# Formative Evaluation for Shigellosis Sexual Health Materials for Men Who Have Sex with Men

**Generic Information Collection (0920-1154)**

Supporting Statement Part A

**Submitted: May 8, 2017**


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- The goals of the formative evaluation are to assess the knowledge, perceptions, and behaviors of men who have sex with men regarding *Shigella* infections, as well as to obtain feedback on initial health messaging to develop sexual health materials for MSM.
- Results of the evaluation will be used to inform the development of shigellosis prevention materials for MSM. Materials to be developed from results include: campaign concepts, messages, and materials to motivate MSM to prevent multidrug-resistant *Shigella* infections and be alert to shigellosis through early detection of infections.
- This qualitative formative evaluation will use stratified, non-probability purposive sampling to recruit consumers for focus groups (FGs). We will recruit potential respondents by advertising the evaluation through various community and social media outlets as well as health care and social service providers serving the LGBT community in Georgia. Passive recruitment will occur through these partners via printed materials that describe the evaluation and direct interested participants to call the evaluation telephone number. We will also incorporate the snowball method of recruitment, in which callers are asked to share the evaluation's contact information with their network. All participants will reside in Georgia.
- The MSM FGs will be stratified by: race (African American, Hispanic, and Caucasian) and HIV-status.
- Data analysis: Qualitative data will be analyzed using thematic or grounded theory analysis that will identify relevant, common, and cross-cutting themes within FG responses in order to summarize participants' knowledge, perceptions, and behaviors regarding shigellosis and its prevention.

## 1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) is requesting approval for a new generic information collection (gen-IC), "Formative Evaluation for the Shigellosis Sexual Health Materials for Men Who Have Sex with Men."

This information collection involves formative evaluation to understand the knowledge, perceptions, and behaviors of men who have sex with men regarding *Shigella* infections, as well as to obtain feedback on initial health messaging to develop sexual health materials for MSM. This information collection uses qualitative data consisting of focus group discussions.

This information collection is authorized by Section 301 of the Public Health Service Act (42 U.S.C.241) (Attachment 1).

Shigellosis is a nationally notifiable disease with an annual estimated incidence of 500,000 cases in the United States [1]. *Shigella* infections are characterized by diarrhea, fever, and stomach cramps, starting 1 to 4 days after exposure to shigellae, and lasting between 5 and 7 days after symptom onset. An estimated 20% of shigellosis patients are hospitalized, and about 40 shigellosis-related deaths occur each year [2]. Shigellosis has a very small infectious dose and is transmitted through the fecal-oral route. This can happen when an infected or convalescent patient contaminates food, beverages, or water that is then ingested by another person, through person-to-person contact that results in unintended transfer of shigellae to the hands of another

person, through contamination of objects with shigellae that are later unintentionally ingested, or through sexual activity. Shigellosis is most commonly transmitted from person-to-person among young children and their caretakers; however, many outbreaks have recently been documented among MSM [3-6]. Furthermore, shigellosis may be more severe, and shedding of shigellae in stool may be prolonged, among HIV-infected MSM [7].

Multidrug-resistant (MDR) shigellosis is emerging in the United States. Shigellosis patients frequently are treated with antimicrobial medications to reduce illness duration and to attempt to reduce transmission. Over the last several years, high rates of resistance to ampicillin and trimethoprim/sulfamethoxazole have made ciprofloxacin, ceftriaxone, and azithromycin the preferred antimicrobial agents for adults and children with shigellosis; ceftriaxone is also the preferred treatment for invasive shigellosis [8-10]. Recently, shigellae resistant to these preferred antimicrobials have emerged in the United States and abroad [3, 5, 11-18], and in 2013 CDC declared MDR shigellosis a serious threat in the United States [19]. Although shigellosis is most commonly reported in children <5 years old [20], most reports document ciprofloxacin- or azithromycin-resistant shigellosis largely among MSM [3-5, 10, 11, 18, 21-23]. Furthermore, MSM-associated shigellosis clusters appear to be 3–77 times more likely to be resistant to preferred antimicrobials than clusters with non-sexual transmission routes [24].

