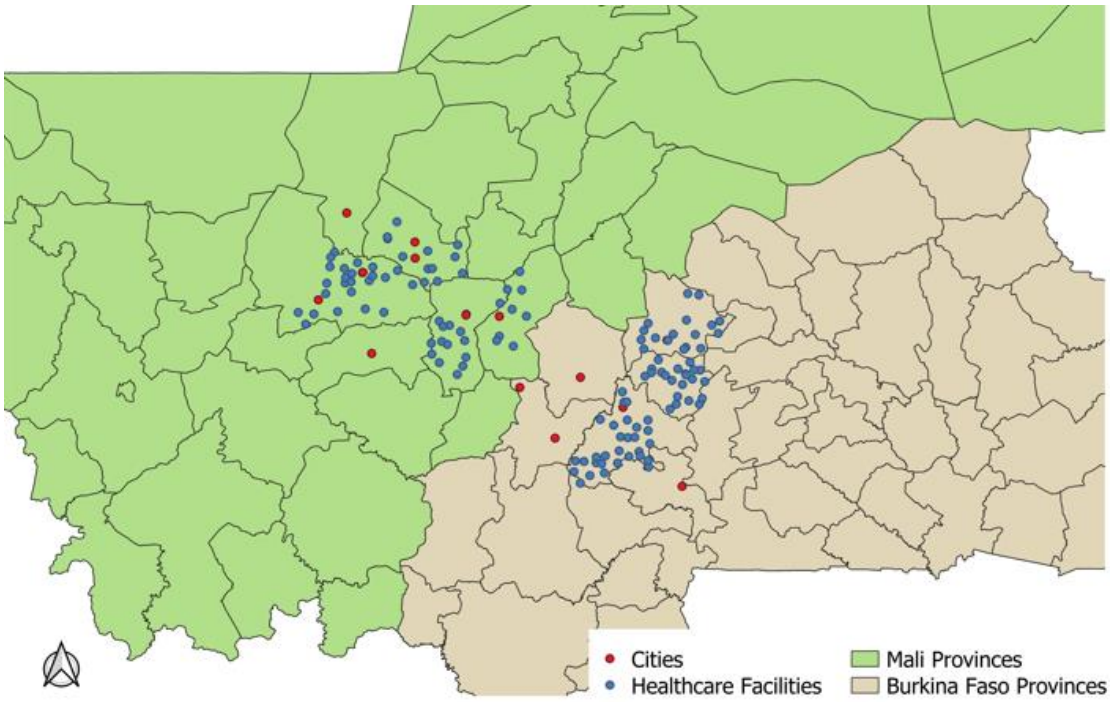


Figure 2: Map of potential health care facilities assessed in a pilot phase of the h4h project in the provinces of Markala, Macina, San, and Tominian in Mali, and in the provinces of Moughon, Nayala, and Sourou in Burkina Faso.

Table 1: Health care facility information assessed during a h4h pilot phase*

Characteristic	Measure	Mali (n=60)	BF1 (n=53)	BF2 (n=48)
Number of employed staff	Median	6.0	8.0	5.0
Number of outpatients during the busiest month	Median	365.0	470.0	651.0
Total number of births during the busiest month	Median	19.0	17.0	18.0
Water source which is not directly accessible in the building	Percentage	65.0	86.8	83.3

* Due to security concerns in the facilities of the first pilot phase in Burkina Faso (BF1), a second pilot phase (BF2) took place in more accessible facilities. Both are displayed in the table.

3 OBJECTIVES AND PURPOSE

3.1 Study rationale and objectives

3.1.1 Study rationale

Despite increased awareness about the importance of hand hygiene in the post-COVID-era and global efforts to improve WASH, data gaps about access to basic hygiene persist, especially in rural sub-Saharan Africa (3). Hand hygiene in health care facilities is crucial for the prevention of HAIs. Unfortunately, data about HAIs in LMICs is scarce due to the lack of diagnostic facilities, patient records, and necessary expertise of HCWs in HAI control and surveillance (12, 13). The few available data on HAIs are usually collected in tertiary care settings (hospitals) because patient follow-up is much easier with in-patients and HAIs can better be distinguished from community-acquired infections (41). Consequently, there is a big data gap on the occurrence of HAIs in primary health care settings in LMICs (13). Overall, HAIs in LMICs are estimated to be higher than in high-income countries because infection control measures rarely exist, staff lack the necessary training, insufficient infrastructure and hygiene material and the health facilities are often overcrowded by populations with high prevalence of infectious diseases (13). The most commonly reported HAI in LMICs is the surgical site infection, caused by unhygienic procedures of the HCWs (12).

Hand hygiene interventions have been proven to be effective in reducing a variety of infections in community, school and health care settings (4, 7, 8). However, information about additional benefits of these interventions is rarely available. Evidence about satisfaction, saving of costs or other resources, and the number of patients visiting the PHCFs would be important indicators for the success of an intervention.

Knowledge about the effectiveness of hand hygiene campaigns in the context of humanitarian emergencies is extremely scarce due to the lack of baseline data and monitoring and evaluation activities (37, 39). In conflict settings, hand hygiene is mostly being investigated in community settings, but not in health care facilities where infections can easily spread (39, 40). In addition, data mainly relies on self-reporting and can therefore rarely be triangulated. Moreover, information about barriers and motivators of handwashing campaigns in emergency settings is scarce (37). Finally, data on handwashing interventions in complex emergencies is rarely shared publicly and therefore is not being used to inform other handwashing campaigns (37).
The Gravit'eau handwashing station is a promising invention to increase access to water in settings suffering water scarcity and humanitarian crisis. However, its impacts on health determinants and outcomes of its users have to date never been assessed in a real-world setting over long time periods (25). For scaling up the use of Gravit'eau, scientific evidence about its impact and potential barriers for implementation are much needed.

3.1.2 Primary objective

Evaluate the effects of the comprehensive h4h handwashing intervention on hand hygiene in PHCFs in Mali and Burkina Faso.

3.1.3 Secondary objectives

3.2 Additionally to the primary objective, the h4h project aims to address the following secondary objectives and research questions:

1) Assess hygiene-related risks, attitudes, norms, abilities and self-regulation (RANAS) behavioural factors of health care providers

RQ 1.1: What is the level of hygiene-related RANAS behavioural factors of health care providers?

RQ 1.2: What is the current water and hygiene infrastructure of the health care facility?
RQ 1.3: Are hygiene-related RANAS behavioural factors associated to selected independent variables (demographic indicators, previous training, water infrastructure, etc.)?

2) **Assess the effect of the h4h intervention package on hygiene-related RANAS behavioural factors of health care providers**
RQ 2.1: Can the h4h intervention package be associated to a change in hygiene-related RANAS behavioural factors of health care providers?
RQ 2.2: Which factors promote the uptake of the intervention?
RQ 2.3: Does the change in hygiene-related RANAS behavioural factors differ between the two study countries?

3) **Explore perceived effects on health and wellbeing of the hands4health intervention package in PHCFs**
RQ 4.1: What are the perceived potential effects of the h4h intervention package?
RQ 4.2: How can the h4h intervention be further improved to fit the local needs?
RQ 4.3: What are potential barriers for district / region / country-wide implementation of the h4h intervention?
RQ 4.4: What are the potential opportunities for district / region / country-wide implementation of the h4h intervention?
RQ 4.5: How did the HCWs perceive the implementation of the h4h intervention package?

3.2.1 Explorative objectives

1) **Assess effects of the h4h intervention package on health outcomes and absenteeism**
RQ 3.1: What are the differences in hygiene-related health outcomes of patients in the health care facilities receiving the h4h intervention compared to control facilities?
RQ 3.2: What are the differences in absenteeism due to disease in HCWs over time in the two arms of the h4h study?

3.3 Scientific justification of study population

The study countries were both chosen because they have been affected by ongoing conflicts caused by armed extremist groups over the past years (32, 33) while suffering severe water shortages (42, 43). In Mali, the region of Ségou hosted in May 2022 35’702 IDP. This is the highest number of IDP in a still accessible region of Mali. Mopti, Tombouctou, and Gao hosted more IDP but are not secure enough to visit (44). Additionally, the region of Ségou was described in the last WASH cluster report of Mali as one of the regions with one of the highest needs for water acces while having only very few NGOs working in the area (42). In 2019, Tdh`s evaluation in 60 Health centres in the Ségou Region showed that 59% had no WASH service and 34% had limited service. Similary, the Boucle du Mouhoun region in Burkina Faso is one out of six regions affected by a water crisis in the country (43). Boucle du Mouhoun hosted in February 2022 almost 81’000 IDP. PHCFs were chosen as study clusters for several reasons: (i) NGO interventions usually focus on communities and do not specifically target health care facilities (39, 40), (ii) access to water in health care facilities is crucial to avoid the spread of HAIs (15), (iii) research about HAIs in PHCFs of LMICs is very scarce (41). Finally, (iv) if HCWs can protect themselves from infections, the health care facility is more likely to have a sufficient number of staff members, who can then deliver their service to the population. Tdh has established offices in Mali and Burkina Faso supporting health and WASH interventions in health care facilities to complement its maternal, newborn and child health programme. Tdh collaborates closely with local authorities and most relevant stakeholders who expressed their support to this project.

