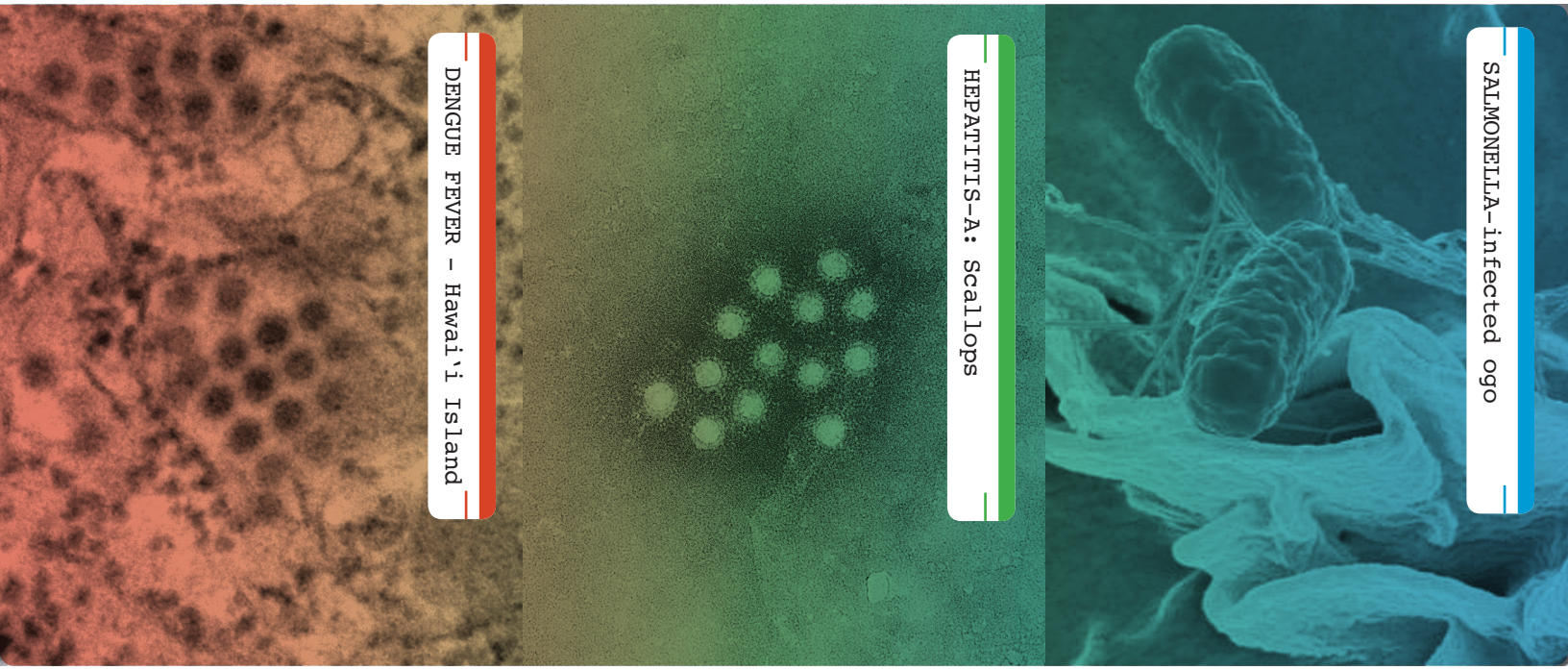
Audit of the Disease Outbreak Control Division of the Department of Health

A Report to the Governor
and the Legislature of
the State of Hawai‘i

Report No. 17-14
December 2017



OFFICE OF THE AUDITOR
STATE OF HAWAI‘I

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STATE OF HAWAIʻI

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COVER PHOTOS: DENGUE VIRUS - CDC / FREDERICK MURPHY, HEPATITIS A VIRUS - CDC / BETTY PARIN, SALMONELLA BACTERIA - NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Foreword

Our audit of the Disease Outbreak Control Division of the Department of Health was conducted pursuant to article VII, section 10 of the Hawai‘i State Constitution and section 23-4, Hawai‘i Revised Statutes, requiring the Auditor to conduct postaudits of the transactions, accounts, programs, and performance of all departments, offices, and agencies of the State and its political subdivisions.

We express our appreciation to the officials and staff of Hawai‘i Department of Health, and other individuals whom we contacted during the course of our audit for their cooperation and assistance.

Leslie H. Kondo
State Auditor

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Auditor's Summary

Audit of the Disease Outbreak Control Division of the Department of Health

Report No. 17-14

PHOTO: CDC / PROF. FRANK HADLEY COLLINS

What problems did the audit identify?

IN REPORT NO. 17-14, *Audit of the Disease Outbreak Control Division of the Department of Health*, we assessed the division's surveillance and response to three disease outbreaks: dengue fever on Hawai'i Island, hepatitis-A involving frozen scallops on O'ahu and Kaua'i, and salmonella-infected ogo on O'ahu. We found that, during these outbreak responses, the Disease Outbreak Control Division (the Division) and the Department of Health (DOH) experienced communication breakdowns with other DOH divisions, State and County response representatives, and the general public. During the outbreaks, DOH did not have a formal communications plan that would have provided established guidance on issues such as the timing of the first public announcement about the outbreak and procedures for sharing outbreak information with other agency officials. The confusion and, at times, discord, may have been avoided if DOH had established and followed a full communications plan.

We also found that the Division has inconsistent processes and procedures for recordkeeping, internal reviews, and reporting. We note that neither DOH nor the Division could provide us with a comprehensive account, timeline, or summary of the outbreak responses. In addition, the Division does not follow the disease-specific investigation protocols it does have in place. These deficiencies result in limited accountability to the public and could also result in missed investigation steps and possible delays and/or replication of efforts during an outbreak response.

In our review of the summary and final reports for the outbreaks, we found that the Division's final summary reports do not consistently follow a scientific format as recommended by the Centers for Disease Control and Prevention. The Division also does not consistently complete end-of-outbreak reviews, debriefs, or after-action reports. Such a review would help assess lessons learned and determine areas for improvement so that the Division is better prepared for future outbreaks.

Why do these problems matter?

As State agencies, the Division and DOH are obligated to collect and maintain proper records to help ensure an open and accountable government. State agencies must maintain sufficient documentation to allow the State Legislature — and more importantly, the public — to be assured that public resources are being used effectively, efficiently, and responsibly. Perhaps just as important is that proper recordkeeping preserves institutional memory, so that agency officials and their successors can make decisions informed by past results. In other words, even though a disease may be unique, with complete documentation and reliable data available for reference, the ensuing outbreak response need not be a one-of-a-kind effort.

