Water, Sanitation, and Hygiene Mobile Health Messages as an Innovative Tool to Facilitate Behavior Change

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JHSPH IRB Research Plan for New Data Collection

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I. Aims of the Study: Describe the aims/objectives of the research and/or the project's research questions or hypotheses.

Aim 1. Develop an evidence and theory based WASH mHealth intervention for households in areas with confirmed cholera patients in Dhaka, Bangladesh through formative research
a. Conduct formative research through in-depth interviews, focus group discussions, and intervention planning workshops with caregivers and household members of young children, and government officials to identify perceptions of WASH behaviors and to inform the development of intervention materials.
b. Pilot the WASH mHealth intervention in a subset of households, and revise according to feedback.

Aim 2: Evaluate the effectiveness of the developed WASH mHealth intervention in increasing WASH behaviors and reducing fecal contamination on hands and in stored drinking water by conducting a RCT
a. Recruit and prospectively follow for 12 months 300 households (1200 participants, 4 per household) with a child under five years of age assigned to one of two study arms (150 households per arm). The first arm will receive the CHoBI7 mHealth program (CHoBI7 mHealth program Arm) and the second arm will serve as a Control Arm and only receive a general message on oral rehydration solution (ORS).
b. Compare the 2 study arms using structured observation of handwashing with soap at stool and food related events, unannounced spot checks of the presence of soap in the cooking and latrine areas of the household, and fecal coliform counts on caregiver hands and in stored drinking water.

II. Background and Rationale: Explain why this study is being done. Summarize briefly what is already known about the issue and reference previously published research, if relevant.

Rationale for New Study. The current CHoBI7 WASH mHealth program focuses on patients and their family members during the time of severe illness in the household, but does not consider neighboring households. Most households surrounding cholera patients will not have had this recent experience of severe illness; because of this perceptions of cholera and the psychosocial factors influencing WASH behaviors may be different for this population. Therefore it is important to tailor the current CHoBI7 intervention for these households living in areas around cholera cases.

III. Study Design:

A. Provide an overview of your study design and methods. The study design must relate to your stated aims/objectives. Details will be requested later. If your study also involves analysis of existing data, please complete Section XI, "Secondary Data Analysis of Existing Data" in the last part of this research plan. If your study ONLY involves analysis of existing data, please use the research plan template for secondary data analysis (JHSPH IRB Research Plan for Secondary Data Analysis of Existing Data/Specimens).

We will conduct 30-40 in-depth interviews (IDIs), 6-8 focus group discussions (FGDs) (60-80 participants), and 3-4 intervention planning workshops (45-60 participants) to identify appropriate mHealth messages for household living in areas where cholera patients have been identified. We anticipate 2-4 focus group discussions with children (20-40 participants). These will be with children only and stratified by gender. This will be conducted with key audience segments including households living in areas identified to have cholera patients, health facility staff and directors, and government officials. FGDs will include pilot and non- pilot participants, pilot participants will be included in FGDs at the end of their surveillance period for the pilot and will be administered a separate consent form. Government officials will include employees at the Ministry of Health and Family Welfare. Health staff will be employees at government and private hospitals, including directors, doctors, nurses, and health educators. IDIs and FGDs will focus on perceptions on WASH behaviors among our target populations, and preferences for intervention delivery. The final number of IDIs and FGDs may vary with the goal of reaching data saturation [1]. All qualitative data will analyzed using ATLAS.ti or a similar software.

