

SUPPORTING STATEMENT - PART A

(Comparing Hospital Hand Hygiene in Liberia: Soap, Alcohol, and Hypochlorite – 0720-XXXX)

1. Need for the Information Collection

This information collection is necessary for the Department of Defense (DoD) to successfully execute a Global Health Engagement (GHE) research study. Per post- Ebola epidemic interests, this study will investigate Liberian hospital hand hygiene behaviors which will directly contribute to the development of Liberian hospital interventions.

During the recent Ebola epidemic centered in West Africa, aqueous hypochlorite/dilute bleach solutions were used widely for hand hygiene and environmental decontamination in hospitals, Ebola treatment units (ETUs), community care centers as well as travel and community checkpoints. The epidemic resulted in 28,646 reported cases and 11,323 deaths as of March 2016, compounded by health worker infections and deaths. Health workers were found to be 20-30 times more likely to be infected with Ebola than the general adult population. In the absence of effective vaccine or post-exposure prophylaxis during most of the epidemic, the only method of prevention was strict adherence to infection control which included hand hygiene.

Since the 1990s, guidelines have recommended soapy water or alcohol sanitizer for hand hygiene and hypochlorite solutions for environmental decontamination. Official guidelines provided by the Center for Disease Control and World Health organization (WHO) during the recent Ebola epidemic approved 0.5% hypochlorite for environmental decontamination and 0.05% hypochlorite for hand hygiene. The WHO now recommends that as the Ebola emergency response has ended, West African health facilities should use soapy water or alcohol sanitizer instead of hypochlorite. The WHO has also recommended a hand hygiene implementation strategy that includes improving hand hygiene infrastructure, training, monitoring of behavior, providing visual reminders of desired behaviors and creating an institutional culture of patient safety. We have found only one published study on the successful implementation of the WHO hand hygiene program in a low-income country. This study, however, was externally funded, had only a 6 month intervention period and observed hand hygiene compliance was low. Despite substantial hand hygiene research, there are gaps in the knowledge of how to successfully implement hospital hand hygiene programs in resource-limited settings which this collection seeks to address.

The investigation of actionable hand hygiene interventions and implementation strategies is critical to planning hospital infection control programs in countries most affected by and still under threat of Ebola. Hospital infection control is a critical piece of the U.S. global health response and capacity-building of the Liberian health system. This study could contribute to how the U.S. government and military continue humanitarian assistance after

immediate public health disaster responses and build host nation capacity to prevent future infectious disease outbreaks with pandemic potential.

This study is part of a U.S. – Liberia collaboration funded by the U.S. Department of Defense Center for Global Health Engagement. This study's focus is critically relevant to Liberia's national strategy of building a 'resilient' health system. The findings from the associated survey of Liberian hospital healthcare workers will shape how the U.S. government and military continue humanitarian assistance after immediate public health disaster responses and build host nation capacity to prevent future global pandemic threats.

The DoD is authorized to collect this information pursuant, Executive Order 13747, 10 U.S.C. 2358, Section 715 of Public Law 112-239, and DoDI 2000.30. E.O. 13747 authorizes the Secretary of Defense to facilitate coordination and implementation of DoD programs to further the Global Health Security Agenda, and measure and evaluate progress in countries the United States has made a commitment to assist. 10 U.S.C 2358 authorizes the Secretary of Defense to engage in basic and applied research that is of interest to the Department of Defense. Section 715 of Public Law 112-239 authorizes the Secretary of Defense, in coordination with the Under Secretary of Defense for Policy and the Assistant Secretary of Defense for Health Affairs to ensure health engagement conducted by the Department of Defense are effective and efficient in meeting the national security goals of the United States. Section 715 defines health engagement as a health stability operation conducted by DoD outside in US in coordination with a foreign government or international organization to establish, reconstitute, or maintain the health sector of a foreign country. DoDI 20003.0 establishes policy and prescribes procedures for the conduct of GHE activities with partner nation (PN) activities. Specifically, DoDI 2000.30 identifies the promotion and enhancement of PN stability and security, coordination of mutual activities to support the U.S. Government national security objectives as DoD policy.

2. Use of the Information

Respondents are Liberian hospital healthcare workers and hospital administrators in Liberian health facilities that provide inpatient services. Responses to this collection are being solicited in order to explore whether hypochlorite could be used for routine hand hygiene and how best to implement hand hygiene changes in health facilities.

This collection is composed of four phases; an exploratory study including a cross-sectional baseline survey of hand hygiene infrastructure and behavior in all hospitals and health centers in the counties of Lofa and Bong, intervention development of hand hygiene interventions with key stakeholders using locally-available soap, alcohol, and hypochlorite, pilot interventions for eight months in select hospital wards, and full interventions for twelve months across three hospitals with a 4th hospital as a control and comparing pre-post intervention hand hygiene.