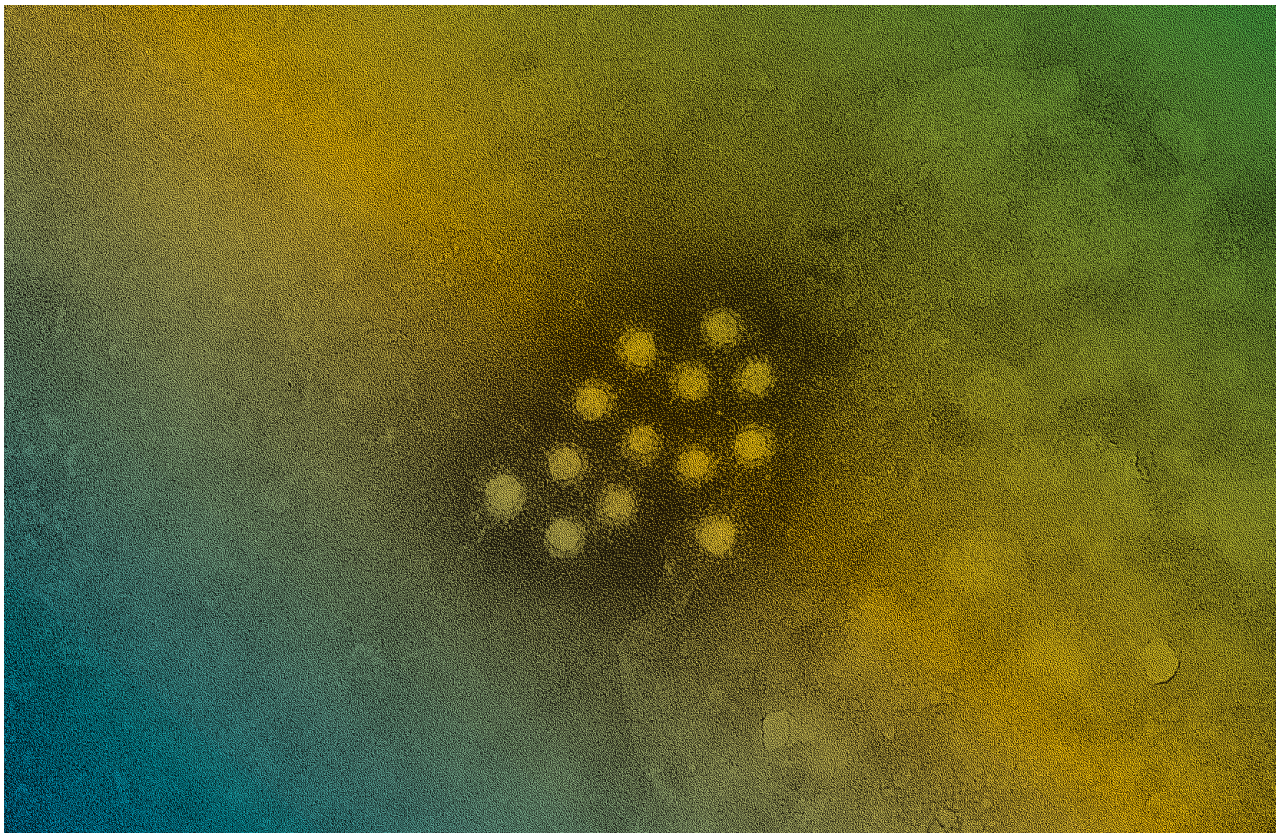


PHOTO: CDC / BETTY PARTIN

An electron micrograph of the hepatitis-A virus.

Every Outbreak is Different: Audit of the Disease Outbreak Control Division of the Department of Health

The Disease Outbreak Control Division of the Department of Health has some of the more unique and challenging responsibilities in State government. First, the Division is responsible for the control and prevention of infectious diseases, emerging disease threats, and potential acts of terrorism, as well as all hazards that threaten the public's health throughout the State of Hawai‘i. In addition, the disease outbreaks that the Division is tasked with identifying and responding to are urgent emergencies, and decisions need to be made rapidly and actions need to be taken promptly. Moreover, while disease outbreaks are frequent and inevitable events, every disease is different and every outbreak of that disease has its own unique set of circumstances. As a result, while guidelines exist, there is no one set of steps that is appropriate for every outbreak.

In our audit of the Disease Outbreak Control Division (the Division), we assessed the Division's surveillance and response to three disease outbreaks: dengue fever on Hawai‘i Island, hepatitis-A involving frozen scallops on O‘ahu and Kaua‘i, and salmonella-infected ogo on O‘ahu. We found that, during these outbreak responses, the Division and the Department of Health (DOH) experienced communication breakdowns with other DOH divisions, State and County response representatives, and the general public. During the outbreaks, DOH did not have a formal communications plan that would have provided established guidance on issues, such as the timing of the first public announcement about the outbreak and procedures for sharing outbreak information with other agency officials on a need-to-know basis. We also found that the Division has inconsistent processes and procedures for recordkeeping, internal reviews, and reporting. In addition, the Division does not follow the disease-specific investigation protocols it does have in place. These deficiencies result in limited accountability to the public and could also result in missed investigation steps and possible delays and/or replication of efforts during an outbreak response.

Every disease is different and every outbreak has characteristics specific to its time and place, which make identifying and responding to disease outbreaks especially difficult. We acknowledge that every disease outbreak presents its own unique challenges; however, responses to those outbreaks should not be unique, one-of-a-kind efforts when agencies have plans, policies, and protocols that are in place and properly communicated to those responding to a disease outbreak.

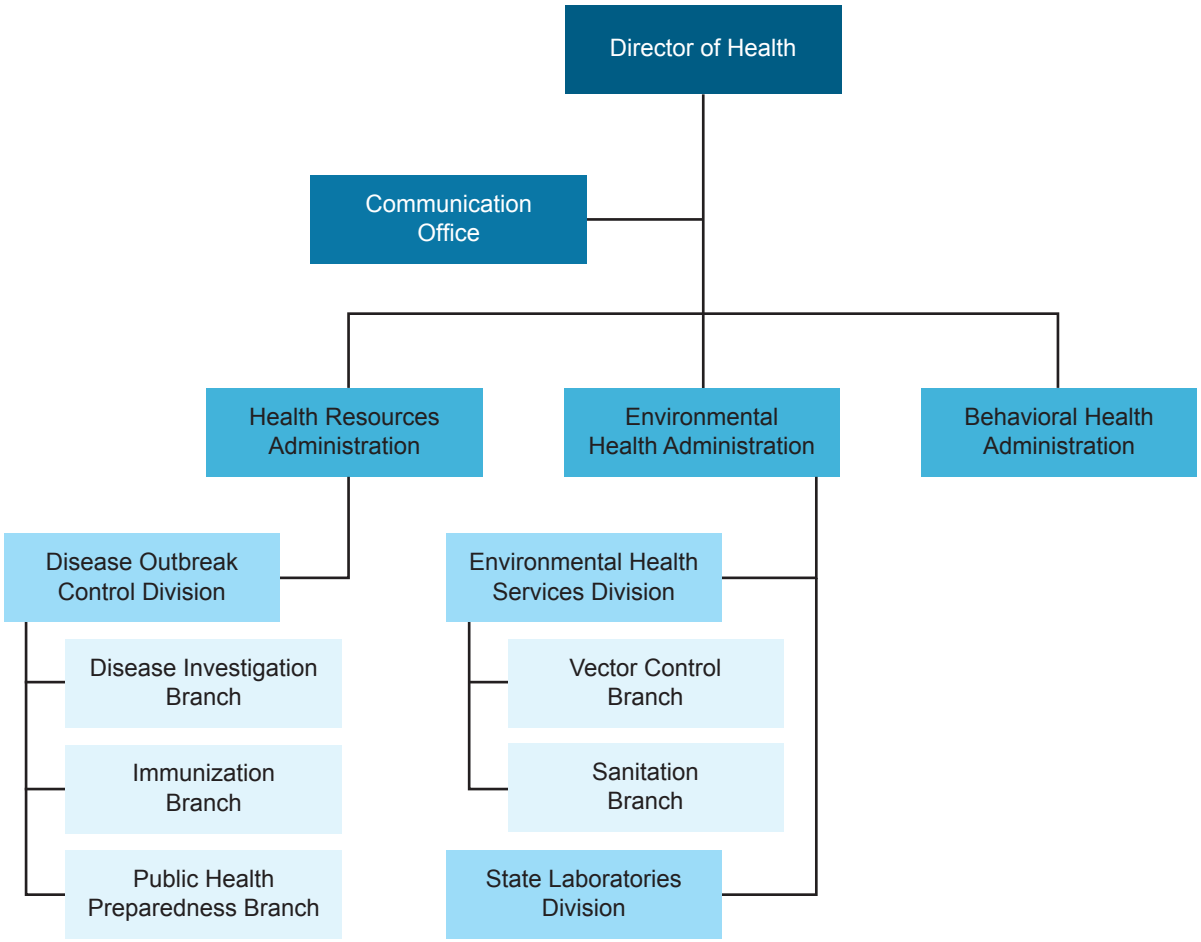
Overview of the Disease Outbreak Control Division

