Case Study III – Salmonellosis in Oregon

Objectives / topics for Case Study III

1. Understanding public health's role in investigating natural outbreaks of disease.
2. Recognizing that public health expects certain patterns or findings to explain natural disease outbreaks.
3. Recognizing that certain unusual or unnatural findings in a disease investigation may suggest intentional / covert action.
4. Identifying procedures and mechanisms to communicate suspicions of intentionality to law enforcement officials.

Problem and questions

Background: This scenario involves the September 1984 outbreak of gastroenteritis (an illness characterized by fever, vomiting, and diarrhea) caused by a specific bacterium, *Salmonella* Typhimurium (this specific bacterium is a member of a much larger family of salmonella bacteria). The outbreak occurred among persons living in the community of The Dalles, Oregon. The Dalles (1980 population: 10,500) is the county seat of Wasco County, population of 21,000 and a region of orchards and wheat ranches. The Dalles is located off Interstate 84 and is a frequent stop for travelers. From 1980 through 1983, there had been only 16 isolates of salmonella reported by the local health department (the Wasco-Sherman Public Health Department), and of these, only 8 were *Salmonella* Typhimurium. In 1981, followers of Bhagwan Shree Rajneesh purchased a large ranch in Wasco County to build a new international headquarters for the guru. Construction of the commune was controversial because of issues involving cultural values and land-use. Part of the commune's ranch was incorporated as the city of Rajneeshpuram, but the charter was challenged in the courts, effectively limiting new construction. Commune members believed that the outcome of the November 1984 elections for Wasco County commissioners would have an important impact on further land-use decisions. One measure commune members took to further their interests was to implement a national program to bus hundreds of homeless persons to the commune for the purpose of registering these persons to vote in the election.

Facts I: On September 17, 1984, a disease control expert for the Wasco-Sherman Public Health Department began to receive reports of recent cases of gastroenteritis in persons who had eaten meals in either of two local restaurants in The Dalles several days before symptom onset.

Question 1: What is a county health department's responsibility when it receives reports of cases of illness among persons in a community, and what is the threshold for beginning an investigation?

Answers / discussion points: A county / local health department has front-line responsibility for conducting public health surveillance. It is responsible for receiving and collecting information about reports of cases of specified diseases

which are "notifiable" as required by law, then determining whether the number of cases of a given disease exceed that which would be expected in that setting for a given period of time. Cases of notifiable diseases may be reported from a variety of sites (e.g., physicians' offices, diagnostic laboratories, and hospitals). In addition, however, illness reports are often reported directly from citizens and, depending on circumstances, may trigger an investigation.

If the number of cases of a given disease exceeds the historical baseline, then the health department might conclude that an outbreak is occurring and some persons remain at continued risk of exposure. The health department might then proceed with a more extensive investigation to identify additional cases, determine the source and cause of the outbreak, and put preventive measures in place. The local health department also would notify the state health department about the problem and, if necessary, request assistance from the state. Individual cases of a disease are distinguishable from clusters of cases (i.e., a group of cases occurring among persons in a defined geographic area during a specific time, but for which there is no information regarding background levels), as well as from an outbreak situation.

Facts II: The disease control expert collected stool samples from recently ill persons and sent those samples to the state public health laboratory to be cultured. By the end of the week, cultures of stool samples obtained from about 15 persons were reported as being positive (+) for the bacterium, *Salmonella* Typhimurium, a bacterium known to cause gastrointestinal illness of the sort reported among people in the community. The disease control expert's preliminary investigation suggested that some persons with cases of gastroenteritis had eaten at salad bars at restaurants in the community before becoming ill. One week later, on about September 24, the disease control expert learned that there were additional cases of illness in the community and that some affected persons had been hospitalized because of their illnesses. As a result, on September 24, the county health department contacted the Oregon Health Division (i.e., the state health department), and on September 25, the state contacted CDC for assistance. In addition, because of the possible link between having eaten at salad bars and becoming ill, salad bars (but not entire restaurants) were closed.

Question 2: Under what conditions should a health department begin a full formal epidemiological investigation of a health problem?

Answers / discussion points: A health department might begin a full formal investigation when there is evidence of an outbreak (i.e., the number of cases exceeds that expected for a given place and time period) in order to identify the sources and modes of spread of the disease-causing agent. The health department could then use the findings to stop the outbreak and prevent future recurrences. Other factors that might influence decisions regarding a full-scale investigation include the severity of the disease, the numbers of cases, and community and political pressures to intervene.

Question 3: What are the usual procedures for investigating a possible food borne disease outbreak?

