

Mass Gathering Outbreaks: Assessment of Frequency, Policy, and Communication Strategies

OSTLTS Generic Information Collection Request
OMB No. 0920-0879

Supporting Statement – Section A

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- The purpose of this data collection is to identify the frequency of mass gathering-related outbreaks due to respiratory infections, and determine the policy and communication strategies to prevent or control these outbreaks.
- Intended use of the resulting data is to strengthen CDC's Pre-Pandemic Community Mitigation Guidance
- The methods used for this information collection is the administration of a short online assessment tool.
- The subpopulation to be studied is 50 state health department epidemiologists and 31 local health department directors.
- Responses will be analyzed using SAS statistical software to estimate the frequency of mass gathering related respiratory disease outbreaks and to conduct univariate analysis of the mean size and duration of these outbreaks. Bivariate analysis will be performed to estimate the use of certain prevention and control measures by type of mass gathering.

Section A – Justification

1. Circumstances Making the Collection of Information Necessary

Background

This data collection is being conducted using the Generic Information Collection mechanism of the OSTLTS OMB Clearance Center (O2C2) – OMB No. 0920-0879. The respondent universe for this data collection aligns with that of O2C2. Data will be collected from 50 state health department epidemiologists (see **Att. A - State Health Department Epidemiologists**) as well as 31 local health department directors (see **Att. B - 31 Local Health Department Directors**). These local health departments were selected because each of these health departments serves a population > 250,000. As the largest local health departments in the country, they are the most likely to have mass gatherings (e.g. sporting events, music festivals, fairs) in their jurisdiction and have the staff to investigate and report on these outbreaks. Although smaller health departments such as those in college towns, for example, could also have numerous mass gatherings, we elected to recruit the largest 31 local health departments in the country to increase the chances of capturing as many mass gathering-related respiratory disease outbreaks as possible. There will be no duplication across the 31 local health departments and the 50 state health department included within this assessment, making 81 the respondent universe total.

This information collection is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241). The information collection falls under the essential public health service(s) as indicated below.

1. Monitoring health status to identify community health problems

- 2. Diagnosing and investigating health problems and health hazards in the community
- 3. Informing, educating, and empowering people about health issues
- 4. Mobilizing community partnerships to identify and solve health problems
- 5. Development of policies and plans that support individual and community health efforts
- 6. Enforcement of laws and regulations that protect health and ensure safety
- 7. Linking people to needed personal health services and assure the provision of health care when otherwise unavailable
- 8. Assuring a competent public health and personal health care workforce
- 9. Evaluating effectiveness, accessibility, and quality of personal and population-based health services
- 10. Research for new insights and innovative solutions to health problems ¹

Mass gatherings can create environments conducive for infectious disease transmission, including pandemic influenza. The risk of transmission is likely to be associated with the type, duration, and size of the mass gathering as well as the susceptibility of the participating population². Some mass gatherings, such as outdoor sporting events, may involve limited social mixing and are held in settings with ample ventilation. Other mass gatherings, however, can involve significant social mixing over several days, such as trade shows and music festivals³. Travelers to a mass gathering can not only introduce an infectious disease to a previously unaffected area, but also amplify transmission at the gathering and further disseminate transmission following their return home⁴. Even when a circulating pathogen has a relatively low transmission probability, intensely crowded settings can lead to high secondary attack rates.

During a pandemic, public health officials will have to consider whether the mass gatherings should be postponed or cancelled depending on the timing, duration, and size of the event and whether people will be traveling to and from the event from other (affected or not-yet-affected) communities. If this risk is low, other non-pharmaceutical interventions (e.g., enhancing personal protective measures) could be used to minimize the potential for influenza transmission. These recommendations are outlined in the Pre-Pandemic Community Guidance developed by the Centers for Disease Control and Prevention. The most recent version of the Pre-pandemic Planning Guidance was distributed to state and local health departments in 2007⁴. The guidance was developed to help states, local, and county health departments to prepare and respond to an evolving pandemic of influenza depending on varying levels of severity and transmissibility.