The Disease Outbreak Control Division is headed by a division chief (also known as the State Epidemiologist) and consists of the Disease Investigation Branch, Immunization Branch, and Public Health Preparedness Branch. Approximately 90 percent of the Division's funding comes from the Federal government. As described in Hawai‘i Administrative Rules, Title 11, Chapter 156, the Disease Investigation Branch and Immunization Branch are primarily responsible for the investigation of the 66 diseases or conditions declared to be communicable or dangerous to the public health. In 2015 and 2016, there was a total of 6,199 and 8,796 reported cases, respectively, which were handled by 24 Division personnel consisting of the State epidemiologist, Deputy State epidemiologist, Division epidemiologist, biostatistician, physician, Disease Investigation Branch manager and 11 epidemiological specialists, and Immunization Branch manager and 6 epidemiological specialists.[1]

[1] Twelve of these 24 Division personnel are federally funded.

Exhibit 1

The following organization chart only reflects the Disease Outbreak Control Division and other DOH functions that are referenced in this report.



Source: Office of the Auditor

Central to the Division's surveillance and response efforts is the Hawaii Electronic Disease Surveillance System, a web-based case management tool for disease surveillance that provides the capability to create (manually and by receiving electronic laboratory reports), enter, manage, and analyze surveillance data for specific diseases. The information is maintained in Maven, the Division's official recordkeeping database for its investigations. Accordingly, all required documentation should be stored in Maven.

Outbreak Investigation Process

According to the Centers for Disease Control and Prevention (CDC), the following are the steps of an outbreak investigation. In practice, several steps may be done at the same time, or the circumstances of the outbreak may dictate that a different order be followed.

Epidemiologic Steps of an Outbreak Investigation Process

Source: CDC, Principles of Epidemiology in Public Health Practice, Third Edition

One of the first steps in an outbreak investigation is to verify that a cluster of cases is indeed an outbreak. Once that has been verified, the next step is to verify the diagnosis by reviewing clinical findings and laboratory results and interviewing patients with the disease. This information should be recorded and maintained in a database, which summarizes information about persons who may be associated with an outbreak. As information is gathered on the persons with the disease, epidemiological analyses (e.g., epidemic curves and geographic information systems mapping) are performed to summarize data by key demographic variables, which can provide a comprehensive characterization of the outbreak, identify the population at risk for the disease, provide clues about the source and modes of transmission, and determine the where and whom of the disease to allow intervention and prevention measures.

Once such control and prevention measures have been implemented, the measures must be monitored through active surveillance to ensure that the measures are working. The final step is to summarize the investigation, its findings, and its outcome in a report, and communicate the report in an effective manner.

Audit Objective, Scope, and Methodology

Our audit objective was to assess the Disease Outbreak Control Division's surveillance and response to disease outbreaks that occurred during 2015 and 2016. The audit was performed pursuant to Article VII, Section 10 of the Hawai‘i State Constitution and Section 23-4, Hawai‘i Revised Statutes (HRS), which require the Auditor to conduct post-audits of the transactions, accounts, programs, and performance of all departments, offices, and agencies of the State and its political subdivisions. This is our first audit of the Disease Outbreak Control Division.

Our audit was performed from November 2016 through May 2017 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe the evidence obtained provide a reasonable basis for the findings and conclusions in this report.

To achieve our audit objective, we reviewed statutes, administrative rules, Division reports, emails, case files from the Divisions's Maven electronic disease surveillance and outbreak management system, and

other relevant documents and records. We also reviewed guidance from CDC, the World Health Organization (WHO), and the Council to Improve Foodborne Outbreak Response. We interviewed personnel within the Division, DOH, the County of Hawai‘i, and CDC, who were involved with the selected outbreaks.

Throughout our audit, we requested information and various documents from the Division. While the Division provided us documents and access to their Maven system, the documentation and records we were given did not provide a clear account of the analysis and discussions that occurred during the selected outbreaks. Absent such information, we interviewed Division and DOH staff, as well as other key individuals involved, but found inconsistencies in their recollections of events and the details of their efforts during the selected outbreaks. As a result,

Best Practitioners

THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES Centers for Disease Control and Prevention (CDC), identifies and defines preventable health problems; maintains active surveillance of diseases through epidemiologic and laboratory investigations and data collection, analysis, and distribution; conducts operational research aimed at developing and testing effective disease prevention, control, and health promotion programs; and develops and implements a program to sustain a strong national workforce in disease prevention and control.

WORLD HEALTH ORGANIZATION (WHO) is the directing and coordinating authority on international health within the United Nations system. WHO provides leadership on matters critical to health and engages in partnerships where joint action is needed; shapes the research agenda and stimulates the generation, translation, and dissemination of valuable knowledge; sets norms and standards and promotes and monitors their implementation; articulates ethical and evidence-based policy options; provides technical support, catalyses change, and builds sustainable institutional capacity; and monitors the health situation and assesses health trends.

THE COUNCIL TO IMPROVE FOODBORNE OUTBREAK RESPONSE consists of national associations and federal agencies working together to improve methods to investigate, control, and prevent foodborne disease outbreaks. Member organizations represent epidemiology programs, environmental health programs, public health laboratories, and regulatory agencies involved in foodborne disease surveillance and outbreak response. The Council identifies barriers to rapid detection and response to foodborne disease outbreaks and develops projects that address these barriers.

we could not verify the use of analytical methods and the timeliness of the Division's actions during the outbreaks. Additionally, we did not evaluate the effectiveness and efficiency of the Division due to the technical subject matter expertise that would be required and given the extent of involvement by outside parties in the selected outbreaks.

During the period of January 2015 to December 2016, the Division investigated a total of 148 outbreaks of varying sizes. Based on the magnitude of public impact and nature of diseases responded to by the Division, we selected three outbreaks that occurred during 2015 and 2016: (1) dengue fever–Hawai'i Island; (2) hepatitis-A: scallops; and (3) salmonella-infected ogo. We selected up to 25 confirmed cases within each outbreak to perform audit testwork, including reviewing for compliance with the Division's existing protocols as well as other industry standards and best practices.

Dengue Fever – Hawai'i Island

Time Frame: Oct. 2015 – Apr. 2016

No. of Cases Investigated

1,643 – 2,136[2]

No. of Confirmed Cases

264

Hepatitis-A: Scallops

Time Frame: June 2016 – Nov. 2016

No. of Cases Investigated

735 – 1,211[2]

No. of Confirmed Cases

292

Salmonella-infected Ogo

Time Frame: Oct. 2016 – Dec. 2016

No. of Cases Investigated

15 – 43[2]

No. of Confirmed Cases

15

SOURCE: Disease Outbreak Control Division

[2] A range is provided here as we were unable to identify the exact number of cases investigated because there were differing counts provided by the Division.

