

**Epidemiologic Study of Health Effects Associated With Low Pressure Events in
Drinking Water Distribution Systems**

Request for a New Data Collection

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This is a request from CDC for 2 years of new data collection.

A. Justification

1. Circumstances Making the Collection of Information Necessary

In the United States, drinking water distribution systems are designed to deliver safe, pressurized drinking water to our homes, hospitals, schools and businesses. However, the water distribution infrastructure in the U.S. is aging, with many of our pipes 50-100 years old and in need of replacement. The U.S. Environmental Protection Agency (EPA) estimates that over 250 billion dollars (U.S. Environmental Protection Agency 2009) will be needed over the next 20 years to upgrade, maintain, and replace the several million miles of pipelines and components that comprise our water infrastructure. Failures in the distribution system such as water main breaks, cross-connections, back-flow, and pressure fluctuations can result in potential intrusion of microbes and other contaminants into the distribution system that can cause acute gastrointestinal and respiratory illness (Swerdlow, Woodruff et al. 1992; LeChevallier, Gullick et al. 2003; Borchardt, Haas et al. 2004; Lambertini, Spencer et al. 2011) .

Approximately 200 million cases of acute gastrointestinal illness (AGI) occur in the U.S. each year (Mead, Slutsker et al. 1999) but we do not have reliable data to assess how many of these cases are associated with drinking water. From 1971-2006, over 800 waterborne disease outbreaks associated with drinking water were reported to the Centers for Disease Control and Prevention (CDC) by state, local, and territorial health departments, resulting in close to 600,000 cases of AGI (Craun, Brunkard et al. 2010). Exposure to waterborne pathogens through drinking water distribution systems accounted for approximately 15% of outbreaks in community water systems and 10% of outbreaks in public water systems (Craun, Brunkard et al. 2010). Still, outbreak surveillance systems only capture a small fraction of waterborne illness; the true burden of drinking water-related AGI and acute respiratory illness (ARI) in the U.S. is unknown. More specifically, limited data are available on human health risks associated with exposure to drinking water during and after the occurrence of low pressure events (LPEs) in drinking water distribution systems.

Past epidemiological studies have found conflicting results regarding the association between drinking water and AGI (Table A1.1). In intervention trials, the amount of gastrointestinal illness attributed to drinking municipal tap water has ranged from less than 11% (Colford, Wade et al. 2005) in the U.S. to 34% (Payment, Richardson et al. 1991) in Canada. This variation may be due in part to differences in the quality of the underlying source water (Hellard, Sinclair et al. 2001), treatment processes, participant blinding issues (Payment, Richardson et al. 1991; Payment, Siemiatycki et al. 1997), or other factors (Colford, Roy et al. 2006). The only study thus far that systematically

examined low pressure events and gastrointestinal illness using a prospective cohort study design was conducted in Norway from 2003-2004 (Nygard, Wahl et al. 2007). This study found that individuals exposed to low pressure events in the distribution system (e.g., water main breaks or repairs) were at a higher risk for gastrointestinal illness during the one week period after the break or repair as compared to individuals in unexposed areas. Among those exposed to a low pressure event, approximately 37% of cases of gastrointestinal illness were attributable to drinking tap water.

Table A1.1 – Studies of association between tap water consumption and acute gastrointestinal illness.

Country	Principal Investigator	Year	Incidence Rate Ratio	Risk Attributable to Tap Water (%)
Canada	Payment	1988–89	1.52	34%
Canada	Payment	1993–94	1.14	14%
Australia	Hellard	1997–99	0.99	—
U.S.	Colford	2000–02	0.98	—
Norway	Nygard	2005–06	1.58	37%

CDC is now requesting OMB approval of a new data collection (Table A1.2). The purpose of this data collection is to conduct an epidemiologic study in the U.S. (similar to the Norway study described above (Nygard, Wahl et al. 2007)) to assess whether individuals exposed to low pressure events in the water distribution system are at an increased risk for acute gastrointestinal or respiratory illnesses. This study would be, to our knowledge, the first U.S. study to systematically examine the association between low pressure events and acute gastrointestinal and respiratory illnesses. Study findings will help the EPA, CDC, and other drinking water stakeholders prioritize and direct future research and policy efforts that address public health risks associated with drinking water distribution systems. The study will have over 90% statistical power to detect an association of the magnitude identified in the Nygard study (~1.6). Smaller effect sizes might still have policy relevance, and finding a non-significantly increased risk in the current study would indicate that more research is needed to achieve the level of precision needed to verify health effects from low pressure events in the United States.

