

I Left My Heart (and more) in San Francisco*

(Instructor Version)

Center for Infectious Disease Preparedness
University of California, Berkeley
<http://www.idready.org>

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*This module is based on an actual field outbreak investigation. The names of involved parties have been changed. This module is for training purposes only and cannot be used for commercial gain.

Instructions

This outbreak investigation is based on an actual outbreak in San Francisco in the late 1990s. It occurred at a time when public health departments were less focused on preparing for public health emergencies from natural disasters and intentional threats. Based on what we know today, there are many aspects of this investigation we would do differently. This makes this exercise a better learning experience.

Learning objectives

After completing this outbreak module, participants will be able to

1. understand the components of a public health infectious disease emergency operations response;
2. understand the components of a public health infectious disease emergency epidemiologic investigation;
3. describe the conceptual steps of conducting an outbreak investigation;
4. describe the steps of designing an outbreak analytic study;
5. describe the steps of designing a outbreak field survey;

For students

Read this module and provide written answers. Use any resources at your disposal. Your instructor may have you work in groups.

For instructors

This module should be facilitated by an experienced investigator and can be used in two ways:

- Use the module as a stand alone to teach the steps of conducting an outbreak investigation.
- Use the module as a follow up to a lecture on conducting an outbreak investigation.

The instructor version has our suggested answers. Feel free to adapt the answers to your audience, situation, or geography. Also, feel free to use your best answers. Make sure to tailor the training to meet the learning needs of your audience. Is your audience primarily public health nurses? public health investigators? epidemiologists? physician health officers? administrators?

Competencies represent a set of skills, knowledge, and abilities necessary to participate in or lead an epidemiologic field investigation. There are three level of competencies:

- **Aware:** Basic level of mastery of the competency. Individuals may be able to identify the concept or skill but have limited ability to perform the skill.
- **Knowledgeable:** Intermediate level of mastery of the competency. Individuals are able to apply and describe the skill.
- **Proficient:** Advanced level of mastery of the competency. Individuals are able to synthesize, critique or teach the skill.

Decide what level of competency you and your audience expect. If you have mostly non-epidemiologists, then emphasize concepts over technical details. However, if you have mostly experienced epidemiologists who are now re-tooling for outbreak investigations, then feel free to address technical details. But a word of advice: do not focus on technical details for non-epidemiologists that will never be expected to be proficient in technical areas. They are more likely to be part of an interdisciplinary investigative team: they need to understand how an outbreak investigation works, and how they can productively contribute to an investigation.

Feedback

Please contact us and give us feedback and suggestions. How can we improve this module? How are you using this module?

Resources

1. UC Berkeley Center for Infectious Disease Preparedness, A CDC Center for Public Health Preparedness: <http://www.idready.org>. We make most of our materials freely available online.
2. Essential Field Epidemiology Quick Reference Guide, available at <http://www.medepi.net/epitools/QuickRefGuide.pdf>.
3. University of North Carolina Center for Public Health Preparedness: FOCUS on Field Epidemiology at <http://www.sph.unc.edu/nccphp/focus/>. This is an excellent newsletter and tutorial for learning about field epidemiology.
4. Centers for Disease Control and Prevention, Epidemiologic Case Studies at <http://www2a.cdc.gov/epicasestudies/>. This site contains excellent outbreak investigations modules.

1 The Outbreak Hotel

On Sunday, January 25, in the late 1990s, Dr. Juan Nieve, Deputy County Health Officer for the City and County of San Francisco, was at home relaxing and enjoying a very exciting National Football League Super Bowl game. During the second quarter, Dr. Nieve received a telephone call from the County Health Officer and was notified that 63 people at the Twin Peaks Hotel¹ had been evaluated by paramedics for nausea and vomiting. Seven patients were transported to nearby hospital emergency rooms. There were no hospitalizations and no deaths. No additional information was available at that time.

Question 1 *If you were Dr. Nieve, what would you do at this point?*

Answer: ANSWER:

Ask the audience what they would do at this point?

In general, there are no wrong answers. Many of the answers provided are based on the Essential Field Epidemiology course conducted by the UC Berkeley Center for Infectious Disease Preparedness (<http://www.idready.org>).

After listening to several answers, explain that CIDP uses this question as an opportunity to review the importance of having an infectious disease emergency operations plan in place before an event. At this point in time, Dr. Nieve only knows that 63 persons have been evaluated by paramedics. This could be a public health emergency where a rapid investigation and response could mean the difference between life and death for victims.

Displayed in Figure 1 on page 6 is an Incident Command System (ICS) structure for an Infectious Disease Emergency Operations Response. The most important point to emphasize is that the ICS approach identifies the core FUNCTIONS necessary for an infectious disease emergency investigation and response. The core functions are the same whether you have one responder or one-hundred.

Hopefully, Dr. Nieve has an infectious disease emergency operations plan in place. He knows who to call for help. He knows how to contact someone 24/7. His team has tested aspects of the plan through drills, tabletops, and functional exercises.

The most important points about the ICS approach to infectious disease operations planning is the following:

- Develop an ICS infectious disease operations plan based on FUNCTIONS, not people or organization hierarchy.

¹This is a fictitious name; any resemblance to any hotel name is purely coincidental.

- Activate only what you need.
- Use real outbreaks as opportunities to test aspects of your investigation and response plan.
- When you exceed your capacity to meet functional demands, request for human and material resources using the ICS chain of command.
- Infectious disease emergency operations planning is an ITERATIVE PROCESS
 - Develop your plan
 - Train to your plan
 - Test and evaluate your plan (drills, tabletops, functional and full-scale exercises)
 - Revise your plan

Figure 1 on the next page displays the incident command structure (ICS) for the Infectious Disease Emergency Response (IDER). Under IDER Operations is the Epidemiology and Surveillance (Epi) Branch. This structure is not the final answer, but a schematic of one approach. An ICS structure consists of Command, Operations, Planning, Logistics, and Finance/Administration Sections. This structure is based on functions, not agency or organizational hierarchy. Conceptually, these functions apply at all levels and are useful for organizing your thoughts and actions.

Command (“incident commander”) sets and disseminates the operational objectives to accomplish the mission. The Operations function carries out these objectives. In this scenario, the county health officer might be the IC, and Dr. Nieve might be the Epi Branch leader. All other functions support Operations. The Planning function studies, anticipates, and communicates Operations needs and demands. Planning also develops the Incident Action Plan (IAP) for the operational period. The IAP is approved by Command. The Logistics Section provides logistical support (human and material resources). Finance/Admin tracks costs and provides administrative support. The Command Staff functions includes Public Information Officer (PIO), Liaison Officer (LO), and Safety Officer (SO). The PIO coordinates internal and external communications. The LO coordinates with assisting agencies, and the SO assures the safety of all response personnel. Remember, these are functions that need to be addressed at every level; however, at the health departmental level there will be actual positions that will be filled.

The Epi Branch can be under Operations or Planning. For example, they may be part of Operations, although their analyses will help inform and guide Planning. Figure 1 on the following page has a suggested Epi Branch emergency operations structure. The structure is designed to scale up to