4 STUDY DESIGN

The overall project will follow an multi-center cluster-randomized controlled trial (cRCT) design (Figure 3). Prior to this study, the Facility and Evaluation Tool for WASH in Institutions (FACET)

has been used to assess the WASH infrastructure of the PHCFs in the study regions. From these PHCFs a subsample was identified which fulfils certain inclusion criteria (for the inclusion criteria see chapter 5.2 Inclusion criteria).

This subsample was handed over to the local Tdh collaborators who carefully assessed the security situation around the facilities. The Tdh collaborators then chose 24 facilities which are most probable to still be accessible for data collection within the next year. These 24 PHCFs will then be distributed into two arms (intervention vs. control) with stratified randomization using computer-generated randomization code provided by an statistician not involved in any field activities. The intervention arm will receive the full intervention package (handwashing station, behavioural change intervention, capacity development, management support, chlorination training and WASH FIT). The control arm will receive nothing for the duration of the intervention (9 months). Afterwards they will receive the same intervention package with potential improvements identified in the former intervention group.

In the chosen PHCFs all HCWs present at the day of data collection who fulfil the inclusion criteria will be asked to participate in the study. We aim to have as many of the HCWs in all of the Modules 1 and 3 as possible. For Module 2, only a maximum of 10 HCWs per facility will be observed.

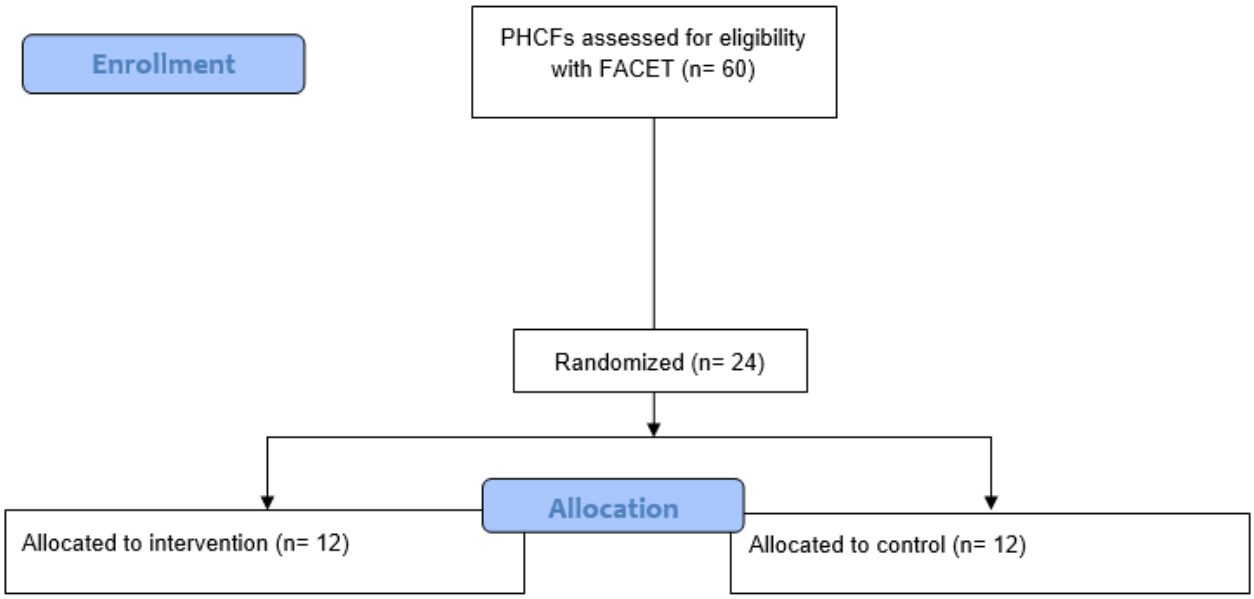


Figure 3: Consort flow diagram of the PHCF selection for the h4h cRCT in Mali

The methods to achieve the different objectives of this project are summarized in Table 2. These modules will include qualitative and quantitative data approaches in order to enable a triangulation of the overall project results. The following modules will be used in the cRCT and the overall project: (i) Module 1: Combined RANAS and KAP survey, (ii) Module 2: Structured handwashing observations, (iii) Module 3: Microbiological analysis of hand rinse samples, (iv) Module 4: Diary approach for pre-defined health outcomes, (v) Module 5: Focus Group Discussions (FGDs) and (vi) Module 6: Key informant interviews (KIIs).

Table 2: Overview of different project modules and analysis by objective

Module	Objective	Analysis
Module 1: Combined RANAS and KAP survey	SO1: Hygiene-related RANAS behavioural factors of HCWs at baseline	- Descriptive statistics, multiple linear and logistic regression models
Module 2: Structured handwashing observations	SO1: Hygiene-related RANAS behavioural factors of HCWs at baseline SO2: Impact of h4h intervention on hygiene-related RANAS behavioural factors of HCWs	- Descriptive statistics, multiple linear regression models and logistic regression models
Module 3: Microbiological analysis of hand rinse samples	SO1: Hygiene-related RANAS behavioural factors of HCWs at baseline SO2: Impact of h4h intervention on hygiene-related RANAS behavioural factors of HCWs	- Analysis of *E. coli* and total coliforms - Descriptive statistics, multiple linear regression models
Module 4: Diary approach for pre-defined health outcomes	EO1: Effects of h4h intervention package on health outcomes and absenteeism	- Descriptive statistics
Module 5: Focus Group Discussions	SO3: Perceived effects of the h4h intervention package	- Framework methodology
Module 6: Key informant interviews	SO3: Perceived effects of the h4h intervention package	- Framework methodology

The Swiss TPH assessed the health care worker's understanding of hygiene and expected positive and negative impacts of the intervention with Gravit'eau with focus group discussions (FGDs) in 18 facilities in Mali and 9 facilities in Burkina Faso (more facilities are still being investigated). Local collaborators from Tdh and the regional ministries of health were involved from the study's kick-off meeting onwards and are regularly being consulted in bi-weekly meetings and additional ToC workshops led by Skat Foundation. The data collection methods for each module will be described in further detail:

Module 1: Combined RANAS and KAP survey: The survey will be developed through the RANAS approach and will not only include attitude and belief questions, but also target the underlying psychological factors postulated by the RANAS model that are important precursors for effective behaviour change (43). If needed, this survey will be enriched with additional questions to assess knowledge and self-reported handwashing practices of the participants. The survey will be administered to HCWs three times in total; as a baseline survey before the intervention package, about two months after the intervention and about a year after the baseline survey with the software Open Data Kit (ODK) Central (version 2022.3.1) on Android tablets.

Module 2: Structured handwashing observations: Structured handwashing observations are perceived as a gold standard method to assess handwashing behaviour (12, 44). Data from Module 1 and the observations can later be combined through a unique ID of the study participants. The observations will be administered with HCWs three times at the same time points

as the survey in Module 1. In this study, two scenarios for structured observations are suggested. They will be chosen according to what functions better and is deemed more appropriate by our local collaborators during the piloting phase. Scenario 1 is a structured handwashing observation by a trained observer, whereas scenario 2 is the observation of a consultation room with a camera at the ceiling.

Scenario 1: A trained observer from a Tdh team, who normally works in the health care facilities with a different function will visit the facility under the pretence of their usual function. They will be equipped with an observation tool and will follow a healthcare worker for a minimum of one hour at the peak time for patient visits. The observer will not declare that he/she is observing handwashing practices. Consent will be obtained at a health care facility level, from the director of the health care facility. To avoid making patients feel uncomfortable during sensitive procedures, such as giving birth, only patient visits containing physical examination, injection, and blood sampling will be observed and the patients will be asked for their oral consent prior to entering a room with them.

Scenario 2: A small camera will be placed at the ceiling of a consultation room in a way that heads are only seen from above and patient's remain unrecognizable. At the beginning of the study, the HCWs will be informed that the cameras will operate several hours a day to observe their quality of care. They will be asked to give consent prior to the installation of the cameras. In addition, each patient will be informed before entering the consultation room and they will be asked for their consent as well. The recordings of 1 hour intervals during peak time of patient visits will be analysed by a researcher from the h4h team.

Module 3: Microbiological analysis of hand rinse samples: Hand rinse samples of HCWs will be collected after the survey with a modified glove juice method as described by Pickering et al. 2010. First, the enumerators will visually assess the cleanliness of the participant's hands with an observation form prompting for visible dirt in different areas of the hands, such as the thumb and under the fingernails (28, 45).