A prospective cohort study will be conducted in partnership with selected water utilities. The water utilities will provide information about low pressure events, including water main breaks and distribution system maintenance and repair activities. Households in areas exposed to the low pressure event and an equal number of households in an unexposed area will be randomly selected and sent a survey questionnaire. Study participants will be able to choose their method of survey response from a paper or web-based survey. After consenting to participate, the selected households will be asked to respond to questions about symptoms and duration of AGI and acute respiratory illness (ARI) that occurred during the 3-week period following the low pressure event.

Respondents will also be asked about relevant exposures during the 3-week period, such as their household water use, changes noted in their water service, international travel, children or adult household member employed at daycare, pets in the household and other animal contact, and recreational water exposure. Participation in this study will be voluntary. No financial compensation will be provided to study participants. A refrigerator magnet showing a 2-year calendar will be provided as a small token of appreciation to those invited to participate. The magnet will also serve as a visual aid for the study, because reference dates for the 3-week period queried in the study will be highlighted with removable tape.

We will conduct a pilot study before launching the full multi-site study. The pilot study will serve to (1) allow the study team to become familiar with the study implementation and logistical aspects of the study (e.g., selection of exposed and unexposed households, participant recruitment, water sampling and shipping, etc.), and (2) provide an opportunity to evaluate whether study procedures yield sufficiently high-quality data to answer the research questions. Following the pilot, the study team will modify study instruments and protocols accordingly before launching the full multi-site epidemiologic study across five water utilities. We have developed a Logical Framework tool for evaluating the data and procedures from the pilot study (Appendix C), and anticipate that evaluating the pilot, modifying and seeking approval of data collection instruments or modifying protocols and training materials will take no more than three months.

The pilot study will be a small-scale prospective cohort study among households that receive water from one participating water utility. For the pilot study, we will contact approximately 630 households following approximately 6 low pressure events. We anticipate that 378 surveys will be completed. Assuming that 2 people answer per household, on average, these will provide data on 756 individuals. A total of 51 estimated annualized hours of respondent burden will be required for the pilot study. As a result of conducting the pilot study, we expect to identify and address any potential challenges in identifying exposed and unexposed households, achieving an acceptable household participation rate, avoiding survey item non-response, and obtaining water samples from the water distribution system.

For the full multi-site study, we will conduct a prospective cohort study among households that receive water from five water utilities across the United States. The water systems will be geographically diverse and will include systems that use chlorine and monochloramine as their secondary disinfectants. These water utilities will provide information about low pressure events that occur during the study period. Following approximately 65 (one per month per utility, on average) LPEs, an estimated 6,750 households (2,250 from areas exposed to the LPE and 4,500 from comparable but unexposed areas) will be invited to participate. We estimate that 4,050 surveys will be completed and returned, providing data on 8,100 individuals. A total of 537 estimated annualized hours of respondent burden are expected for the full multi-site epidemiologic study. Thus, for the pilot and the multi-site study combined, 588 annualized burden hours are expected.

Table A1.2 -- Summary of Study Design

Study design	Prospective cohort study
Setting	Households receiving water from one of five water utilities across the U.S. Water utilities will be geographically diverse and will include systems that use both chlorine and chloramines as their secondary disinfectants
Primary outcome	Self-reported AGI
Secondary outcome	Self-reported ARI
Sample Size	Pilot Study: 756 individuals (252 exposed; 504 unexposed) Multi-site Study: 8,100 individuals (2,700 exposed; 5,400 unexposed)
Analytic methods	Calculate incidence rates for both exposed and unexposed groups, odds ratios, risk difference, and attributable risk percent; conduct conditional logistic regression, matched on low-pressure event.
Duration	24 months

This data collection supports CDC's research agenda goal of "Decreasing health risks from environmental exposures," as waterborne illnesses are environmental exposure health risks. Data collection authority is found in Section 301 of the Public Health Service Act (42 U.S.C. 241) (Appendix A).

Privacy Impact Assessment

Overview of the Data Collection System

Information for this data collection will be obtained from the public in two ways: paper surveys filled out by study respondents and returned via postal mail to CDC study staff; and web-based surveys filled out by respondents who respond via a password-protected website housed at CDC. Data from the paper surveys will be entered into a Microsoft Access (2007) database and data from the web-based survey will be provided from the computer developers in a SAS® 9.3 file.

Data will be collected by CDC staff and CDC contractors affiliated with the study. No other data collection partners will be involved. Data will be maintained for the lengths of time outlined in the sections below. Contact information (which is the only Information in Identifiable Form (IIF) that will be collected during this study) will be kept in a password-protected database separate from the survey information and will be deleted and blacked out from paper records within two years of study completion.