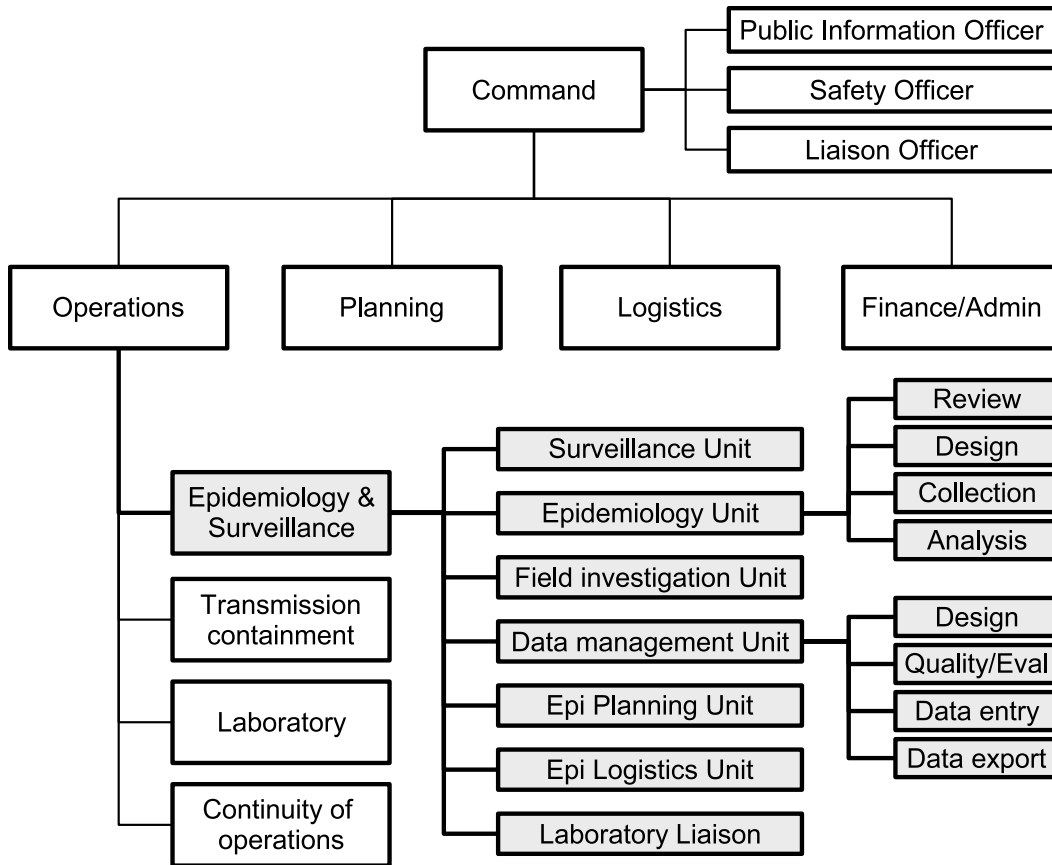


Figure 1: Incident command structure for an infectious disease emergency investigation and response: Displayed are details for the Epidemiology and Surveillance Branch, the Epidemiology Unit, and the Data Management Unit.

potentially involve many team members implementing discrete investigative tasks. For example, the “Epi Logistics Unit” function means that someone is assessing the logistical needs of the Epi Branch: computers, software, cables, powerstrips, Internet access, paper supply, meeting space, communication equipment, etc. In a small scale event, the Epi Branch leader may be making this assessment, but in a large scale event, a Unit may be needed just to carry out this function.

Notice that the “Epi Branch” functions are set up like branches of a tree where multiple, related tasks can be run in parallel (rather than in series) to speed up the investigative response time. In a public health emergency, a rapid investigation can be a major factor determining an effective response. Where does case finding belong? It depends: case finding for surveillance

purposes belongs in the Epi Branch; however, case finding for isolation, contact tracing for quarantine, and case management should be under Transmission Containment activities. Some preparedness documents lump containment activities under “epidemiologic response,” but they should be separate.

In a public health emergency, the health department operations center (DOC) will have an ICS structure similar to Figure 1 on the previous page. Under DOC Operations (not shown), it may have several branches including Infectious Disease Emergency Response (Figure 1 on the preceding page), Environmental Health Emergency Response, Mental Health Emergency Response, Mass Casualty Care, etc.

Dr. Nieve arranged for two epidemiologists and two environmental health inspectors to meet him at the Twin Peaks Hotel that evening (at 7 pm). They met with the hotel general manager and chief of security. Here is what they learned: At 3:30 am, Sunday morning, January 25th, paramedics responded to a non-emergent call of a person ill with nausea and vomiting at the hotel. By 6:15 am, 8 additional patients were evaluated. By 1:00 pm that afternoon, paramedics evaluated 63 persons with similar complaints, many of whom required primarily medical advice. Seven patients were transported to nearby hospitals for evaluation. The hotel general manager reported that all ill persons attended the Company X Executive Forum meeting hosted at the hotel. Over 300 persons from throughout the United States attended this meeting. By Sunday evening most conference attendees that were staying in the hotel had already left San Francisco to fly home. The hotel manager outlined the course of events in the preceding 72 hours and provided access to hotel staff and remaining hotel guests, provided detailed meal information, and provided logistical support (conference room, telephones) to help launch an investigation.

Question 2 *What would you suggest that Dr. Nieve do at this point?*

Answer: ANSWER:

Ask the audience what they would do at this point? In general, there are no wrong answers.

After listening to several answers explain that CIDP uses this question as an opportunity to review the steps of an outbreak investigation. The major focus is identifying the *cause* and implementing *control measures*. Although there are several lists, CIDP has summarized seven conceptual steps:

1. Case investigation
2. Cause investigation
3. Control measures (do early)

4. Conduct analytic study (if necessary)
5. Conclusions (epidemiologic and causal inference)
6. Continue surveillance (detection and monitoring)
7. Communicate findings (risks, recommendations, report)

The purpose of the case investigation is to confirm the outbreak and to establish preliminary causal hypotheses. The purpose of the cause investigation is to review suspected and known causal factors. Using a systematic approach, we review the public health and biomedical literature and consult experts². Next, we implement control measures based on steps 1 and 2. If we've done our homework well, we're done. We identified likely causes, control measures are working, preventive measures were implemented to avoid future outbreaks, and there would be no need to conduct further investigations.

However, if no cause is implicated, the outbreak continues, or control measures are failing, then it may be necessary to identify, prioritize, and test some causal hypotheses. To test causal hypotheses, we conduct an analytic study. Conducting an analytic study is resource intensive and is only done when necessary. And even then, the chance of implicating the likely cause is generally low. Hence, the importance of steps 1 and 2: you may still need to implement control measures in the setting of continued uncertainty.

In an investigation, we are drawing conclusions (inferences) to guide our next steps and interventions. Drawing conclusions from epidemiologic data we collect is called *epidemiologic inference*. Threats to making valid epidemiologic inferences include random error (chance), systematic error (bias), and confounding (alternative causal explanations). Inferences we draw about whether a suspected factor is causal is called *causal inference*. Drawing causal inferences involves integrating information from our investigation and other sources to decide whether we believe a factor is likely to be causal and, therefore, merits an intervention or further investigation (for example, a traceback and traceforward of an implicated food item).

Naturally, it makes sense to continue surveillance systems that may have detected the outbreak in the first place, or implement a new surveillance system to detect new cases or monitor the impact of control measures. The primary purpose of a surveillance system is to detect and monitor events in a target population before, during, and after an outbreak.

Finally, we will need to communicate findings, risks, and recommendations. Communicating to involved parties, the public, or the media should be done

²For a systematic approach see our Essential Field Epidemiology Quick Reference Guide at <http://www.medepi.net/epitools/QuickRefGuide.pdf>

by a public health official or spokesperson (e.g., public information officer). We will also need to prepare a report to summarize our investigation, findings, and recommendations.

This has been a brief outline of the seven conceptual steps of conducting an outbreak investigation. We emphasize the conceptual steps because many of the detailed steps emerge naturally by convening of an interdisciplinary team to discuss and guide the investigation. In fact, investigative teamwork should be the rule. To see a more detailed description of conducting an outbreak investigation, view or download the Essential Field Epidemiology Quick Reference Guide at <http://www.medept.net/epitools/QuickRefGuide.pdf>.

A more detailed time line of events emerged. Most attendees arrived at the conference on Thursday, January 22nd and stayed at the Twin Peaks Hotel. From Friday, January 23rd through Saturday, January 24th, they attended several common events and meals. Except for the Friday dinner meal at Restaurant A (a seafood restaurant at Fisherman's Wharf), and the Saturday dinner meal at Restaurant B (a yacht cruise ship with restaurant services), all other common meals were provided by the hotel. All apparent illnesses were only among the Company X attendees. No hotel staff (who regularly eat the same food) were reported ill. Because of the abrupt onset of symptoms that occurred only in conference attendees that shared several large-group meals, a common source food-borne exposure was strongly suspected.