For the hand rinse sample collection, the enumerators will have to wear sterile gloves. The participant's randomly selected hand will be inserted into a 69-oz Whirl-Pak bag (NASCO Corp., Fort Atkinson, WI) filled with 350 mL of clean water. Then, the participant has to shake her/his hand in the water and rub her/his thumb and fingers together for 15 seconds. Afterwards, the enumerator will massage the participant's hand through the bag for another 15 seconds. The participant will be provided with a paper towel to dry the hand, once it is retrieved from the bag (45). Afterwards, the procedure will be repeated with the other hand.

The Whirl-Pak bags containing the samples will be kept on ice in an isolation box and processed within 4 hours of sampling (45). Membrane filtration will be used to detect colony-forming units (CFUs) of *E.Coli* and total coliforms. In a field laboratory, the content of the bags will be passed through a 47-mm-diameter 0.45 µm cellulose filter. The filter paper will then be placed on growth media and incubated at 35°C ± 0.5°C for a duration of 24 hours for *E.Coli* and total coliforms (45). We plan to filter 100 mL per bag to detect CFUs of *E.Coli* and total coliforms. The exact amount of mL will be established during piloting as the volume used is dependent on the degree of bacterial contamination on the hands. Compact dry plates will be used for the detection of *E.coli* and total coliforms.

The lower detection limit of CFUs will be calculated by dividing 1 CFU/plate by the filtrate volume and then multiplying it with the total Whirl-Pak volume of 350 mL. The upper detection limit will be calculated by dividing 500 CFUs/plate by the filtrate volume and then multiplying it with the Whirl-Pak volume. For the statistical analysis, the CFUs per hand will be normalized and and $\log_{10}$ transformed (45).

Module 4: Diary approach for pre-defined health outcomes: Longitudinal data on hygiene-related health outcomes of patients and disease-related absences of HCWs will be collected during

9 months after the intervention in both of the study arms from the cluster-randomized controlled trial with a diary approach (Table 3). Every time a pre-defined health outcome takes place at facility level, this outcome will be reported in a diary by the director of the PHCF (or someone who was appointed by the director). No patient names or birth dates will be recorded to keep this data fully anonymous. For each health outcome the director will report when it happened, if applicable how long it took, if applicable the number of days of treatment, if known the reason for the outcome and if it was an infection the outcome (recovered, death, unknown) (Table 3). These health outcomes either occur directly at the health care facility, if the facility offers inpatient care, or are reported if the patients report their outcome after a visit (e.g. by calling or re-visiting the facility). The diary consists of one table per month containing all of the different health outcomes and subcategories. Consequently, the HCWs can keep track of these outcomes with a minimal administrative effort. The local study team is still discussing if a paper table, which will be collected once a month will be used, or if alternatively, the team sends the doctor in charge once a month a mobile survey to fill in the data.

Module 5: Focus Group Discussions: The FGDs will be used to capture the common norms and beliefs of the HCWs. This tool offers many insights in shorter time compared to other qualitative methods such as participatory observation (46, 47). Data will be collected by a small local team with experience in qualitative data collection and if the security situation allows, by the Swiss TPH PhD student in autumn 2023. The team containing at least one moderator and one observer/note taker will be trained by the PhD student prior to data collection. A field research journal will be used throughout the study to take structured notes and observations of the FGDs. The discussions will be audio recorded and then transcribed into the local language and translated to French or English for further analysis.

Field notes, observation notes and focus group transcripts will be analysed using the framework method with the software MaxQDA (VERBI Software, Marburg, Germany) or NVivo (QSR International, Melbourne, Australia) (48).

Module 6: Key informant interviews: The KIIs will engage with other stakeholders outside of the health care facilities who have an influence on the intervention areas of the project. Some of these key informants will have been identified through the Theory of Change analysis, while others will be suggested by local partners. Individual interviewees were chosen as a tool to gain the insights of these stakeholders, such as people from the ministry of health or the mayor, so that their status does not influence other participant's freedom of speech (47). The KIIs can be additionally used to inquire further about questions or topics which came up during the FGDs. Further, the format of interviewing can also be used on the health care facility level, in case not enough participants are available for a FGD. The KIIs will take place in autumn 2023.

Interviewers will receive the same training as for the Focus Group Discussions. The interviews will be audio recorded and then transcribed into the local language and translated to French or English for further analysis. In some instances, interviews may be carried out remotely (online) from Switzerland, in French, if it is appropriate. They will be audio recorded, transcribed, and translated if necessary for further analysis.
As the FGD transcripts, the interviews will be analysed using the framework method with the software MaxQDA (VERBI Software, Marburg, Germany) or NVivo (QSR International, Melbourne, Australia) (48).

4.1 Primary endpoint

The primary endpoint is the number of times a participant performs good handwashing practice with soap at critical moments assessed by structured handwashing observations over half an hour to an hour per HCW. The number of critical moments serves as denominator. Critical moments are defined by the WHO as:

i) Before touching a patient
ii) Before clean/aseptic procedures
iii) After risk/exposure to body fluids
iv) After touching a patient
v) After touching a patient's surroundings

4.2 Secondary endpoints

The most important secondary endpoints in the survey are:

A) Self reported handwashing practice to answer for each critical moment on a Likert scale ranging from almost never to almost always.
B) The log-transformed number of total coliforms and E.coli CFUs per hand before handwashing.
C) Hygiene-related health outcomes which are summarized in table 3. The sum of each outcome variable seperately per facility will be used as a measure for statistical analysis. The health outcomes will be reassessed with local experts of the respective countries to assure feasibility before the start of the intervention.

Table 3: Hygiene-related health outcome variables for Module 4.

Outcome variable	Details
Absenteeism of health care worker	• Record of the event • Number of days absent • Reason for absence
Maternal mortality	• Record of the event • If known, reason of passing
Neonatal mortality	• Record of the event • If known, reason of passing
Neonatal sepsis(49)	• Record of the event • Number of days treated • Outcome (healthy, unknown, death)
Umbilical cord infection	• Record of the event • Number of days treated • Type of infection • Outcome (healthy, unknown, death)
Wound infection after stitching of surgical procedures	• Record of the event • Number of days treated • Outcome

Covariates were assessed with a directed acyclic graph (DAG) with RANAS variables as exposure variables and good handwashing practice as outcome variable (Appendix). Covariates for estimating the total effect of RANAS on good handwashing practice are age, education, sex, socio-economic status, previous training in hygiene, handwashing practices, position in the health care facility, and the water infrastructure of the health care facilities.

4.3 Measures to minimize bias

Different biases might arise in this project. To prevent selection bias and confounding in the two study arms, we will use stratified block randomization to balance the two arms with respect to important baseline characteristics. Due to the nature of the intervention, neither the participants, nor the data collectors of the study, nor the statistician can be blinded. However, to reduce

selective counting of CFUs on the hand-rinse samples, the lab workers assessing the number of CFUs will be blinded.

In Module 1, the RANAS and KAP survey, we expect a recall bias and a desirability bias. To minimize the recall bias, participants will not be asked to report any events which have taken place longer than a week ago with the exception of one question about their last training on handwashing. To reduce the desirability bias, the people administering the survey will not lable themselves clearly as Tdh staff members, because local people know that Tdh often delivers humanitarian aid in the region and might want to impress the Tdh team. Additionally, to reduce any study personnel bias, the data collectors will all receive a training in advance. Their ID will be recorded in the survey form in order to be able to conduct quality control.

For Modules 1 to 3, data collectors have to upload the completed surveys every night, once they have a stable internet connection. All of the surveys will have the data collector's ID. The PhD student from Swiss TPH will control every second day how long the data collectors took to complete a survey, if certain answers are always the same for specific data collectors and the amount of missing data per survey. In addition, the GPS location of the tablet will be recorded to make sure that the data collection actually took place at the predefined location. These components will be correlated in the statistical software R (version 4.1.3) to test for significant differences between data collectors. In case a data collector delivers significantly different results which are not deemed realistic by the Swiss TPH study team and the local main correspondent of Tdh, the staff will be asked to comply to predefined rules once. If they still do not comply afterwards, they will be replaced. Faulty data from these staff members can then not be used any more for analysing the results of the h4h project. Modules 1-3 will be repeated two months after the intervention and nine months after the intervention. For Module 5, the proportion of reported health outcomes per year will be correlated with the health care facility four times during the survey year.

For Module 2, the handwashing observations, a Hawthorne effect is to be expected. Once the participants notice that they are being observed, they might change their behaviour accordingly. We will not be able to completely eliminate this bias. However, by not declaring that the observer is part of the h4h project, the participants will not know that the observer is focussing on handwashing behaviour. In scenario 1 of the observation technique, a bigger Hawthorne effect is expected, as people can ignore a camera more easily than an observer who constantly takes notes. However, we expect that with scenario 2 more handwashing opportunities or actions will not be clearly visible because the HCW or patient might obscure the view from the camera by their position in the room.