After developing the new mHealth modules we will conduct a pilot study to assess the uptake of the intervention. The sample size for the pilot will be 300 participants (~75 households) (60 standard ORS message participants and 240 WASH mHealth participants). The in-depth interviews, focus group discussions, and intervention planning workshops will be conducted in parallel with the pilot. This combined approach will allow us to learn about the effectiveness of our messages in terms of the uptake of the promoted WASH behaviors (through spot checks and structured observation) and participant and stakeholder perceptions around the developed messages (qualitative activities). The pilot study will be conducted using an iterative process where we will have 3 phases. During each phase approximately 80 participants (~20 intervention households) will be given our developed mHealth messages, and 20 participants (~5 households) will receive only the standard message on the use of ORS for dehydration. mHealth messages will be refined and expanded throughout the pilot as we learn more about the effectiveness of our messages in terms of the uptake of the promoted WASH behaviors and participant perceptions of messages. Each household will be followed for a duration of 3 months to investigate sustained WASH practices over time.

Intervention Evaluation

Our objective is to first establish if the intervention can improve our behavioral outcomes and fecal contamination in the household. The primary outcomes are: (1) handwashing with soap at stool and food related events during structured observation, (2) fecal coliform counts on hands and in stored drinking water, and (3) the presence of soap in cooking and latrine areas (within 10 steps) during unannounced spot checks.

Psychosocial factors potentially related to WASH behavior will be measured using a Likert-scale questionnaire at baseline and 1 week, and at the 1, 6, and 12 month follow-up.[2]

Five-hour structured observation will be conducted at baseline, 1 week, and 1 month (habit formation), and 3, 6, 9, and 12 (habit maintenance) months after enrollment to observe handwashing with soap at the following food and stool related events: (1) after using the toilet; (2) after cleaning a child's anus; (3) before eating; (4) before feeding a child; and (5) before preparing food (see our recent publications). [3, 4]

Unannounced spot check visits will be conducted at baseline, 1 week, and 1 month (habit formation), and 3, 6, 9, and 12 (habit maintenance) months after enrollment in households to observe: (1) the presence of soap in the latrine and cooking areas of the household (within 10 steps); and (2) measure fecal coliform counts in stored drinking water and on hands.

Clinical Surveillance. Participants will be asked questions about their health (e.g. diarrhea, vomiting), and if they have visited a health provider for care or have taken medication (e.g. antibiotics) at baseline, 1 week, and monthly thereafter for the 12 month study period. Participants will also be asked about their intervention exposure (e.g. visits and mobile messages received). Child height and weight will be measured at baseline, and 6 and 12 months.

Power Calculation and Statistical Analysis. Our sample size of 300 households is based on the largest number of households we could recruit based our budget. Our power calculation is summarized in Table 2 below. We will compare demographic and socioeconomic factors between arms to determine whether randomization was successful in defining similar groups of households. We will conduct linear regression models for continuous variables and logistic regression models for binary outcomes to compare intervention arms at specific follow-up times. The predictors in these models will be study arm. Generalized estimating equations will be used for individual level variables to account for clustering in the household, as well as comparing the rate of change over time within households. To investigate potential psychosocial factors mediating the intervention effect, mediation models will be performed using the "INDIRECT" macro. [2, 5] All analyses will be performed using SAS 9.3.

Table 2. Power calculation. Detectable differences for outcomes between intervention and comparison arm for 80% power, assuming 10% loss to follow-up among 300 enrolled households resulting in 270 households at the 12 month follow-up

Outcomes	N	Anticipated % in Control Arm (Based on Current Trial)	Detectable Difference Between Intervention and Control Arms
% Individuals handwashing with soap at a stool or food related event during structured observation (100 randomly selected households per timepoint (400 participants at each visit with 10% loss to follow-up))*	360	25%	16%
% Households with soap present in cooking area at a spot check	270	31%	17%
% Households with soap present in latrine area at a spot check	270	51%	17%
% Household with stored drinking water <1 CFU/100 Ml *E.coli* (100 randomly selected households per timepoint)	90	8%	23%
% of Hand rinses samples with detectable fecal coliforms (100 randomly selected households per timepoint with 10% loss to follow-up)	90	90%*	24%

*****Assuming an intra-class correlation of 0.1 for handwashing with soap of individuals in the same household, for a design effect of 1.3.