The epidemiologists were able to interview 12 of the 20 Company X guests still in the hotel. More than half of them reported symptoms (nausea, vomiting, and watery diarrhea). They collected information on the symptoms, time of symptom onset, and meals consumed. Several interviewees mentioned that the "food" at Restaurant B seemed "spoiled." No stool specimens were collected. The lead environmental health inspector mentioned that Restaurant B had a history of repeated health code violations. These observations, along with the abrupt onset of illness, led investigators to suspect a short incubation food-borne bacterial toxin acquired at Restaurant B. The following timeline outlines the sequence of events understood to date:

- 1/22 Thursday: Attendees arrived in San Francisco and checked into Twin Peaks Hotel
- 1/23 Friday: 12:00 (12 pm): Lunch at Twin Peaks Hotel
- 1/23 Friday: 18:00 (6 pm): Dinner at Restaurant A (Seafood restaurant at Fisherman's Wharf)
- 1/24 Saturday: 18:00 (6 pm): Dinner at Restaurant B (yacht & restaurant)
- 1/25 Sunday: From 3:30 am to 1:00 pm, 63 attendees evaluated for illness at hotel

On the evening of January 25th, environmental health inspectors visited Restaurant A and Restaurant B to obtain information regarding meals eaten by conference attendees at these establishments. The preliminary inspection at Restaurant A did not reveal any problems. The shift manager provided the inspectors with copies of the menu, meals served, information on suppliers, and time of service for the private dinner party meal in question. By the time the health inspector arrived, Restaurant B was closed for the day.

That evening, no other food-borne outbreaks were reported or detected in San Francisco. No control measures were implemented at the hotel at this time.

Question 3 *If Restaurant B (yacht restaurant) is the source of the outbreak, what is the differential diagnosis of potential food-borne agents?*

Answer: ANSWER:

Let audience provide some answers.

The differential diagnosis of potential food-borne agents is the following [MMWR 2004;53(RR-4)]:

- Infectious
 - Bacterial (including toxins)
 - Viral
 - Parasitic
- Non-infectious
 - Marine toxins
 - Fungal toxins
 - Chemical contaminants

The etiologic agents to consider for various manifestations of foodborne illness include the following:

- Gastroenteritis (viral, food poisoning)
- Noninflammatory diarrhea (any pathogen)
- Inflammatory diarrhea (Shigella, etc)
- Persistent diarrhea (E. histolytica, G. lamblia)
- Neurologic manifestations (Botulism)
- Systemic illness (Listeria, Brucella, hepatitis A)

Unless you work with foodborne illnesses on a regular basis, one should NOT be expected to remember all these facts. The most important point is to recognize your limits in knowledge and seek authoritative answers either

through references (e.g., MMWR) or consultation. Do not hesitate to ask for help! In fact, seeking assistance should be the rule rather than the exception.

Question 4 *What is the primary purpose of interviewing available cases?*

Answer: ANSWER:

Interview cases to characterize the illness and to identify common exposures that may hint at the cause.

Question 5 *What important step did the investigators not do? What else might you do differently?*

Answer: The investigators were not prepared to collect stool specimens for laboratory testing. Today, health departments generally have field “go kits” with biologic specimen collection kits.

Be cautious of being led astray by comments from ill subjects and environmental health inspectors that a specific restaurant seems to be the source.

On Monday, January 26th, the San Francisco Department of Public Health, Communicable Disease (CD) Control Unit launched an epidemiologic investigation, and environmental health inspectors returned to the Twin Peaks Hotel and Restaurants A and B to conduct full food service inspections. The CD Control Unit conducted an epidemiologic study.

Question 6 *What kind of study (descriptive vs. analytic) should be conducted and why?*

Answer: ANSWER:

For this outbreak, investigators need to conduct a descriptive *and* analytic study. A descriptive epidemiologic study summarizes the “what” (case definition), “who” (person), “where” (place), “when” (time), and “how” many (case count) of the outbreak. They must characterize the clinical illness, including gathering any clues that suggest the microbial agent and/or toxin, mode of transmission, source, and whether the agent is transmissible person-to-person. The epidemic curve can suggest whether there is a common source or propagated person to person. To calculate the incubation period we will need well-defined times of exposure and times of symptom onset. To completed the descriptive epidemiology in this outbreak, we need the answers from an analytic study.

An analytic study attempts to determine the “how” and “why” of the outbreak. Causal hypotheses are tested by measuring whether suspected exposures are statistically associated with becoming a case.

Question 7 *What study design should they use?*

Answer: ANSWER:

In general, for outbreak investigations we conduct either a retrospective cohort study or a case-control study. A cohort study is conducted when we can identify and enumerate the at-risk (target) population, we can measure the suspected exposures, and we can follow them forward in time to assess who developed the illness. A cohort study is retrospective when the outbreak has already occurred and we are reconstructing the experience of the identifiable, enumerable at-risk population. For example, an outbreak occurring among attendees of a wedding banquet where we have a reliable attendee list and contact information is amenable to a retrospective cohort study.

In contrast, suppose the outbreak was associated with a restaurant but there is no easy way to identify and enumerate the at-risk population. In this scenario, a case-control study would be used. From the cases that are identified, controls could be identified from those that ate at the same table but did not become ill. In general, cases are compared to controls with respect to suspect exposures. Case-control studies are also conducted for community outbreaks of reportable communicable diseases, such as shigellosis. In this scenario, controls may be recruited from the community using telephone survey methods.

In this hotel outbreak, because the convention attendees can be identified, enumerated, and contacted, it makes sense to conduct a retrospective cohort study. An advantage of this study design is that we can directly estimate the risks associated with specific exposures. In case-control studies, we cannot directly estimate the risks. The measure of association for a cohort study is the risk ratio (or the odds ratio); for a case-control study, it can only be the odds ratio.

Question 8 *Describe the steps you would perform to conduct this study.*

Answer: ANSWER:

Let audience provide some answers.

Designing and conducting a study under the scrutiny and pressure of an outbreak investigation can be stressful and, potentially, overwhelming. This is easier to accomplish if we prepare a study protocol before embarking on a study, even if it is a one-page outline. Here are the six steps:

1. Primary question(s) (What questions will the study address?)
2. Significance (Why are these questions important and to whom?)

3. Study design (Will this be a cohort or case-control study?)
4. Study subjects (Who are the subjects and how will they be selected and recruited? For a case-control study, how are controls defined and recruited?)
5. Measurement variables (What is the case definition? What exposures will be measured and how? What are potential confounders [alternative explanations]?)
6. Statistical issues (How many subjects do we need? What is our analytic approach? How will we control for confounders?)

Conducting a study requires two phases: study design and study implementation. At both phases, we are always thinking of ways to prevent or mitigate threats to validity (chance [random error], bias [systematic error], and confounding). The six-step study protocol helps us systematically approach the study design and implementation. For example, here is an outline of a protocol for this outbreak:

1. Primary question(s): For this outbreak, we are assuming the mode of transmission is foodborne; i.e., ingestion of a microbe or toxin. The primary questions might include the following:
 - What is the microbial agent?
 - How many cases occurred?
 - Which meal was associated with illness?
 - Which food item at the implicated meal was associated with illness?
 - What is the incubation period?
 - Is the agent transmissible person-to-person?
 - What is the distribution of symptoms?
2. Significance: This was a large outbreak involving more than 63 cases and 7 patients taken to the hospital.
3. Design (address confounding)
 - Time frame: The outbreak has already occurred so the time frame is retrospective.
 - Epidemiologic approach: Because you can enumerate the at-risk population, a retrospective cohort study is appropriate.
4. Subjects (address selection bias):
 - Selection criteria: The target population would be the convention attendees.
 - Sampling design: Target population, sample (intended sample), and respondents (actual sample).

5. Measurement variables (address measurement error (bias), confounding):
 - Outcome variables (cases: collected sufficient information for possible case definitions).
 - Exposure variables (causes: meals attended, and food items consumed at each meal).
 - Confounders: None were considered in this investigation. However, potential confounders would be causal risk factors that could distort the primary exposure-outcome relationship under consideration; for example, for a medical condition that influences food choice might be treated with a medication that causes diarrhea.
6. Statistical issues (address random error, power, confounding):
 - Hypotheses to test
 - Which meal is associated?
 - Which food item at implicated meal?
 - Sample size: Sample might be all convention attendees.
 - Analytic approach: Retrospective cohort study with 2×2 tables and the calculation of risk ratios (and odds ratios).