In Module 3, the microbiological analysis, a study personnel bias could influence the quality of the hand rinse samples and the accuracy of counting the CFUs. To be aware of differences between the data collectors, their ID will be stored during the sample collection on ODK. The number of CFUs per plate will be correlated with the people who collected the data to see if there are any significant differences between data collectors. The people counting the number of CFUs will be blinded and therefore do not know if the sample comes from the intervention or the control group. Additionally, every 10^{th} sample will be duplicated during the data collection and the CFUs on every 10^{th} plate will need to be counted additionally by another staff member as a quality control.

In Module 4, the reporting of pre-defined health outcomes, different biases might arise. Depending on how dutifully the HCWs report and on the severity of the outcomes, a detection bias might occur. We will test for this bias by correlating the health care facility with the proportion of reported outcomes over a year. In order to intervene in case such differences exist, we will correlate the data in each quarter of the study year as a form of quality control. In addition, a form of selection bias can happen if a certain group of patients does not report back after suffering any form of infection they contracted at the health care facility. For example, if neonatal sepsis occurs, patients might directly go to a tertiary health care facility instead of a PHCF. We are aware that this module is suboptimal due to a rather small sample size and a lack in possibilities of patient-follow up.

However, this is only part of an exploratory objective. We still think that if differences can be observed between the two intervention arms, this module is of high importance as it would demonstrate the significance of good hand hygiene in PHCFs. If these differences can be demonstrated on a local level, motivating local HCWs for future handwashing interventions might become easier.

To assure the quality and functioning of the Gravit'eau handwashing stations, regular integrity tests and water quality tests will show if the systems are still functional and capable to remove the bacteria. *E.coli* tests of handwashing water will show if there is any recontamination or any integrity problem. In case there is a problem, we will provide an alternative solution (e.g. bucket with soap) and rehabilitate the handwashing systems or dose chlorine into handwashing systems and repeat the test.

In case a facility has 25% higher negative health outcomes than the average of all facilities, the regional Ministry of Health will be consulted to check if this is usual. If not, the study will have to be stopped in this facility.

4.4 Study duration and duration of participant's participation

HCWs will be regularly approached for data collection. First, the data collection phase starts with the observations and is then followed by the Ranas questionnaire and the hand-rinse samples (Figure 3). For practical reasons, the hand-rinse samples can be taken right after the questionnaire.

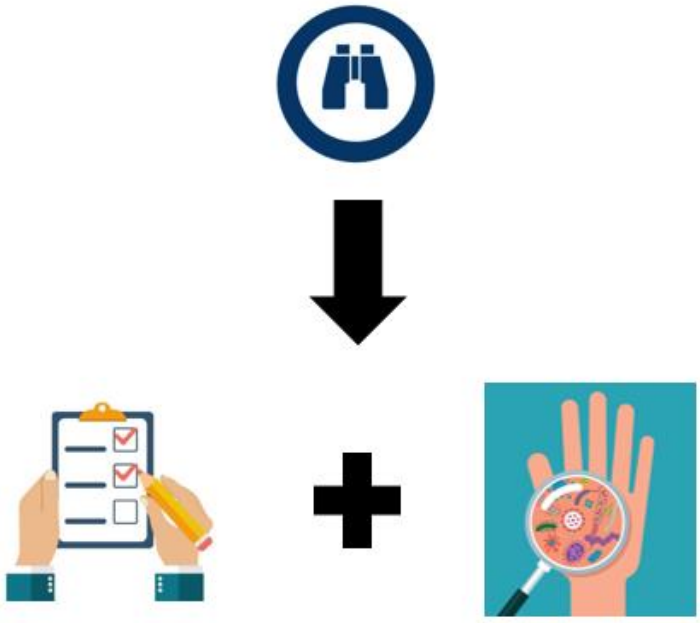


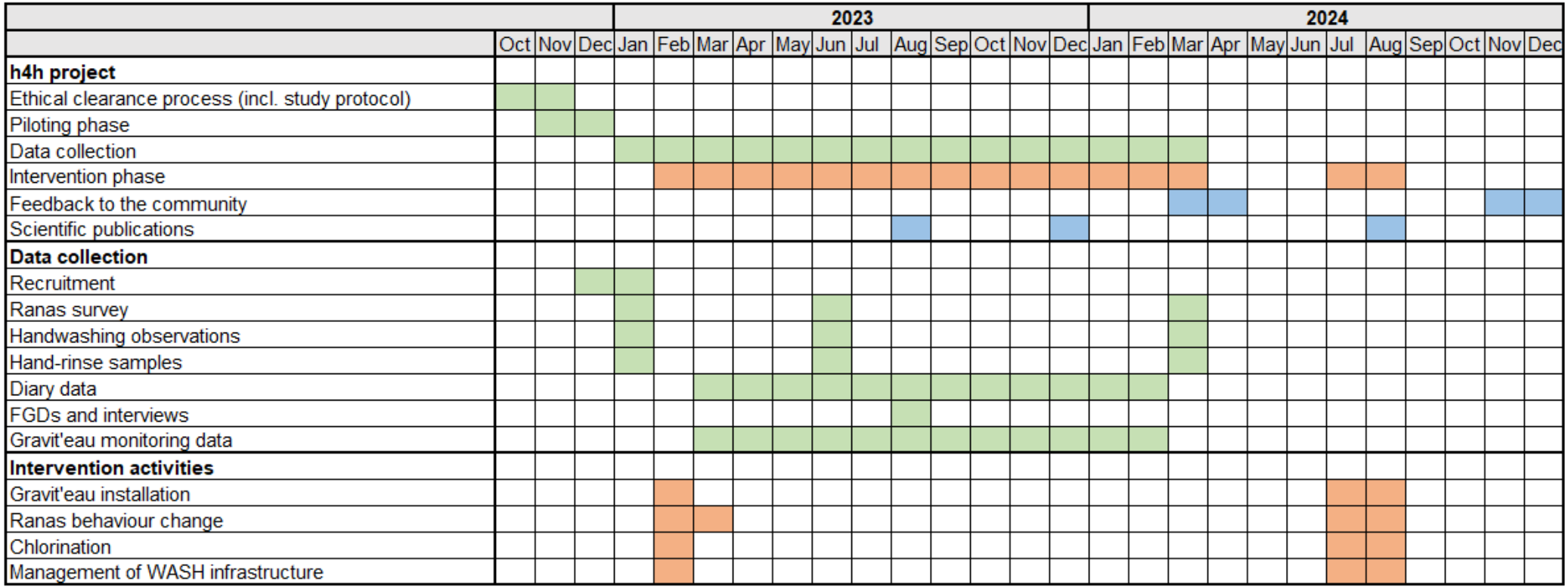
Figure 4: Flow-chart of data collection activities at baseline, follow-up and endline of the project depicting observations, the Ranas questionnaire and the hand-rinse samples.

The observations will take approximately 30 minutes to one hour per HCW depending on how many patients visit and hence how many handwashing opportunities arise. The questionnaire will take a maximum of 40 minutes and the hand-rinse samples about 10 minutes. This means that for the Ranas questionnaire and the hand-rinse samples together with the informed consent, the participant will be asked for about an hour of his/her time.

Entering the pre-defined health outcomes in the diary over the course of the year will not take much time of the HCWs. To write down an event will take the HCW about two minutes per event.

Finally, the HCWs of the 12 intervention facilities will be asked to take part in FGDs or interviews. This should not take them longer than one hour. KIIs with stakeholders outside of the health care facilities will also be limited to one hour.

4.4.1 Schedule of events



4.5 Amendments

All of the different modules will be piloted in pilot facilities of the study regions and adapted to local needs and circumstances.
Substantial changes to the project set-up; the protocol and relevant project documents will be submitted to all of the Ethics Committees for approval according to the local and Northern EC guidelines.

4.6 Withdrawal and discontinuation

Participants may stop their participation at any time and withdraw their consent. Local staff is recruited and employed by Tdh and has to follow the terms and conditions of the local Tdh offices which are written in their work contract.
The overall h4h project or specific project sites can be discontinued due to several reasons by the project leader, such as:

- Ethical concerns (e.g. non-acceptance of proposed technical solutions)
- Insufficient participant recruitment
- Natural hazards (e.g. heavy floods, earthquakes)
- Damage and vandalism of infrastructure, technical failure of interventions
- Alternative interventions and projects at the same facilities not coordinated with us
- Limited access by Tdh staff due to any reason out of their control including pandemics, natural hazards or deterioration of security situation
- Political constraints restricting access to the health care facilities or the project implementation

4.7 End of project

The biological material from the microbiological analysis will be destroyed upon completion of data analysis. Health-related data will be stored in an anonymized form for a minimum of 10 years at a password protected server of Swiss TPH. Photos, videos and recordings from the project will be stored on a password protected server of Swiss TPH, Terre des hommes or FHNW. If photos or videos contain pictures of people, they will be asked for their oral consent.