Items of Information to be Collected

The only IIF that will be collected will be contact information for the study participants (i.e., name, mailing address, phone number, e-mail if available). No dates of birth, social security numbers or other types of IIF will be collected. Within one week following an LPE, the water utilities will provide contact information of residential customers (service connections) affected by the LPE and residential customers (service connections) in an area unaffected by the LPE (e.g., persons in a different pressure zone) to CDC study staff, using a secure, encrypted file transfer protocol (FTP) site. From this address list, a

random sample of exposed and unexposed households will be generated by CDC study staff. Households will only be surveyed once (either as a household exposed to an LPE or as an unexposed household).

Information will be collected from the public on water service and use and self-reported illnesses (see Appendices D-M for survey instruments and related documents).

Information obtained through this data collection will include:

- Symptoms and duration of AGI and ARI
- Impact of illnesses, including hospitalization and loss of school/work
- Presence of chronic health condition with gastrointestinal or respiratory symptoms
- Household water service, use and consumption (type of drinking water, number of glasses of tap water consumed per person/per day, change in taste, color, or odor of tap water)
- Recent international travel
- Children or adult household member employed at daycare
- Pets in the household and other animal contact
- Recreational water exposure
- Basic demographics: age, race/ethnicity and sex

Our primary outcome measure will be self-reported AGI. AGI will be defined as an episode of vomiting or diarrhea (≥ 3 loose stools in a 24-hour period) during the three weeks after the low pressure event (“three week period”). Our secondary outcome will be self-reported ARI. ARI will be defined as at least two of the following: fever, sore throat, runny nose, or cough during the three week period of interest.

Participants’ initials will be asked for on the questionnaire in order to facilitate individual-specific responses. Initials will only be maintained in the study database until data cleaning is complete, after which they will be destroyed. Where paper records exist (i.e., paper surveys), initials will be blacked out within two years of data cleaning completion. Utility customer names will be used to facilitate communication, because personalized correspondence has been shown to improve survey response rates (Dillman 2007). Address information is necessary in order to identify households that are within the potentially exposed and unexposed areas and will also be used to address correspondence and estimate water distribution system-specific variables. Once these variables have been created, addresses will be deleted and blacked out from paper records within two years of data cleaning completion. Address information will be kept in a password-protected database separate from the survey information. Records of any address not selected to participate in the study will be deleted within two years of study completion.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

Should they choose to participate, survey respondents will have the opportunity to respond to the survey via the internet. No children (<18 years of age) will be asked to respond to the web-based (or postal version) of the survey. Regardless of which manner a

person chooses to participate in the study, for households where children <18 years of age are present, we will ask a parent or guardian to answer questions and provide information on behalf of the child. The consent brochure specifies that only an adult (≥ 18 years of age) is eligible to complete the questionnaire (see Appendix F), and this information is reiterated in the survey booklet (see Appendices G and H).

2. Purpose and Use of Information Collection

Contamination of water in distribution systems is a risk factor for disease, accounting for approximately 15% of drinking water outbreaks in community water systems reported during 1971–2006 (Craun, Brunkard et al. 2010). Each year, approximately 250,000 water main breaks occur in the U.S. (U.S. Environmental Protection Agency 2009) -- occasionally boil water advisories are issued, but we do not have good data to assess whether people are getting sick when water pipes break and pressure is lost. Few published studies have identified the human health risk associated with low pressure events in drinking water distribution systems (Payment, Siemiatycki et al. 1997; Hunter, Chalmers et al. 2005; Nygard, Wahl et al. 2007; Etheridge 2011). Two of these were prospective studies conducted outside the United States (Payment, Siemiatycki et al. 1997; Nygard, Wahl et al. 2007), and two were retrospective studies that relied on self-report of low pressure as well as self-report of symptoms (Hunter, Chalmers et al. 2005; Etheridge 2011). One retrospective study conducted in the United States, following a water emergency in Alabama, identified significant dose-response associations between number of days of low water pressure or loss of water service and increased prevalence of self-reported AGI (Etheridge 2011).

