Emergency Cruise Ship Outbreak Investigations (CSOIs)

OMB Control No. 0920-NEW

Existing Collection in Use without an OMB Control Number

Supporting Statement Part B –

Collections of Information Employing Statistical Methods

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Part B. Collections of Information Employing Statistical Methods

B.1. Respondent Universe and Sampling Methods

The respondent universe is the population (sampling frame) to which results will be generalized. The respondent universe for each individual CSOI will vary, depending on the outbreak or event, but is not a mechanism to collect data that can be generalized to the broader population. The population to which results are generalizable is limited to those potentially exposed to or affected by the health event under investigation. For example, the respondent universe might be defined by identity (e.g., crew members on a particular cruise ship), a behavior (e.g., participation in a particular shore excursion), or geotemporal (e.g., people whose cabins are located in a particular area of the cruise ship). VSP, in collaboration with external partners, identifies the respondent universe for each CSOI.

The sampling methods also will vary depending on the AGE outbreak or event. Most CSOIs include collecting information from all individuals onboard the ship during the affected voyage. However, in certain investigations, such as those involving larger numbers of people experiencing AGE, investigators might choose to collect information from a sample of affected individuals and appropriate controls.

For some investigations there will be more than one study design, thus multiple sampling methodologies might be used. For example, when little is known about a specific outbreak or event, a hypothesis-generating investigation might be conducted with a convenience sample of individuals. Information from this initial investigation might be used to identify an appropriate respondent universe for the hypothesis-testing phase of the investigation. Additional information then might be collected from either a ship's manifest or sample, depending on the size of the respondent universe. In case-control studies, different sampling methods might be used to select case-patients and controls. For example, case-patients might be randomly selected from a line list and controls might be selected based on pair-matching (i.e., one or more matching controls selected for each case based on certain characteristics such as age, sex, geographic location, having eaten at a particular restaurant, etc.). VSP, in collaboration with the external partners receiving epidemiological assistance, identifies the sampling methodology for each CSOI based on the information needed to identify the agents, sources, modes of transmission, or risk factors.

When sampling methods are used, the number of respondents selected for each investigation will depend upon obtaining a sufficient number of respondents to determine the agents, sources, modes of transmission, or risk factors to implement prevention and control measures.

When appropriate, power calculations will be conducted to ensure the number of respondents will provide sufficient power for reliable statistical inferences. VSP, in collaboration with the external partners receiving epidemiological assistance will determine the sample size for each CSOI. Based on data from previous CSOIs, on average, the expected number of respondents per investigation is 2,500.

Procedures for each investigation, including the method and mode of data collection, depend on the nature of the outbreak or event, hypotheses to be tested, time and resources available, number of persons involved, and other circumstances unique to the emergency at hand. CSOIs often utilize one or more methodological approaches such as: epidemiologic investigation, environmental assessment, and laboratory testing. The components employed will vary depending on the information needed to determine the agents, sources, modes of transmission, or risk factors in order to inform prevention and control measures.

CSOIs often include the steps below, though the steps included in each CSOI will vary depending on what information already has been determined at the time CDC assistance is requested and the amount of information needed to identify prevention and control measures.

1. Establish the existence of an outbreak
2. Prepare for field work
3. Define and identify cases
4. Verify the diagnosis
5. Describe and orient the data in terms of time, place, and person
6. Develop hypotheses
7. Evaluate hypotheses
8. Refine hypotheses and carry out additional studies
9. Implement control and prevention measures
10. Communicate findings

Study Design

Epidemiologic Investigations
CSOI steps 1 – 6 often are carried out using descriptive study methods. Steps 7 – 8 often are carried out using analytic study methods. Methods commonly used in epidemiologic investigations are described below, though this list is not exhaustive.[1] Environmental assessments and laboratory testing also are briefly described, though these methods often do not involve respondent burden.

- Descriptive Study

[1] Definitions adopted from *Principles of Epidemiology in Public Health* Practice, 3rd Edition. Developed by: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Office of Workforce and Career Development, Career Development Division, Atlanta, GA 30333. Available: http://www.cdc.gov/ophss/csels/dsepd/SS1978/SS1978.pdf.

Definition: A study designed to organize and summarize data regarding the persons effected (e.g., the characteristics of those who became ill), time (e.g., when they become ill), and place (e.g., where they might have been exposed to the cause of illness).