During the 2009 Influenza A H1N1 pandemic, the document was used as a reference for recommendations on the use and timing of nonpharmaceutical interventions for mitigating the pandemic until an effective vaccine was developed. However, as the pandemic evolved over time a number of gaps were noted in the evidence-base about the effectiveness and feasibility of the use of nonpharmaceutical interventions at various settings, including at mass gatherings. The U.S. Department of Health and Human Services requested that CDC address this gap in order to strengthen the Pre-Pandemic Community Guidance before the next pandemic (**Att. C – CDC presentation to Department of Health and Human Resources**). Although CDC collects information from state health departments on outbreaks through CDC’s Notification of Outbreak

Reporting System (NORS), this is an annual voluntary reporting system and does not focus on mass gatherings or respiratory infections. Within this context, CDC aims to better understand the frequency, type and location of mass gatherings with the greatest risk for infectious disease outbreaks, with a focus on outbreaks of influenza and other acute respiratory diseases. To date, there is no aggregate report or publication on mass gathering related outbreaks in the United States.

Due to concerns about the possible impact of mass gatherings during a pandemic of influenza as well as SARS-like viruses, or MERS, CDC is collaborating with the Council of State and Territorial Epidemiologists (CSTE) and the National Association of County and City Health Officials (NACCHO) to learn more about mass gathering related outbreaks. CSTE and NACCHO members (state and local health departments) will serve the front lines during a pandemic or other public health emergency. In this collaborative project, the purpose is to obtain information on mass gathering outbreaks due to acute respiratory infections occurring in the United States from January 2009 through December 2014. These dates were agreed upon by CDC, CSTE, and NACCHO in order to capture adequate information on mass gathering-related infectious disease outbreaks while minimizing the response burden. From discussions with CDC field staff (Career Epidemiology Field Officers), it was estimated that approximately 3 mass gathering outbreaks due to an acute respiratory disease occurred during the assessment time frame from each jurisdiction included in our respondent universe (50 state health departments and 31 selected local health departments). We included the year of 2009 in anticipation of capturing information on influenza or influenza-like outbreaks occurring at mass gatherings due to the Influenza A H1N1 pandemic. The assessment will capture information on approximately 243 (i.e., 3 outbreaks per 81 health jurisdictions) mass gathering-related respiratory disease outbreaks. A longer assessment time frame would create higher burden on respondents; a shorter time frame may minimize the amount of information available to address the assessment questions. Since state and local health departments have the option of reporting outbreaks in any setting, including mass gatherings, to NORS, this assessment will only request information on mass gathering-related respiratory outbreaks not previously reported to NORS.

The resulting information will cover six full years and capture any possible seasonal effects for type of mass gathering (e.g., outdoor vs. indoor) and circulation of certain respiratory infections (e.g., increases in influenza and influenza-like illnesses during the winter months). For the reported mass gathering-related respiratory disease outbreaks, the aim is to describe the type of outbreak (e.g., cause, number of cases, methods of detection) as well as the purpose (e.g., conference, sporting evening, or festival), venue (indoors or outdoors), duration (number of days), size (number of participants or attendees), target population (age of participants), geographic scope (national, state-wide, or local), and seasonality of the mass gathering related to the identified outbreak.

The purpose of this data collection is to identify the frequency of mass gathering-related outbreaks due to respiratory infections, describe the outbreaks (i.e., cause, size, duration), and determine the policy and communication strategies to prevent or control these outbreaks. CDC will estimate the

frequency of mass gathering-related outbreaks, and of this, determine the type and location of outbreaks due to acute respiratory diseases, including influenza. More information on the risk of mass gathering related outbreaks, including influenza, will assist in revising CDC's Pre-Pandemic Guidance as well as in identifying the type or location of mass gatherings where CDC could help to strengthen policy and communication strategies for controlling and preventing infectious disease transmission, especially during a pandemic.