The U.S. EPA estimates that we will need to invest approximately \$300 billion over the next 20 years to upgrade and replace our aging drinking water infrastructure (U.S. Environmental Protection Agency 2009). In development of the Revised Total Coliform Rule (TCR) under which water quality in the distribution system is measured and regulated (as part of the Safe Drinking Water Act), EPA established a Research and Information Collection Partnership (RICP) to identify the highest priority research needs regarding drinking water distribution systems and to help determine whether regulatory action is needed to address distribution system risks (U.S. Environmental Protection Agency 2008). This study was selected as one of ten high priority areas for the drinking water sector (U.S. Environmental Protection Agency and Water Research Foundation 2010). CDC, EPA and the Water Research Foundation (WRF) have provided financial support for the study, recognizing the importance of understanding the risk that low pressure events in the nation's water distribution system infrastructure present for public health. While no single study can provide all information needed to inform EPA regulations, and the proposed study cannot claim to fully represent all utilities in the U.S. or conclusively determine whether small increases in risk (i.e., 50% or less increase) occur, the proposed study will supply the first systematically collected epidemiologic data on health effects from low pressure events in the U.S.

This study will also supply data that can contribute to a larger effort to estimate the burden of waterborne disease in the U.S., an activity which has been proposed in multiple agency budgets and is funded in part with full time equivalent (FTE) and other

programmatic support by the Waterborne Disease Prevention Branch within the Division of Foodborne, Waterborne and Environmental Diseases at CDC. These gaps include the association between low pressure events and illness (largely unknown in the U.S.), swimming frequency, and the amount of tap water consumed per day.

CDC, EPA, and other drinking water stakeholders will use the data generated from this study to inform regulation and rule development, and to direct future research efforts that address public health risks associated with drinking water distribution systems. The results from this epidemiologic study will also address EPA's research goals by providing a characterization of the baseline risks of adverse health effects associated with low or negative pressure events in the distribution system and the potential for reduction in those risks associated with different water treatment types or repair strategies. The negative impact of not conducting this study is that policy-makers, government agencies and the water sector will not have the data and information they need on the potential health impact associated with low pressure events and other breakdowns in our nation's drinking water infrastructure, which is critical to assess the safety and reliability of our public drinking water supply.

Privacy Impact Assessment Information

The only IIF that will be collected will be the contact information of potential study participants, which will be provided from utility billing records; no other personally-identifiable information will be collected. Address information is necessary in order to identify households that are within the potentially exposed and unexposed areas, and names will only be used to personalize study correspondence. Survey participants' addresses will also be used to calculate water distribution system-specific variables, such as water residence time in the distribution system, distance from the address to the site of the break or repair and other factors. These data will only be made available to the study team. The collection of contact information is expected to have minimal impact on the respondents' privacy.

3. Use of Improved Information Technology and Burden Reduction

This data collection will involve two response options for survey participants: mail and internet. All respondents will have the opportunity to respond via the internet, but based on previous studies we anticipate that 60% of respondents will respond using the web-based version of the survey (S. Roy, personal communication) (Smith, Smith et al. 2007).

A web-based version of the survey is being offered because it will:

- Reduce the time burden on respondents as compared to other methods of survey completion because of the built in skip patterns and internal logic controls for efficiently routing the respondent to the relevant questions;
- Employ a variety of prompts to encourage survey completion;
- Have data entry validation to limit data entry errors and reduce data cleaning efforts; and
- Data entry into the database is automatic thereby eliminating the need for manual data entry, which also limits data entry errors.

We expect both versions of the survey to take approximately 12 minutes to complete.

Participation in this data collection is voluntary, individuals will be able to discontinue participation at any time point, and all efforts will be made to reduce the time burden on participants.

4. Efforts to Identify Duplication and Use of Similar Information

During the past two decades, only a handful of epidemiologic studies looking at the risk for gastrointestinal illness associated with drinking water have been conducted globally (see Table A1.1). Two of these studies looked at distribution system risks using a prospective study design, and neither of these studies were conducted in the U.S.

Through consultation with other government agencies and national and international water experts, we feel confident that this type of study has not been conducted in the U.S. and would not be a duplication of efforts. Additionally, we have searched databases of scientific literature in the disciplines of public health, environmental engineering, and water microbiology (e.g., PubMed, Web of Science, Google Scholar), and attended national meetings (American Public Health Association, American Water Works Association, and American Backflow Prevention Association meetings as well as EPA symposia) to attempt to identify similar epidemiological studies that may have been conducted in the U.S. and elsewhere. This study would be, to our knowledge, the first U.S. study to prospectively examine the association between low pressure events in the water distribution system and illness (AGI or ARI). There are no similar data available and this study would not be a duplication of any studies currently being conducted in the U.S.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this data collection.

6. Consequences of Collecting the Information Less Frequently

Respondents will be asked to respond to this data collection only one time. There are no legal obstacles to reduce the burden.

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

This request fully 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 was published in the *Federal Register* on March 23, 2012, vol. 77, No. 57, pp. 17066-68 (see Appendix B). One non-substantive comment was received by a private citizen.