Shigellosis has been linked repeatedly to sexual behavior during recent decades. Rates of *S. flexneri* infection began increasing among U.S. adult males in the 1970s, particularly among men 20 – 39 years old, but remained stable or decreased in other demographic groups [25]. A population-based case-control study in San Francisco found shigellosis was strongly associated with MSM, HIV infection, and direct oral-anal contact [21]. Recent shigellosis cases in the United Kingdom also related to sexual practices. From January 2009 to October 2012, 37 of 38 *S. flexneri* cases in the UK were among men; 36 (97%) self-identified as MSM. Of the 36 MSM, 88% were known to be HIV-infected, 58% reported at least one casual male partner during the previous month, and seven (62%) recalled oral-anal contact [26]. Moreover, during an outbreak in Australia among 98 MSM, visiting a sex venue in the 2 weeks before onset of illness was the only identified risk factor [27]. Several qualitative studies corroborate the association between shigellosis and sexual behavior. One study of 42 men aged ≥18 years who were diagnosed with shigellosis between October 2012 and May 2013 found that 34 (81%) were sexually active MSM, of whom many reported meeting casual sexual partners through social media outlets or using recreational drugs during sex, which may have increased risky sexual behaviors [28]. Despite the data linking shigellosis to sexual behavior during recent decades, few data exist to guide shigellosis prevention campaigns among the MSM population, and campaigns to prevent transmission of sexually transmitted non-enteric infections may not fully apply to prevention of shigellosis among MSM.

Shigellosis prevention materials will require not only clearer understanding of shigellosis knowledge, attitudes, and perceptions among MSM, but also creativity that accounts for wariness of sexual health messaging in this population. Since the beginning of the HIV epidemic, HIV prevention messaging has targeted MSM, as one of the most at risk populations in the United States. HIV prevention initiatives have been associated with effective risk reduction among most at risk populations, including MSM [29]. Over the past decade, however, rates of HIV and sexually transmitted infections among some groups of MSM appear to be increasing [30-32].

Some researchers attribute this resurgence to boredom or psychological resistance to HIV prevention messages resulting from repeated exposure [33, 34]. Researchers have continued to study the effectiveness of HIV prevention messaging, most recently in light of the clinical effectiveness of pre-exposure prophylaxis (PrEP) [35, 36], and found that MSM, regardless of HIV status, view PrEP and condoms as effective and important tools to prevent HIV. However, both HIV negative and HIV positive MSM do not accept that assertion of an undetectable viral load mitigates HIV transmission, and HIV negative MSM's attitude regarding treatment as prevention leans significantly more toward "strongly disagree" than their HIV positive counterparts [37]. In addition, some MSM see PrEP as an "excuse," or rather means to forgo condoms [38]; and, this perception appears to be corroborated by sexually transmitted disease infection rates among MSM on PrEP [30-32]. Among MSM of color, those at greatest risk for HIV, a recent study on attitudes toward PrEP and condoms found that Latinos favor condoms over PrEP, while African American MSM prefer the increased level of protection offered by combining PrEP with condoms [39]. That is, recent research reveals critical variation in attitudes and receptiveness to prevention messages mediate the effectiveness of prevention efforts across different communities of MSM [40, 41]. More generally, prevention research further suggests that successful prevention messaging includes several key elements: 1) prevention messages must appeal to the targeted community [42], 2) the messages should be brief [43, 44]; and 3) multiple messages are most effective [45]. In sum, when attempting to convey information to or motivate at-risk communities to take action, the messaging should appeal to the community, briefly state the case, and involve a series of messages that convey the intended point(s).

**2. Purpose and Use of Information Collection**

Given the increasing rates of shigellosis among MSM, and the unknown knowledge and awareness among MSM regarding shigellosis and its prevention, CDC is proposing to create health materials aimed at informing MSM about shigellosis and preventing infections. The goal of creating health materials for MSM is to raise awareness of shigellosis and its prevention among MSM who are most at risk for antibiotic resistant shigellosis.

The Shigellosis Sexual Health Materials for MSM goals are to:

- Raise awareness and knowledge of shigellosis among MSM to prompt shigellosis prevention and early recognition.
- Decrease cases of multidrug-resistant shigellosis.
- Support CDC's contributions to the National Strategy to Combat Antibiotic Resistance: https://www.cdc.gov/drugresistance/federal-engagement-in-ar/national-strategy/index.html

The primary evaluation questions in phase one are:

1. Where do MSM go for health related questions?
2. What sources do MSM trust for health information?
3. What are MSM's preferred ways (message, channel, and source) to obtain information about sexual health?
4. What are MSM's general awareness about shigellosis?
5. What do MSM know about shigellosis?

a. What are perceptions (beliefs or general thoughts) about shigellosis (e.g., the severity of shigellosis)?
6. Before having sex, do MSM discuss if they recently had diarrhea?
7. Do MSM believe they are at risk for shigellosis?
8. How do MSM seek information about sexual health?
9. What are MSM's reactions to initial sexual health message sets?

Following completion of the phase one formative research, a second round of information collection will be done. Phase two will consist of health message testing and will be submitted to OMB for review separately using CDC's health message testing generic package (0920-0572).

MSM will be screened for eligibility prior to recruitment for the focus groups. Exhibit 1 provides an overview of the data collection activities.