Summary of Findings

Dengue fever is a virus primarily spread through the bite of an infected mosquito; hepatitis-A, also a virus, is usually transmitted person to person through contact with infected fecal matter; and salmonella, a bacterium, is most commonly transmitted by the ingestion of food or water that has been contaminated with human or animal feces. And other variables are myriad, such as incubation times and rates of infection. Every disease is different and every outbreak has characteristics specific to its time and place, which make identifying and responding to disease outbreaks especially difficult. However, plans, policies, and protocols can provide disease response agencies with clarity and direction during the emergency conditions of an outbreak. Therefore, if responding agencies have such measures and agreements in place prior to an outbreak, the response need not be a unique, one-of-a-kind effort.

While we acknowledge that the tracking and control of an outbreak is a complicated operation often undertaken during emergency conditions, DOH and the Division are State agencies and must be accountable for their actions and funding, whether from Federal grants or State appropriations.

DOH and the Division did not have all of these essential components in place. Additionally, DOH and the Division were unable to provide adequate documentation and consistent information related to their responses to the selected outbreaks.

In our report, we present chronologies of the three outbreak responses we reviewed. The chronologies include details of our findings as well as other observations. We note that neither DOH nor the Division could provide us with a comprehensive account, timeline, or summary of the outbreak responses as described in our chronologies. Without such foundational documents, we assembled the chronologies ourselves after requesting and reviewing dozens of documents and conducting numerous interviews with DOH and Division personnel as well as staff of other involved agencies.

While we acknowledge that the tracking and control of an outbreak is a complicated operation often undertaken during emergency conditions, DOH and the Division are State agencies and must be accountable for their actions and funding, whether from Federal grants or State appropriations. They must adequately document their work and how they manage their resources. Without such documentation, DOH and the Division cannot demonstrate that they are operating effectively, efficiently, and responsibly.

Our overall findings are summarized below, followed by chronologies of the three outbreak responses we reviewed. Throughout the chronologies, we use the icons associated with each finding to note specific situations that give rise to and support that particular finding. Definitions for select terminology are provided in the Glossary on page 14.

Finding No. 1
DOH and Division communication plans should be formalized.

According to WHO, responses to outbreaks share certain fundamental objectives: to take care of patients, to prevent further cases, to end the outbreak quickly, and to prevent recurrence. Contributing, either directly or indirectly, to each of these objectives is effective communication with the public. For the organization, good communication during an outbreak response is as important as epidemiological training and laboratory analysis. Considered an essential element of outbreak management, an outbreak communications plan provides policy guidance on issues such as the timing of the first announcement and the limits of transparency, establishes a chain of command, and assigns responsibility for various activities. WHO recommends having a communications plan ready before it is needed.

As noted above, the Division and DOH experienced communication breakdowns between other DOH divisions, State and County response representatives, and the general public. The confusion and, at times, discord, as well as possible resulting delays in the outbreak response, may have been avoided if DOH had established and followed a full communications plan.

Finding No. 2
Consistent end-of-outbreak reviews and reports would better prepare the Division for future outbreaks.

According to CDC, the final task of communicating to the public is summarizing the investigation, its findings, and its outcome. These written reports should follow a scientific format, which should include an introduction, background, methods, results, discussion, and recommendations. By formally presenting recommendations, the reports can serve as a blueprint for action and a reference if a similar situation occurs in the future. WHO recommends that an outbreak response review also include a formal debriefing meeting with all parties involved in the investigation. Aims of the debriefing include ensuring that control measures for the outbreak were effective; clarifying resource needs, structural changes, or training needs to optimize future outbreak response; and changing current guidelines and developing new materials, if required.

For the Record

KEEPING COMPLETE and accurate records may seem like an obvious, commonsensical task for any organization, a best practice for everything from a household to the U.S. House of Representatives. But for the State of Hawai‘i and the Federal government, the retention of complete and accurate documentation of discussions, decision-making, and actions is a foundational element of good government.

Some of the benefits of proper recordkeeping are practical. According to the National Archives, complete and accurate documentation allows Federal agencies to protect the legal and financial rights of the government and of the individuals directly affected by government activities. Proper recordkeeping also preserves institutional memory so that agency officials and their successors can make decisions informed by past results.

This best practice is also a characteristic of an open, accountable government. According to Section 92F-2, *Hawai‘i Revised Statutes*, opening governmental processes to public scrutiny protects the public’s interest, and it is State policy that “… the formation and conduct of public policy — the discussions, deliberations, decisions, and action of government agencies — shall be conducted as openly as possible.”

The National Archives concludes that **“poor documentation may result in an unresponsive government or a government that cannot account for its actions, or both.”**

In our review of the summary and final reports for the dengue fever, hepatitis-A, and salmonella outbreaks, we found that the Division's final summary reports do not consistently follow the format as recommended by CDC. The Division also does not consistently complete end-of-outbreak reviews, debriefs, or after-action reports. While it is understandable that a formal review or debriefing may not be cost-beneficial for every outbreak, for larger, more significant outbreaks, particularly those where multiple divisions or agencies are involved in the outbreak response, such a review would help assess lessons learned and determine areas for improvement so that the Division is better prepared for future outbreaks. Without such a reference, the Division is more likely to repeat past inefficiencies and oversights.

Finding No. 3

Lax procedures and records management may be hampering outbreak response.

Records management is an important element of successful outbreak investigation and response. According to the Council to Improve Foodborne Outbreak Response, appropriately managed records support the outbreak investigation by giving team members quick access to needed information. Requiring team members to use standard protocols for collecting and organizing information associated with an outbreak can serve a quality-assurance role and help ensure that important investigation and response steps are followed. We found that the Division has inconsistent procedures related to recordkeeping, internal reviews, and reporting. It does not have written policies and procedures on its general investigation and outbreak response processes. While the Division has disease-specific investigation protocols, we found multiple instances where the Division did not follow those protocols, such as required forms and internal reviews that were not completed.

There also appears to be confusion within the Division as to the required processes and documentation for specific disease outbreaks. For example, when we asked various personnel why certain required forms were not included in Maven, some responded that such forms were not required. When we inquired why workflows for certain case files were not completed, we were told that there was not always time to review all case files. Additionally, the Division was unable to provide complete documentation of analysis methods used. The missing data and lack of internal reviews could be resulting in incomplete data sets needed for outbreak analysis and surveillance, and potential missed investigation steps or possible replication of steps.

Conclusion

The Disease Outbreak Control Division has a unique and uniquely challenging job in State government — to identify and respond to disease outbreaks, often during emergency conditions. While every disease may be different, and every outbreak may have qualities particular to the place, time, and myriad other conditions, does that mean every outbreak response is a one-of-a-kind effort?

For the Division and DOH, this may be the practice. We found an absence or a lack of adherence to plans, policies, and protocols, all of which provide disease response agencies with clarity and direction during the emergency conditions of an outbreak. In addition, neither the Division nor DOH could provide us with sufficient documentation of the analysis and discussions that occurred during the selected outbreaks. Absent such information, we interviewed staff, as well as other key individuals involved, but found inconsistencies in their recollections of events and the details of their efforts during the selected outbreaks.

As State agencies, the Division and DOH are obligated to collect and maintain proper records to help ensure an open and accountable government. State agencies must maintain sufficient documentation to allow the State Legislature — and more importantly, the public — to be assured that public resources are being used effectively, efficiently, and responsibly. Perhaps just as important is that proper recordkeeping preserves institutional memory, so that agency officials and their successors can make decisions informed by past results. In other words, even though a disease may be unique, with complete documentation and reliable data available for reference, the ensuing outbreak response need not be a one-of-a-kind effort.