5 SELECTION OF STUDY PARTICIPANTS

5.1 Recruitment

Recruitment will differ according to the study modules. Participants will always be recruited within the clusters (HCFs). For the surveys (Module 1) and the microbial testing (Module 3), all HCWs in the intervention facilities will be targeted. For the handwashing observations (Module 2), a maximum of ten HCWs will be followed. If a PHCF has more than ten HCWs, they will be selected at random by drawing blindly their names from a closed bag. The patients who will be in contact with the HCWs during the observation period will all be asked to participate and to allow the observer to watch the interaction with an oral informed consent.

For the FGDs (Module 6), HCWs from the intervention arm of the h4h study will be invited to participate. If more than 3-4 HCWs are present at the day of the FGD, they will be selected randomly and asked for their consent to participate. In addition, the potential of inviting patients or their care takers will be explored in order to assess if the h4h intervention brings noticeable changes and improvements on the level of quality of care. Structures of hierarchy and gender in the health care facilities will be identified with the local partners to avoid mixing strongly differing hierarchies in mini groups of 3-4 participants. The group size of HCWs will be kept small as the participants should all have high expertise in hand hygiene in the intervention group (46). Depending on the hierarchical levels and if patients will be invited for discussion, one to four FGDs will take place per facility. If the FGDs are only done with HCWs, 6-10 FGDs per country will take

place or until saturation[1] is reached. In case interviews are held within the HCFs instead of FGDs, we expect to have 10-20 interviews or until saturation is reached.

For the KIIs (Module 7), local partners will be consulted on who they see as a suitable stakeholder for an interview. The sampling procedure will therefore be a purposeful sampling. Interviewees will be contacted by the local partners. Interviews will be held until saturation is reached.

5.2 Inclusion criteria

Study participants will be HCWs of the PHCFs which were chosen to be included in this study. PHCFs were chosen based on accessibility for the study teams, not having a water source directly connected to the building of the facility, having a maternity ward, having at least five employees and being impacted by conflict. All of the HCWs who are present in the PHCFs of the day of data collection will be invited to participate in the project for Modules 1 and 3.

Inclusion criteria Modules 1-3: HCWs must fulfil all the inclusion criteria:
- Minimum age of 18 years
- HCWs, men and women, who are in direct (body) contact with the patients

During the handwashing observations, health workers will consult with patients. In order to protect patients, they must meet these inclusion criteria for an observer to be allowed into the consultation room with them:
- Minimum age of 18 years or be accompanied by a legal guardian 18 years or older.
- Going to the SSE for a physical examination, injections/vaccinations or blood test.
- Oral consent to enter the room with them

Inclusion criteria Module 4: As the data will be collected on the health care facility level, all facilities in the project will be included.

Inclusion criteria Module 5:
- HCWs of the intervention facilities
- Minimum age of 18 years

Inclusion criteria Module 6:
- The participant needs to be:
  a) a stakeholder within the community, state, region or country of the intervention who's position is related in any way to WASH in HCFs
  b) working in one of the intervention PHCFs. They do not need to be HCWs, they can also be hygiene technicians or in a leading position of the facilities.
- Minimum age of 18 years

5.3 Exclusion criteria

Exclusion criteria Modules 1-3: HCW participants must not fulfil any of the following exclusion criteria:
- HCWs, whose primary occupation is not in the PHCF of the h4h project
- Suffering from any skin conditions not allowing the HCW to use soap or alcoholic hand rub
- Refusals to participate

Exclusion criteria Module 5: Refusals to participate.

[1] Saturation is reached when answers of participants start repeating and no new information can be gained through additional FGDs.

Exclusion criteria Module 6: Refusals to participate

5.4 Criteria for discontinuation of study

5.4.1 Discontinuation of individual participants

A participant can be discontinued from the study for the following reasons:

1. Withdrawal of informed consent
2. Changing work situation
3. Long-lasting absence of at least 6 months
4. Death
5. Inaccessibility of the HCF due to a high risk security situation

6 STATISTICS

6.1 Hypothesis

6.1.1 Primary hypothesis

The primary hypothesis stems from the research question: Does the h4h handwashing intervention package increase the hand hygiene of HCWs in PHCFs in Mali and Burkina Faso?

$H_{1.1}$= The comprehensive h4h handwashing intervention increases hand hygiene in primary HCWs in Mali and Burkina Faso.

$H_{0.1}$= The comprehensive h4h handwashing intervention will have no effect on hand hygiene of primary HCWs in Mali and Burkina Faso.

6.1.2 Secondary hypotheses

Depending on the secondary objective, different secondary hypotheses were formed:

$H_{1.1}$= Hygiene-related RANAS variables will differ between participants based on their demographic indicators, previous training, and the water structures available in the health care facilities.

$H_{0.1}$= Hygiene-related RANAS variables will not differ between participants based on their demographic indicators, previous training, and the water structures available in the health care facilities.

$H_{1.2}$= Hygiene-related RANAS variables of health care providers in the intervention facilities will be significantly better compared to the health care providers in the control facilities.

$H_{0.2}$= Hygiene-related RANAS variables of health care providers will be the same in health care providers of intervention and control facilities.

$H_{1.e}$= Hygiene-related health outcomes will be significantly less frequent in intervention health care facilities compared to control health care facilities.

$H_{0.e}$= Hygiene-related health outcomes will be the same in intervention health care facilities and control health care facilities.

6.2 Determination of sample size

To determine the required sample size, we run a series of simulation using the software R. Assuming a mean number of six staff members (range two to nine) per health facilitry and a mean number of five times a person was supposed to wash their hands (SD=5) and an intra cluster correlation coefficient of 0.15, we need to enrol 10 health facilities in each trial arm to detect difference of 15%-points in the proportion of handwashing during the five criticall moments of the WHO (30% control versus 45% intervention) with 81% power at a two-sided 5% significance level. To account for potential loss to follow-up we aim to enrol in total 24 health facilities.

For Modules 1 and 3, all HCWs who are present during data collection and eligible will be asked to participate in the study. For Module 2, the observations a maximum of 10 HCWs per PHCF will be followed in order to avoid disturbing the daily routines of the PHCF too much. Module 4 follows the sample size calculation of the cRCT design, hence 24 PHCFs will be monitored. For Module 5, 6-10 FGDs will be administered and for Module 6, 10-20 interviews.

6.3 Description of statistical methods

Baseline characteristics will be summarized using descriptive statistics. The difference in the observed proportion of always handwashing in the five critical moments as defined by WHO between two study arms at follow-up will be investigated using mixed effect logistic regression models with random intercepts for health care facilities. In the primary analysis only the intervention will be included as predictor.

6.3.1 Datasets to be analysed, analysis populations

For the primary analysis we will use the available case population of HCWs which will be analysed according to the intention-to-treat principles.

6.3.1.1 Primary Analysis

Module 1: Combined RANAS and KAP survey: The data will be summarized using descriptive statistics. Associations of RANAS behavioural factors with good handwashing practices and health care worker's characteristics with the other outcome variables from RANAS behavioural factors will be estimated using random effect linear regression modelling and random effect logistic regression modelling. Missing data will clearly be reported but not imputed.

Module 2: Structured handwashing observations: To quantify the intervention effect logistic regression with binomial distribution with random intercepts for health care facilities models will be applied.

Module 3: Microbiological analysis of hand rinse samples: For investigating factors associated to *E.coli* and total coliform prevalence on HCWs hands, random effect linear regression models will be applied.

Module 4: Diary approach for pre-defined health outcomes: . The sum of each outcome variable separately per facility will be used as a measure for statistical analysis. To quantify the intervention effect on hygiene-related health outcomes, random effect linear regression modelling will be used.

Modules 5 and 6, FGDs and KIIs: FGDs and KIIs will be audio recorded, transcribed, and translated if necessary for further analysis. The local perception of the success and sustainability of the h4h intervention will be analysed using the framework method with the software MaxQDA (VERBI Software, Marburg, Germany) or NVivo (QSR International, Melbourne, Australia) (48).

6.3.1.2 Secondary Analyses

In a secondary analysis the models will be adjusted for known confounder and additional predictors imbalanced at baseline.

6.4 Handling of missing data

Because imputation of missing data in cluster randomised trials is challenging, no imputation of missing data will be done.