Question 9 *What are the threats to drawing valid conclusions and how would you address them?*

Answer: ANSWER:

We saw previously how we used the study protocol to address threats to validity. In fact, at each step we ask ourselves, what can we do to prevent or mitigate threats to validity at the design and implementation phases. Briefly, the threats are chance, bias, and confounding.

- Chance (random error)
- Bias (systematic error)
 - Selection bias
 - Information bias (measurement error)
- Confounding

The primary approaches to addressing random error (chance) are (1) having a sufficient sample size to detect effects of exposure (if they exist), (2) calculating confidence intervals to assess the precision of the estimates, and (3) calculating p values to estimate the probability that an observed value differs from some reference value. The technical aspects of addressing random error are beyond the scope of this module. However, we need to be aware that random error threatens validity.

Selection bias occurs when the subjects that are recruited into our study are not representative of the target population. For example, suppose that the study subjects we recruit for this outbreak are those that answer their home phone. Those that died or are hospitalized cannot answer their phones. Therefore, the subjects in our study are not representative of the overall experience of the target population.

Information bias (measurement error) occurs when the information we collect from the study subjects is not accurate. The error can occur in measuring the exposure or the outcome. Errors occur because of the subjects, our measurement instruments, or our interviewers. For example, to improve subject recall, we don't ask "what did you eat for dinner on Friday?", but rather, "Please answer yes or no. At the Friday dinner, did you eat item A? Did you eat item B? . . ." Survey instruments should be pilot tested, and interviewers should be trained to be objective and unbiased in the way they ask questions and interact with study subjects.

Confounding occurs when alternative causal factors are operating. For example, in investigating a foodborne diarrheal illness, several of your subjects may be taking medications that also cause diarrhea. If subjects that are taking these medications tend to avoid or favor certain types of food, then a false association may occur between consuming a food item and developing diarrhea. The technical aspects of controlling for confounding are beyond the scope of this module. However, it's important to consider potential confounders and to measure them.

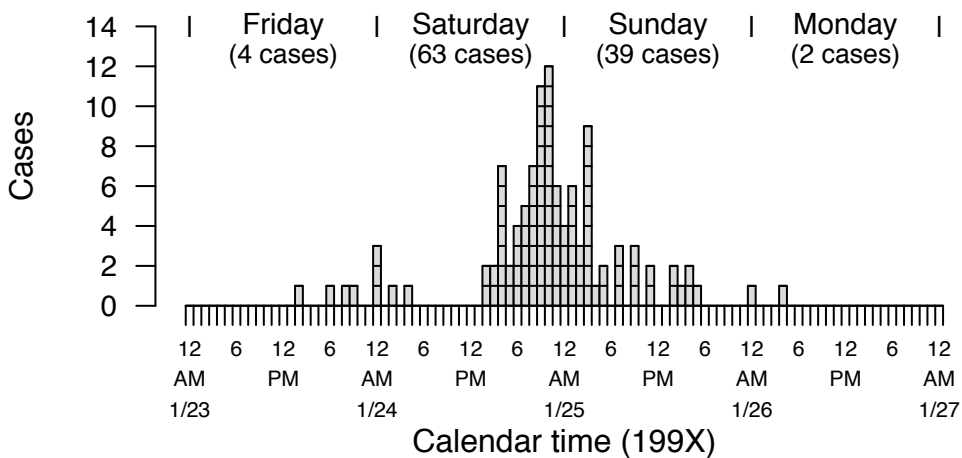


Figure 2: Outbreak of gastroenteritis at the Twin Peaks Hotel, San Francisco, California, 199X. Displayed is the distribution (histogram) of onset hour for diarrhea or vomiting for 108 cases.

2 The study

The CD Control Unit conducted a retrospective cohort study to identify which meal(s) and food item(s) was/were associated with the suspected foodborne illness. A survey questionnaire was designed utilizing information and food menus provided by the Twin Peaks Hotel and Restaurant A and B (see survey instrument in Appendix A on page 30). A list of 306 names and phone numbers of registered conference attendees was obtained from Company X and became the target population. The list was randomly ordered and divided into groups of twenty and assigned to interviewers (the target population became the intended sample). From Tuesday, January 27th through Wednesday, January 28th, as many attendees as feasible were contacted by interviewers without any knowledge of their symptoms or meal or food item exposures. Attendees were questioned about specific meals, food items consumed at each meal, gastrointestinal symptoms during this period, and the occurrence of potential secondary cases among household contacts after their return home. A case was defined as anyone that reported the occurrence of vomiting and/or diarrhea during the period January 23rd to January 27th. All data were entered

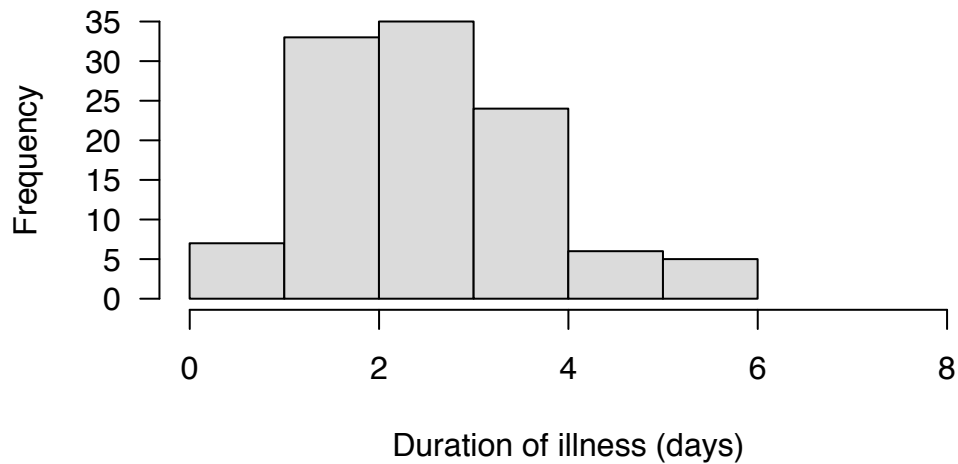


Figure 3: Outbreak of gastroenteritis at the Twin Peaks Hotel, San Francisco, California, 199X. Displayed is the distribution (histogram) of gastroenteritis symptoms (diarrhea or vomiting) for 108 cases. The median duration is 2.0 days, and the mean duration is 2.15 days.

into Epi Info ⁶³ and exported to R⁴ for analysis.

Question 10 *What is the difference between target population, sample (intended sample), and respondents (actual sample) and why does it matter?*

Answer: ANSWER:

The target population is the target of our epidemiologic inferences; this is usually the population at risk.

The sample is who we intend to sample from the target population. The sample is based on a sampling plan to minimized random error (chance) and systematic error (selection bias).

The respondents (actual sample) is the group of subjects that make it into our study. Even if the sampling plan eliminated selected bias, biased recruitment can let selection bias creep in (see Figure 4 on the next page).

³For basic data entry we now recommend EpiData; it is freely available from <http://www.epidata.dk>

⁴R is an open source program for statistical computing and graphics; it is freely available at <http://www.r-project.org>.

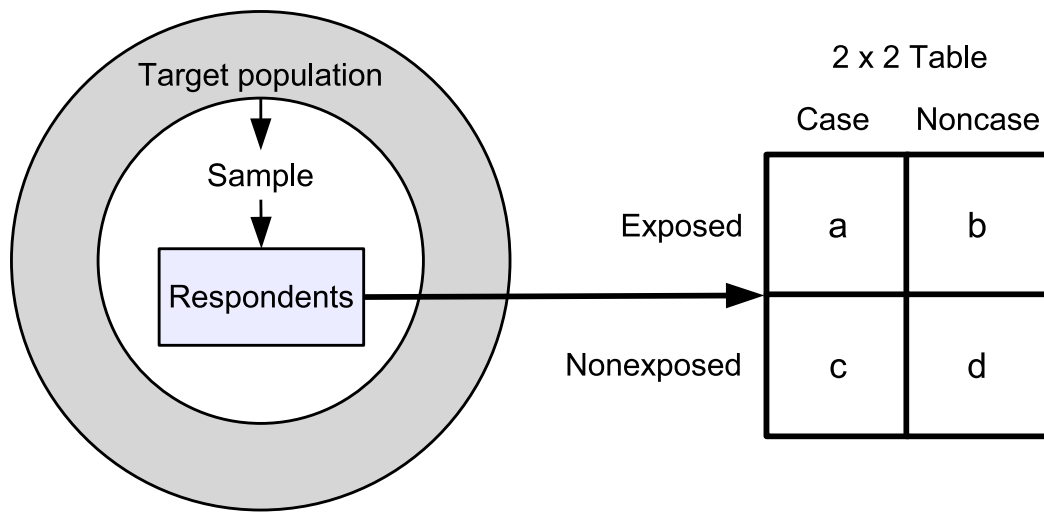


Figure 4: The population at risk (target population) is the target of our epidemiologic inferences. The intended sample is designed to minimize random error and systematic error (selection bias). The actual sample are the subjects that make it into your study.