Common Uses: Descriptive studies will be employed by almost all CSOIs where the person, place, and time of a particular outbreak or event are not already understood. This information is critical for identification of the population at risk, development of the case definition, case finding, and hypothesis generation.

- Cohort Study

  Definition: An analytic study in which enrollment is based on status of exposure to a certain factor or membership of a certain group. Populations are then compared according to whether they experienced disease, death, or other health-related outcome. In retrospective cohort studies, the exposures and outcomes already have occurred at the time of the investigation.

  Common Uses: Cohort studies are commonly used in investigations where 1) the exposure is rare or can be precisely defined, 2) the population at risk is a well-defined group (such as workers at a particular factory or attendees of a wedding), or 3) the disease is common.

- Case-control Study

  Definition: An analytic study that enrolls one group of persons with a certain disease, chronic condition, or type of injury (case-patients) and a group of persons without the health problem (controls) and compares differences in exposures, behaviors, and other characteristics to identify and quantify associations, test hypotheses, and identify causes.

  Common Uses: Case-control studies often are used when 1) the disease or outcome is rare, 2) persons with the disease or outcome can be readily identified, 3) multiple exposures are under investigation or the exposure is common, or 4) the population at risk is unknown.

Environmental Assessment and Laboratory Testing

CSOIs employ environmental assessment and laboratory testing in addition to epidemiologic investigations. These investigation components can be critical in verifying diagnoses, identifying cases, and developing hypotheses or verifying hypotheses. Environmental assessments can provide important source and exposure information. Laboratory testing can provide important information about diagnoses or source of disease. For example, if descriptive data indicate all case-patients ate at a particular food establishment on the ship, an environmental assessment and laboratory testing might identify a specific contaminated food item, eliminating the need for additional data collection. In another example, descriptive data might not yield sufficiently conclusive results to inform an environmental assessment or laboratory testing. Instead, hypotheses might be generated and tested, and then environmental assessment and laboratory

testing might be used to confirm or verify results of the analytic study. CSOIs might involve laboratory testing of environmental or biospecimen samples. In these situations, VSP will use the appropriate OMB-approved laboratory mechanism for collection and processing of samples and clinical specimens.

Data Collection Mode

Data collection modes commonly used by CSOIs are described below; other modes also might be used as appropriate. Many CSOIs use multiple modes to collect data. Ultimately, the type of mode(s) used will be determined based on the location and availability of respondents, the speed with which information is needed, and the specific information needed to identify the agents, sources, modes of transmission, or risk factors so that effective prevention and control measures can be implemented.

- Survey Modes
  - Face-to-Face Interview

    Definition: An in-person interview in which a trained interviewer administers a questionnaire to the respondent.

    Common Uses: Face-to-face interviews are a common mode used in CSOIs because they allow for rapid data collection and are conducive to open-ended responses. This makes them particularly useful during the hypothesis-generating stage of the investigation. They also are useful when the information to be collected is particularly complex and interviewer prompts or explanation might be needed. Face-to-face interviews are most feasible when respondents are centrally located.
  - Self-administered Paper-and-Pencil Questionnaire

    Definition: A paper questionnaire that is completed by the respondent.

    Common Uses: Self-administered paper-and-pencil questionnaires are often used when interviews are not feasible due to resource limitations and the information to be collected can be captured using straight-forward questions with fixed response options.
  - Clinical Sample

    Definition: A sample of material, such as stool, emesis, or blood.[2]

    Common Uses: clinical specimens are often used to determine case definitions, verify case status, or identify the infectious agent or source.
  - Environmental Sample:

[2] Definition from the NCI Dictionary of Cancer Terms available: http://www.cancer.gov/dictionary?cdrid=561324.

Definition: A sample of any material that is collected from an environmental source.

Common Uses: Environmental samples are often used to determine the agents, sources, or modes of transmission of the health problem.

B.2. Procedures for the Collection of Information

Because of the acute nature of the outbreaks or events to be investigated, periodic data collection is not employed in CSOIs. Data collection to identify agents, sources, modes of transmission, or risk factors occur over a period of no greater than 30 days to allow for rapid implementation of effective prevention and control measures.