Recommendations

1. The Department of Health should:

    a. Continue developing the All Hazards Preparedness Plan or an alternative strategy that establishes a defined chain of command, communication guidelines, and roles and responsibilities for responding to significant outbreaks; and

    b. Determine the type of information that can/should be shared with external agencies and parties involved in jointly responding to an outbreak and develop procedures for sharing such information (e.g., HIPAA/confidentiality agreement). DOH may consider seeking advice and counsel from the Department of the Attorney General and oversight agencies such as CDC.

2. The Disease Outbreak Control Division should:

   a. Develop and enforce administrative procedures related to the opening, investigating, and closing of cases, clusters, and outbreaks. Such procedures should include review and recordkeeping requirements, reporting requirements, responsible parties involved with each process, and established deadlines;

   b. Continue to develop and implement guidelines for summary report and after-action assessments for epidemiological investigations. These should include input from responsible parties, established deadlines, and a scientific format as recommended by CDC. We note that Epidemiological Investigation Summary Report Guidelines have been drafted by the Disease Investigation Branch.

   c. Complete summary reports and after-action assessments for each significant outbreak, including documentation of key activities to ensure accountability.

Glossary

Case-Control Study – An observational 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 (control subjects) and compares differences in exposures, behaviors, and other characteristics to identify and quantify associations, test hypotheses, and identify causes.

Epidemic Curve (Epi Curve) – A histogram that displays the course of an outbreak or epidemic by plotting the number of cases according to time of onset.

Epidemic Information Exchange (Epi-X) – CDC's web-based communications solution for public health professionals to access and share preliminary health surveillance information quickly and securely.

Foodborne Coordinator – Disease Investigation Branch's Foodborne Disease Surveillance and Response Coordinator responsible to plan, organize, and coordinate investigation and education epidemiologic activities related to foodborne disease surveillance and control.

Frequency Distribution – A complete summary of the frequencies of the values or categories of a variable, often displayed in a two-column table with the individual values or categories in the left column and the number of observations in each category in the right column.

Geographic Information Systems (GIS) – Automated systems for capturing, storing, retrieving, analyzing, and displaying spatial data.

Health Insurance Portability and Accountability Act (HIPAA) – Enacted in 1996, HIPAA addresses the privacy of a person's medical information as well as postemployment insurance and other health-related concerns.

Incident Command Structure System – A management system designed to enable effective and efficient domestic incident management by integrating a combination of facilities, equipment, personnel, procedures, and communications operating within a common organizational structure.

Line List – A table that summarizes information about persons who may be associated with an outbreak. A line list helps organize preliminary information gathered during the early part of an outbreak investigation. The data obtained during a case finding can provide clues about the outbreak and potential risk factors associated with illness.

Pulsed-field Gel Electrophoresis – Laboratory technique used by scientists to produce a DNA fingerprint for a bacterial isolate. A bacterial isolate is a group of the same type of bacteria.

Serotypes – Serotypes are groups within a single species of microorganisms, such as bacteria or viruses, which share distinctive surface structures. Fewer than 100 serotypes account for most human infections.

Statistical Analysis Software – Software tool used for both specialized and enterprise-wide statistical needs.

Traceback – Method used to determine and document the distribution and production chain, and the source(s) of a product that has been implicated in a foodborne illness investigation.

OUTBREAK: DENGUE FEVER

LOCATION: HAWAI'I ISLAND

Aedes albopictus mosquito

PHOTO: DEPARTMENT OF HEALTH

DENGUE FEVER is a potentially fatal illness closely related to yellow fever, West Nile virus, Japanese encephalitis, and Zika virus. Dengue fever is primarily spread through the bite of an infected mosquito. In Hawai'i, the common vector is *Aedes albopictus*, or the Asian tiger mosquito, identified by the distinctive white and black stripes on its legs. There is no direct person-to-person spread. The incubation period for dengue may vary from three to 14 days but is usually four to seven days.

Dengue fever is characterized by sudden onset of fever, extreme malaise, severe retro-orbital (behind the eyes) headache, muscle aches, and joint aches. Other common symptoms include rash, nausea, vomiting, diarrhea, constipation, photophobia, cough, sore throat, lethargy, and anorexia. Although 75 percent of individuals infected with dengue fever will be asymptomatic, about 5 percent of individuals will progress to severe dengue. The case-fatality rate of severe dengue cases can be as high as 10 percent if untreated, or less than 0.1 percent with appropriate clinical management.

DOH's Vector Control Branch is responsible for responding to suspected or confirmed cases of mosquito-borne disease and having the resources to control mosquitoes and their breeding areas to reduce the risk of spreading. Information regarding suspected or confirmed cases is communicated to the DOH Vector Control Branch.

October 21, 2015

The Division receives a call from a doctor reporting a case of dengue fever infection. The case is assigned to a Disease Investigation Branch investigator, who interviews the patient to obtain demographics and illness history. Two other members of the patient's family also show symptoms of infection. No recent travel was taken by the patient or family members; however, all visited Ho'okena Beach.

October 22, 2015

DOH Vector Control Branch surveils 200 yards of the patient's area of residence to control mosquitoes and their breeding areas. DOH State Laboratories Division's tests confirm that the patient has dengue fever.

October 24, 2015

The Division receives four additional cases of suspected dengue fever infection from mainland U.S. visitors who had traveled throughout Hawai'i Island. However, the Division suspects that the cases could also be leptospirosis.

Lax Procedures (Finding No. 3)

The Division did not follow the disease-specific investigation protocols that it has in place.

We tested 25 dengue fever cases and noted the following required forms were missing:

- 2 CDC Dengue Case Investigation forms
- 13 Vector Control work order forms
- 25 Specimen order forms

Patient Confidentiality vs. Protecting Public Health

Communication Breakdown (Finding No. 1)

According to the Division chief and the County of Hawai'i Civil Defense Director, they had differing perspectives on whether GIS maps based on patients' addresses should be shared with the County, and once disclosed, how such information could and should be used to respond to the outbreak and protect the public health and safety.

The DOH director stated that the County of Hawai'i needed to know the information but needed to be careful when providing patient-related information to the public.

DOH subsequently provided information to the County of Hawai'i related to the County's responsibilities in handling confidential patient health information. DOH acknowledged that they should have required the County of Hawai'i to execute an agreement stating that it was aware of and responsible for following Federal and State laws when communicating certain individual health information to the public.

At the time of our audit, DOH had yet to resolve the question of whether Federal and State laws prevent the public dissemination of individual patient health information, including general geographical descriptions, in situations involving public health and safety and, if so, the limits of the confidentiality required by those laws. DOH said that it was starting to work on its All Hazards Preparedness Plan, which it hopes would address this and other issues.

October 27, 2015

The Division epidemiologist starts GIS mapping to analyze the associations in case data by exposure locations and case status.

A break in the case

October 28, 2015

DOH State Laboratory Division confirms that the four additional cases have dengue fever. The results indicate to the Division that they are dealing with a widespread infection.

October 29, 2015

DOH releases a medical advisory to Hawai‘i Island healthcare providers to report patients who were evaluated on or after September 1, 2015, for dengue fever. DOH issues a press release notifying the public that it is investigating two confirmed and four probable cases of dengue fever. It posts a call for cases on the CDC's Epidemic Information Exchange website to identify other suspected cases of dengue fever in travelers who had visited Hawai‘i Island.

November 5, 2015

DOH's Vector Control Branch surveils and sprays the Ho‘okena Beach area. This area is subsequently sprayed multiple times.