Question 11 *In addition, to the epidemiologic investigation, what other investigations need to occur at the same time?*

Answer: ANSWER:

Let the audience provide some answers.

A thorough environmental health investigation is needed.

In general, the types of investigations that may be needed include:

- Epidemiological/Clinical
- Laboratory
- Environmental
- Veterinary
- Forensics/Law enforcement

Epidemiologists completed and entered into a database interviews from 164 subjects. The case definition was met by 110 of 164 subjects (67%). The remaining 54 subjects were considered non-cases. Five cases and zero non-cases reported secondary illness among household contacts after their return.

Question 12 *What are the general types of epidemic curves that you might see as you continue the investigation?*

Answer: ANSWER:

Part of case investigation is orienting the cases by person, place, and time.
An epidemic curve can:

- Suggest agent or incubation period
- Suggest magnitude and time course
- Suggest pattern of spread:
 - Common source (point, intermittent, or continuous in time)
 - Propagated (person-to-person)
 - Time limited vs. ongoing outbreak
- Show where we are in the course of the epidemic
- Be used for evaluation/monitoring
- Provide additional clues (outliers, etc)

In this outbreak, although a common source, point exposure was suspected, none has been identified yet; therefore, we cannot calculate an incubation period.

Study the epidemic curve (Figure 2 on page 16) and duration of symptoms (Figure 3 on page 17).

Question 13 *What is your interpretation?*

Answer: ANSWER:

Most of the cases started appearing Saturday evening and early Sunday morning, and is consistent with a common source, point exposure.

The duration of illness (about 2 days) is consistent with a bacterial food poisoning or viral gastroenteritis.

Question 14 *What additional information do you need to appropriately interpret the curve?*

Answer: ANSWER:

To calculate the incubation period, we need to identify the point time of exposure, if it exists. Knowing the incubation period will help us shorten the list of possible microbial agents.

Question 15 *Based on Figure 3 on page 17, why do the median duration and mean duration of symptoms differ?*

Answer: The mean is the arithmetic average: sum the values and divide by the number of values. The median is that value that puts half of the sorted values below it and half of the sorted values above it. The mean is influenced by “outliers” and the median is not. In this example, the histogram’s right tail is skewed, therefore we expect the mean to be larger than the median—and it is.

If the mean and median value differ significantly, use the median value since it is more representative of the most common values.

In this outbreak investigation, the epidemiologists designed and conducted an interviewer-administered questionnaire (IAQ).

Question 16 *What are some key steps in developing and implementing a survey questionnaire?*

Answer: ANSWER:

The seven key steps in designing and conducting a survey are listed below. The survey is an instrument we use to make measurements on the study subjects. These steps are incorporated into our study protocol (p. 12).

1. Establish survey goals
2. Design survey sampling
3. Design survey instrument
4. Evaluate survey instrument
5. Train survey interviewers
6. Conduct survey
7. Analyze survey data

Now here are the steps in more detail:

1. Establish survey goals
 - Objectives and timelines
 - Planning, logistics, and finance/admin requirements
2. Design survey sampling
 - Target population
 - Frame population
 - Sample (intended sample)
 - Recruitment plan
 - Respondents (actual sample)

- Post-survey adjustments
3. Design survey instrument
 - Construct
 - Measurement
 - Select survey mode
 - * Interviewer-administered questionnaire (IAQ)
 - Face-to-face survey
 - Telephone survey
 - * Self-administered questionnaire (SAQ)
 - Mail survey
 - Web-based survey
 - Design questions
 - Response
 - Edited response
 4. Evaluate survey instrument
 - Pilot test questionnaire
 5. Train survey interviewers
 6. Conduct survey
 7. Analyze survey data
 - Entry and quality control
 - Management
 - Processing
 - Analysis

First, establish the goals of the survey and a timeline. It's useful to adopt an ICS perspective (planning, logistics, finance/admin). Second, design the sampling protocol. In this outbreak, the target population would be the conference attendees. The frame population (also called sampling frame) is some list that is used to sample the target population (see Figure 5 on the next page). In this outbreak, Company X had a list of employees that registered for the conference. Unfortunately, the list may have contained names of persons that did not attend the conference: they were not at risk for becoming ill from a conference exposure and, therefore, are ineligible to be sampled. Conversely, the list may not have the names of persons that actually attended (undercoverage). Any remaining gap between the frame and target population is called coverage error. Can the audience think of ways to reduce coverage error?

Third, design the survey instrument. The *construct* is what we are trying to measure; for example, individual food item consumption. Next, decide

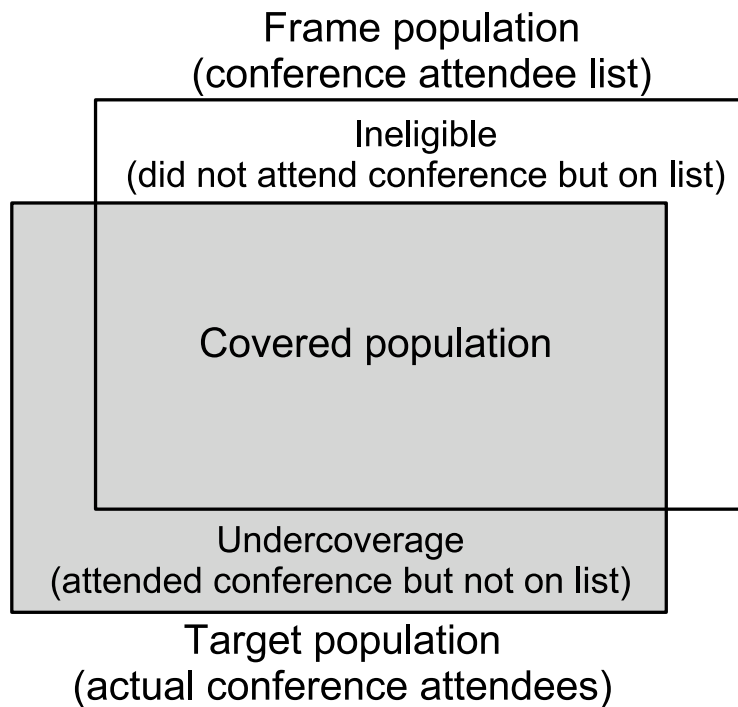


Figure 5: Coverage error occurs when our frame population (conference attendee list) does not cover the target population (actual conference attendees).

decide how to measure the construct. Select a survey mode: interviewer-administered questionnaire or a self-administered questionnaire, then design the questions and the possible responses. Fourth, evaluate the survey by pilot testing it. Fifth, train interviewers to the recruitment protocol and survey administration. Finally, conduct the survey and analyze the data.

Study the IAQ that starts in Appendix A on page 30.

Question 17 *Why did the investigators put the outcome assessment questions at the end of the survey?*

Answer: ANSWER:

Remember the threats to validity: chance, bias, and confounding. Bias (systematic error) is either selection bias or information bias (measurement error). Information bias can occur because of the respondent, the survey instrument, or the interviewer. When the interviewer contacts the respondent, he or she does not know whether the respondent was a case or not. We want the interviewers to elicit a responses in an unbiased manner. If

the interviewer knows the respondent's case status, it might influence how he or she elicits the responses.