Exhibit 1. Data Collection Activities

| Instruments | |
|---|---|
| Recruitment Screener (Attachment 2) | The recruitment screener will be used to determine eligibility and recruit appropriate MSM for focus groups. The screener will request demographic information, inclusion criteria, and willingness to participate in focus groups. The screener will be administered by telephone by an investigator from Georgia State University and takes 5 minutes to complete. |
| Participant Recruitment Script (Attachment 3) | Georgia State University will recruit potential respondents by advertising the evaluation through various community and social media outlets as well as health care and social service providers serving the LGBT community in Georgia. Passive recruitment will occur through these partners via printed materials that describe the evaluation and direct interested participants to call the evaluation telephone number. We will also incorporate the snowball method of recruitment, in which callers are asked to share the evaluation's contact information with their network. All data collected as part of screening is subject to confidentiality and human subject protections. |
| Focus Group Moderator Guide (Attachment 4) | We will conduct six focus group discussions, each lasting up to one hour or until we reach the point of saturation. Focus groups will allow us to determine the knowledge and perceptions of MDR shigellosis infections and shigellosis prevention among MSM, and to assess preferences for the tone and format of shigellosis prevention materials. These discussions will be led using a phase-specific focus group moderators' guide. |

## 3. Use of Improved Information Technology and Burden Reduction

Data will be collected via focus groups discussions at Georgia State University. A note taker will be present to take notes for each focus group; all focus groups will be recorded to ensure participant responses are captured accurately. Items on the focus group moderators have been limited to only those relevant to the target audience to reduce burden on respondents.

## 4. Efforts to Identify Duplication and Use of Similar Information

To date, there has been no research conducted that has attempted to identify MSMs awareness of shigellosis.

## 5. Impact on Small Businesses or Other Small Entities

Georgia State University investigators anticipate MSMs participation in focus groups will be conducted at times that would not impact their employment in a small business or small entity (if applicable). We will provide flexibility in scheduling focus groups to minimize the potential impact on small businesses and other small entities.

### 6. Consequences of Collecting the Information Less Frequently

This is a one-time information collection request.

### 7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances with this information collection package. This request fully complies with the guidelines in 5 CFR 1320.5 and will be voluntary.

### 8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. This information collection request does not require publication of a 60-day notice in the *Federal Register*.

B. CDC has been working with Georgia State University investigators on the design, instrumentation, and initial message sets for this evaluation. Several CDC experts provided input on target audiences, instrument content, and initial message sets developed by Georgia State University investigators.

Individuals consulted outside the agency include:

- Eric Wright, Georgia State University
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- Ebony Townshed, Georgia State University
  Etownsend1@student.gsu.edu

### 9. Explanation of Any Payment or Gift to Respondents

Focus group participants will receive a monetary gift of appreciation for their participation. It is assumed that many of these participants will be taking time either during work hours or personal time to complete the focus groups, and may have children. Therefore the monetary gift may serve to offset costs related to participating in the evaluation in the amount of $40 for participation in 60-minute focus group.

### 10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The CDC Human Subjects Advisor has determined that the Privacy Act does not apply to this information collection. Focus groups participants will be recruited and moderated by Georgia State University investigators. CDC will not have direct contact with participants or access to any personally identifying information (PII) about the participants and PII will not be linked to responses.

PII (e.g., name, address, e-mail address, and telephone number) will be used by Georgia State University to make contact with and send reminders to respondents. This information will be kept separate from any information collected in the focus groups (i.e., participant responses will not be connected to any identifiable information). Screeners will be kept in a locked file cabinet at Georgia State University or in password-protected computer files. The recruiter will only provide a summary of participant information on the recruitment grids, which will be stripped of PII. No PII will be transmitted to CDC. Georgia State University investigators will be instructed to destroy their project-related records upon completion of the evaluation.

All findings will be reported in the aggregate only. The contractor will take precautions to secure participants' identifiable information (see Attachment 6). Participants will use only first names or pseudonyms during the discussions. Notes will not include participants' names. Audio files of the groups will be stored by Georgia State University investigators on a secure share drive and password-protected computers. Reports will not include PII and will be stored on a secure share drive and password-protected computers.

## 11. Institutional Review Board (IRB) and Justification for Sensitive Questions

Institutional Review Board (IRB)

To ensure the privacy of data compiled for the protection of human subjects, the data collection protocol and instruments were reviewed and approved through CDC's Institutional Review Board (IRB) (Attachment 7). This review ensures compliance with the spirit and letter of HHS regulations governing such projects.

Justification for Sensitive Questions

The majority of questions asked will not be of a sensitive nature. All participants will be informed that they need not answer any question that makes them feel uncomfortable or that they simply do not wish to answer (Attachment 6). To address any concerns about inadvertent disclosure of sensitive information, respondents will be fully informed of the applicable privacy safeguards.