DOH releases a medical advisory to statewide healthcare providers informing them that dengue fever should be reported as soon as the infection is first suspected. The Division's Dengue Outbreak 2015-16 website goes live.

Communication Breakdown
(Finding No. 1)

According to the former County of Hawai‘i Civil Defense director, County of Hawai‘i officials learned of the island's dengue fever outbreak and the plan to spray Ho‘okena Beach for mosquitoes after the general public was notified. He said they were concerned about the Division's lack of forewarning to and consultation with the County of Hawai‘i since Ho‘okena Beach is heavily used by campers, who should have been informed of the possible dengue infection in the area.

November 6, 2015

DOH contracts with a public relations firm for public relations and communications assistance. The firm provides strategic communication services, including creation and coordination of the branding strategies, messaging, promotional and educational materials, press conferences, press releases, press kits, social media content, website content, and information scripts for public facing personnel and for internal communications. The contract ends in December 2015 after the contracted amount of $100,000 was expended.

Communication Breakdown
(Finding No. 1)

DOH has one public information officer on staff, who is responsible for issuing press releases and media advisories, as well as arranging press conferences and media interviews, for DOH's numerous divisions and officers. The public information officer said that she had difficulty receiving information from the Division, eventually having to request dengue fever outbreak details from the County of Hawai'i district health officers and DOH Vector Control Branch staff. The Division's lack of cooperation was not unique to the dengue outbreak.

027
CONFIRMED CASES

Source: Disease Outbreak Control Division

November 9, 2015

"Fight the Bite" education and outreach campaign launches at a press conference held by the County of Hawai'i Mayor's Office to urge Hawai'i Island residents and visitors to prevent, prepare, and protect against mosquito-borne diseases.

November 19, 2015

DOH holds a press conference regarding the dengue fever outbreak featuring the governor, DOH director, Division chief, DOH Environmental Health Services Division administrator, and DOH State Laboratory director. During the press conference, they discuss the efforts by the County of Hawai'i, the State, and others to get the outbreak under control.

November 20, 2015

The Division chief requests assistance from the CDC's Dengue Branch Division of Vector-Borne Diseases, the National Center for Emerging and Zoonotic Infectious Diseases, and CDC regarding entomological expertise on mosquitoes. CDC will later provide communications assistance.

The DOH director, the Division chief, and the former County of Hawai'i Civil Defense director brief the State Legislature on the status of the dengue fever outbreak and their efforts to treat, monitor, and prevent further disease transmission.

December 8, 2015

CDC releases its interim assessment of the response by DOH to the dengue fever outbreak. Major findings of the interim assessment include the need for more epidemiologic staffing within DOH to address staff fatigue during current outbreaks; the need for entomology expertise for mosquito-borne diseases; and the need for a media strategy and effective communication within DOH, its partners, other agencies, and the public during an Incident Command Structure outbreak.

Communication Breakdown
(Finding No. 1)

Although the Disease Investigation Branch is responsible for the investigation of non-vaccine preventable diseases, which includes dengue fever, the branch was not an active participant in higher-level meetings regarding this outbreak. Branch personnel were thus unable to gain a big-picture perspective of the outbreak and possessed limited information regarding new cases reported and updates to status counts. The branch was not aware that CDC had been invited to consult on the dengue fever outbreak and was not included in laboratory results meetings with them.

Who's in Charge?

Communication Breakdown
(Finding No. 1)

Incident command structure is a management system designed to enable effective and efficient domestic incident management by integrating a combination of facilities, equipment, personnel, procedures, and communications operating within a common organizational structure.

According to DOH, the former County of Hawai'i Civil Defense director was the acknowledged incident commander throughout the response effort. However, that designation does not seem to have been clearly understood, as the Division's first incident command structure summary report, dated November 4, 2015, lists the Division chief as incident commander. The November 23, 2015, summary report, identifies the DOH's Environmental Health Administration deputy director as incident commander. Then, in the January 13, 2016, summary report, the deputy director is replaced by the former County of Hawai'i Civil Defense director as incident commander.

The DOH Environmental Health Administration deputy director stated that the key to being an incident commander is receiving timely and accurate information, especially data regarding confirmed cases, suspected cases, and the location of cases. The Division did not provide the County of Hawai'i and County of Hawai'i Civil Defense director with updates on the number of cases, key demographics, or disease "hot spots," making it difficult for them to respond to the outbreak.

215
CONFIRMED CASES

January 13, 2016

DOH releases a medical advisory reminding healthcare providers to report cases as soon as they are first suspected.

February 8, 2016

The County of Hawai'i mayor issues an emergency declaration for Hawai'i Island.

255
CONFIRMED CASES

February 12, 2016

The governor issues an emergency declaration for the State.

February 22, 2016

The Division epidemiologist creates epidemic curves of confirmed cases to display the course of the outbreak by onset date of illness and region of residence.

March 17, 2016

The last onset of outbreak illness is noted for all cases. The Division epidemiologist prepares the final statistical analysis software distributions based on key demographics as the last case was reported.

264

CONFIRMED CASES

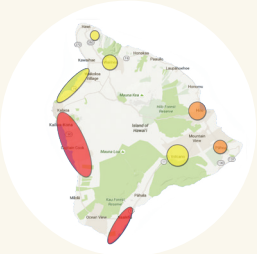
April 15, 2016

The Division epidemiologist prepares the final GIS mapping based on the last onset of illness.

November 3, 2016

The after-action report and improvement plan is completed by DOH. DOH staff report a need to improve communications between department divisions, between State and County response representatives, and between DOH and the public. Participants also feel that the implementation of incident command structure could have been better, as some report confusion over DOH and County responsibilities. Participants also state that DOH does not have enough trained personnel to fully monitor and manage all aspects of communications.

Mosquito Coasts



Map shows risk level for potential dengue infection:

- High Risk
- Moderate Risk
- Some Risk

SOURCE: Disease Outbreak Control Division

Inconsistent Reports
(Finding No. 2)

The final summary report was not finished as of the completion of our audit fieldwork. The Division told us that the after-action report serves as a substitute for the final summary report. However, it did not include all the reporting elements recommended by CDC.

Agree to Disagree

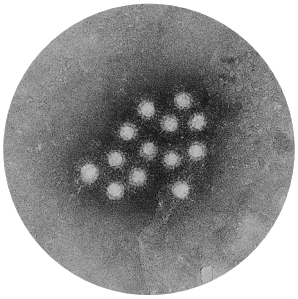
Communication Breakdown
(Finding No. 1)

DOH, Division, and County of Hawai‘i personnel involved in the outbreak acknowledged that the communication and coordination between the Division and the County were tense and challenging.

As a result of the issues that arose during the dengue fever outbreak, and as part of the department's Zika virus preparation, the DOH Environmental Health Administration deputy director was tasked with developing the Joint Hawai‘i Mosquito-borne Disease Outbreak Emergency Operations Plan to provide essential and evidence-based guidance to State and County agencies prior to, during, and immediately after a mosquito-borne disease outbreak. At the time of our audit, the plan was still in draft form. According to DOH, the plan will serve as a template for its to-be-developed All Hazards Preparedness Plan. The All Hazards Preparedness Plan is intended to support incident command structure and address DOH's current communication issues. At the time of our audit, the All Hazards Preparedness Plan was still in the discussion phase.

OUTBREAK: HEPATITIS-A: SCALLOPS

LOCATION: O'AHU AND KAUA'I



An electron micrograph of the hepatitis-A virus.

