

**IDI study of *Legionella* and legionellosis detection, treatment, remediation and prevention activities, messages, and materials**

Generic Information Collection  
OMB No. 0920-0800  
New

Supporting Statement Part A

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- Goal of this study: To examine the knowledge, attitudes, and behaviors related to *Legionella and legionellosis* and to assess messages and materials for use in the prevention, detection, management, treatment, and remediation of the disease, including the toolkit, “Developing a Water Management Program to Reduce *Legionella* Growth and Spread in Buildings” and a *Legionella* fact sheet for clinicians.
- Intended use of the resulting data: Findings will help CDC’s *Legionella* team fine tune messaging, avoid unintended consequences of untested messages and materials, assess additional information needs of target audiences, develop an effective dissemination strategy, and ensure that the most effective guidance tools are produced and disseminated. Study findings will help the CDC *Legionella* team develop an effective communication education campaign including tools to help targeted audiences respond to *Legionella* outbreaks and to work to prevent them.
- Methods to be used to collect the data (cohort; randomized trial; etc.): 48 in-depth interviews will be conducted across the U.S.; 16 interviews will be conducted in five areas that have had recent legionellosis outbreaks.
- The subpopulation to be studied: The target population for CDC’s *Legionella* study are:
  - Clinicians who treat legionellosis
  - Infection control clinicians
  - Building managers and/or water maintenance staff
  - Water system risk management and remediation staff
- How the data will be analyzed: Analysis of the interview data will employ a transcript and note-based approach. The transcript/note-based analysis will rely primarily on transcripts, observation notes, and any debriefing sessions, and summary comments made after the conclusion of interviews. The interviews will be audio recorded and transcripts, with identifying information removed, will be prepared. Analysis will include the identification of key findings and overarching themes, which will be presented in a report to NCIRD.

## A. JUSTIFICATION

### 1. Circumstances Making the Collection of Information Necessary

The incidence of Legionnaires’ disease, a type of serious pneumonia, has increased dramatically since 2000. People can get Legionnaires’ disease when they breathe in a mist (small droplets of water in the air) that has been contaminated with *Legionella*. *Legionella* is found naturally in fresh water environments, but can become a health concern in human-made water systems. Most Legionnaires’ disease outbreaks are linked to buildings with large or complex water systems, and *Legionella* contamination is most common in hotels, long-term care facilities, and hospitals. Additionally, nearly all of water problems that cause these outbreaks can be detected early or prevented. Rapid response and effective communication is critical to infection control and preventing additional outbreaks.

CDC recently released a *Vital Signs* that highlighted the latest findings on deficiencies in environmental control of *Legionella* that led to the building-associated Legionnaires’ disease outbreaks CDC investigated from 2000 through 2014. These investigations show that about 9 in 10 outbreaks were caused by problems that could have been prevented with more effective water management. In conjunction with *Vital Signs*, CDC developed a practical guide, “Developing a Water Management Program to Reduce *Legionella* Growth and Spread in Buildings”. This new toolkit, based on ASHRAE Standard 188, provides guidance; a checklist to help identify if a water management program is needed; examples to help identify where *Legionella* could grow and spread in a building; and ways to reduce the risk of *Legionella* contamination.

Building managers, remediation companies, and healthcare professionals have a critical role to play in preventing and managing outbreaks of Legionnaires’ disease.

Activities to prevent and manage *Legionella* outbreaks are a high priority for CDC’s Division of Bacterial Diseases. As one of the first steps in developing a campaign, CDC’s *Legionella* communication team completed a literature and environmental scan on *Legionella* formative research activities and message-testing and found no existing research and very few materials on legionellosis prevention practices for these key groups. The planned data collection efforts will address the gap in research and allow CDC’s *Legionella* team to understand knowledge, attitudes, and behaviors and test messages aimed at these audiences and to more effectively design, produce, and disseminate an effective campaign.