Answers / discussion points: The basic steps and procedures are similar to those used in investigating a problem like the anthrax cluster in Florida. An exception is that investigators usually approach a food-borne disease outbreak as a "naturally-occurring" problem in the absence of evidence suggesting deliberate, intentional human efforts to cause illness in others. The investigation of such a naturally occurring illness typically focuses efforts on looking for a known pattern. Examples are an improperly handled or stored food or a breakdown in the food manufacturing process. This pattern would explain what is happening, primarily on the basis of our knowledge of how this organism typically causes illness in humans.

Facts III: On September 26-27, two medical epidemiologists from CDC arrived in The Dalles to provide assistance with the investigation, including the identification of additional cases, collecting patient specimens, analyzing data, and assessing the basis for and impact of the intervention of closing the salad bars. Over the next 6 weeks, a public health team – which included persons from the local and state health departments and from CDC – continued this extensive investigation, collecting additional data and samples, conducting numerous interviews, and carrying out complex studies. Ultimately, investigators identified a total of 751 persons with cases of *Salmonella* gastroenteritis. With an outbreak this large, investigators were initially optimistic that they would be able to find a common pattern or thread that could explain the occurrence of illness in so many people.

Despite these efforts, the investigators could not identify a single food item or contamination of a single food item that could have accounted for the *Salmonella* Typhimurium gastroenteritis outbreak. In the midst of this investigation, some residents of The Dalles contacted public health officials to express concerns about the possible suspicious behavior of some restaurant employees and of some religious commune members in relation to salad bars. These concerns included general rumors and a few very specific allegations, and raised questions about the possibility of the intentional contamination of food to cause illness within the community.

Question 4: What circumstances should cause public health officials investigating an outbreak to suspect that the outbreak is intentional?

Answers / discussion points: Suspicion that an outbreak is intentional might be triggered under the following circumstances.

- The cases are of a common disease but are out of season or are in an unusual geographic area, or the epidemiology points to a very unusual or novel mode of spread, or the disease is unusually virulent or contagious.
- The cases are a disease thought to be caused by a likely BT agent and cannot be readily explained.
- Investigators cannot solve / explain the outbreak by usual techniques.

- The outbreak could not have occurred by natural means (including human error).
- The outbreak corresponds to threats that have been received.
- A group claims credit for causing the outbreak.
- There are plausible accusations against particular persons (e.g., by fellow employees of a restaurant or by informants).

Question 5: What should public health personnel do when specific allegations of intentionality are raised during the course of a public health investigation?

Answers / discussion points: In the setting of an outbreak investigation, law enforcement officials should be notified promptly when specific allegations – such as those in The Dalles – are raised during the investigation.
Note: public health agencies may have reason to contact the law enforcement system under other circumstances. For example, a contact may be triggered when public health officials, during the course of providing routine public health services (e.g., STD contact tracing, prenatal care, or provision of other clinical services), suspect the occurrence of crimes such as child abuse or rape.

Question 6: What law enforcement agency(ies) should be notified (e.g., local, state, or federal)?

Answers / discussion points: Relevant issues are cited below.

(1) Early notification to the FBI by state and local public health and/or the CDC is important when the circumstances of incidents of disease are unusual or may not be consistent with natural occurrences.
(2) The use, or threatened use, of a biological agent against humans, animals, or plants is a federal crime under the Weapons of Mass Destruction Statute (Title 18, U.S.C. Section 2332[a]) and may constitute a bioterrorism attack against the U.S. affecting multiple jurisdictions.
(3) The conduct of the FBI-led Interagency Threat Assessment process will assist the FBI, the CDC, and state and local authorities in determining the extent of the threat based upon access to all relevant law enforcement, public health, and intelligence information.
(4) The FBI may initiate investigative activities with the assistance of State and local authorities to augment the on-going public health investigation.Often this is accomplished through established Joint Terrorism Task Forces (JTTFs) or other standing law enforcement working groups.

In some cases, local and/or state law enforcement authorities may be contacted initially by local public health officials. In each case, however, a notification should be placed to the local FBI office, who will initiate additional notifications and the Interagency Threat Assessment Process through the FBI's Weapons of Mass Destruction Operations Unit (WMDOU). Information from this assessment will assist the local FBI and state and local officials in evaluating the situation through the assistance of subject matter and technical experts. In addition, the

CDC has developed protocols to notify FBI's WMDOU in the event that a notification has not yet been placed to the local FBI field office.

If the situation is assessed as potentially an intentional use of disease-causing organisms, federal policy and authorities designate the FBI as the lead agency for crisis management operations. This includes initiating a criminal investigation to complement the public health investigation. The local FBI field office will work closely with other federal, state and local law enforcement partners to determine the possibility of criminal intent and to identify and arrest potential perpetrators.

Question 7: What does law enforcement do in response to such reports and under what authority?