B. Consultation outside the CDC began in 2008 with the following persons and is ongoing:

U.S. Environmental Protection Agency (EPA)

Stig Regli (2008-2011)
 Scientist, Office of Ground Water and Drinking Water
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Nick Ashbolt (2008-2010)
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 Water Research Foundation (WaterRF)
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John Albert (2012)
 Senior Account Manager
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9. Explanations of Any Payment or Gift to Respondents

Study participants will receive a refrigerator magnet calendar that includes information on emergency preparedness from the CDC with the initial survey mailing. This magnet will highlight the three week period of interest for the study, thus serving as a visual aid to improve recall for participants. The magnet can also be regarded as a token gift. Including a token gift has been shown to improve response rates in mailed surveys (Dillman 2007).

10. Assurance of Confidentiality Provided to Respondents

IRB Approval

This study has been approved by CDC's IRB (see Appendix N).

Privacy Impact Assessment Information

A. The Privacy Act applies to this data collection because personally identifying information (e.g., contact information) will be requested and could potentially be linked to survey responses, although its intended use is (a) to randomly select study participants,

(b) to identify exposed and unexposed households and (c) to calculate water distribution system-specific measures (e.g., water residence time, distance from location of low pressure event, etc.) of consented participating households. The applicable System of Records Notice is 09-20-0136.

B. To protect respondent privacy, the study team has put the following technical, physical, administrative and procedural safeguards in place:

- Personal identification information (e.g., mailing address and other contact information) for each household is collected by water utility collaborators as part of their routine business operations (e.g., for billing and service purposes). Once an LPE has been identified, the water utility will provide the CDC study team with a list of addresses in the area potentially exposed to the LPE and a comparable or larger number of addresses in an area not exposed to the LPE, through a secure, encrypted website. At CDC, mailing addresses will be entered into the study address database (which will be separate from the study questionnaire database).
- Address information from households that participated in the study will be used to identify the households as an “exposed” or “unexposed” household and to calculate water distribution system-specific characteristics. Once these variables have been created and linked to the study questionnaire database, address information will be deleted. This will occur no later than two years after study completion. All addresses of households that were not selected to receive a survey will be deleted within two years of study completion. At no point will identifiable data exist in the study questionnaire database. Thus, permanent data will be anonymous. Respondents will not and cannot be contacted for further follow-up.
- We plan to report only anonymous, aggregate data.
- We have no plans to share participant personal identification information (e.g., address) and will keep individuals’ answers private and secure to the extent allowed by law. The measures to safeguard privacy are described to respondents in the informed consent process (Appendix F).
- Access to the web-based questionnaire will be obtained through the use of a personal pass code that is sent to each household in the survey packet that includes the paper version of the questionnaire. The personal pass code allows only that specific household to access the website. No personal identification information will be collected in the web-based version of the questionnaire.
- Personal identification information (e.g., mailing address) and questionnaire answers (including from the web-based and paper-based versions of the survey) will be stored on a CDC password-protected computer server. Completed paper surveys will be stored in a locked office. Access to the electronic data and to the paper documents will only be granted to authorized personnel at CDC who are working on the study.

CDC study staff who are contractors are subject to a non-disclosure agreement.

C. Return of a completed survey constitutes consent, as stated in the instructions on the cover of the survey booklet. (Appendices G and H).

Participants are told that the information they provide will be treated in a secure manner and that no identifying information will be shared or appear on any reports. Specifically, the consent brochure states:

“When the study is complete, your contact information will be removed from our files. No personal information about you will appear on any report. Survey responses will be treated in a secure manner and will not be disclosed, unless otherwise compelled by law.”

D. Study participants are informed that participation is voluntary and that they are not required to answer any specific questions. Specifically, the consent form states:

“There is no penalty if you decide not to participate. However, we hope that you will choose to participate in this important study.”

11. Justification for Sensitive Questions

There are no sensitive questions in this data collection. We do ask participants to provide information on race/ethnicity as this information can be used to help identify differences that may inform the development of evidence-based guidelines and health messaging.