Phase one includes qualitative interviews with hospital administrators and healthcare workers. Information and data collected during phase one will be used to develop and test hand hygiene interventions.

During phase two, these findings will be presented to key stakeholders and used to conduct a series of participatory focus group discussions. Key stakeholders include hospital administrators, healthcare workers, family caregivers, and patients. The participatory sessions will be moderated by researchers and include representatives from all stakeholder groups. Each session will consist of half or full-day 'workshops' with no more than ten participants. The participants will then be divided into smaller groups and asked to share their experiences and insights on hospital hand hygiene, brainstorm intervention design ideas, create prototypes, and then iteratively test and refine the prototypes. At the beginning of the test period for the hypochlorite intervention, volunteers will be asked to fill out a self-assessment of their skin including questions on rashes, abrasions, dryness, itching, burning, or soreness.

In phase three we will pilot our soap, alcohol, and hypochlorite interventions for eight months in select inpatient wards in three different hospitals. At each hospital we will engage a team of stakeholders including hospital administrators, healthcare workers, community and patient representatives to help adapt intervention designs to each hospital and support implementation. We will conduct interim interview with stakeholders; the feedback from which will be used to iteratively modify interventions.

During phase four, the full intervention phase, we will expand soap, alcohol, and hypochlorite hand hygiene interventions from pilot wards to entire hospitals. Implementation and intervention effectiveness outcomes will be measured at 4 months, 8 months, and 12 months. We will use feedback interviews of key stakeholders, in addition to spot checks of intervention materials and an implementation checklist, to measure implementation effectiveness outcomes.

The collection instrument is a series of semi-structured, guided interviews. The interviews will be conducted by experienced qualitative researchers. Researchers will record respondents' answers on paper. The researcher will then manually enter the responses into an electronic database or, if feasible, responses will be entered directly into electronic forms. No invitations or other communications will be sent to respondents.

The data gathered throughout this collection will be used to improve Liberian hospital hand hygiene behaviors and improve DoD humanitarian assistance efforts. The end result of the successful collection will include determination of the most appropriate cleansing materials for routine hand hygiene. This collection will evaluate acceptability, feasibility, effectiveness, and cost of interventions in order to ultimately develop a strategy for expanding and implementing best hospital hand hygiene intervention(s) to the rest of Liberian counties. Additionally, the information collected will potentially support prevention of infectious disease outbreaks with pandemic potential.

3. Use of Information Technology

0% of responses are collected electronically. Field researchers will record interview responses on a paper form (see Appendix B) then manually enter into an electronic

database or, if feasible, responses will be entered directly into electronic forms. The health facilities field researchers will be conducting the survey in do not have access to reliable Internet, and in some occasions, reliable sources of electricity.

4. Non-duplication

The information obtained through this collection is unique and is not already available for use or adaptation from another cleared source.

5. Burden on Small Businesses

This information collection does not impose a significant economic impact on a substantial number of small businesses or entities.

6. Less Frequent Collection

This collection of information will be collected one time, as required, and is the most infrequent collection interval possible. Should the information be collected less frequently, the integrity of the information collected would be compromised. The study would not be able to fulfill mission requirements without the information collection.

7. Paperwork Reduction Act Guidelines

This collection of information does not require collection to be conducted in a manner inconsistent with the guidelines delineated in 5 CFR 1320.5(d)(2).

8. Consultation and Public Comments

Part A: PUBLIC NOTICE

A 60-Day Federal Register Notice for the collection published on Thursday, December 20, 2018. The 60-Day FRN citation is 83 FRN 65350;

No comments were received during the 60-Day Comment Period.

A 30-Day Federal Register Notice for the collection published on Monday, March 11, 2019. The 60-Day FRN citation is 84 FRN 8699.

Part B: CONSULTATION

This information collection has been peer reviewed by external experts including, the Stanford University Institutional Review Board and the Liberian National Research Ethics Board.

Additionally, public comments were solicited through the 60-Day Federal Register Notice published for this submission.

9. Gifts or Payment

No payments or gifts are being offered to respondents as an incentive to participate in the collection.

10. Confidentiality

A Privacy Act Statement is not required for this collection because we are not requesting individuals to furnish personal information for a system of records.

A System of Record Notice (SORN) is not required for this collection because records are not retrievable by PII.

A Privacy Impact Assessment (PIA) is not required for this collection because PII is not being collected electronically.

Records Retention and Disposition:

Records will be maintained in accordance with the following approved disposition schedule:

- Subject: Quality Assurance Studies and Analyses of Healthcare Quality
- Cutoff: Annually
- Disposition: Destroy when 5 year(s) years old
- OSD RCS Series #: 905-02.2
- NARA Authority: NC1-330-77-5

Or if the study and analyses results in issuance of new standards utilize the following approved disposition schedule:

- Subject: Quality Assurance Studies and Analyses of Healthcare Quality
- Cutoff: Annually
- Disposition: Permanent. Retire to the WNRC when no longer required for reference.
- OSD RCS Series #: 905-02.3
- NARA Authority: NC1-330-77-5"

11. Sensitive Questions

No questions considered sensitive are being asked in this collection.