7 DESCRIPTION OF DATA MANAGEMENT

7.1 Specification of source documents

The source documents needed in this study are listed in the table below:

Source document	Where can the source document be found / way of collection	Storage

List of health care facilities	Produced during the pilot phase of the h4h project with a Facility and Evaluation Tool for WASH in Institutions	Electronic storage in password-protected secure server at Swiss Tropical and Public Health Institute and FHNW
Informed Consent Forms (ICFs)	Will be signed at the health care facility and scanned	Destruction of paper form and storage of the scan on the password-protected secure server of Terre des hommes.
Electronic case report form (CRF) for the Ranas and KAP survey	Will be collected with a password-protected tablet with automatic deletion of data after transmission to server	Electronic storage in password-protected secure server at Swiss Tropical and Public Health Institute, Switzerland and during the study duration on a password-protected Swiss TPH Laptop of the local study coordinator.
Electronic CRF for the structured handwashing observations (scenario 1)	Will be collected with a password-protected tablet with automatic deletion of data after transmission to server	Electronic storage in password-protected secure server at Swiss Tropical and Public Health Institute, Switzerland and during the study duration on a password-protected Swiss TPH Laptop of the local study coordinator.
Electronic videos of handwashing observations (scenario 2)	Will be collected with a video camera which will be collected by the Tdh research teams from the study site.	Video material will be stored electronically in a password-protected secure server at Swiss TPH, Switzerland and during the study duration on a password-protected Swiss TPH Laptop of the local study coordinator. The material on the video tape will be directly deleted after the transfer to the secure server.
Electronic CRF for the microbiological handrinse samples	Will be collected with a password-protected tablet with automatic deletion of data after transmission to server	Electronic storage in password-protected secure server at Swiss Tropical and Public Health Institute, Switzerland and during the study duration on a password-protected Tdh Laptop of the person responsible for data entry.
Paper & electronic CRF for FGDs	Will be read and moderated to the participants during the FGDs	Electronic storage in password-protected secure server at Swiss Tropical and Public Health Institute, Switzerland and during the study duration on a password-protected Swiss TPH Laptop of the local study coordinator. Paper CRF will be disposed at the study centre after the FGD.
Electronic and paper output of FGDs	Audio recordings of the FGD will be transcribed in a word file on a password-protected Tdh Laptop.	Electronic storage in password-protected secure server at Swiss Tropical and Public Health Institute, Switzerland and during the study duration on a password-

	FGD notes from the field journal will be collected	protected Tdh Laptop of the person responsible for transcription. The written paper notes will be stored in a locked cabinet at the study site.
Electronic and paper output of KIIs	Audio recordings of the KII will be transcribed in a word file on a password-protected Tdh Laptop.	Electronic storage in password-protected secure server at Swiss Tropical and Public Health Institute, Switzerland and during the study duration on a password-protected Tdh Laptop of the person responsible for transcription. Any written paper notes will be stored in a locked cabinet at the study site.
Participant identification list	Will be obtained during the baseline survey	Locked cabinet at study site (only accessible by field coordinator and the staff conducting the follow-up surveys)
Paper or electronic CRF for spot checks of Gravit'eaus	Data entry into a table on paper or an excel sheet at the study site. If previously collected on paper, the data will have to be entered into an excel sheet in a second step.	Electronic storage in password-protected secure server at Swiss Tropical and Public Health Institute, Switzerland and during the study duration on a password-protected Tdh Laptop of the person responsible for data collection. If the data is being collected on paper, storage is in a locked cabinet at the study site.
Paper CRF for the diary approach of hygiene related health outcome reporting	Data will be collected continuously in the health care facilities by HCWs on monthly sheets of paper. Once a month, Tdh staff then collects these paper sheets.	First in a locked cabinet at the health care facility and after pick up by Tdh in a locked cabinet at the Tdh office.
Electronic CRF for the diary approach of hygiene related health outcome reporting	Data will be entered from the paper CRF to an excel sheet	Electronic storage in password-protected secure server at Swiss Tropical and Public Health Institute, Switzerland and during the study duration on a password-protected Tdh Laptop of the person responsible for data entry.

7.2 Data recording and source data

Informed consent, the participant identification, the structured observation CRF, the spot check CRFs, and the health outcome diary CRFs will be obtained on paper forms. All the forms will then be stored in a locked cabinet at the study site at the Tdh office. Participant identification will not be kept in the same cabinet as the rest of the forms.

The survey CRF will be collected electronically using password-protected tablets from Swiss TPH and Open Data Kit (ODK) software (University of Washington, Seattle WA, USA). The content on the tablets will be deleted automatically after the transmission to the server at Swiss TPH, Switzerland. The server is secure and password protected. The list of healthcare facilities,

electronic CRFs for the handwashing observations, the microbiological analysis, and the health outcome diary, and the transcripts of the FGDS and KIIs will be stored on the same password protected Swiss TPH server. Microsoft Word and Excel documents will have a clear and uniform name structure including the place of data collection, date and version number to guarantee data traceability. Each time someone works at one of these documents, they have to store it under an updated name with a new version number and date.

7.3 Confidentiality and coding

Project data will be handled with uttermost discretion and is only accessible to authorized personnel who require the data to fulfil their duties within the scope of the research project. On the CRFs and other project specific documents, participants are only identified by a unique participant number (ID). The CRFs contain the ID assigned to the participant by the field staff. The name of the participant will be kept in a separate confidential enrolment log that matches identifying codes with the participants' names and residencies during the study. This will only be accessible by the local study coordinator and the people conducting the survey. The document will be stored in the locked cabinet on site and destroyed after the end survey in order to completely anonymize participants.

Biological material (the hand rinse samples) in this project is not identified by participant name but by a unique participant ID. Biological material is appropriately stored in a restricted area only accessible to authorized personnel for a maximum of 48h to be analysed.

7.4 Retention and destruction of study data and biological material

The study data, including video and audio material, will be stored on the Swiss TPH server and stays there for a time span of 10 years after publication of the research project. The informed consent forms on paper will be kept in a folder, locked at the study site for 10 years. After 10 years electronic data will be deleted and the papers will be shredded and disposed of. The participant identification list and the paper informed consent forms after scanning will be immediately destroyed after the end survey to guarantee anonymity after the survey.

Biological material, more specifically the compact dry plates containing hand-rinse samples will be destroyed and disposed after a maximum of 48 hours. The plates have to be disinfected before being disposed of in waste bins. This can either happen by a) putting them into a covered bucket containing 1% bleach solution over night. The next morning, the bleach solution will be emptied into the waste water and the plates can be disposed in a plastic bag in any normal waste bin. Or b) the closed plates are placed in a pot of boiling water for a minimum of 10 minutes. After the water cools, it can be emptied into the waste water and the plates can be disposed in a waste bin.

7.5 Data security, access, archiving and back up

An electronic data capture system (EDCS) will be set up which allows to accurately reflect what happened with the study data and the CRFs during the lifetime of the study. This includes a computer-generated time-stamped trail that records all actions performed on the databases (e.g. the individual performing an alteration). For the paper-based CRFs entries and changes need to be signed and the dated.

The EDCS contains access restrictions which makes sure that data can only be accessed by qualified and appropriately trained staff who are part of the study delegation, allow for checking the user access against the study delegation log including its documentation, and ensures that the Standard Operating procedures are in place.
Data is stored on the server of the study centre and back up.
All study data must be archived for a minimum of 10 years after study termination or premature termination of the study.

8 QUALITY CONTROL AND QUALITY ASSURANCE

8.1 Supervision / Continuous Checks

For the Modules 1 to 3, the electronically collected CRFs will be uploaded to the server every evening. The Swiss TPH PhD student (Anaïs Galli) will therefore be able to control the data collection process remotely and intervene if necessary. Additionally, there will be regular debriefings with the data collection staff to react to arising problems or questions. As for the start of Modules 1 to 3, also for Module 5, the Swiss TPH PhD student will be based close to the study locations if the security situation permits. Like this daily debriefings about the FGDs can take place and if the security situation permits, the PhD can even join the discussions to observe. In case the PhD student is not able to travel, a minimum of bi-weekly debriefings with the field staff will take place online via Zoom.

8.2 Confidentiality, data protection

All people involved in the study will have access to the study protocol. On request, the protocol can be shared with other parties as well. The participant identification list used for coding is only accessible by the local field coordinator and the people conducting the survey in order to know whom they have to visit. After the end survey, the participant identification list will be destroyed and not accessible to anybody. The datasets and statistical code will be available to everyone involved in the study who needs it in the anonymized form. Data can be published and disseminated because it is anonymized. Also, if there are requests for the dataset or the statistical code from third parties, it can be shared in the anonymized form.

8.3 Translations - Reference language

The reference language of all study documents is French.

The survey questions and important key words of the FGD guide will be translated to Bambara, Moré and Dioula by the Tdh staff in Mali and Burkina Faso. The Swiss TPH staff will then come together with the local Tdh staff for a back translation to French and check if the meaning of the words is still appropriate.