Answers / discussion points: The threatened or actual delivery / release of a bioterrorism agent is a violation of federal law (and may be a violation of state law). Federal law enforcement authorities have legal jurisdiction to initiate investigations (as may state law enforcement authorities). In an actual or a suspected bioterrorism incident, the FBI would be the lead federal agency responsible for conducting the criminal investigation. The FBI would initiate a joint investigation with public health to ascertain whether there is any indication that an outbreak of disease was the result of an intentional act. If the situation expands into a full-fledged joint investigation, the FBI would establish a Joint Operations Center (JOC) and Joint Information Center (JIC) with federal, state and local public health, law enforcement, and emergency management agencies to provide strategic direction and coordination of response activities. Any information suggesting intentional acts of bioterrorism that come to the attention of public health officials should be promptly communicated to the FBI through the local FBI field office or, if established, the JOC.

To protect the integrity of the investigation and any potential evidence to be eventually submitted into court, law enforcement should check with its state's attorney before observing or participating in interviews conducted by public health. One item to cover with the state's attorney is how to inform an interviewee that law enforcement is present.

Question 8: What factors may guide how law enforcement communicates with public health about such reports and vice versa?

Answers / discussion points: In a bioterrorism incident, the traditional paradigm for the law enforcement response to criminal activity (i.e., to "protect" the findings of a criminal investigation) may not optimally serve the public's interests and safety. However, in certain instances, such as when a federal grand jury obtains documents and testimony of witnesses, federal law mandates that such information and evidence must be kept confidential. Absent any such laws or rules to the contrary, frequent and candid communications between law enforcement and public health authorities must occur in order for the objectives of

each to be achieved and to best serve their common mission of protecting the public.

Law enforcement's objective of identifying, apprehending, and prosecuting the perpetrator(s) may require that certain investigative leads be kept confidential. However, information relating to the type of agent used, the manner of delivery / release, and the probable target(s) of the attack may need to be shared with public health officials so they can identify, protect, and treat potentially exposed persons.

Public health and law enforcement must be mindful that there may be limits on the sorts of information public health authorities may share with law enforcement agencies. These limits may be in the form of express statutes, regulatory rules, or case law, and they may vary by jurisdiction.

In a suspected covert bioterrorism investigation, the FBI, state and local law enforcement, the CDC, and state and local public health – within the constraints noted above – must readily share information resulting from laboratory tests, interviews, analysis, and subject matter experts. As such, the FBI and public health's joint investigation should involve joint interviews, whenever possible, and a mechanism to funnel all relevant public health and law enforcement information into the JOC.

Question 9: In a situation such as in The Dalles, long after the exposures and outbreak may have occurred, how does the FBI / law enforcement approach the matter of collection of evidence and establishment of chain of custody? In this case, what is the evidence?

Answers / discussion points: The FBI / law enforcement will depend upon information supplied by public health officials for the initial information that indicates that the disease outbreak may not be the result of natural causes. Law enforcement also would require assistance from public health in understanding how the bioterrorism agent was created, how it was delivered / released, and what evidence might exist for identifying the perpetrator(s) and linking them to the delivery / release, and/or to the bioterrorism agent. Through joint investigative activities, the FBI will rely upon the technical assistance of public health authorities for the conduct of laboratory analysis for suspected bioterrorism agents. The FBI will also rely on public health authorities to provide the characteristics of the particular disease, surveillance data, and results of interviews with potentially exposed persons.

At the point when the FBI becomes involved in a case, public health activities will need to be closely coordinated with law enforcement to ensure that all evidence is properly handled and documented, and that no actions are taken that might inadvertently jeopardize the criminal investigation.

Law enforcement investigators would interview laboratory workers and other public health personnel regarding their activities and findings, and would obtain copies of relevant documentation regarding relevant public health activities and findings.

The investigation in The Dalles also raises as an issue how law enforcement might use epidemiologic findings and / or laboratory data in the course of pursuing a criminal prosecution. In a situation such as that in The Dalles, a criminal investigation might be carried out at a point in time distant from that of a public health investigation in which epidemiologic and laboratory studies implicated a source or mode of spread for the outbreak. In such a situation, the epidemiologic findings may be critical as evidence in a subsequent criminal prosecution that links suspected perpetrators to disease-causing agents and to illness in persons exposed to the disease-causing agents. In The Dalles, for example, the evidence also might include questionnaires that epidemiologists administered during interviews of sick and unaffected people, the analyses of those data, and the epidemiologists' final written report.

Evidence that an outbreak is due to a particular disease-causing agent spread in a particular way may depend critically on epidemiologic evidence from the pattern of cases, results of questionnaire surveys, and results of laboratory testing of specimens obtained from ill persons. This may be especially true for cases in which environmental sampling is not feasible: because the original material may longer exist or the pathogen may be one that cannot be cultured from the environment.