Question 18 *Who should conduct the interviews?*

Answer: ANSWER:

At the stage of administering a survey instrument, we need interviewers that are unbiased and professional. Interviewers are not conducting an investigation, they are collecting data, and it must be done in a standardized way. If we administer the survey as an interviewer, then we have to be able to put aside our own biases. For example, clinicians interview patients with probing open-ended questions followed by focused confirmatory questions in order to establish and prioritize a differential diagnosis for their individual patients. For example, a clinical provider might say "So what's bothering you today?" "So your throat is sore. Do you have trouble swallowing? Have you had chills? Did you take your temperature? Do you have a runny nose?". This approach will not work with a survey; although it might be useful in the case investigation when we are generating hypotheses.

Question 19 *How would a self-administered questionnaire (SAQ) differ?*

Answer: ANSWER:

The investigators conducted an interviewer-administered questionnaire (IAQ). The survey instrument had scripts for the interviewers to read, and skip-patterns to facilitate efficient data collection. A SAQ differs in that the interviewee must be able to read and navigate the questionnaire. Therefore, it must be user-friendly and at the appropriate reading level.

A limitation of a SAQ is that some respondents may not be able to read and/or understand the survey.

Question 20 *What is the case definition and how could you improve it's sensitivity and specificity? What are the trade-offs?*

Answer: ANSWER:

"A case was defined as anyone that reported the occurrence of vomiting and/or diarrhea during the period January 23rd to January 27th." (p. 16)

This is a "loose" case definition; that is, a more sensitive case definition is likely to pick up more cases. This more sensitive case definition results in decreased specificity; hence, it will also pick up more false positives.

A more specific case definition might be "2 or more loose stools in a 24 hour period during the period January 23rd to January 27th." However, this case definition would also be less sensitive.

Table 1: Setting up the 2×2 table for the sensitivity and specificity of a case definition

Meets Case Definition	Actual Disease Status	
	Disease (D)	No Disease (\bar{D})
Yes (C)	True Positive (TP)	False Positive (FP)
No (\bar{C})	False Negative (FN)	True Negative (TN)

FOR EPIDEMIOLOGISTS:

Review Table 1. Sensitivity is the probability of a subject meeting the case definition given that a subject actually has the disease. The sensitivity of a case definition is determined by the number of subjects that are mistakenly classified as non-diseased (false negatives). A highly sensitive case definition will have a low number of false negatives, giving us confidence in using negative results to rule out a case (“SnOut”).

$$\text{Sensitivity} = P(C | D) = \frac{TP}{TP + FN}$$

Specificity is the probability of a subject not meeting the case definition given that a subject actually does not have the disease. The specificity of a case definition is determined by the number of subjects that are mistakenly classified as diseased (false positives). A highly specific case definition will have a low number of false positives, giving us confidence in using positive results to rule in a case (“Spln”).

$$\text{Specificity} = P(\bar{C} | \bar{D}) = \frac{TN}{TN + FP}$$

The predictive value positive (PV+) is the probability of a subject having disease given that the subject met the case definition. The PV+ is a function of the sensitivity and specificity of the case definition, and the prior probability of the subject being a true case. Generally a major determinant of the prior probability is the prevalence of the condition in the at-risk population and any additional information that makes the condition more or less likely. In this equation $P(D)$ is the prior probability of having the disease.

$$PV+ = P(D | C) = \frac{P(C | D)P(D)}{P(C | D)P(D) + P(C | \bar{D})P(\bar{D})}$$

To summarize, here are the “take home points” to remember:

1. A more sensitive (“loose”) case definition (low FN) will pick up more cases (at the expense of specificity [more FP]);
2. Use a more sensitive case definition if the benefits of picking up more mild cases outweigh the burden of picking up more false positives.
3. A more sensitive case definition (low FN) is better for ruling out a case (because you have more confidence in a negative result);
4. A more specific case definition reduces misclassification in analytic studies, improving the validity of findings;
5. A more specific case definition (low FP) is better for ruling in a case (because you have more confidence in a positive result);
6. Predictive value positive $[P(D | C)]$ is a function of sensitivity, specificity, and prior probability. Prior probability is affected by disease prevalence and other relevant information.

Question 21 *Based on the results of this survey, how many of the the 306 conference attendees became ill during this period? Discuss the types of biases that would affect this estimated number.*

Answer: ANSWER:

“The case definition was met by 110 of 164 (67%) subjects interviewed.”
Therefore, 67% or 206 out of 306 conference attendees were ill.

This assumes no selection bias and no measurement bias.

Question 22 *Calculate the risk ratios and the odds ratios for Table 4 on page 27 and interpret your findings.*

Answer: ANSWER:

For a cohort study, Table 2 on the following page has the 2×2 table set up to test the hypothesis that a single exposure is associated with becoming a case. The risk of becoming a case among the exposed is estimated by the proportion $R_1 = a/N_1$, and the risk among the nonexposed is estimated by the proportion $R_0 = c/N_0$. Based on this set up, the risk ratio is

$$RR = \frac{R_1}{R_0} = \frac{a/N_1}{c/N_0},$$

and the odds ratio is

$$OR = \frac{R_1/(1 - R_1)}{R_0/(1 - R_0)} = \frac{(a/N_1)/(b/N_1)}{(c/N_0)/(d/N_0)} = \frac{ad}{bc}.$$

Table 2: 2×2 table for cohort binomial data

Exposure	Case		Total
	Yes	No	
Yes	a	b	N_1
No	c	d	N_0

Table 3: 2×2 table to test the hypothesis that eating at breakfast on January 23rd was associated with becoming a case

Ate meal	Case		Total
	Yes	No	
Yes	88	34	122
No	22	19	41

For example, the 2×2 table to test the hypothesis that eating breakfast on January 23rd was associated with becoming a case is displayed in Table 3. Based on this set up, the risk ratio is

$$RR = \frac{R_1}{R_0} = \frac{88/122}{22/41} = 1.34,$$

and the odds ratio is

$$OR = \frac{ad}{bc} = \frac{(88)(19)}{(34)(22)} = 2.24.$$

Under the null hypothesis of no association ($RR = 1$), the p value is the probability of observing a risk ratio of 1.34 or more extreme (or an odds ratio of 2.24 or more extreme). This p value was calculated using Fisher's Exact Test which is available for 2×2 tables in modern statistical software packages.

The risk ratios and odds ratios for each meal are reported in Table 4 on the following page.

Question 23 *Which meal is likely implicated?*

Answer: ANSWER:

The Friday noon lunch at the hotel is most strongly associated with illness.

Question 24 *Why do the risk ratios and odds ratios differ?*

Table 4: Meal-specific attack percent (AP) for persons who ate at the Company X conference meals

Meal	Ate item			Did not eat item			RR	OR	P value
	Cases	Total	AP	Cases	Total	AP			
Friday (1/23)									
Breakfast	88	122	72.1	22	41	53.7	1.34	2.24	0.0349
Lunch ^a	109	146	74.7	0	17	0.0	26.2	102	< 0.0001
Dinner ^b	94	138	68.1	16	26	61.5	1.11	1.34	0.5045
Saturday (1/24)									
Breakfast	87	123	70.7	23	41	56.1	1.26	1.89	0.0889
Lunch	65	88	73.8	45	76	59.2	1.25	1.95	0.0664
Dinner ^c	86	124	69.4	24	40	60.0	1.16	1.51	0.3337

AP = attack percent; RR = risk ratio; OR = odds ratio.

All p values calculated using Fisher's Exact Test.

^a 0.5 added to all cells to calculate RR and OR

^b Dinner served at Restaurant A

^c Dinner served at Restaurant B

Answer: ANSWER:

For a risk ratio > 1, the odds ratio is more extreme (for a risk ratio < 1, the odds ratio is closer to 0). This is a mathematical property of odds ratio. When the proportions affected are > 10% this difference is more apparent. Hence, the "rare disease assumption" (where the odds ratio approximates the risk ratio) is often incorrect in infectious disease outbreaks.

Question 25 Which measure of association do you prefer and why?

