SUPPORTING STATEMENT – PART B

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

1. Description of the Activity

Describe the potential respondent universe and any sampling or other method used to select respondents. Data on the number of entities covered in the collection should be provided in tabular form for the universe as a whole and for each of the strata in the proposed sample. Indicate the expected response rates for the collection as a whole, as well as the actual response rates achieved during the last collection, if previously conducted.

This is a mixed methods study that uses qualitative research methods (e.g. interviews) and quantitative research methods (e.g. structured observations of hand hygiene behavior) to evaluate 3 hospital hand hygiene interventions: handwashing with soap, alcohol hand sanitizer, and hand rinse with 0.05% chlorine solution. The study is designed in 4 phases to allow for formative research to then inform intervention design before pilot testing the interventions. Our study is composed of 4 parts: 1) exploratory study including a cross-sectional baseline survey of hand hygiene infrastructure and behavior in all hospitals and health centers in Lofa and Bong counties, 2) intervention development of hand hygiene interventions with key stakeholders using locally-available soap, alcohol-based hand sanitizer, and 0.05% chlorine solution, 3) pilot interventions for 8 months in select hospital wards, and 4) full interventions for 12 months across 3 hospitals (1 each for soap, alcohol, and chlorine) with a 4th hospital as a control. The primary evaluation is comparison of pre-intervention and post-intervention hand hygiene behavior rates.

Respondents will include Liberian hospital administrators, healthcare workers, family caregivers, and patients in four study hospitals in Liberia. Please see summary table below for information on study phases, methods in each phase, sample size, and respondent hours. We anticipate 10% nonresponse rate.

Study phase	Methods	Sample size	Respondent hours
Phase 1: Exploratory Study	1. In-depth interviews with hospital administrators and health workers	1. 84 interviews total (up to 12 interviews per hospital; 7 hospitals)	1. 84 hours
	2. Spot checks of hand hygiene infrastructure	2. n/a – not interviews	2. n/a – not interviews
	3. Direct observation of hand hygiene actions	3. 56 hours total (8 hours per hospital; 7 hospitals)	3. n/a – not interviews
Phase 2: Intervention Design	1. Stakeholder meetings and participatory discussions	1. n/a – not interviews	1. n/a – not interviews
	2. Testing 0.05% chlorine solution skin safety	2. 20 volunteers, 2 time points	2. 40 hours
	3. Feedback interviews with health workers	3. 36 interviews total (up to 12 interviews per intervention; 3 interventions)	3. 36 hours
Phase 3: Pilot Intervention	1. Interim feedback interviews	1. 36 interviews total (up to 12 interviews per intervention; 3 interventions)	1. 36 hours
	2. Spot checks of intervention materials	2. n/a – not interviews	2. n/a – not interviews
	3. Direct observation of hand hygiene actions	3. 64 hours total (8 hours per hospital; 4 arms including control; 2 time points)	3. n/a – not interviews
Phase 4: Full Intervention	1. End line feedback interviews with stakeholders	1. 48 interviews total (up to 12 interviews per intervention; 4 hospitals)	1. 48 hours
	2. Spot checks of hand hygiene infrastructure	2. n/a – not interviews	2. n/a – not interviews
	3. Implementation checklists	3. n/a – not interviews	3. n/a – not interviews
	4. Direct observation of hand hygiene actions	4. 128 hours total (8 hours per hospital; 4 time points; 4 hospitals)	4. n/a – not interviews
	5. Tabulating total costs and inputs	5. n/a – not interviews	5. n/a – not interviews

2. Procedures for the Collection of Information

a. Statistical methodologies for stratification and sample selection;

For qualitative interviews, we aim to interview a representative sample of hospital administrators, healthcare workers (doctors, nurses, lab technicians, pharmacists, and cleaners), and patients/family in each hospital site. We estimate 8-12 interviews per hospital site as this is generally sufficient to reach data saturation. Each interview will be up to 1 hour.

b. Estimation procedures;

None

c. Degree of accuracy needed for the Purpose discussed in the justification;

None

d. Unusual problems requiring specialized sampling procedures; and

None

e. Use of periodic or cyclical data collections to reduce respondent burden.

The study is designed to ask respondents to give iterative feedback of interventions.

3. Maximization of Response Rates, Non-response, and Reliability

We will first explain study purpose and procedures to each potential participant to increase understanding about our study and maximize response rates. We will only conduct interviews or questionnaires if informed consent is given by participants.

4. Tests of Procedures

Our primary outcome will be change in hand hygiene behavior/compliance from baseline to end line for each hospital. This outcome measures both intervention effectiveness and implementation adoption/uptake. Secondary intervention outcomes will include: availability and maintenance of hand hygiene materials. Secondary implementation outcomes will include: acceptability, appropriateness/fit, feasibility, and cost of the interventions.

For the primary outcome of hand hygiene compliance, we calculate an estimated sample size of 199 hand hygiene opportunities per measurement period of baseline versus end line (or 398 total for pre-post comparison per hospital) would be required to detect a 10% increase in recommended hand hygiene from a baseline of 10% to 20% with 80% power, 0.05 α, and 2-sided test (the WHO Mali study showed an increase from 8% to 22%).[47] Assuming 30 opportunities for hand hygiene per hour (the WHO Mali study averaged 38 opportunities per hour), then 6.6 hours of observation per hospital are needed. We plan for at least 8 hours of hand hygiene observation per hospital which may be divided across different days to catch different time periods/ worker shifts.

Missing data and outliers will be examined for systematic data collection errors. If possible, missing data will be collected, otherwise we will compare strategies analyzing only available data versus imputing missing data values. Comparing pre-post intervention data for each hospital will account for some confounding such as hospital facility characteristics (e.g. private hospitals may have better baseline and thus end line infrastructure). Secular trends in national or county-wide infection control improvements will be captured by also examining pre-post data for the control hospital.

5. Statistical Consultation and Information Analysis

a. Provide names and telephone number of individual(s) consulted on statistical aspects of the design.

None

b. Provide name and organization of person(s) who will actually collect and analyze the collected information.

Data collection will be done by in-country Liberia-trained field researchers through our collaborator the National Public Health Institute of Liberia (NPHIL). Data analysis will be conducted by our group of collaborators, and only de-identified data will be accessed by the Uniformed Services University of the Health Sciences (USUHS), Naval Medical Research Unit Three (NAMRU-3), and Stanford University collaborators for data analysis.