CDC plans to conduct a qualitative research study with four key audiences: facility managers and water maintenance staff; water system risk management and remediation company staff; infection control clinicians; and clinicians who have or could treat patients with Legionnaires’ disease. Qualitative information will be collected to provide insights about respondents’ knowledge, attitudes, beliefs, and behaviors related to *Legionella* and legionellosis. CDC will also assess understanding, clarity of *Legionella* materials and guidance documents including the “Developing a Water Management Program to Reduce *Legionella* Growth and Spread in Buildings” toolkit and a *Legionella* fact sheet with clinicians; building managers and water maintenance staff; and water system risk management and remediation company staff. Qualitative findings from this research will be used to fine tune existing materials, avoid unintended consequences of untested messages and materials, inform development of future messages and materials and develop a dissemination strategy. Table 1 outlines the target group, activity, and objectives by audience for this study.

<b>Table 1. Methods and Objectives</b>		
<b>Audience</b>	<b>Activity</b>	<b>Objective</b>
Treating clinicians	16 IDIs <ul style="list-style-type: none"> <li>• 8 in areas with recent legionellosis outbreaks</li> <li>• 8 in areas without recent legionellosis outbreaks</li> </ul>	To better understand the current legionellosis diagnosis and prevention practices in hospitals and how CDC materials and messages support this
Infection control clinicians	16 IDIs <ul style="list-style-type: none"> <li>• 8 in areas with recent legionellosis outbreaks</li> <li>• 8 in areas without recent legionellosis outbreaks</li> </ul>	To better understand the current legionellosis surveillance and prevention practices in hospitals and how CDC materials and messages support this
Building managers and water maintenance staff	8 IDIs with staff working anywhere in the United States	To better understand the current water maintenance and <i>Legionella</i> prevention practices

		in buildings with buildings with large or complex water systems and how CDC materials and messages support this
Water system risk management and remediation company staff	8 IDIs with staff working anywhere in the United States	To better understand current <i>Legionella</i> risk management and remediation practices of employees and how CDC materials and messages support this

48 one-on-one, 60-minute interviews will be conducted with respondents to better understand:

1. Legionellosis prevention, diagnosis, management, reporting, and tracking practices in hospitals
2. Current *Legionella* prevention and water system risk management and remediation practices in different types of buildings including hotels, long-term care facilities, and hospitals
3. What improvements can be made to how CDC communicates with the four target audiences (e.g., trusted sources, framing, content, format, and channel)
4. What additional informational opportunities or outstanding informational needs exist for each audience

Table 2 outlines the inclusion criteria for the study.

Table 2. Inclusion Criteria	
Audience	Inclusion criteria
Treating clinicians	<ul style="list-style-type: none"> <li>• MD or DO who diagnoses and treats patients in a hospital</li> <li>• Spends at least 20% of his/her time diagnosing and treating patients in a hospital setting</li> <li>• Regularly diagnoses and treats patients with respiratory diseases like pneumonia</li> </ul>
Infection control clinicians	<ul style="list-style-type: none"> <li>• One of the people primarily responsible for oversight of infection control in his/her hospital</li> </ul>
Building managers and water maintenance staff	<ul style="list-style-type: none"> <li>• Oversight of water systems, such as cooling towers, hot tubs, or potable water, is a part of his/her professional responsibilities</li> <li>• Spends at least 20% of his/her time managing or conducting water-system related activities</li> <li>• Works with buildings that are at least 11 stories (including the basement) or contain a cooling tower</li> </ul>
Water system risk management and remediation company staff	<ul style="list-style-type: none"> <li>• Risk management or remediation of water systems, such as cooling towers, hot tubs, or potable water, is a major part of his/her professional responsibilities</li> <li>• Tests for <i>Legionella</i> as part of his/her work</li> <li>• Has conducted water system risk management or remediation in a one of the following: <ul style="list-style-type: none"> <li>○ Residential building, hotel or office that is at least 11 stores</li> <li>○ Medical facility</li> <li>○ Public building</li> <li>○ Other building that is at least 11 stories</li> </ul> </li> </ul>

