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

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Non-substantive Change Request

Part B

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1. Respondent Universe and Sampling Methods

The pilot demonstrated the feasibility of the study design and survey methods. The customer service lists were a reliable source of contact information, with deliverable addresses available for 98% of contacted households. The pilot survey response rate of 37% was comparable to recent CDC surveys about waterborne illnesses. A CDC survey that was administered after a community-wide drinking water outbreak used water utility billing information to contact households for a postal survey and attained a 33% response rate (Ailes et al., 2013). A CDC and

National Park Service survey about illness, including AGI, and injury among backcountry travelers attained a 39% response rate among respondents that consented to participate prior to the survey administration; respondents specified a preferred method of either e-mail or postal contact, and researchers implemented a multiple contact strategy (Rajasingham et al., 2013). Additionally, the pilot survey response rate was similar to a series of population studies on gastrointestinal illness and drinking water consumption patterns in Canada, in which researchers used a similar strategy of selecting random samples of households from contact lists, first contacting households with an advance letter, and then utilizing a multiple contact strategy, although these studies used a telephone mode of survey administration (44%) (Jones et al., 2007; Thomas et al., 2006). The strategy of cold contacting random samples of water utility customers by mail was resource efficient compared to conducting in-person interviews; however, the trade-off might have been a lower response rate. Higher response rates are more likely to be achieved in in-person interviews (59%) (Arnold et al., 2013). The goal for the full study is to reach a 60% response rate to ensure generalizability of findings and to provide enough statistical power to conduct stratified analyses by utility disinfectant type. See section B.3 for a discussion on methods for improving the anticipated response rates.

The power calculations were not changed following the pilot.

2. Procedures for the Collection of Information

2.1 Methods

The study design and protocols were piloted at one utility site and evaluated by CDC; the evaluation was used to streamline and improve the study processes, protocol, and materials. During the LPE, water utility personnel completed a standard LPE form describing the event and repair process. The utility collected water samples from exposed (low pressure) and unexposed (normal pressure) areas. Households in exposed and similar but unexposed areas were mailed a questionnaire about recent illness symptoms, household water exposures, and other risk factors to assess the increased risk associated with the LPEs.

The study team collected field and laboratory data from the six LPEs from December 2013 to March 2014. Data collection for the household survey administration was completed in May 2014. A total of 646 households were contacted, LPE forms were completed for each event, and 24 ultrafiltration water samples and 36 grab samples were collected and analyzed. Data were collected and stored securely in several databases, housed at CDC. LPE form data were summarized to assess the usability of the form, data quality, and burden of work for the utility (see Attachment G for revised LPE form). Survey data were summarized using descriptive percentages of both household-level and individual-level data to assess data quality and completeness.

2.1.1 Identification of Potential Study Participants – no change

2.1.2 Eligibility – To exclude potentially ineligible residential properties (e.g., rental properties or seasonal homes), we excluded addresses for which the mailing and premise addresses did not match (see Attachment H for revised customer contact list).

2.1.3. Advance letter – We made minor changes to the wording to improve clarity and reduce reading time. (see Attachment I for revised advance letter)

2.1.4 Enrollment – survey materials will be mailed to selected households 2 weeks after the LPE, instead of 3 weeks after. We will add an email contact with link to secure web survey, user name, and password (Attachment F); this will be timed to arrive at about the same time as the postal survey packet. (see Attachment J for paper cover letter)
2.1.5 Consent Process – no change (see Attachment K for consent brochure)
2.1.6 Survey Questionnaire (see Attachment L for revised paper version and Attachment M for revised web version)

The pilot survey helped the study team identify items that could be eliminated, information gaps that could be filled, and response options that should be added to existing questions. Minor changes have been made to the survey instrument to improve the quality of the data and facilitate ease of participation. The recall period has been changed from three weeks to two weeks because this time period should be easier for respondents to recall, and because it is more appropriate given the incubation period of most waterborne gastrointestinal pathogens. Specific question changes are detailed in the justification.

Descriptive data were used to simplify the survey. Survey data indicated that the household water use question could be removed, and the wording of the individual water use question could be simplified to focus on determining which respondents drank their home tap water (i.e., determining which respondents in the exposed areas were not actually exposed to the LPE because they did not consume any tap water), rather than describing each respondents' main drinking water source. One answer option was added to each of the household filter, pets, and water use questions, informed by what respondents wrote in the "other" categories.

To facilitate creating illness definitions from the AGI symptom questions, the illness details section was moved directly after the stomach problem questions and simplified to only ask details about the stomach problems. Additionally, the 3-week recall period was shortened to 2-weeks to improve the recall of the illness onset date and number of symptoms.

To further simplify the illness sections, the cold/flu section was changed to a section on other recent symptoms that asked more general questions about more varied symptoms (e.g., rash, eye infection). The follow-up questions regarding illness onset date and number of days of symptoms were substituted with more general questions about illness impact (i.e., health care seeking behavior, missed school/work).