Overview of the Information Collection System

The data collection system consists of a web-based data collection instrument (**see Att. D - Data Collection Instrument: MS Word version** and **Att. E - Data Collection Instrument: Online version**) designed to capture information on the frequency, cause, size, and duration of mass gathering-related respiratory disease outbreaks in the United States occurring between January 1, 2009 and December 31, 2014. The data collection instrument was reviewed and approved by the Infectious Disease Committee of the Council for State and Territorial Epidemiologists (CSTE) (**see Att. F - CSTE approval letter**) and the National Association of County and City Health Officials (NACCHO) (**see Att. G - NACCHO approval letter**). A pilot test was completed with 4 states and 1 county health department. Results from this pilot were used to refine questions as needed, ensure accurate programming and skip patterns and establish the estimated time required to complete the information collection instrument.

Items of Information to be Collected

A simple online information collection form will be used to capture information on 1) mass gathering related outbreaks occurring in the United States between January 1, 2009 and December 31, 2014, and about 2) current intervention and communication strategies used by health departments before or during a mass gathering related outbreak. The majority of the questions are check boxes to minimize respondent burden. Below is an outline of the information to be collected.

Introduction - respondent information (for tracking purposes only)

- From state or local health department
- Position title
- Time with jurisdiction
- Which state or local health department

Part 1 – mass gathering-related outbreaks

- Whether there were any mass gathering related respiratory disease outbreaks
- Name or description of mass gathering
- Dates of mass gathering
- Type of gathering (conference, fair, etc.)
- Venue type (indoor or outdoor)
- Size of mass gathering
- Onset dates of outbreak
- Mode of transmission (person to person, food-borne, etc)

- Type of respiratory infection and etiology (if known)
- Number and ages of identified cases
- Geographic spread of transmission (local community, state wide, etc.)

Part 2 – Policy and Communications

- Conducted onsite surveillance to prevent or control outbreak
- Implemented nonpharmaceutical interventions to prevent or control outbreak
- Used public health messaging before and during a mass gathering
- Use of other prevention and control strategies
- Suggestions for improving CDC’s response to state health department needs during a mass gathering outbreak

2. Purpose and Use of the Information Collection

The purpose of this information collection is to identify the frequency, cause, duration, and size of mass gathering-related respiratory disease outbreaks, and determine the types of interventions and communication strategies used to prevent or control these outbreaks. This information will be used to better understand the frequency and characteristics of mass gathering-related outbreaks in the United States (including during 2009 A H1N1 pandemic), as well as to assess the use of nonpharmaceutical interventions and communication strategies at mass gatherings (through information on the venue type, participant density, type of social mixing, and control strategies implemented by local and state authorities) for preventing or limiting infectious disease transmission. Insights gained from this information collection will strengthen the evidence-base for CDC’s Pre-pandemic Community Guidance on mass gatherings.

3. Use of Improved Information Technology and Burden Reduction

Data will be collected via a web-based questionnaire allowing respondents to complete and submit their responses electronically. This method was chosen to reduce the overall burden on respondents. The data collection instrument was designed to collect the minimum information necessary for the purposes of this project. There are a maximum of 42 questions in the assessment if all of the questions apply to the respondent’s jurisdiction; however, the respondent will have the option to only answering questions that apply to the mass gatherings in his/her jurisdiction.

4. Efforts to Identify Duplication and Use of Similar Information

Prior to implementing this information collection, a review was conducted of the published literature, examined the National Outbreak Reporting System (NORS) database and Epi-X Reports (an online exchange forum for public health professionals) for information on mass gathering-related outbreaks. From these sources, it was determined that there is very limited information on the frequency, cause, size, and duration of mass gathering-related outbreaks occurring in the United States. Individual reports were identified of water- and food-borne outbreaks that are both notifiable from NORS, other modes of infectious disease transmission (e.g., person to person transmission) were frequently under-reported. Furthermore, linking the notifiable outbreaks to specific mass gatherings was not possible due to current limitations of NORS. Epi-X provides current but often incomplete information on infectious disease outbreaks. There are only a few published articles about individual mass gathering-related respiratory disease outbreaks, and these primarily focused on international events, such as World Health Day in Sydney, Australia, Music festivals in Belgium, Serbia, and Hungary, and religious mass gatherings in France². Other than a report of an influenza outbreak at the 2002 Winter Olympics in Salt Lake City, Utah, information on mass gathering-related outbreaks and efforts to prevent and control these outbreaks in the United States is lacking². Given these facts, this data collection will support the need to collect the data that has not been previously reported.