Additionally, participants will be asked to provide feedback on words, phrases, images, design, and clarity of selected CDC materials designed to raise awareness about preventing legionellosis. The materials that will be discussed with each audience are taken from the toolkit “Developing a Water Management Program to Reduce *Legionella* Growth and Spread in Buildings” and a clinician fact sheet (see appendices 13-16). Because of the length and complexity of the materials to be tested, select information will be identified to be tested with each audience. When multiple materials are tested with each audience, individual participants will either be shown only one of these materials or portions of each material. This qualitative data collection and analysis will help to confirm the appeal and usability of existing campaign messages and materials, as well as provide information about knowledge gaps among the key audiences that can be addressed in future material development or refinement of existing materials.

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

The purpose of this information collection is to conduct formative evaluation through materials testing of the *Legionella* education and guidance campaign materials. Interview participants will be asked questions that allow CDC to assess their knowledge, attitudes, and behaviors related to *Legionella* and to provide feedback and opinions about guidance and educational materials, creative concepts and images, and approaches they are shown. Outcomes include the development of specific, targeted, appropriate campaign products in accordance with the knowledge gained, as well as refinement of current materials. The information collected will be used by NCIRD to tailor existing efforts, and develop additional campaign materials in an iterative manner consistent with the Health Communication Process (National Cancer Institute 2002). Additionally, findings will also be used to develop a dissemination strategy for campaign educational materials to reach key targeted audiences. CDC may also disseminate key findings about public perceptions and educational needs via PowerPoint presentations to various audiences.

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

Interviews will be conducted by telephone while using an online screen-sharing platform to reduce burden to the respondents. If a participant is unable to use a screen-sharing platform (e.g., GoToMeeting), he/she will be sent the materials prior to the call using either the USPS or email. CDC will also use a teleconferencing service to listen remotely offline. Interview questions have been designed to be easily understood, non-duplicative in nature, and minimally burdensome. Efforts will be made to ensure the number of questions posed will be held to the minimum required in order to elicit the necessary formative and materials testing data. To the extent possible, interview opportunities will be available throughout the day and evenings to make it convenient for respondents.

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

The planned data collection efforts do not duplicate any other current or previous information collection efforts related to NCIRD’s *Legionella* campaign. A literature and environmental scan with state and local health departments, facilities management and prevention partners found no existing research on prevention practices for legionellosis with the groups targeted for this study. This research gap on *Legionella* regarding basic prevention and response activities and effective messaging with any audiences—including the four audiences targeted for this study—and the increases in outbreaks, provides the rationale for NCIRD to move forward on this study.

**5. Impact on Small Businesses and Other Small Entities**

Respondents will be individual persons. There is no impact on small businesses or other small entities.

**6. Consequences of Collecting Information Less Frequently**

A literature and environmental scan on *Legionella* formative research activities and message-testing found no existing research and very few materials on legionellosis prevention practices for the groups targeted for this study. The planned data collection efforts will be a first effort for NCIRD's *Legionella* campaign to understand knowledge, attitudes, and behaviors and test campaign messages with the four targeted audiences.

Formative evaluation is a critical part of the health communication process. Formative evaluation, which encompasses material testing activities, is essential to assess appeal, saliency, clarity, cultural appropriateness, and readability/understandability. If materials are not assessed, then resources could be expended without necessary attention and preparation paid to the overall communication objective and a scientifically sound campaign effort. Not testing materials can also increase the likelihood of unintended consequences from a message that is not understood and perceived as relevant by the target audiences—thereby decreasing credibility of an organization and/or health officials.