12. Estimates of Annualized Burden Hours and Costs

A. Annualized Burden to Respondents

We anticipate a response rate of approximately 60%. Previous recent mailed surveys conducted in the U.S. pertaining to drinking water have achieved response rates of approximately 40%; however, we plan to implement several study design modifications following the Dillman Tailored Design Method to encourage participation and improve response rates compared to previous studies (see section B.3 for a discussion of how this was derived) (Dillman 2007). We plan to include a total of 71 low pressure events in this study (6 at a single utility in the pilot phase and 13 at each of 5 utilities in the multi-site phase). Based on the expectation that the multi-site study will include 15 small events that affect at least 10 households, 35 medium events that affect at least 37 households, and 15 large events that affect at least 53 households, we expect to obtain data on approximately 4,050 households from 65 events. We estimate that survey responses will include data on 2 individuals per household, on average, resulting in health outcome data on approximately 8,100 individuals. The proposed recruitment schedule will provide over 85% power to detect an odds ratio of 1.8 in a stratified analysis, thus we will be able to analyze data separately by secondary disinfectant type. The recruitment schedule will provide over 90% power to detect an odds ratio of 1.6, the effect size identified in the Nygard study, in an overall analysis (see section B.1 for a description of how this was calculated).

The following estimates represent the average annualized burden to respondents. For each version of the questionnaire, we based our estimates of the average burdens per response on the following:

- For the paper-based version of the survey, we conducted an informal pretest with five CDC staff members and one member of the general public. The paper-based

survey took, on average, approximately 12 minutes for these individuals to complete.

- For the web-based version of the survey, we estimated that the web-based survey would take the same amount of time to complete as the paper-based survey but we did not do a formal pre-test of this version of the survey. A survey conducted within our Branch found that web-based surveys took significantly less time than paper-based surveys (S. Roy, personal communication) so we feel confident that the web-based version will not take longer than the paper version.

Of the estimated total 4,428 households that return the survey (4,050 from the full study, 378 from the pilot), we anticipate that 60% of respondents (2,430 households from the full study, 227 from the pilot) will respond via the web-based survey, and 40% (1,620 households from the full study, 151 from the pilot) via paper (see section B.1 for a discussion of how this was calculated). Each household respondent will complete only one survey and the average burden per response for both versions of the survey is expected to be 12 minutes. The estimated annual burden hours to respond to web-based questionnaire is 266 hours ($1/2 \times (2,430 + 227) \times 12/60$), and the paper-based questionnaire 178 hours ($1/2 \times (1,620 + 151) \times 12/60$), for a total of 444 (266+178) annual burden hours for households filling out the household survey.

Utility personnel will assume some additional burden through their participation in the study. We consulted with one water utility for input on the time needed to complete the data collection for each event. The estimated time required to complete the Low Pressure Event (LPE) Form is 45 minutes (15 minutes to write in the information and 30 minutes to collect and ship the water samples). The estimated time to provide contact information on affected and unaffected households is 3 hours (2 hours for environmental engineer to run pressure models and 1 hour of clerical time for a total of 3 hours). The estimated annualized burden for the LPE form is 9 hours for the multi-site study and 1 hour for the pilot, the estimated annualized burden for the water samples is 18 hours for the multi-site study and 2 hours for the pilot study, and the estimated annualized burden for the address lists is 105 hours for the multi-site study and 9 hours for the pilot.

Thus, the total annualized response burden for this data collection is estimated at 588 hours (537 hours for the multi-site study and 51 hours for the pilot study) (See Table A.1.3). The total burden for the two-year study is estimated to be 1,176 hours.

Table A.1.3- Estimates of Annualized Burden Hours

Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (hours)	Total Burden* (hours)
Multi-site Study				
Web-based questionnaire	1,215	1	12/60	243
Paper-based questionnaire	810	1	12/60	162

LPE form & samples	5	7	45/60	27
Line listings	5	7	3	105
Total (full study)				537
Pilot Study				
Web-based questionnaire	114	1	12/60	23
Paper-based questionnaire	76	1	12/60	16
LPE form & samples	1	3	45/60	3
Line listings	1	3	3	9
Total (pilot study)				51
Total (pilot and full study)				588

*Estimates have been rounded up to the nearest whole number.

B. Annualized Cost to Respondents

The annualized cost to water utility customer survey respondents for the multi-site study was estimated using the total annual burden (243 + 162 = 405 hours) and the mean hourly wage in the U.S. for all occupations (\$21.74, obtained from the U.S. Department of Labor's May 2011 national occupational employment and wage estimates data, available at: http://www.bls.gov/oes/current/oes_nat.htm/oes113111.htm#00-0000). Given these numbers, the maximum total annualized cost of this data collection to utility customer respondents is estimated to be \$8,804.70 (405 x \$21.74 = \$8,804.70) (See Table A.1.4). Using the same assumptions, the maximum annualized cost to water utility company survey respondents for the pilot study is estimated to be \$847.86 (23 + 16 = 39 hours at \$21.74 per hour) (see Table A.1.4).