B. Provide a sample size and a justification as to how you arrived at that number. If you use screening procedures to arrive at a final sample a table may be helpful.

- **In-Depth Interviews (30-40 Participants)**: We will conduct in-depth interviews with key audience segments to identify appropriate mHealth messages, including households living in areas identified to have cholera patients, health facility staff and directors, and government officials.
- **Focus Group Discussions (60-80 Participants, 6-12 participants per group)**: We will conduct focus group discussions with the same segments of key stakeholders as the in-depth interviews to identify appropriate WASH intervention messages.
- **Intervention Planning Workshops (45-60 participants)**: These workshops will be held with government officials and health providers to review mHealth messages, and to discussion integration of these messages into the national program for cholera outbreaks.
- **Pilot Study** (**300 Participants (75 households, approximately 4 participants/household)**): We will recruit 300 participants (~75 households) for a pilot study of developed mHealth messages. We will follow these households prospectively for up to three months to observe the uptake of the promoted behaviors. Modifications of intervention and study tools will be made according to feedback from pilot study participants.

Randomized Controlled Trial (**1200 Participants (300 households, approximately 4 participants/household)**): We will recruit 1200 participants (300 households) for a randomized controlled trial of the developed mHealth messages. We will follow these households prospectively for up to twelve months to observe the uptake of the promoted behaviors.

IV. Participants:

Describe the study participants and the population from which they will be drawn. Specify the inclusion and exclusion criteria. If you plan to include children, note their ages and whether you will include children in foster care. Note if the participants are particularly vulnerable in terms of cognitive limitations, education, legal migration status, incarceration, poverty, or some combination of factors.

Participants will include households living in areas identified to have cholera patients, government officials in Bangladeshi Ministry of Health and Family Welfare, and health facility staff and directors. Study participants will be recruited from Dhaka, Bangladesh. The majority of the study population will be Asian, but that is not an inclusion/exclusion criteria. Children living in households will be included in the pilot of the developed intervention approaches. There is no age restriction for enrollment into the pilot trial or randomized controlled trial newborn or older). For the In-Depth Interviews and the Focus Group Discussions we will include only participants that are 12 years of age and older. For the Intervention Planning workshops we will only include adults 18 years of age or older.

Individuals under 18 years of age who are married or otherwise considered “emancipated” will complete the consent form and if not considered “emancipated”, a parent may complete the Parental Permission Form.

- **Inclusion Criteria:**

Eligibility Criteria

- **In-depth Interviews and focus group discussions** will include households living in areas identified to have cholera patients, health facility staff and directors, and government officials. In-depth interview and focus group discussion participants living in areas with identified cholera patients must have: (1) at least one household member reporting ownership of an active mobile phone in their possession on the day of enrollment; and (2) must also have a child under 5 years of age in their household.
- **Intervention planning workshops** will include government officials in the Bangladeshi Ministry of Health and Family Welfare and health facility staff and directors.
- **Pilot households** must have: (1) at least one household member reporting ownership of an active mobile phone in their possession on the day of enrollment; (2) must also have a child under 5 years of age in their household; and (3) must plan to reside in their household for the next three months.
- **Randomized Controlled Trial** participants must have: (1) at least one household member reporting ownership of an active mobile phone in their possession on the day of enrollment; (2) must also have a child under 5 years of age in their household; (3) must live in an area identified to have cholera patients by the icddr,b surveillance system; and (4) must plan to reside in their household for the next 12 months

- **Exclusion Criteria:**

Children in foster care will be excluded from all research study activities. If the interviewer becomes aware when talking to an adult respondent (18 years or older) that they appear to have a cognitive limitation, an adult household member may sign the Consent form on their behalf.

No one will be excluded because of age, sex, religion, or sexual preference.

Children younger than 12 years of age will be excluded from the in-depth interviews, focus group discussions, and workshops. Children younger than 12 years of age will not complete the psychosocial factors.