**7. Special Circumstances Relating to Guidelines of 5 CFR 1320.5**

This request complies with the regulation 5 CFR 1320.5

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

A. A 60-day Federal Register Notice (Attachment B) was published in the *Federal Register* on 06/25/2014, Vol 79, No. 122, pp. 36064-36065. CDC did not receive public comments related to this notice. The current submission does not require publication of an additional Federal Register Notice.

B. Consult Outside the Agency

The toolkit, "Developing a Water Management Program to Reduce *Legionella* Growth and Spread in Buildings," was reviewed by experts external to CDC including state and local health department staff, infection control practitioners and other hospital staff, building managers, the U.S. Environmental Protection Agency, the U.S. Veterans Health Administration, and the Council for State and Territorial Epidemiologists.

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

Each participant will receive a nominal monetary acknowledgement as a token of appreciation to facilitate the recruitment of the identified professionals who are in very specific specialty roles and expected to be hard to reach and recruit. This acknowledgement will reduce the number of no shows and the time of the research and government staff will have to invest for no shows. This will also help reduce the labor hours of recruiters, representing a potential cost savings to the Government. To the extent possible, interview opportunities will be available throughout the day and evenings to make it convenient for respondents.

To assess the need for and amount of an appropriate token of appreciation to participants, four IDI planners and moderators who work on government initiatives as well as for the private sector were

consulted. These individuals have extensive experience in planning and conducting in-depth interviews, and are in constant contact with research firms who recruit research participants around the country. They are up-to-date with recruitment challenges and current practices related to incentives that aid in recruitment of in-depth interview participants. The tokens of appreciation proposed here are the minimum recommended based on our consultation with these experts and their extensive knowledge and experience in effective recruitment and participation. They are also consistent with past practices related to CDC's research with clinicians. Participants are required to have phone and are preferred to have computer access and participate in the interview for 60 minutes.

Providing each clinician group (treating clinicians and infection control clinicians) with \$200 helps to show appreciation for his or her participation and recognize the effort involved in rearranging their schedule, workload, and/or patient load in their practice, hospital, or other job site to participate in the interview. They will also need to use a personal or business phone and computer during the 60 minutes. Additionally, clinicians are a specialized group and half of the clinicians interviewed will be from five areas with recent legionellosis outbreaks and with this limited catchment area and the fact that IDI interviews/research is not core to their practice, incentives that aid in recruitment will be important.

Building managers and water maintenance staff and water system risk management and remediation company staff are two critical target audiences for this research, as they are the end users of the guidance and educational materials being tested and the senior leaders in charge of prevention, detection, treatment, management, and remediation practices at the national, regional, state, and local community level. Their participation in this research is critical. This will be the first time that NCIRD has engaged these groups in research. We anticipate that this audience may be challenging to reach and may not have a high level of awareness of public health issues specific to legionellosis outbreaks and their impacts. These two groups will receive \$100.00 as a token of appreciation. This acknowledgement will be critical to aid in recruitment and to boost participation in the interviews.

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

The NCIRD Information Systems Security Officer reviewed this submission and determined that the Privacy Act does not apply.

Information collection and analysis will be conducted by contractors who specialize in health communication and education. All information will be kept private and secure to the extent permitted by law throughout the project. Contractors will treat the information in a secure manner and will not disclose, unless otherwise compelled by law. No personal information in identifiable form will be collected by or transmitted to CDC.

Respondents will be recruited by a professional market research firm that maintains its own records system. No new records system will be created. The contractor will recruit and screen respondents to participate interviews. The recruitment and screening process is designed to identify respondents who are in the target groups. Additional demographic questions are designed to ensure that interviewees include a mix of respondents from outbreak areas and non-outbreak areas. Recruiters will ask respondents a limited number of questions (see attachments 1-4) to help understand if respondents fit into target groups. Consent Forms (attachments 5-8) will be provided to participants. Personal identifying information needed by the recruiting firm or other personnel used to recruit and remunerate participants will not be shared with the researcher conducting the interviews or the contractor staff analyzing data. The identifiable information needed for scheduling purposes will be maintained in the



contractor's proprietary record system. CDC will not be privy to names, mailing addresses, telephone numbers or email addresses, or hospital/job location of any interviewees.