- *Statistical method for stratification and sample selection*

  When statistical methods are employed in the collection of information, VSP provides statistical assistance relating to sampling methodology and selection of controls.

- *Estimation procedure*

  Data analysis is conducted under the advice of statisticians or data analysts from CDC or the requesting organization and will involve descriptive statistics. Additional bivariate and multivariate analyses are conducted as needed to identify the agents, sources, modes of transmission, or risk factors so that effective prevention and control measures can be implemented.

- *Degree of accuracy needed for the purpose described in the justification*

  The purpose of the CSOI is to collect information rapidly to identify unknown information (e.g., agents, sources, modes of transmission, or risk factors) necessary for instituting effective prevention and control measures. Quality control procedures will be implemented in each CSOI to the extent possible given the rapid nature of the data collection. For example, when possible, instruments and methodology will be pilot tested. In each investigation, the goal is to collect the best data possible in the timeliest manner possible to direct public health action.

- *Unusual problems requiring specialized sampling procedures*

  VSP does not expect unusual problems requiring specialized sampling.

- *Any use of periodic (less frequent than annual) data collection cycles to reduce burden*

Because of the acute nature of the outbreaks or events to be investigated, periodic data collection is not employed. Data collection to identify agents, sources, modes of transmission, or risk factors occur over a period of no greater than 30 days to allow for rapid implementation of effective prevention and control measures.

B.3. Methods to Maximize Response Rates and Deal with No Response

In CSOIs, nonresponse bias typically is expected. For example, case-patients who have experienced a negative health event may have more interest in responding than will controls. Often, controls (unaffected by the health event under investigation) will be oversampled to account for this potential bias. In another example, case-patients who are most ill might be least likely to respond. This might be countered by follow-up procedures with non-respondents. Also, for each CSOI, response rates are maximized by informing potential respondents of the critical nature of the outbreak or event and the importance of collecting information to identify effective prevention and control measures. Before collecting information, investigators inform respondents that participation is voluntary, that respondents are not personally identified in any published reports of the study, and that their privacy will be protected to the extent allowed under federal law. Study designs and epidemiologic methods are chosen to minimize the effect of non-response bias and CSOI investigators will acknowledge when and how it might impact their results.

B.4. Test of Procedures or Methods to be Undertaken

Though each data collection instrument is tailored to the needs of each specific outbreak or event, questions from instruments employed in previous investigations are used when possible. In this way, data collection instruments that are refined over time can be utilized. A data collection instrument library (similar to Attachments E1-E4) is maintained by archiving the final data collection instruments administered in CSOIs under this generic ICR.

It is expected that CSOI data collection instruments will need to be refined in the field (e.g., risk factors unknown prior to VSP team deployment may need to be added or removed, or wording may be changed).

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

VSP CSOI investigators are trained in biostatistics and epidemiology. In most cases, investigators collaborate extensively with health officials of the external partners receiving assistance. Individuals who may participate in collecting and/or analyzing the data are listed below. 021909

Data Collection Designers and Analysts

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List of Attachments

A. Authorizing Legislation

A1. 42 USC Section 264 – Quarantine and Inspection - Regulations to Control Communicable Diseases

A2. 42 USC Section 269 – Quarantine and Inspection – Bills of Health

A3. 42 CFR Part 71 – Foreign Quarantine

B. 60-Day Federal Register Notice

C. Vessel Sanitation Program Delegation

C1. 1985 Federal Register Notice VSP in DGMQ

C2. 1987 CDC Memo VSP from DGMQ to NCEH

D. VSP 2018 Operations Manual

E. Example Questionnaires

E1. Acute Gastroenteritis (AGE) Example Questionnaire (Passenger or Crew)

E2. Semi-structured Interview Guide Example (Passenger or Crew)

E3. Example Questionnaire for Undetermined Agent

E4. Example Questionnaire for Undetermined Exposure and Undetermined Risk Factor

F. Steps for Conducting a CSOI

G. CSOI Advance Notification Email

H. Request for Emergency CSOI

I. CSOI Burden Memo

J. Consent Forms (sample)

K. CDC Laboratory Forms (approved under OMB Control No. 0920-0004)

K1. National Calicivirus Laboratory Form

K2. CDC Specimen Submission Form: Specimens of Human Origin (CDC Form No. 50.34)

L. CSOI Research Determination

M. Privacy Impact Assessment