2.1.7 Thank you/reminder notecard – no change (Attachment N)
2.1.8 Replacement questionnaire mailing – no change. (Attachment O)
2.1.9 Final Appeal Letter (Attachment P)

Prior to mailing this appeal, the study team will add an outbound telephone call as a reminder before the final appeal letter is sent in an attempt to further increase the response rate. (Attachment C)

2.1.10 Low Pressure Event Information (Attachment G)

The study team reviewed information collected in the Low Pressure Event Form and received feedback from the utility participating in the pilot study, and made minor modifications to simplify and improve the ease of completing the form.

We have modified the utility customer information form to include a template for a hydraulic map and a checklist of attributes of the exposed and unexposed areas to

standardize and simplify the collection of this information. (Attachment H) This replaces the collection of information on hydraulic model outputs described in the original submission, but is performed by similar staff and takes a similar amount of time, so no net change in the burden is expected. Additionally, during the pilot we learned that the utility could produce one customer service list for both areas; we also learned we need to collect the premise and mailing address for data quality checks (e.g., excluding part-time residents, "snow birds", that are potentially not home during certain times of the year to receive the survey). Finally, phone number and email address were added to the form. The fields for the customer number and reclaimed water service were removed as these were not used in the pilot.

2.1.11 Quality Control Procedures – No change

3. Methods to Maximize Response Rates and Deal with Non-response

In the pilot study, the overall survey response rate was 37%, the response rates for each event ranged from 32-43% and did not appear to vary by event type or size. Additionally, the response rates were similar in LPE (38%) and non-LPE areas (36%). The non-response rate was < 10% for the main survey items. There was higher non-response for follow-up questions for the illness details onset date and number of days with symptoms. Other illness detail questions such as the number of days of school or work missed because of the illness, or healthcare seeking behavior were nearly complete. Skip patterns were built into the web survey interface; for the paper surveys, data from the mail surveys indicated that the majority of respondents correctly skipped or answered the appropriate questions. System data demonstrated that the web-based survey took customers a median of 11 minutes to complete, suggesting that the time burden for participation was low and in line with the anticipated time of 12 minutes. Most (94%) of the web surveys were submitted successfully, demonstrating there was limited survey break-off.

To improve response rates in the full study, the study team will modify the survey procedures and will increase efforts to promote the study in the participating communities. Nearly half of the page views for the study website (46%) occurred in the 30 days following the press release, before any survey materials were mailed out, suggesting that additional ongoing publicity in the study communities has potential to motivate participants. The study team will implement additional community outreach throughout the study period to improve community acceptance of the study and to boost response rates. Possible methods include implementing local public service announcements or periodic advertisements in local print media. Improving the study response rates is a priority for CDC branch-level management, who has prioritized obtaining resources for targeted communications efforts, including contract time with a health communicator.

The multiple mailing contact strategy encouraged participation, evidenced by boosts in survey response following the mail prompts. The majority of respondents chose to return the survey by postal mail (70%), using the provided return envelope. The data quality of the web surveys was higher than the paper surveys because data verification rules and question skip patterns were built into the survey interface. Since the web survey instructions and access information were printed on the survey materials, rather than sent electronically to customers, it might have been

inconvenient for respondents to access a computer, type the link to the website, and log-in to take the survey. To encourage web survey participation and reduce respondent burden in hopes of increasing response, the study team will send the survey link electronically to customers that have email addresses on file (approximately 10% of pilot utility customers). Additionally, the study team will add an outbound phone call as a reminder before the final appeal letter is sent.

Additional minor changes to the survey will be made to help boost the response rate. The survey recall time period will be shortened from 3 weeks to 2 weeks, and the illness questions and water use questions will be simplified. The specific changes to the content are outlined in Tables 1 and 2 of the Justification of Change document.

The survey supplemental materials will be modified slightly to make them easier and faster to read. For example, the advance letter was edited to improve clarity and readability, and the web survey will have fewer questions per screen to make the survey easier to read. The study team does not have the resources to provide financial incentives.

Although 94% of the web survey respondents successfully completed the survey, indicating survey break-off was not a major concern, additional measures will be taken to encourage respondents to finish the web survey, including reformatting the survey and simplifying instructions to make the survey appear shorter and to reduce reading time.

4. Tests of Procedures or Methods to be Undertaken

The data collection instruments and the participant information materials were piloted at one water utility site and evaluated by CDC. Overall, the pilot demonstrated that the study design and procedures will allow the study team to collect the data needed to meet the study goal and aims. Following the minor modifications to the study materials and protocols to streamline field data collection and improve the household survey response rates outlined in this non-substantive change request, the study team will be ready to implement the full study to determine whether LPEs are associated with illness.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Statistical consultants for study design:

- Add Xin (Lucy) Lu, CDC/ORISE (Tracy Ayers is supervisor) – ph. 404-718-4868, email: xjp2@cdc.gov
- Add Mark J. Lamias, Leidos Contractor to CDC (Robert Fish is supervisor) – ph. 404-248-6413, email: bnz6@cdc.gov

Persons who designed the data collection:

- Add Elizabeth Adam, CDC/ORISE (Julia Gargano is supervisor) – ph. 404-718-4873, email: wsi7@cdc.gov

Persons who will collect the data:

- Add Vincent Hill, CDC – ph. 404-718-4151, email: veh2@cdc.gov
- Add Chandra Schneeberger, contractor for CDC (Vincent Hill is supervisor) - ph. 404-718-4154 email: ipq7@cdc.gov

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