The annualized cost to the water utility company personnel who complete the LPE forms and collect the environmental samples for the multi-site study was estimated to be 27 hours and the mean hourly wage in the U.S. for industrial machinery mechanics \$23.09 (obtained from the U.S. Department of Labor's May 2011 national occupational employment and wage estimates data, available at: <http://www.bls.gov/oes/current/oes499041.htm>). Given these numbers, the maximum total annualized cost of this data collection to utility company mechanic respondents is estimated to be \$623.43 (27 x \$23.09 = \$623.43) (See Table A.1.4). Using the same assumption, the maximum annualized cost to water utility company mechanics for the pilot study is estimated to be \$69.27 (see Table A.1.4).

To provide line listings of customer contact information, the utilities will first run pressure models to identify affected and unaffected areas (to be performed by an engineer, taking approximately 2 hours), and then use utility billing records identify household contact information (performed by clerical staff, taking approximately 1 hour) for CDC staff to randomly select participants from (Appendix M). The annualized cost to the water utility company personnel who run pressure models for the multi-site study was estimated using the annual burden (105 hours x 2/3 = 70 hours) and the mean hourly wage in the U.S. environmental engineers (\$40.17, obtained from the U.S. Department of

Labor's May 2011 national occupational employment and wage estimates data, available at: <http://www.bls.gov/OES/Current/oes172081.htm>). Given these numbers, the maximum total annualized cost of this data collection to utility company engineer respondents is estimated to be \$2,804.90 (70 x \$40.07=\$2,804.90) (See Table A.1.4). Using the same assumption, the maximum annualized cost to water utility company water engineers for the pilot study is estimated to be \$240.42 (see Table A.1.4).

The annualized cost to water utility clerical staff who provide CDC with the line listings of addresses of affected and unaffected residents for the multi-site study was estimated using the annual burden (105 hours x 1/3 = 35 hours) and the mean hourly wage in the U.S. for billing and posting clerks (\$16.31, obtained from the U.S. Department of Labor's May 2011 national occupational employment and wage estimates data, available at: <http://www.bls.gov/oes/current/oes433021.htm>). Given these numbers, the maximum total annualized cost of this data collection to billing clerks is estimated to be \$570.85 (35 x \$16.31 =\$570.85) (See Table A.1.4). Using the same assumption, the maximum annualized cost to water utility company clerical staff for the pilot study is estimated to be \$48.93 (see Table A.1.4).

Summing across the four respondent categories, we anticipate that the maximum total annualized cost for the multi-site study would be \$12,803.88, the maximum total cost for the pilot study would be \$1,206.48, and the pilot and full study combined would be \$14,010.36.

Table A.1.4- Annualized Cost to Respondents

Respondent	Annualized Burden Hours	Hourly Wage Rate	Annualized Respondent Cost
Multi-site Study			
Water Utility customer	405	21.74	8,804.70
Water utility environmental engineer	70	40.07	2,804.90
Water utility maintenance worker	27	23.09	623.43
Water utility billing clerk	35	16.31	570.85
Total (full study)			12,803.88
Pilot Study			
Water Utility customer	23	21.74	847.86
Water utility environmental engineer	6	40.07	240.42
Water utility maintenance worker	3	23.09	69.27
Water utility billing clerk	3	16.31	48.93
Total (pilot study)			1,206.48
Total (pilot and multi-site study)			14,010.36

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

There are no other costs to respondents or record keepers.

14. Annualized Cost to the Government

The costs incurred by the government for this one-time data collection include the costs for personnel time, printing and mailing paper-based surveys, laboratory supplies, travel, and publication charges (see Table A.1.5). The estimated annualized cost to the federal government for the pilot and full study is \$319,796 (Table A.1.5).

Table A.1.5 – Annualized Budget, Multi-site and Pilot Study Item	Hours or Units per Year	Hourly or Unit Cost	Total Cost per Year
Epidemiologist	520	51.38	26,718
Sr. Environmental Engineer (Research)	416	71.76	29,853
Environmental microbiologist	936	37.25	34,866
Project coordinator	2080	33.65	69,992
IT Support staff	104	62.50	6,500
Student Assistant	333	12.00	3,996
Laboratory support staff (contractor)	250	59.00	14,750
Laboratory supplies	426	125.00	53,250
Printing and mailing	6,854 ^a	10.5 ^b	71,971
Water utility site visits (2 CDC staff/visit)	3	2,300	6,900
Page charges and reprints for publishing study paper	1	1,000	1,000
Total:			319,796

^aThe annual units of mailings were determined from the statistical power calculations and an expected 60% participant response rate. Since the mailings will be sent at different frequencies throughout the study, 6,854 annual units reflects the average number of units needed to reach the total cost of \$71,971 from our itemized budget.