Interviews will be led by a professional interviewer, attended by note-takers, and observed by CDC staff members. During interviews, participants will discuss their background knowledge, attitudes and beliefs about *Legionella* and provide feedback on the messages and materials to be tested. This information is needed to assess the salience and appeal of materials designed to prevent *Legionella* and to respond to outbreaks. Participants will be informed that participation is voluntary as explained in the consent forms; they do not have to answer questions if they do not want to, and they can stop participating at any time. To maintain privacy and security within the limits of the law, participants will be asked to give only their first name when joining the call and when using any online meeting software. At the beginning of the interview, interviewees will be informed that the interview will be audio-recorded and transcribed, and that their names will not be included in the summary of findings provided to CDC. They will be given a chance to ask any questions they may have, and the interview will not begin until all questions have been answered. During the conversation, participants will be identified by first name only. Any recordings will be audio only, and any personal identifying information will be omitted from transcripts.

Analysis of the interview data will employ a transcript and note-based approach. While identifying information may be disclosed during screening and interviews (i.e. hospital where clinician works), it will be omitted from transcripts and all reporting. Analysis will include the identification of key findings and overarching themes. We do not plan to allow anyone outside of this project to listen to, watch, or read anything that is recorded.

Findings from the research will be grouped and summarized for the purpose of reporting and presentation, including a slide set and summary report. To ensure privacy is maintained in reporting, information will be summarized and will not include any personal identifying information or attribution to a specific participant. It will not be possible in any of the reporting to identify any individuals or organizations. The topline PowerPoint presentation and final summary report delivered to CDC will include background, methods, findings, direct quotes, and recommendations. It will include the screening instrument and interview guide as attachments. No identifying information will be included in any reporting to CDC. It will not be possible in any of the reporting to identify any individuals or organizations.

The audio files will be stored separately, and in a password protected location, from other deliverables on the project. All raw data collected during the process, including consent forms, notes, audio recordings of conversations, and printed transcripts, will be kept under strict control by the researchers involved; either in locked file cabinets in a protected area or on a password protected server. Screening information, held by the recruiting firm, will be held on a password protected server. Personally identifying information will not be linked in any fashion to this study. This raw data will be destroyed within five years after study completion.

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

This study was reviewed by CDC's Human Research Protection Office determined the research activity is exempt from IRB review under 45 CFR 46.101(b)(2).

The majority of questions asked will not be of a highly sensitive nature.

Some interviewees could consider questions about race, ethnicity, or other demographic characteristics to be sensitive, although such questions are unlikely to be highly sensitive. Additionally, a portion of the respondents may feel uncomfortable answering some questions about their level of disease awareness and/or measures to prevent (or lack thereof) *Legionella*. Others may be uncomfortable answers some questions if they have been personally involved in an outbreak. These questions, are necessary for to assist in the development of a targeted communication campaign and thus to the information collection. To minimize psychological distress, the interviewer will inform interviewees that they do not have to respond to any questions they do not want to answer and they may stop participating in the interview at any time.

**12. Estimates of Annualized Burden Hours and Costs**

***A12. Estimates of Annualized Burden Hours and Costs***

A. This is a one-time collection activity with the total burden estimate of 66 hours. Burden hours are summarized in Table 1.

Table 1 – Estimate of Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Individual_ Infection Control Clinicians	Interview Guide	16	1	1	16
Individual_ Treating Clinicians	Interview Guide	16	1	1	16
Individual_ Building Managers & Water Maintenance Staff	Interview Guide	8	1	1	8
Individual_ Water System Risk Management and Remediation Company Staff	Interview Guide	8	1	1	8
Individual_ Infection Control Clinicians	Screeener	32	1	10/60	6
Individual_ Treating Clinicians	Screeener	32	1	10/60	6
Individual_ Building Managers & Water Maintenance Staff	Screeener	16	1	10/60	3
Individual_ Water System Risk Management and Remediation	Screeener	16	1	10/60	3

Company Staff				
<b>Total</b>		144		66

There are 4 specialized respondents included in this collection activity including clinicians; senior level professionals from building managers and water maintenance staff; and water system risk management and remediation company staff.