Answer: ANSWER:

For a cohort study, we can calculate risk ratios or odds ratios. For a case-control study, we can only calculate odds ratios. If you are interested in comparing risks and making risk comparison statements, use the risk ratio (or the odds ratios if the "rare disease assumption" is valid). If you are interested only in a measure of association, then the odds ratio is generally better:

- Odds ratio can be calculated from either study design,
- Reciprocal of the odds ratio is the correct measure of association for the reciprocal of the ratios of the odds (this is not true for risk ratios)
- Odds ratio is the measure of association used in multivariable logistic regression analysis

Table 5: Food item-specific attack percent (AP) for person who ate at hotel lunch on Friday, January 23rd

Food item	Ate item			Did not eat item			RR	OR	P value
	Cases	Total	AP	Cases	Total	AP			
Mixed green salad	103	140	73.5	5	5	100.0	0.74	0.0	0.3291
Ranch dressing	47	60	78.3	48	68	70.6	1.11	1.51	0.4184
Vinaigrette dressing	54	72	75.0	46	64	71.2	1.04	1.17	0.7013
Beef lasagna	104	137	75.9	5	8	62.5	1.21	1.89	0.4101
Seasonal vegetables	87	116	75.0	16	23	69.6	1.08	1.31	0.6070
Sourdough rolls	66	88	75.0	41	54	75.9	0.99	0.95	1.0000
Dutch crunch rolls	39	46	84.8	66	93	71.0	1.19	2.28	0.0941
Lemon custard tart ^a	103	127	81.1	5	18	27.8	2.92	11.2	< 0.0001
Unbottled water	95	125	76.0	10	17	58.8	1.29	2.27	0.1464

AP = attack percent; RR = risk ratio; OR = odds ratio.

All p values calculated using Fisher's Exact Test.

^a Garnish and mixed berry coulis

- Odds ratio, because they are more extreme than risk ratios, are better for "detecting" potential causal factors

Question 26 *How would these findings now direct the field investigation?*

Answer: ANSWER:

This analysis suggests that the exposure occurred at the Friday lunch on January 23rd. If the hypothesis is that an individual food item is the cause, then the next analysis would be to evaluate which individual food item served at that lunch is associated with illness. Remember, the analysis must match the hypothesis we are testing.

Based on your analysis of Table 4 on the previous page, you have decided to analyze the data from Table 5.

Question 27 *Calculate the risk ratios and the odds ratios for Table 5 and interpret your findings. Which food item might be implicated? How would these findings now direct the field investigation?*

Answer: ANSWER:

The lemon custard tart is moderately associated with illness (RR = 2.92; OR = 11.2; $p < 0.0001$).

Now that we believe it may have been the lemon custard tart, the following should happen:

- Review how the lemon custard tart was produced, packaged, transported, handled, prepared, and served, and by whom.
- Do food item trace back (who produced the food item or ingredients?)
- Do food item trace forward (where else was the food item or ingredients delivered?)

Question 28 *Based on the likely time of exposure (from analysis of Table 4 on page 27, type and duration of symptoms (Figure 3 on page 17), the symptoms summarized in Table 6 on the following page and Table 7 on the next page, and the occurrence of secondary cases, re-interpret the epidemic curve. What is the likely microbial agent of this outbreak? Explain your rationale. How would this direct your investigation?*

Answer: ANSWER:

The microbial agent was most likely norovirus:

- Incubation period of about 36 hours
- Symptoms of nausea, vomiting, diarrhea
- Signs of fever
- Median duration of illness was 2 days
- Occurrence of secondary household cases among cases only

At the time of this outbreak (late 1990s), norovirus was diagnosed by electron microscopy of large volumes of stools. The method was insensitive. Our currently available test, the polymerase chain reaction (PCR), was not available.

Table 6: Comparison of symptoms for those that ate and did not eat lunch, Friday, January 23rd

Symptom	Ate lunch			Did not eat lunch		
	Yes	Total	(%)	Yes	Total	(%)
Nausea	111	145	76.6	0	17	0.0
Vomiting	76	144	52.8	0	17	0.0
Abdominal cramps	96	144	66.7	3	17	17.6
Diarrhea	89	144	61.8	0	17	0.0
Fevers	70	133	52.6	0	17	0.0
Chills	85	143	59.4	1	17	5.9
Lightheadedness	84	143	58.7	1	17	5.9
Bloating	61	137	44.5	2	17	11.8
Bodyaches	87	144	60.4	1	17	5.9
Headaches	84	142	59.2	1	17	5.9

Table 7: Comparison of symptoms for those that ate and did not eat the lemon custard tart, Friday, January 23rd

Symptom	Ate tart			Did not eat tart		
	Yes	Total	AP	Yes	Total	AP
Nausea	109	126	86.5	1	17	5.6
Vomiting	73	125	58.4	2	18	11.1
Abdominal cramps	94	125	75.2	1	17	5.6
Diarrhea	85	125	68.0	3	18	16.7
Fevers	68	114	59.6	1	17	5.6
Chills	83	124	66.9	1	17	5.6
Lightheadedness	84	125	67.2	0	18	0.0
Bloating	57	118	48.3	3	18	16.7
Bodyaches	84	125	67.2	2	16	11.1
Headaches	82	123	66.7	1	18	5.6

Appendix A: Survey Instrument

The actual survey used for this outbreak investigation starts on the next page.

Outbreak Exposure and Outcome Survey

Assigned ID: _____

First Name: _____ Last Name: _____

Work Phone: _____ Home Phone: _____

Exposure assessment

Hello, may I speak to (name) _____. My name is _____. I am calling you from the San Francisco Health Department because you attended a conference in San Francisco organized by Company X. As you probably know, several people became ill with gastrointestinal symptoms while at the conference. The Health Department is trying to determine the source of the problem. I am interested in speaking with you whether or not you became ill at any time during or after the conference. All of this information will be kept confidential.

To begin, I would like to verify your name and address:

READ NAME AND ADDRESS TO RESPONDENT. THEN ASK,

1. Were you in San Francisco for the Company X conference anytime between Thursday, January 22nd and Saturday, January 24th?

1 [] YES 2 [] NO →→ **STOP AND THANK INTERVIEWEE**

2. a) Is there anyone else who came with you who may not have been listed on the conference participant list?

1 [] YES 2 [] NO



- b) Could you please give me the name and phone number of each person?

Name

Phone numbers

Name

Phone numbers

7 [] REFUSED

3. a) Did you stay at the Twin Peaks Hotel at anytime from Thursday, January 22nd to Sunday, January 25th.

2 [] NO 1 [] YES



- b) Did you stay in your own home?

1 [] YES

2 [] NO

4. On what date did you first come to the conference?

1 [] EARLIER THAN THURSDAY, JANUARY 22

2 [] THURSDAY, JANUARY 22

3 [] FRIDAY, JANUARY 23

4 [] SATURDAY, JANUARY 24

5 [] SUNDAY, JANUARY 25

8 [] DON'T KNOW or DON'T REMEMBER

5. On what date did you leave the conference?

1 [] EARLIER THAN FRIDAY, JANUARY 23

2 [] FRIDAY, JANUARY 23

3 [] SATURDAY, JANUARY 24

4 [] SUNDAY, JANUARY 25

5 [] AFTER SUNDAY, JANUARY 25

8 [] DON'T KNOW or DON'T REMEMBER

In the next section, I am going to ask you about meals that were served to a large number conference participants on Friday, January 23rd and Saturday, January 24th. Later, I will ask you about whether or not you had symptoms. For each meal you went to, I will ask you about specific foods that you might have eaten.

6. a) Did you eat breakfast at the Twin Peaks Hotel on Friday, January 23rd?

1 [] YES

2 [] NO →→→ **GO TO QUESTION 7**



b) I am going to read you a list of foods that were served at that meal. For each food, tell me whether or not you ate that food.

<i>Food/Beverage</i>	<i>YES</i>	<i>NO</i>	<i>DON'T REMEMBER</i>
Orange juice	1 []	2 []	8 []
Grapefruit juice	1 []	2 []	8 []
Sliced seasonal fruit (cantalope)	1 []	2 []	8 []
Sliced seasonal fruit (watermelon)	1 []	2 []	8 []
Sliced seasonal fruit (pineapple)	1 []	2 []	8 []
Sliced seasonal fruit (strawberries)	1 []	2 []	8 []
Plain yogurt	1 []	2 []	8 []
Fruit yogurt with berries	1 []	2 []	8 []
Granola	1 []	2 []	8 []
Scrambled eggs	1 []	2 []	8 []
Salsa for eggs	1 []	2 []	8 []
Bacon	1 []	2 []	8 []
Sausage links	1 []	2 []	8 []
Griddle potatoes with peppers and onions	1 []	2 []	8 []
Croissant	1 []	2 []	8 []
Danish	1 []	2 []	8 []
Fruit and nut muffins	1 []	2 []	8 []
Warm grits	1 []	2 []	8 []
Water (not bottled)	1 []	2 []	8 []
# Glasses of water _____			
Other _____	1 []	2 []	8 []

7. a) Did you eat lunch at the Twin Peaks Hotel on Friday, January 23rd?