^bThe unit cost for mailings include the cost for printing, envelopes, labels, and the calendar magnet. Since there are multiple mailing items that have different unit costs, the unit cost of 10.5 represents the total unit costs for all mailing items.

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Table A-16 provides the data collection activity schedule.

Table A.1.6- Data collection activity schedule

Activity	Time Frame
Data collection	12-18 months after obtaining OMB approval
Data analysis	18-24 months after obtaining OMB approval
Manuscript development	24-36 months after obtaining OMB approval

This is a prospective cohort study. The goal of the analysis is to assess whether households in areas exposed to LPEs have an increased risk for AGI and ARI. The primary unit of analysis will be the individual. Secondary analyses may be conducted using the household as the unit of analysis. We will measure the incidence of AGI and ARI among exposed and unexposed individuals and calculate odds ratios (OR), risk difference, and attributable risk percent for AGI and ARI associated with LPEs in drinking water distribution systems. Since the exposed and unexposed households selected for each LPE will be matched on housing type, pipe material and size, and drinking water source, conditional logistic regression will be implemented to account for this matched sampling design. By conditioning on the LPE, we will be able to appropriately control for these matching variables and evaluate the effect of LPE exposure within each LPE. We will also control for individual-level covariates, such as age and chronic medical conditions. In addition to analyzing data from participants across all utilities combined, we plan to stratify our analyses by type of water treatment used (i.e., chlorine versus monochloramine as a secondary disinfectant). Descriptive and inferential statistical analyses will be conducted using statistical software SAS v.9.3 (SAS Institute, Cary, NC).

We anticipate that the participation rate in this study will be approximately 60%, however; in the event that we do not reach full participation, we have planned for the possibility of assessing non-response bias. We will conduct a non-response bias analysis by comparing responders to non-responders with respect to available exposure data (e.g. exposure to LPE) overall and stratified by water system, characteristics of LPE, and water utility characteristics. We will also conduct a sensitivity analysis to determine the potential impact on study results given different assumptions about illness rates in exposed and unexposed non-responders. If our response rate is lower than anticipated, we will still have 80% power to detect an odds ratio of 1.6 in the overall analysis as long as at least 40% of invited households participate; however, our power to conduct a stratified analysis would be limited (see Part B section 3 for details of power calculations with 40% response rate).

In the pilot study, we will employ a multiple contact mailing strategy (Dillman 2007). The pilot study will help us refine our estimates of response rates using this contact methodology. Based on the response rates obtained during the pilot phase, we will evaluate this contact strategy, and may revise our contact methods for the full study with the goal of improving our response rate. Contingency strategies might include staffing a phone bank to call non-responders and attempt to conduct the survey by telephone, and conducting the surveys in-person using teams of trained interviewers who travel to the selected households. We do not anticipate that these alternative strategies would impact respondent burden, although they might be more labor-intensive for the study team.

Illustrative table shells:

Table X. Number of low pressure events (LPEs) and exposed and unexposed persons by treatment type

Water Treatment Type	Low Pressure Events (LPEs)	<u>Exposed Persons</u>		<u>Unexposed Persons</u>	
		Total	Interviewed	Total	Interviewed
Chlorine					
Monochloramine					
Total					

Table Y. Baseline characteristics of exposed and unexposed persons

Characteristic	Exposed Persons	Unexposed Persons	<i>p</i>
Characteristic A			
B			
C			
[etc...]			

Table Z. Attack rate (AR) and odds ratio (OR) of acute gastrointestinal illness (AGI) (or acute respiratory illness [ARI]) in persons exposed to LPEs compared to persons unexposed to LPEs, by water treatment type

Characteristics	<u>Exposed Persons</u>			<u>Unexposed Persons</u>			OR	95% CI	Risk Difference	Attributable Risk %
	Ill	Total	AR (%)	Ill	Total	AR (%)				
<i>Strata 1 (water treatment type 1)</i>										
Characteristic A										
B										
C										
[etc ...]										
<i>Strata 2 (water treatment type 2)</i>										
Characteristic A										
B										
C										
[etc ...]										

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

We are not requesting an exemption to the display of the OMB expiration date.

18. Exceptions for Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

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List of Attachments

- A. Authorizing legislation
- B. 60 day Federal Register Notice
- C. Pilot evaluation logical framework
- D. Advanced letter
- E. Cover letter
- F. Consent brochure
- G. Household survey (paper version)
- H. Household survey (web version screen shots)
- I. Thank you / reminder letter
- J. Replacement survey cover letter
- K. Final appeal letter
- L. Low pressure event form
- M. Utility Customer Information form
- N. IRB Approval Continuation Memo