BLS currently does not have wage data specific to the environmental remediation industry. Engineers who work in environmental remediation devise technical solutions for cleaning up pollution. They work closely with scientists and other remediation workers to implement the best methods for remediating polluted areas. They also might be responsible for developing methods to increase safety and to reduce the risk of illness and injury for a company's employees.

[http://www.bls.gov/green/environmental\\_remediation/remediation.htm](http://www.bls.gov/green/environmental_remediation/remediation.htm)

#### Estimated Annualized Burden Costs

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Individual_ Infection Control Clinicians	Interview Guide	16	\$90.00	\$1440.00
Individual_Treating Clinicians	Interview Guide	16	\$90.00	\$1440.00
Individual_ Building Managers & Water Maintenance Staff	Interview Guide	8	\$45.43	\$363.44
Individual_ Water System Risk Management and Remediation Company Staff	Interview Guide	8	\$40.68	\$325.44
Individual_ Infection Control Clinicians	Screeener	6	\$90.00	\$540.00
Individual_Treating Clinicians	Screeener	6	\$90.00	\$540.00
Individual_ Building Managers & Water Maintenance Staff	Screeener	3	\$45.43	\$136.29
Individual_ Water System Risk Management and Remediation Company Staff	Screeener	3	\$40.68	\$122.04
<b>Total</b>				\$4,907.21

According to the United States Department of Labor, Bureau of Labor Statistics, the 2015 median pay of a Health and Safety Engineer, an example of the individual from Water System Risk Management and Remediation Company Staff is \$40.68 hour

(<http://www.bls.gov/ooh/architecture-and-engineering/health-and-safety-engineers.htm>). A medical and health services manager, an example from Building Managers & Water Maintenance Staff, the 2015 median pay is \$45.43 an hour (<http://www.bls.gov/ooh/management/medical-and-health-services->

managers.htm). The 2015 median pay for Physicians and Surgeons is \$90.00 an hour (<http://www.bls.gov/ooh/healthcare/physicians-and-surgeons.htm>)

The total estimate of the cost to respondents for the burden hours for the collection of information is \$4,907.21 Bureau of Labor Statistics, U.S. Department of Labor, *Occupational Outlook Handbook, 2014-15 Edition*.

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

There are no capital and maintenance costs incurred by respondents.

**14. Annualized Cost to the Government**

The estimated annual cost to the Federal government is \$196,000. The annual cost reflects contractor and subcontractor labor in developing a research protocol, interview screener, consent forms, interview guides, recruiting, data collection, data transcription, data analysis, reporting, and a nominal monetary acknowledgement to participants as a token of appreciation. This is a one-time cost; this is not a recurring or on-going activity.

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

This is a new information collection submitted as part of an approved generic clearance.

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

The estimated timeline for conducting the interviews and study activities will begin after OMB clearance is received. Information will be collected over approximately a 8 week time period and will not exceed the approved expiration date. The anticipated timeline for key study activities is detailed below:

- August: Begin recruitment of participants
- August/September 2016: Conduct interviews
- September 2016: Transcription and analysis of interviews
- September 2016: Report writing, PowerPoint presentation, and summary report based on findings to CDC

Findings may be disseminated through presentations at meetings. All presentations will undergo CDC clearance review.

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

The display of the OMB expiration date is not inappropriate

**18. Exceptions to Certification for Paperwork Reduction Act Submission**

There are no exceptions to the certification

## References

Centers for Disease Control and Prevention. Legionella (Legionnaires' disease) Web site.  
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