8.4 Storage of biological material and related health data

Water samples and hand-rinse samples will be stored in a refrigerator for a maximum of 48 hours until analysis. If unfiltered water is left from health care facilities, it will be discarded in the drain after resting for 30 minutes with 10mg/L of chlorine. For the analysis, CFUs will be counted and the plates will be photographed. The pictures will be stored in the same way as other health-related data. After counting the CFUs and recording the compact dry plates with pictures, they have to be destroyed immediately to prevent any further growth of potentially harmful bacteria (see chapter 7.4 Retention and destruction of study data and biological material).

9 ETHICAL CONSIDERATIONS

9.1 Independent Ethics Committee (IEC)

Any protocol amendments, the informed consent, and all other forms of participant information related to the study and any other necessary documents have to be reviewed by an Independent Ethics Committee (IEC). The following IECs will be asked for approval: the Ethikkommission Nordwest- und Zentralschweiz (EKNZ) in Switzerland, the National Institute of Public Health (INSP) in Mali, and the Comité d'Ethique pour la Recherche en Santé (CERS) in Burkina Faso.

9.2 Risk-benefit ratio

With the h4h intervention the health care facilities will receive much needed handwashing infrastructure. An added benefit of Gravit'eau is that it only has to be refilled with water about once a month. This can save the HCWs precious time at work and water can be saved at the health care facility level to be used as drinking or cleaning water. With the Ranas behaviour change program, the HCWs will receive valuable information on how to maintain a good hand hygiene during their work. This knowledge together with the available infrastructure will enable the HCWs to better protect themselves and their patients against infections. In addition, the HCWs can transfer their knowledge to new staff or their families and communities. Finally, if the intervention helps to foster a better hygiene at health care facility level, the facility might become more attractive to patients and offer a better quality of care.

The control health care facilities will not receive any form of intervention during the the year where the intervention package is being tested in the intervention facilities. However, after this year, they will also receive an intervention package.

Depending on the Covid-19 situation in the study location, a slightly increased risk of infection arises during the FGDs. However, by conducting the FGDs outside with the use of masks and hand sanitizer and by distancing, this risk will be reduced to a minimum. In addition, the Gravit'eau does not contain water for drinking. Health effects of regular ingestion of Gravit'eau water have so far not been tested. By clearly introducing the Gravit'eau as a handwashing station and by clearly labelling the station with signs that signify "no drinking water", this risk will be reduced. During the piloting phase, the most appropriate and understandable signs will be chosen with the local staff.

To conclude, the benefits of this study for the participants, the health care facilities, and the patients clearly outweigh the potential risks for study participants. Moreover, the risk of contracting Covid-19 is already a daily risk for HCWs and might even be reduced through better access to handwashing stations.

9.3 Participant information and consent

The Investigator or his/her representative will explain the nature of the study to the participant according to the guidelines referred to, and answer all questions regarding this study, prior to obtaining informed consent.

In the case of illiterate participants, an impartial witness will be called to make sure that the participant understood the information and agrees. This witness must be independent from the research being conducted and cannot be influenced unfairly by the researchers. For example, a literate relative of the participant is eligible as impartial witness. Both, the participant and the impartial witness must sign the ICF. If the participant does not have a signature, a fingerprint will be sufficient.

For the handwashing observations, the regional directory of health and HCWs in the pilot facilities will be consulted if it is appropriate to receive the signed consent at the end of the study retrospectively in order to avoid any Hawthorne effect. Patients who visit the health care facility during the observation time will be asked for their consent orally, as no patient-related data will be collected. If children visit the facility during this time, their guardian has to give oral consent.

If retrospective consent is not appropriate in the respective country setting, the directors of the health care facilities will be informed and asked for consent at health care facility level at least two weeks prior to the data collection. Their written consent will be sought without letting them know, when exactly the observer will visit.

9.4 Participant confidentiality

The Investigators must ensure that the participant's confidentiality will be maintained. HCWs will be identified on the Case Report Forms with a unique participant ID composed of initials of the study country, a number of the health care facility, and a letter from a to z (e.g. BF-01-a). Patients of the HCWs will not be identified, only their gender and age group will be recorded. The Investigators will keep a separate confidential enrolment log that matches identifying codes with the participants' names and residencies.

9.5 Participants requiring particular protection

People in our study regions belong to a vulnerable population because they are living in close proximity to where violent armed groups are active. However, they are capable of judgement and do not apply for any tutelary authority. The h4h project cannot guarantee protection or evacuation in case of a deterioration of the security situation. However, if the security situation would deteriorate so much that the HCWs and patients cannot come to the facilities anymore, the study would be stopped in the affected location.

Children under the age of 18 are a vulnerable group which will be a part of the study during the structured handwashing observations and potentially also during the FGDs. Children are being considered in this study because most of the patients visiting PHCFs are usually children who are accompanied by their guardians or elderly people (50). To protect the children, their guardian has to sign a written ICF and will be accompanying the child during the whole patients visit while the structured handwashing observations take place. If FGDs are held with patients, the child's guardian will be asked about their perception of the quality of care. The child will not have to actively participate at the FGD.
Neither during the handwashing observations, nor during the FGDs, any particular risk for the children is expected.

9.6 Participant compensation

Participant compensation has been defined with the local partners from Tdh. Participants in the modules 1- 4 will not be compensated individually. Participants attending the focus group discussions and interviews will be offered a snack at the end of the work (water, drink, sandwich). In case a participant is obliged to travel especially for a study-related activity and outside his/her working time at the PHCF, his/her transport will be reimbursed.

9.7 Damage coverage / Insurance

Field staff and collaborators visiting the countries are insured by Tdh Lausanne. For the study participants there is no insurance as the project risk class is A.

9.8 Other aspects

Tdh workers are allowed to assist health care facilities with transport, in case an emergency patient needs to be transportet to the nearest hospital. Tdh does have official evacuation documents for this instance.

Field workers will be briefed before their deployment to the health care facilities about the sensitive nature of this study setting. They will be informed that they might encounter emergencies and see people in a very bad health state. In case that a field worker needs psychological support, Tdh will arrange this.

For the security of the field workers, Tdh has a security department which is responsible for security protocols and updates concerned staff about the safety of visiting certain areas.

10 FUNDING

This project is funded by the SDC within their research programme called TRANSFORM (2020-2030) (see supplementary files for the contract with SDC). The research team attests that there is no conflict of interest and that this study will be conducted independently of outside influences in terms of specific intellectual, financial, and proprietary agendas.

The budget of the h4h project is available as supplementary document.

11 DISSEMINATION OF RESULTS AND PUBLICATION POLICY

Data can be shared between project partners. Whoever was responsible and or involved in the collection of data, has the right to publish this data. People involved in the data collection will be approached to be a co-author of upcoming publications if they are willing to contribute to the paper writing process.

11.1 Dissemination to scientific community; incl. lead in publications

The results of the research will be presented in scientific publications, project reports, a PhD Thesis at conferences and potentially as a MSc Thesis.

11.2 Information of community and policy makers

Key stakeholders have been involved in the project from the beginning with the kick-off workshop in 2021, followed by the co-production of the theory of change. They will be approached again for interviews in 2023. At the end of the project sanitary authorities, policy makers and local key stakeholders will be informed with webinars, sector events and workshops. Former health care facilities which have participated in the study will be informed about the results by the local implementation partners from Tdh.