PHOTO: CDC / BETTY PARTIN

The **HEPATITIS-A VIRUS** is transmitted person to person through ingestion of infected fecal matter. Most infections result from close personal contact with an infected household member or sex partner. Hepatitis-A is also transmitted through exposure to contaminated food or water. Uncooked contaminated foods have been recognized as a source of outbreaks. Cooked foods can also transmit the virus if the temperature during food preparation is inadequate to kill the virus or if food is contaminated after cooking. The incubation period for hepatitis-A ranges from 15 to 50 days. Illness caused by the hepatitis-A virus typically has an abrupt onset, which includes flu-like symptoms, fever, malaise, anorexia, nausea, vomiting, abdominal discomfort, dark urine, clay-colored bowel movements, joint pain, and jaundice.

June 20, 2016
The Division receives lab results indicating a hepatitis-A infection. The case is assigned to an Immunization Branch investigator, who interviews the patient to obtain illness history.

June 30, 2016
DOH releases a medical advisory, notifying healthcare providers of a cluster of hepatitis-A infections on O‘ahu.

Disease Investigation Branch foodborne coordinator requests DOH Sanitation Branch inspectors to obtain invoices and distribution records related to ingredients used in ahi poke sold at identified retail stores. The Division chief initiates communication with CDC and U.S. Food and Drug Administration (FDA).

July 1, 2016
DOH issues a press release, notifying the public of a hepatitis-A outbreak on O‘ahu and reminding the public that it is a vaccine-preventable disease. Vaccines are readily available at local pharmacies.

031
CONFIRMED CASES

July 6, 2016
DOH issues a press release, notifying the public of additional cases of hepatitis-A infection.

July 11, 2016
The Division initiates an incident command structure system with the Division chief as incident commander, holding status meetings every few days.

052
CONFIRMED CASES

July 12, 2016
DOH notifies the public of a hepatitis-A infection in an ice cream shop employee and urges the public to seek vaccination.

Lax Procedures
(Finding No. 3)

The Division did not follow the disease-specific investigation protocols that it has in place.

We tested 25 hepatitis-A cases and noted the following required forms and info were missing:

- 12 communicable disease reports
- All 25 viral hepatitis case reports
- 5 case files did not note investigation end date
- 1 case file did not document the method by which DOH was notified
- All 25 case files did not have the case workflow completed, indicating required reviews may not have been performed.

Team Effort

Communication Breakdown
(Finding No. 1)

Prior to 2010, hepatitis-A investigations were performed by the Disease Investigation Branch. However, because of staff shortages, the Division chief assigned investigations of vaccine preventable diseases to the Immunization Branch starting in 2010. Accordingly, the 2016 hepatitis-A outbreak investigation was assigned to the DOH Immunization Branch because it is a vaccine-preventable disease.

Confirmed cases of hepatitis-A continue to rise and the investigation focuses on foodborne sources. However, the outbreak investigation continues to be led by the Immunization Branch, and no additional help from the Disease Investigation Branch is requested. Although the Disease Investigation Branch is responsible for investigating all reportable foodborne diseases within the State and led previous hepatitis-A outbreak investigations, the Division chief did not involve or consult with branch supervisors. The reasons she provided were that the branch had just come off of the dengue fever outbreak and had other activities to perform, such as preparing for the Zika virus. Other Division personnel observed that the Division chief assigned the Immunization Branch to handle this outbreak because she was trying to build their capacity.

The Division chief noted "this [outbreak] may be a foodborne issue and if the number of cases continue to increase, we may need Disease Investigation Branch investigative help." The Disease Investigation Branch's foodborne coordinator was then added to the team.

Hepatitis-A Team/Responsibilities

Division Chief (State Epidemiologist)	Incident commander
Immunization Branch Chief	Led the outbreak investigation and handled issues with vaccinations.
Immunization Branch Pediatrician	Managed the line list to organize information collected from the cases.
Immunization Branch Supervisor	Oversaw the field investigators.
Deputy State Epidemiologist	Performed epidemiological analyses such as GIS mapping and epidemic curves.
Division Epidemiologist I	Performed epidemiological analyses such as GIS mapping and epidemic curves.
Biostatistician	Performed epidemiological analyses such as GIS mapping and epidemic curves.
Epidemiological Specialists	Performed epidemiological investigations of all reported cases.
Disease Investigation Branch Foodborne Coordinator	Added to the team to coordinate with other agencies and perform traceback analysis.

Original team members
Additional team member

July 13-15, 2016

CDC notes no hepatitis-A cases nationally, and the Division notes no cases on neighbor islands, so it believes the source is a product distributed on O‘ahu. Federal partners believe the epidemic curve is indicative of a frozen product.

The Division’s Hepatitis-A Outbreak 2016 website goes live and will be updated weekly. The Division’s Facebook page will also be updated for the outbreak as it evolves. An update is posted on CDC’s Epidemic Information Exchange to identify other suspected cases of hepatitis-A in travelers.

July 19, 2016

Although ice was not included in the frequency analyses of patient exposures, the Division considers ice as a possible source of infection. Disease Investigation Branch foodborne coordinator requests and receives distribution and processing information from an ice vendor, which notes no handling by humans and monthly bacteria testing.

074
CONFIRMED CASES

July 20, 2016

CDC confirms the outbreak, but since the hepatitis-A strain cannot be found in its database, it cannot determine the virus’ sources. DOH Sanitation Branch requests distribution information from Genki Sushi.

093
CONFIRMED CASES

July 28, 2016

FDA assists with traceback on food items of interest from select distributors.

August 1, 2016

The Division performs GIS mapping by exposure to Genki Sushi and discusses conducting a general population survey on frequented restaurants and a possible case-control study with CDC assistance.

August 3, 2016

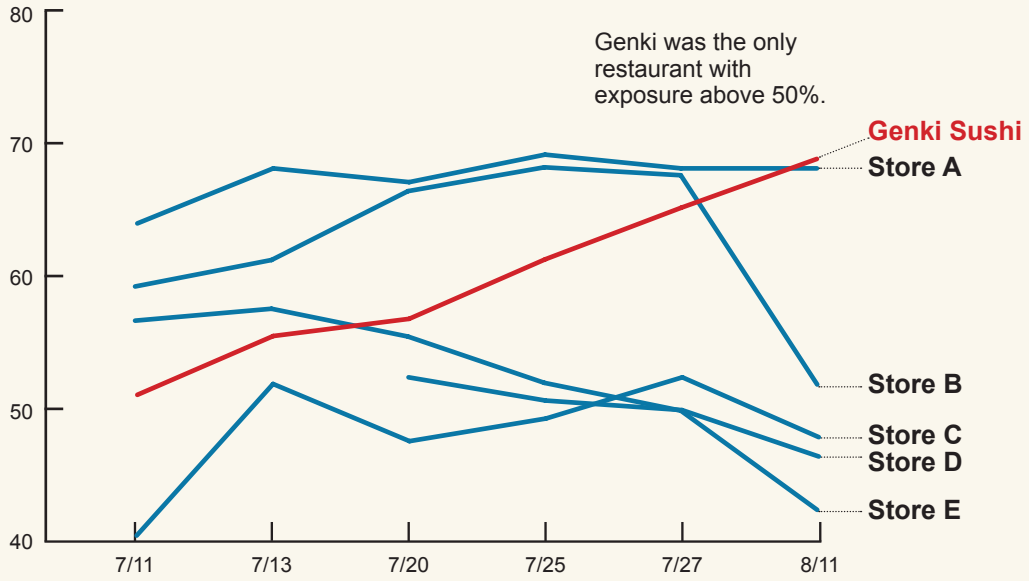
The Division chief requests CDC to provide epidemiology support, assistance with a potential case-control study, facilitation of product traceback, and clinical review of case data.