NOTE: If you are recruiting participants or receiving, accessing, or using data from a U.S. health care provider, HIPAA review is likely to be required. If you plan to bring identifiable health information from a foreign country to a U.S. covered entity (e.g., lab at the Hopkins SOM), HIPAA may be triggered. Check "yes" to the HIPAA question in the PHIRST application.

V. Study Procedures:

In this section, provide details of your procedures, particularly as they relate to human subjects. If this is a multi-center study, make the role of JHSPH clear. If the JHSPH will serve as **data coordinating center**, indicate in the sections below which procedures JHSPH will not be performing. Additional information regarding data coordinating centers is requested in a later section. If your study will develop in phases, address each item below by phase.

A. Recruitment Process:

1. Describe how you will identify, approach, and inform potential participants about your study. Include details about who will perform these activities and what their qualifications are.

Participants in the in-depth interviews, focus groups discussions, intervention planning workshops, and pilot will be recruited by trained research assistants from icddr,b through a combination of purposive and convenience sampling strategies. Individuals participating in an in-depth interview may also be invited to participate in a focus group discussion. Government officials and health facility staff and directors will be contacted by phone or approached at their office. Pilot participants will be selected across the geographic catchment area of Dhaka, Bangladesh based on the neighborhoods (wards) where cholera patients are identified. Randomized controlled trial participants will be randomly selected across the geographic catchment area of Dhaka, Bangladesh based on the neighborhoods (wards) where cholera patients are identified. All potential participants will be read a recruitment script, given an opportunity to ask questions, and then screened and consented to participate by trained icddr,b research assistants. Adults in study households will be recruited before children.

2. Address any privacy issues associated with recruitment. If recruitment itself may put potential participants at risk (if study topic is sensitive, or study population may be stigmatized), explain how you will minimize these risks.

We do not anticipate any privacy issues during recruitment.

B. Consent Process:

1. Describe the following details about obtaining informed consent from study participants. If a screening process precedes study enrollment, also describe the consent for screening.

   A. Who will obtain informed consent, and their qualifications:

In-depth interviews, focus group discussions, and intervention planning workshops: A trained icddr,b research assistant who will be conducting the in-depth interviews, focus group discussions, and intervention planning workshops will obtain informed consent from adult participants and assent from children (12-17 years), and informed consent (parental permission) from a parent or guardian.

Pilot trials: A trained icddr,b research assistant will obtain informed consent from adult participants and assent from children (12-17 years), and informed consent from a parent or guardian for our pilot study.

Randomized Controlled Trial: A trained icddr,b research assistant will obtain informed consent from adult participants (≥18 years) and assent from children (12-17 years), and informed consent from a parent or guardian for our trial. Parental consent will be obtained from guardians before administering the assent form to children 12-17 years of age.

B. How, where, and when the consent discussion(s) will occur:

In-depth interviews, focus group discussions, and intervention planning workshops: A trained icddr,bresearch assistant will discuss and administer informed consent just prior to the beginning of the in-depth interview, focus group discussion, and intervention planning workshops. The in-depth interviews will take place in a location that is convenient for the participant, including the participant's home or office, or our icddr,b main office or satellite office. The focus group discussion and workshops will take place at the icddr,bmain office or satellite office or a government office building.

Pilot Study: a research assistant at icddr,b will discuss and administer informed consent at icddr,b Dhaka Hospital or in the home of the household prior to participant enrollment in the pilot trial.

C. The process you will use to determine whether a potential participant meets eligibility criteria:

In-Depth Interviews and Focus Group Discussions
icddr,b will identify and recruit a convenience sample of the following individuals to participate in our in-depth interviews and focus group discussions: households living in areas identified to have cholera patients, caregivers of young children, health facility staff and directors, and government officials. Individuals will be screened according to the criteria outlined in the previous section, using the appropriate screening questionnaires.