12 REFERENCES

1. WHO. Safer water, better health 2019 update. Geneva; 2019 Contract No.: Licence: CC BY-NC-SA 3.0 IGO.
2. United Nations The sustainable development goals report 2021. New York, USA: United Nations; 2021. Report No.: 2518-3958 Contract No.: ISBN: 978-92-1-101439-6.
3. JMP. Hygiene: WHO Unicef; 2022 [Available from: https://washdata.org/monitoring/hygiene.
4. Aiello AE, Coulborn RM, Perez V, Larson EL. Effect of hand hygiene on infectious disease risk in the community setting: a meta-analysis. Am J Public Health. 2008;98(8):1372-81.
5. Freeman MC, Stocks ME, Cumming O, Jeandron A, Higgins JP, Wolf J, et al. Hygiene and health: systematic review of handwashing practices worldwide and update of health effects. Trop Med Int Health. 2014;19(8):906-16.
6. Ejemot RI, Ehiri JE, Meremikwu MM, Critchley JA. Hand washing for preventing diarrhoea. Cochrane Database Syst Rev. 2008(1):Cd004265.
7. Rabie T, Curtis V. Handwashing and risk of respiratory infections: a quantitative systematic review. Trop Med Int Health. 2006;11(3):258-67.
8. Wang Z, Lapinski M, Quilliam E, Jaykus LA, Fraser A. The effect of hand-hygiene interventions on infectious disease-associated absenteeism in elementary schools: A systematic literature review. Am J Infect Control. 2017;45(6):682-9.
9. WHO. Water, sanitation, hygiene and health: a primer for health professionals. Geneva, Switzerland2019.
10. WHO & UNICEF. WASH in health care facilities: global baseline report 2019. Geneva; 2019. Report No.: CC BY-NC-SA 3.0 IGO.
11. Guo AZ, Bartram JK. Predictors of water quality in rural healthcare facilities in 14 low- and middle-income countries. Journal of Cleaner Production. 2019;237:117836.
12. WHO. Report on the burden of endemic health care-associated infection worldwide: a systematic review of the literature. In: Organization WH, editor. Patient Safety. Geneva Switzerland2011.
13. WHO. WHO Guidelines on Hand Hygiene in Health Care: First Global Patient Safety Challenge - Clean Care is Safer Care. In: WHO, editor. Geneva2009.
14. Vilar-Compte D, Camacho-Ortiz A, Ponce-de-León S. Infection Control in Limited Resources Countries: Challenges and Priorities. Curr Infect Dis Rep. 2017;19(5):20.
15. Murni I, Duke T, Triasih R, Kinney S, Daley AJ, Soenarto Y. Prevention of nosocomial infections in developing countries, a systematic review. Paediatr Int Child Health. 2013;33(2):61-78.
16. WHO. Hand hygiene: the evidence for clean hands 2022 [Available from: https://www.who.int/teams/integrated-health-services/infection-prevention-control/hand-hygiene.
17. McLaws ML. The relationship between hand hygiene and health care-associated infection: it's complicated. Infect Drug Resist. 2015;8:7-18.
18. WHO. Key facts and figures: world hand hygiene day 2021 WHO2021 [Available from: https://www.who.int/campaigns/world-hand-hygiene-day/2021/key-facts-and-figures.
19. Hien H, Drabo KM, Ouédraogo L, Konfé S, Zeba S, Sangaré L, et al. Healthcare-associated infection in Burkina Faso: an assessment in a district hospital. J Public Health Afr. 2012;3(2):e29-e.
20. Millogo T, Agbre-Yace ML, Kourouma RK, Yaméogo WME, Tano-Kamelan A, Sissoko FB, et al. Quality of maternal and newborn care in limited-resource settings: a facility-based cross-sectional study in Burkina Faso and Côte d'Ivoire. BMJ Open. 2020;10(6):e036121.
21. Allegranzi B, Sax H, Bengaly L, Richet H, Minta DK, Chraiti MN, et al. Successful implementation of the World Health Organization hand hygiene improvement strategy in a referral hospital in Mali, Africa. Infect Control Hosp Epidemiol. 2010;31(2):133-41.
22. Muhumuza C, Gomersall JS, Fredrick ME, Atuyambe L, Okiira C, Mukose A, et al. Health care worker hand hygiene in the pediatric special care unit at Mulago National Referral Hospital in Uganda: a best practice implementation project. Int J Evid Based Healthc. 2015;13(1):19-27.
23. Patel B, Engelbrecht H, McDonald H, Morris V, Smythe W. A multifaceted hospital-wide intervention increases hand hygiene compliance. S Afr Med J. 2016;106(4):32-5.

24. Pradhan P, Costa L, Rybski D, Lucht W, Kropp JP. A Systematic Study of Sustainable Development Goal (SDG) Interactions. Earth's Future. 2017;5(11):1169-79.
25. Gravit'eau. The handwashing station 2022 [Available from: https://www.graviteau.ch/handwashing-station.
26. Mosler HJ, Contzen N. Systematic behavior change in water, sanitation and hygiene. A practi al guide using the RANAS approach. In: Eawag, editor. Dübendorf, Switzerland2016.
27. Chidziwisano K, Slekiene J, Kumwenda S, Mosler H-J, Morse T. Toward Complementary Food Hygiene Practices among Child Caregivers in Rural Malawi. Am J Trop Med Hyg. 2019;101(2):294-303.
28. Contzen N, Meili IH, Mosler HJ. Changing handwashing behaviour in southern Ethiopia: a longitudinal study on infrastructural and commitment interventions. Soc Sci Med. 2015;124:103-14.
29. Friedrich MND, Kappler A, Mosler H-J. Enhancing handwashing frequency and technique of primary caregivers in Harare, Zimbabwe: A cluster-randomized controlled trial using behavioral and microbial outcomes. Soc Sci Med. 2018;196:66-76.
30. Gamma AE, Slekiene J, von Medeazza G, Asplund F, Cardoso P, Mosler H-J. Contextual and psychosocial factors predicting Ebola prevention behaviours using the RANAS approach to behaviour change in Guinea-Bissau. BMC Public Health. 2017;17(1):446.
31. WHO. Water and Sanitation for Health Facility Improvement Tool (WASH FIT): a practical guide for improving quality of care through water, sanitation and hygiene in health care facilities. In: WHO and Unicef, editor. Geneva: World Health Organizaiton2022.
32. CIA. The world factbook - Mali Africa 2022 [Available from: https://www.cia.gov/the-world-factbook/countries/mali/.
33. CIA. The world factbook - Burkina Faso Africa 2022 [Available from: https://www.cia.gov/the-world-factbook/countries/burkina-faso/.
34. Bonnet E, Bodson O, Le Marcis F, Faye A, Sambieni NE, Fournet F, et al. The COVID-19 pandemic in francophone West Africa: from the first cases to responses in seven countries. BMC Public Health. 2021;21(1):1490.
35. Sphere Association. The sphere handbook: humanitarian charter and minimum standards in humanitarian response. Geneva, Switzerland2018.
36. Hammer CC, Brainard J, Hunter PR. Risk factors and risk factor cascades for communicable disease outbreaks in complex humanitarian emergencies: a qualitative systematic review. BMJ Global Health. 2018;3(4):e000647.
37. Vujcic J, Blum L, Ram PK. Strategies and challenges to handwashing promotion in humanitarian emergencies. Atlanta, USA: University at Buffalo, the State University of New York; 2014.
38. Connolly MA, Gayer M, Ryan MJ, Salama P, Spiegel P, Heymann DL. Communicable diseases in complex emergencies: impact and challenges. Lancet. 2004;364(9449):1974-83.
39. Als D, Meteke S, Stefopulos M, Gaffey MF, Kamali M, Munyuzangabo M, et al. Delivering water, sanitation and hygiene interventions to women and children in conflict settings: a systematic review. BMJ Global Health. 2020;5(Suppl 1):e002064.
40. Domini M, Guidotti S, Lantagne D. Temporal analysis of water, sanitation, and hygiene data from knowledge, attitudes, and practices surveys in the protracted humanitarian crisis in Myanmar. Journal of Water, Sanitation and Hygiene for Development. 2020;10(4):806-17.
41. WHO. Hand hygiene in outpatient and home-based care and long-term care facilities: a guide to the application of the WHO multimodal hand hygiene improvement strategy and the "my five moments for hand hygiene" approach. Geneva2012.
42. WASH Cluster Mali. Bulletin du cluster WaSH -Mali: Janvier-Septembre 2018. WASH Cluster Mali
2018.
43. MSF. Burkina Faso: how conflict and climate change are worsening a water crisis Médecins Sans Frontières2021 [Available from: https://www.doctorswithoutborders.org/latest/burkina-faso-how-conflict-and-climate-change-are-worsening-water-crisis.
44. Protection Cluster Mali, Mali Rd. Rapport sur les mouvements de populaitons. 2022.

45. Pickering AJ, Boehm AB, Mwanjali M, Davis J. Efficacy of waterless hand hygiene compared with handwashing with soap: a field study in Dar es Salaam, Tanzania. Am J Trop Med Hyg. 2010;82(2):270-8.
46. Eeuwijk P, Angehrn Z. How to...conduct a focus group discussion (FGD). In: TPH S, editor. Key area of activity (KAA-10) 'Society, culture and health'. Swiss tPH2017.
47. Mack N, Woodsong C, MacQueen KM, Guest G, Namey E. Qualitative research methods: a data collector's field guide. In: Family Health International, US Aid, editors. North Carolina, USA2005.
48. Gale NK, Heath G, Cameron E, Rashid S, Redwood S. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. BMC Medical Research Methodology. 2013;13(1):117.
49. Seale AC, Mwaniki M, Newton CRJC, Berkley JA. Maternal and early onset neonatal bacterial sepsis: burden and strategies for prevention in sub-Saharan Africa. The Lancet Infectious diseases. 2009;9(7):428-38.
50. Diaz E, Mbanya VN, Gele AA, Kumar B. Differences in primary health care use among sub-Saharan African immigrants in Norway: a register-based study. BMC Health Services Research. 2017;17(1):509.

13 APPENDICES

We recommend listing the main appendices (without version nr and date) and to create for each a separate document)