1 [] YES

2 [] NO →→→ **GO TO QUESTION 8**



b) I am going to read you a list of foods that were served at that meal. For each food, tell me whether or not you ate that food.

<i>Food/Beverage</i>	<i>YES</i>	<i>NO</i>	<i>DON'T REMEMBER</i>
Green salad	1 []	2 []	8 []
Ranch dressing	1 []	2 []	8 []
Vinaigrette dressing	1 []	2 []	8 []
Beef lasagna	1 []	2 []	8 []
Vegetables	1 []	2 []	8 []
Sourdough rolls	1 []	2 []	8 []
Dutch crunch rolls	1 []	2 []	8 []
Lemon custard tart with fresh fruit garnish and mixed berry coulis	1 []	2 []	8 []
Water (not bottled)	1 []	2 []	8 []
# Glasses of water _____			
Other _____	1 []	2 []	8 []

8. a) Did you eat dinner at Restaurant A on Friday, January 23rd?

1 [] YES



2 [] NO →→→ **GO TO QUESTION 9**

b) I am going to read you a list of foods that were served at that meal. For each food, tell me whether or not you ate that food.

<i>Food/Beverage</i>	<i>YES</i>	<i>NO</i>	<i>DON'T REMEMBER</i>
Grilled marinated vegetables	1 []	2 []	8 []
Olives	1 []	2 []	8 []
Sharp cheeses	1 []	2 []	8 []
Asparagus spears	1 []	2 []	8 []
Yellow and green squash	1 []	2 []	8 []
Artichoke hearts	1 []	2 []	8 []
Pepperoni (small, sweet pepper)	1 []	2 []	8 []
Herb aioli (dip)	1 []	2 []	8 []
Mixed salad	1 []	2 []	8 []
Herb vinaigrette (salad dressing)	1 []	2 []	8 []
Filet of Salmon with Chive Beurre Blanc	1 []	2 []	8 []
Petite Filet Mignon with Cabernet Demi Glaze	1 []	2 []	8 []
Herb roasted potatoes	1 []	2 []	8 []
Vegetables served with entree	1 []	2 []	8 []
Sourdough bread	1 []	2 []	8 []
Butter	1 []	2 []	8 []
Ice cream	1 []	2 []	8 []
Berry puree (ice cream sauce)	1 []	2 []	8 []
Waffle bowl (contained ice cream)	1 []	2 []	8 []
Water (not bottled)	1 []	2 []	8 []
# Glasses of water _____			
Other _____	1 []	2 []	8 []

9. a) Did you eat breakfast at the Twin Peaks Hotel on Saturday, January 24th?

1 [] YES



2 [] NO →→→ **GO TO QUESTION 10**

b) I am going to read you a list of foods that were served at that meal. For each food, tell me whether or not you ate that food.

<i>Food/Beverage</i>	<i>YES</i>	<i>NO</i>	<i>DON'T REMEMBER</i>
Orange juice	1 []	2 []	8 []
Grapefruit juice	1 []	2 []	8 []
Sliced seasonal fruit (cantalope)	1 []	2 []	8 []
Sliced seasonal fruit (watermelon)	1 []	2 []	8 []
Sliced seasonal fruit (pineapple)	1 []	2 []	8 []
Sliced seasonal fruit (strawberries)	1 []	2 []	8 []
Plain yogurt	1 []	2 []	8 []
Fruit yogurt with berries	1 []	2 []	8 []
Granola	1 []	2 []	8 []
Scrambled eggs	1 []	2 []	8 []
Bacon	1 []	2 []	8 []
Sausage links	1 []	2 []	8 []
Griddle potatoes with peppers and onions	1 []	2 []	8 []
Croissant	1 []	2 []	8 []
Danish	1 []	2 []	8 []
Fruit and nut muffins	1 []	2 []	8 []
Warm grits	1 []	2 []	8 []
Water (not bottled)	1 []	2 []	8 []
# Glasses of water _____			
Other _____	1 []	2 []	8 []

10.a) Did you eat lunch at the Twin Peaks Hotel on Saturday, January 24th?

1 [] YES



2 [] NO →→→ **GO TO QUESTION 11**

b) I am going to read you a list of foods that were served at that meal. For each food, tell me whether or not you ate that food.

<i>Food/Beverage</i>	<i>YES</i>	<i>NO</i>	<i>DON'T REMEMBER</i>
Minestrone soup	1 []	2 []	8 []
Grilled chicken	1 []	2 []	8 []
Caesar salad	1 []	2 []	8 []
Sourdough rolls	1 []	2 []	8 []
Dutch crunch rolls	1 []	2 []	8 []
Chocolates	1 []	2 []	8 []
Water (not bottled)	1 []	2 []	8 []
# Glasses of water _____			
Other _____	1 []	2 []	8 []

11.a) Did you eat dinner on the Restaurant B Cruise on Saturday, January 24th?

1 [] YES



2 [] NO →→→ **GO TO QUESTION 12**

b) I am going to read you a list of foods that were served at that meal. For each food, tell me whether or not you ate that food.

<i>Food/Beverage</i>	<i>YES</i>	<i>NO</i>	<i>DON'T REMEMBER</i>
Sirloin of Beef	1 []	2 []	8 []
Horseradish sauce	1 []	2 []	8 []
Grilled chicken breast	1 []	2 []	8 []
Steamed vegetables	1 []	2 []	8 []
Rice pilaf	1 []	2 []	8 []
Caesar salad	1 []	2 []	8 []
Marinated mushroom salad	1 []	2 []	8 []
Rolls	1 []	2 []	8 []
Tartlettes	1 []	2 []	8 []
Water (not bottled)	1 []	2 []	8 []
# Glasses of water _____			
Champagne	1 []	2 []	8 []
Other _____	1 []	2 []	8 []

Outcome assessment

12.a) Did you have any gastrointestinal symptoms or feel ill at any time between Friday, January 23rd and Tuesday, January 27th?

1 [] YES



2 [] NO →→→ **GO TO QUESTION 18**

b) Now I am going to ask if you had any of the following symptoms while you were feeling ill.

Symptom	YES	NO	DK
Nausea	1 []	2 []	8 []
Vomiting	1 []	2 []	8 []
Abdominal cramps	1 []	2 []	8 []
Diarrhea	1 []	2 []	8 []
Fever	1 []	2 []	8 []
Chills	1 []	2 []	8 []
Lightheadedness	1 []	2 []	8 []
Bloating	1 []	2 []	8 []
Body aches	1 []	2 []	8 []
Headaches	1 []	2 []	8 []
Other: _____	1 []	2 []	8 []

13. When did you first start feeling ill?

Day _____ (SAT, SUN, MON, TUE)

Date _____ (1/24, 1/25, 1/26, 1/27)

Time _____ (AM, PM)

14.a) What was the first symptom you had? _____

First Symptom

b) (IF FIRST SYMPTOM WAS NOT NAUSEA, DIARRHEA, OR VOMITING),
When did you begin having nausea, diarrhea or vomiting?

Day _____ (SAT, SUN, MON, TUE)

Date _____ (1/24, 1/25, 1/26, 1/27)

Time _____ (AM, PM)

15. How many days were you ill? _____
#Days

16.a) Did you seek medical help?

1 [] YES

2 [] NO

↓
↓

b) When? _____

c) Where? _____ (NAME & PHONE)

17.a) Have any household contacts become ill with similar symptoms?

1 [] YES

2 [] NO

↓
↓

b) When? _____

c) Where? _____ (NAME & PHONE)

18. So that we may contact you later, may we have your home address and phone number?

Street number Street

City State/Country ZIP code

Home phone _____

INTERVIEWER: PLEASE NOTE THE HOME PHONE NUMBER ON THE FIRST PAGE