Due to these limitations, this current information collection is being proposed. State and large local and county health departments have the capacity to investigate and report on the mass gathering outbreaks targeted by this assessment. Consequently, the information collection will be able to address current gaps in information about the frequency, cause, size, and duration of mass gathering-related outbreaks in the United States over a six-year time frame. Since state and local health departments have the option of reporting outbreaks in any settings, including mass gatherings, to NORS, this assessment will only request information on mass gathering-related respiratory outbreaks not previously reported to NORS. As mentioned in section 1, this time frame was agreed upon by CDC, CSTE, and NACCHO using estimates from Career Epidemiology Field Officers (CEFOs).

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this information collection.

6. Consequences of Collecting the Information Less Frequently

This request is for a one-time information collection. There are no legal obstacles to reduce the burden. If no data are collected, CDC will be unable to:

- Understand the frequency, cause, size, and duration of mass gathering related outbreaks in the United States (including during 2009 A H1N1 pandemic)
- Assess the potential effectiveness of nonpharmaceutical interventions at mass gatherings (through information on the venue type, participant density, type of social mixing, and control strategies implemented by local and state authorities)

- Assess the use of current policies and communication strategies for controlling and preventing mass gathering related outbreaks
- Update CDC's Pre-Pandemic Guidance on current knowledge of mass gathering related outbreaks

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

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

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

This information collection is being conducted using the Generic Information Collection mechanism of the OSTLTS OMB Clearance Center (O2C2) – OMB No. 0920-0879. A 60-day Federal Register Notice was published in the Federal Register on October 31, 2013, Vol. 78, No. 211; pp. 653 25-26. No comments were received.

CDC partners with professional STLT organizations, such as the Association of State and Territorial Health Officials (ASTHO), the National Association of County and City Health Officials (NACCHO), and the National Association of Local Boards of Health (NALBOH) along with the National Center for Health Statistics (NCHS) to ensure that the collection requests under individual ICs are not in conflict with collections they have or will have in the field within the same timeframe.

9. Explanation of Any Payment or Gift to Respondents

CDC will not provide payments or gifts to respondents.

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

The Privacy Act does not apply to this information collection. STLT and governmental staff and / or delegates will be speaking from their official roles and will not be asked, nor will they provide individually identifiable information. The proposed information collection will not involve the collecting respondent's personal identification. We will collect respondents' official title and work place email address – both of which are publicly available. The proposed collection will not impact the respondents' privacy. All collected information will remain secure. Collected information will be entered into appropriate data management systems, and official titles and email addresses will be deleted following information verification and cleaning. The link to the web-based information collection will be forwarded to all 50 State Health Department Epidemiologists and to the 31 large local health department Epidemiologists simultaneous through an invitation email from CDC (sent in collaboration with CSTE and by NACCHO). Data from the information collection will be saved on

a secure server at CDC. Analysis and resulting publications will not include any personal identifying information regarding participants or their health jurisdiction.

This information collection is not research involving human subjects.

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

No information will be collected that are of personal or sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

The total burden for this assessment was based on a pilot test of the data collection instrument at four state health departments (Arkansas, South Carolina, Virginia, and Idaho), and one county health department (Dallas County). In the pilot test, the average time to complete the instrument including time for reviewing instructions, gathering needed information and completing the instrument, ranged between 15-30 minutes (including time to provide comments and feedback on the assessment questions). For the purposes of estimating burden hours, the upper limit of 30 minutes was used.).