## 12. Estimates of Annualized Burden Hours and Costs

Table 1 below describes the burden associated with the information collection.

The burden estimate for the moderator guide includes the burden to review the informed consent, which will be completed by Georgia State University investigators.

*Table 1. Annualized Burden*

| Type of Respondent | Form Name | No. of Respondents | No. of Responses per Respondent | Average Burden Per Response (hours) | Total Burden Hours |
|---|---|---|---|---|---|
| MSM | Screener | 400 | 1 | 5/60 | 34 |
| | Moderator Guide | 45 | 1 | 1 | 45 |
| Total | | | | | 79 |

Table 2 below describes the cost burden associated with this information collection. It was calculated based on the hourly wage rate for "all occupations" in the Bureau of Labor Statistics May 2015 National Occupational Employment and Wage Estimates (BLS, 2015) and from the U.S. Department of Labor Federal Minimum Wage Standards.

| **Type of Respondent** | **Form Name** | **Total Burden Hours** | **Hourly Wage Rate** | **Total Respondent Costs** |
|---|---|---|---|---|
| MSM | Screener | 34 | $23.23 | $789.82 |
| | Moderator Guide | 45 | $23.23 | $1,045.35 |
| **Total** | | | | $1,835.17 |

**13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers**

There will be no direct costs to the respondents other than their time to participate in each information collection.

**14. Annualized Cost to the Government**

The total annualized cost to the government is $43,892 and consists entirely of federal staff time on the project.

Governmental costs for this project include personnel costs for federal staff involved in the plan and data collection design, development of data collection instruments and OMB materials, data collection and analysis, and reporting. This level of effort includes approximately 10 percent of a GS-11 health scientist's time for each campaign assuming a $60,400 annual salary (total $6,040), and 50 percent time of a GS-12 behavioral scientist assuming a $75,705 annual salary (total $37,852). The seed grant award will cover the majority of the costs, thus, the total cost to the government consists of the federal staff's time in the amount of $43,892.

**15. Explanation for Program Changes or Adjustments**

This is a new information collection.

**16. Plans for Tabulation and Publication and Project Time Schedule**

Data will be tabulated and a report will be developed. Qualitative findings may be published in a peer-reviewed journal article.

*Project Time Schedule*

Recruitment, focus groups, data analyses, and creation of health promotion materials will be time consuming and take two years to complete.

| **PROJECT TIMELINE** | Year 1 | | | | Year 2 | | | |
|---|---|---|---|---|---|---|---|---|
| Task | 1st Q | 2nd Q | 3rd Q | 4th Q | 1st Q | 2nd Q | 3rd Q | 4th Q |
| IRB submission (CG) | | | | | | | | |
| Create Focus Group Discussion Guide (CG) | | | | | | | | |
| Recruit Focus Group Respondents (G) | | | | | | | | |
| Conduct Phase 1 Focus Groups (G) | | | | | | | | |
| Transcribe/Analyze Phase 1 Focus Group Data (C) | | | | | | | | |
| Prepare Progress Report (CG) | | | | | | | | |
| Develop Prevention Messages and Creative Concepts (CG) | | | | | | | | |

Principal Partner(s) Responsible: (C) CDC; (G) GSU; (CG) Both

*Analysis*

Thematic or grounded theory analysis of the focus group data collected in phase one will help us understand MSM's knowledge of MDR shigellosis and its prevention, perceptions of MDR shigellosis, and motivation to prevent these infections. Focus group data will be transcribed in a Word document, then uploaded to NVivo for applying the thematic or grounded theory analytic frame.

*Dissemination of results and applications for future funding.*

We will use our findings to develop and disseminate health promotion materials to help prevent sexual transmission of MDR shigellosis infections.

The results of this evaluation will be summarized and shared publically, such as through scientific meetings and peer-reviewed publications. Shigellosis prevention materials developed during this project will be made freely available through the CDC website and will be shared with state and local public health departments and other partners serving LGBT communities. These materials will help inform MSM about preventing sexual transmission of MDR shigellosis.

It is expected that our findings will assist public health departments and other groups as they create messaging around prevention of sexual transmission of other enteric infections, particularly those predominately found among MSM.

Finally, the findings from this evaluation will be used to develop future grant proposals to expand this evaluation program. Depending on the nature of the findings, we anticipate submitting one or more funding applications to the NIH and/or other community foundations dedicated to improving the sexual health and reduce STDs among MSM to further develop the prevention materials identified and identify best practices for integrating shigellosis-related prevention efforts within ongoing prevention initiatives focused on other STDs and HIV.

**17. Reason(s) Display of OMB Expiration Date is Inappropriate**

The expiration date of OMB approval will be displayed on all information collection instruments.

### 18. Exceptions to the Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification. These activities comply with the requirements in 5 CFR 1320.

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