12. Respondent Burden and its Labor Costs

- 1) Phase 1 Interview
 - a) Number of Respondents: 84

- b) Number of Responses Per Respondent: 1
 - c) Number of Total Annual Responses: 84
 - d) Response Time: 1 hour
 - e) Respondent Burden Hours: 84 hours
- 2) Phase 2 Interview
- a) Number of Respondents: 36
 - b) Number of Responses Per Respondent: 2-3¹
 - c) Number of Total Annual Responses: 76
 - d) Response Time: 1 hour
 - e) Respondent Burden Hours: 76 hours
- 3) Phase 3 Interview
- a) Number of Respondents: 36
 - b) Number of Responses Per Respondent: 1
 - c) Number of Total Annual Responses: 36
 - d) Response Time: 1 hour
 - e) Respondent Burden Hours: 36 hours
- 4) Phase 4 Interview
- a) Number of Respondents: 48
 - b) Number of Responses Per Respondent: 1
 - c) Number of Total Annual Responses: 48
 - d) Response Time: 1 hour
 - e) Respondent Burden Hours: 48 hours

Total Submission Burden

- a. Total Number of Respondents: estimated 84 total²
- b. Total Number of Annual Responses: 244
- c. Total Respondent Burden Hours: 244

Part B: LABOR COST OF RESPONDENT BURDEN

- 1) Phase 1 Interview
- a) Number of Total Annual Responses: 84
 - b) Response Time: 1 hour
 - c) Respondent Hourly Wage: \$ 1.15
 - d) Labor Burden per Response: \$1.15
 - e) Total Labor Burden: \$96.00
- 2) Phase 2 Interview
- a) Number of Total Annual Responses: 76
 - b) Response Time: 1 hour

¹ Some respondents complete a follow up to their original response during Phase 2, via a focus group.

² Some respondents are the same throughout the collection's phases.

- c) Respondent Hourly Wage: \$ 1.15
- d) Labor Burden per Response: \$1.15
- e) Total Labor Burden: \$87.40

3) Phase 3 Interview

- a) Number of Total Annual Responses: 36
- b) Response Time: 1 hour
- c) Respondent Hourly Wage: \$ 1.15
- d) Labor Burden per Response: \$1.15
- e) Total Labor Burden: \$41.40

4) Phase 4 Interview

- a) Number of Total Annual Responses: 48
- b) Response Time: 1 hour
- c) Respondent Hourly Wage: \$1.15
- d) Labor Burden per Response: \$1.15
- e) Total Labor Burden: \$55.20

Overall Labor Burden

- a) Total Number of Annual Responses: 244
- b) Total Labor Burden: \$280.00

*The respondent hourly wage was determined by using data collected by the World Bank in a published discussion paper, "Policy Options to Attract Nurses to Rural Liberia: Evidence From a Discrete Choice Experiment", (Vujicic et al., 2010):

[<http://siteresources.worldbank.org/HEALTHNUTRITIONANDPOPULATION/Resources/281627-1095698140167/PolicyOptionstoAttractNursestoRuralLiberia.pdf>].

13. Respondent Costs Other Than Burden Hour Costs

There are no annualized costs to respondents other than the labor burden costs addressed in Section 12 of this document to complete this collection.

14. Cost to the Federal Government

Part A: LABOR COST TO THE FEDERAL GOVERNMENT

This information collection is funded by a DoD grant to the Uniformed Services University Center for Global Health Engagement and the Global Health Engagement Research Program totaling \$832,718. This grants covers travel, consultant, equipment, and supply costs. Liberian field researchers processing responses will be paid a fee of \$500.00 per month during this collection.

Part B: OPERATIONAL AND MAINTENANCE COSTS

1) Cost Categories

- a) Equipment: \$90,600.00
- b) Printing: \$0.00
- c) Postage: \$0.00
- d) Software Purchases: \$0.00
- e) Licensing Costs: \$0.00
- f) Other: \$742,118.00

2) Total Operational and Maintenance Cost: \$ 832,718.00

Part C: TOTAL COST TO THE FEDERAL GOVERNMENT

- 1) Total Labor Cost to the Federal Government: \$0.00
- 2) Total Operational and Maintenance Costs: \$ 832,718.00
- 3) Total Cost to the Federal Government: \$832, 718.00

15. Reasons for Change in Burden

This is a new collection with a new associated burden.

16. Publication of Results

The results of this information collection will not be published.

17. Non-Display of OMB Expiration Date

We are not seeking approval to omit the display of the expiration date of the OMB approval on the collection instrument.

18. Exceptions to "Certification for Paperwork Reduction Submissions"

We are not requesting any exemptions to the provisions stated in 5 CFR 1320.9.