Facts IV: After receiving the initial reports of suspicious activity involving certain persons, public health personnel also began to interview restaurant managers about the behavior of disgruntled employees as a means for assessing the possible occurrence of an intentional act (although these queries yielded no relevant information).

Question 10: What issues arise when public health personnel ask such questions as part of a public health epidemiologic investigation?

Answers / discussion points: Issues raised by this question include the following.

(1) There is a need for public health officials to ask such questions as part of a public health investigation. Relatedly, there is the likely loss of privacy/confidentiality assurances when there is a question of interviewee behavior posing a risk/peril to the public's health and, therefore, an imperative for public health to promptly notify law enforcement.
(2) There are specific procedural issues.For example, given that public health might need to ask such questions, what training do public health officials need in order to conduct such interviews, ask such questions, make a record of the interviews, and transmit relevant information to law enforcement?
(3) There is the need for public health officials to include intentionality in the differential diagnosis of hypotheses either when they hear of specific

allegations of potentially criminal intentional behavior or when they cannot solve the outbreak as a consequence of naturally-occurring or non-criminal behavior.

Question 11: What questions are FBI / law enforcement officials primarily responsible for asking under these circumstances?

Answers / discussion points: While law enforcement may be primarily responsible, public health may be the first point of contact. Therefore, under the circumstances, public health may have the first (or even only) opportunity to obtain such information regarding the possibility of intentional acts. However, at the point when public health officials believe that the outbreak may not be the result of natural causes, the local FBI should be notified and should take the lead role in interviewing witnesses about potential criminal activities.

Law enforcement must be involved as soon as possible because of the importance of determining who should be interviewed and timing for the interviews. For example, if a witness claims to have specific knowledge about the perpetrator(s) of a bioterrorism act, law enforcement authorities might want to conduct other investigative activities (e.g., visual and electronic surveillance, execution of search warrants) before other interviews are conducted that might alert suspects that they are being investigated.

Public health officials who obtain information about possible criminal activities should be informed of the potential subsequent need for them to recount the details of such information. Because their testimony could be critical to the prosecution of a suspected perpetrator, public health officials must be apprized of the importance of careful and thorough documentation of such information.

Facts V: Public health personnel remained in the field for over 6 weeks in order to complete the public health field investigation. At the end of this extensive investigation, they concluded that: (1) illness was associated with salad bar consumption; and (2) because cases of illness occurred in two distinct time clusters, transmission of *Salmonella* Typhimurium probably involved some sort of complex transmission mechanisms. The investigators could neither rule out nor prove intentionality. The investigators recommended that all restaurant food handlers be healthy and have negative stool cultures before being permitted to return to work.

One year later, as part of a wiretapping and immigration fraud investigation of the religious commune, the FBI and other law enforcement officials received key information from informants who were members of the religious commune – that, beginning in August 1984, members of the commune had intentionally contaminated salad bars with *Salmonella* Typhimurium for the purpose of influencing a local election to be held in November 1984. In October 1985, FBI and other law enforcement officials visited the commune's compound; during that visit, a vial of dried *Salmonella* Typhimurium (subsequently determined to be identical to the outbreak strain) was discovered by the state health department's laboratory director who placed the vial into a chain of custody. In March 1986, indictments of some commune members

were handed down. Two commune members, a nurse and the secretary to its leader, were convicted and sentenced.

Question 12: What is the "select agent" rule and how does it apply to *Salmonella* organisms?

Answers / discussion points: Pursuant to the Antiterrorism and Effective Death Penalty Act of 1996, HHS promulgated regulations governing the transfer of specified biological agents and toxins ("select agents" – see list). These regulations (found at 42 CFR 72.6) require facilities that transfer or receive select agents to register with the CDC and implement agent-tracking procedures for each transfer. Violation of the regulations carries both civil and criminal penalties.

On June 12, 2002, President Bush signed the Public Health Security and Bioterrorism Preparedness Response Act of 2002, which required an expansion of the HHS select agent regulations. In addition to regulating the transfer of select agents, the new regulations (found at 42 CFR part 73) prohibit the possession of select agents except in accordance with part 73. Among other things, any individual or entity that possesses select agents must register with the CDC, undergo a risk assessment conducted by the Department of Justice, and comply with enhanced biosafety and laboratory security requirements. Beginning February 7, 2003, part 73 will be phasedin. It becomes fully effective on November 12, 2003. Violation of the regulations carries both civil and criminal penalties.

Salmonella Typhimurium is not currently listed as a select agent in either section 72.6 or part 73.