Intervention Planning Workshops
icddr,b will identify and recruit a convenience sample of governmental officials in the Bangladeshi Ministry of Health and Family Welfare to participate in our intervention planning workshops.

Pilot
A research assistant at icddr,b will administer a screening questionnaire to households to determine if they are eligible for the pilot study.

Main Study Randomized Controlled Trial
A trained icddr,b research assistant will administer a screening questionnaire to households to determine if they are eligible for the pilot study.

D. Whether you will obtain a signature from the participant or will use an oral consent process:

Written informed consent for adults and guardians, and written assent for children 12 to 17 years of age will be obtained from study participants.

E. Whether you will obtain a legally authorized representative's signature for adults lacking capacity:

If the participants are not able to read, the consent or assent form will be read and explained to the participants. The participants will then document their consent with a thumbprint in the presence of a witness. If the interviewer becomes aware when talking to an adult respondent (18 years or older) that they appear to have a cognitive limitation, an adult household member may sign the Consent form on their behalf.

F. If children are included in the study, if and how you will obtain assent from them:

After the study procedures are explained, children between the ages of 10 and 17 years old will be asked to sign an assent form.

G. If children are included in the study, how you will obtain permission for them to participate from their parent, legal guardian, or other legal authority (if child is in foster care or under government supervision) :

Permission for a minor's participation will be obtained from the parent or guardian using a parental permission form. Emancipated minors can provide consent for themselves.

H. If you are seeking a waiver of informed consent or assent, the justification for this request:

Not Applicable

I. Whether you will include a witness to the consent process and why:

If the participants are not able to read, the consent or assent form will be read and explained to the participants. The participants will then document their consent with a thumbprint in the presence of a witness.

J. If the language is unwritten, explain how you will communicate accurate information to potential participants and whether you will use props or audio materials:

Not Applicable

2. Identify the countries where the research will take place, and the languages that will be used for the consent process.

Country	Consent Document(s) (Adult Consent, Parental Permission, Youth Assent, etc.)	Languages
Bangladesh	Adult consent, parental permission, youth assent	Bangla

1. Guest G, Bunce A, Johnson L: **How many interviews are enough? An experiment with data saturation and variability**. *Field methods* 2006, **18**(1):59-82.
2. George CM, Biswas S, Jung D, Perin J, Parvin T, Monira S, Saif-Ur-Rahman KM, Rashid MU, Bhuyian SI, Thomas ED *et al*: **Psychosocial Factors Mediating the Effect of the CHoBI7 Intervention on Handwashing With Soap**. *Health education & behavior : the official publication of the Society for Public Health Education* 2017:1090198116683141.
3. George CM, Monira S, Sack DA, Rashid MU, Saif-Ur-Rahman KM, Mahmud T, Rahman Z, Mustafiz M, Bhuyian SI, Winch PJ *et al*: **Randomized Controlled Trial of Hospital-Based Hygiene and Water Treatment Intervention (CHoBI7) to Reduce Cholera**. *Emerging infectious diseases* 2016, **22**(2):233-241.
4. George CM, Jung DS, Saif-Ur-Rahman KM, Monira S, Sack DA, Rashid MU, Mahmud T, Mustafiz M, Rahman Z, Bhuyian SI *et al*: **Sustained Uptake of a Hospital-Based Handwashing with Soap and Water Treatment Intervention (Cholera-Hospital-Based Intervention for 7 Days [CHoBI7]): A Randomized Controlled Trial**. *The*

American journal of tropical medicine and hygiene 2016, **94**(2):428-436.

5. Preacher KJ, Hayes AF: **Asymptotic and resampling strategies for assessing and comparing indirect effects in multiple mediator models**. *Behav Res Methods* 2008, **40**(3):879-891.
6. Kondo MC, Bream KD, Barg FK, Branas CC: **A random spatial sampling method in a rural developing nation**. *BMC public health* 2014, **14**:338.