Estimates for the average hourly wage for respondents are based on the Department of Labor (DOL) National Compensation Survey estimate for management occupations – medical and health services managers in state governments (<http://www.bls.gov/ncs/ocs/sp/nctb1349.pdf>). Based on DOL data, an average hourly wage of \$57.11 is estimated for all respondents. The same wage estimate was applied to the local health departments since the directors of large local health departments receive salaries similar to their state health department counterparts. Table A-12 shows estimated burden and cost information.

Table A-12: Estimated Annualized Burden Hours and Costs to Respondents

Information collection Instrument: Form Name	Type of Respondent	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Mass gathering outbreak information collection form	State Epidemiologists	50	1	30/60	25	\$57.11	\$1,428
Mass gathering outbreak information	Local Health Department Directors	31	1	30/60	16	\$57.11	\$914

collection form							
	TOTALS	81	1		41		\$2,342

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

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

14. Annualized Cost to the Government

There are no equipment or overhead costs. Contractors, however, are being used to support development of the assessment tool, data collection, and data analysis. The only cost to the federal government would be the salary of CDC staff and contractors. The total estimated cost to the federal government is \$6,800. Table A-14 describes how this cost estimate was calculated.

Table A-14: Estimated Annualized Cost to the Federal Government

Staff (FTE)	Average Hours per Collection	Average Hourly Rate	Average Cost
Epidemiologist, GS-14	40	\$55.00	\$2,200
Data manager, Contractor	40	\$65.00	\$2,600
Health communication specialist, Contractor	20	\$45.00	\$900
Statistician, GS-14	10	\$55.00	\$550
Health communication specialist, GS-14	10	\$55.00	\$550
Estimated Total Cost of Information Collection			\$6,800

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Data captured from the online instrument will be exported into SAS (Cary, NC, version 9.3) for analysis. Data analysis will include descriptive statistics and where appropriate, bivariate statistics to compare mass gathering-related outbreaks by mass gathering type, size, and venue, and season. For each mass gathering characteristic, the most common mode of transmission and etiologic cause of the outbreak will be described. The single open-ended question on the instrument will be converted to text responses and analyzed thematically. Data will be provided in aggregate form within all reports resulting from this assessment.

Project Time Schedule

- ✓ Design questionnaire (COMPLETE)
- ✓ Develop protocol, instructions, and analysis plan (COMPLETE)
- ✓ Pilot test questionnaire (COMPLETE)
- ✓ Prepare OMB package (COMPLETE)
- ✓ Submit OMB package (COMPLETE)
- OMB approval (TBD)
- Conduct assessment (Assessment open 4 weeks)
- Code, quality control, and analyze data..... (4 weeks)
- Prepare reports (4 weeks)
- Disseminate results/reports (4 weeks)

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

We are requesting no exemption.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification. These activities comply with the requirements in 5 CFR 1320.9.

LIST OF ATTACHMENTS – Section A

Att. A - State Health Department Epidemiologists

Att. B – 35 Local Health Departments

Att. C – CDC presentation to Department of Health and Human Resources

Att. D - Data Collection Instrument: MS Word version

Att. E - Data Collection Instrument: Web version

Att. F - Council of State and Territorial Epidemiologists Letter of Support

Att. G - National Association of County and City Health Officials Letter of Support

REFERENCE LIST

1. Centers for Disease Control and Prevention (CDC). "National Public Health Performance Standards Program (NPHPSP): 10 Essential Public Health Services." Available at <http://www.cdc.gov/nphpsp/essentialservices.html>. Accessed on 8/14/14.
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4. Memish ZA, Stephens GM, Steffen R, Ahmed QA. Emergence of medicine for mass gatherings: lessons from the Hajj. *Lancet Infect Dis* 2012;12:56-65.
5. Centers for Disease Control and Prevention. Interim Pre-pandemic Planning Guidance: Community Strategy for Pandemic Influenza Mitigation in the United States-Early, Targeted, Layered Use of Non-Pharmaceutical Interventions, February 2007. Available from: http://www.flu.gov/planning-preparedness/community/community_mitigation.pdf. Accessed April 4, 2013.