According to a CDC representative, some challenges with Genki Sushi were that customer receipts did not itemize the products consumed (instead described by plate color – e.g., red plate, blue plate, etc.) and that a large volume of different ingredients are used to make sushi. Investigators went back to previous interviewees for the specific types of sushi and other food consumed at Genki Sushi, which made the investigation more difficult.

Two cases on the island of Kaua‘i reported consuming scallop mayo sushi at Genki Sushi, and this was the only raw seafood item they consumed. The Division stated that the information from the Kaua‘i patients was a pivotal point in narrowing the suspected source to Genki Sushi and, more specifically, scallops.

Hepatitis-A Exposures

Documented hepatitis-A exposure shows the trend lines of establishments visited during the outbreak. Genki Sushi was the only restaurant with exposure above 50 percent. The others were grocery stores.



Source: Office of the Auditor based on Disease Outbreak Control Division data

Q & A

Data from the questionnaire used in patient interviews served as the foundation for the traceback analysis. The Disease Investigation Branch foodborne coordinator worked with the DOH Sanitation Branch to collect information from grocery stores and restaurants (i.e., ingredients, purchase invoices, specimens). The Division investigated foods that displayed high frequencies of consumption on the initial patient interview questionnaires. According to the Division, because of limited resources, the foodborne coordinator was the only Division staff performing traceback analysis.

Food Exposure Percentages

Based on patient interviews as of July 20, 2016, the following are food items with exposure above 50%:

Raw fish	**93%**
Lettuce	78%
Onions	69%
Bananas	66%
Uncooked tomatoes	58%
Cucumbers	53%

Source: Disease Outbreak Control Division

A Break in the Case

The Immunization Branch chief and pediatrician, who are active in the outbreak investigation, are taken off the hepatitis-A team to support the Division's *Stop Flu at School* program.

168
CONFIRMED CASES

August 4, 2016

Frequency distribution, based on interviews with the 26 new cases, identifies 85 percent had exposure at Genki Sushi.

August 8, 2016

CDC epidemiologic intelligence service officers arrive on O'ahu to provide outbreak support, as previously requested by the Division chief. Local FDA officials visit three distributors to collect items and samples of tobiko, masago, ahi tuna, and scallops.

The DOH director and the Division chief attend a legislative informational briefing and provide an update on the status of the hepatitis-A outbreak.

Communication Breakdown (Finding 1)

On August 4, 2016, the Division chief stated in an email: "That's it, we need to collect whatever Genki may still have from that time or see if their distributors have anything from that time." However, information is not yet shared with the public.

On August 9, 2016, The Honolulu Star-Advertiser reports the Division chief as saying, "The investigators have narrowed the suspected source of the outbreak to a couple of products that are brought to O'ahu and widely consumed here. But I can't comment any further because it would be too premature at this point, because we could be wrong still. We feel really good now, but we also are cautious because we know that we could go down this route and it's all for naught."

August 10, 2016

An online survey posted on the Division's hepatitis-A outbreak website asks how frequently Hawai'i residents eat at 35 restaurants and obtain food from nine grocery stores. According to the Division, the survey results are used to substantiate their hypothesis that Genki Sushi is the source of the outbreak. Thus, a case-control study, which is typically very labor and time intensive, is deemed not necessary.

August 15, 2016

The source of the hepatitis-A infection is identified as frozen imported scallops served raw at Genki Sushi. Koha Oriental Foods and True World Foods are identified as the distributors. All O'ahu and Kaua'i Genki Sushi locations are ordered closed immediately, and frozen scallops are embargoed.

August 16, 2016

DOH issues a press release notifying the public that frozen imported scallops served raw at Genki Sushi are the likely source of the hepatitis-A infection.

August 18, 2016

FDA confirms hepatitis-A in Sea Port Products Corporation brand of bay scallops, and a voluntary recall is initiated.

August 30, 2016

CDC confirms that the link between the hepatitis-A strains from the scallop samples and patients are identical.

Survey Says...

In a case-control study, the investigator asks both case-patients and a comparison group of persons without the disease (control group) about their exposures. However, such a study can be labor and time intensive.

Instead, the Division conducted an online survey of food consumed between May 24, 2016, and July 12, 2016, by Division staff who did not contract hepatitis-A to provide an unscientific control group to compare against the outbreak patients. Survey results were inconclusive.

On August 10, 2016, the Division conducted an online survey of the general public to determine if the exposure analysis was accurate. The online survey was available from August 10 to 15, 2016. Survey results were used to compare the exposures of the general population to the exposures of patients interviewed in the outbreak. Based on 4,969 survey responses, 22.7 percent of the public frequented Genki Sushi as compared to almost 70 percent of the hepatitis-A patients.

The traceback analysis compared the distribution patterns of tobiko, masago, ahi tuna, and scallops. Specimens were collected and tested by FDA. The implicated scallops were imported to the United States by Sea Port Products Corp. via Washington state. FDA indicated Sea Port Products Corp. had recently switched from a Chinese supplier to a Philippine supplier known as De Oro Resources, Inc. Lot #5887 was the first lot obtained from the supplier in the Philippines. Koha Oriental Foods provided sales records of the Sea Port Products Corp. scallops for the dates of April 1 to July 31, 2016. During that time, the scallops were only sold to Genki Sushi locations on O'ahu and Kaua'i. In depth traceback efforts revealed that the distribution pattern of frozen scallops best explained the outbreak. A single distributor supplied the Genki Sushi locations where cases reported exposure, and the dates of case exposure coincided with the period of time when the implicated scallop lot would have been served at Genki Sushi locations on O'ahu and Kaua'i.

PHOTO: DISEASE OUTBREAK CONTROL DIVISION

CDC noted: "The traceback efforts undertaken by DOH, FDA, and CDC were vital to the implementation of public health initiatives that curtailed further transmission of hepatitis-A. DOH undertook numerous public health actions to mitigate the adverse effects of HAV [hepatitis-A virus] on the public [such as encouraging the public to consider getting vaccinated for hepatitis-A]."

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CONFIRMED CASES

September 9, 2016
Genki Sushi meets sanitation requirements and receives approval to reopen all locations. The investigation remains open for the incubation period (up to 50 days) from the last confirmed case to monitor for any additional cases.

November 29, 2016
The Division closes the hepatitis-A outbreak investigation.

January 20, 2017
The final summary report of the hepatitis-A outbreak is completed. →

Inconsistent Reports
(Finding No. 2)

The final summary report of the outbreak was finalized and approved during our audit fieldwork. The final summary report did not follow the format as recommended by CDC. It also did not contain recommendations, the effectiveness of the investigation, and control measures taken, as recommended by WHO. Debriefings to determine lessons learned and areas of improvement were not performed.

OUTBREAK: SALMONELLA-infected ogo

LOCATION: O'AHU

An electron micrograph of salmonella bacteria

PHOTO: THINKSTOCK.COM

SALMONELLA is a member of the family *Enterobacteriaceae*. It contains two species, *S. enterica* and *S. bongori*. S. enterica can be further divided into six subspecies using their phenotypic profile. Some serotypes are specific to animals while others are widely distributed between many different animals and humans.

Salmonella is transmitted via the fecal-oral route. The most common mode of transmission is the ingestion of food or water that has been contaminated with human or animal feces. This includes raw or undercooked poultry, eggs and egg products, undercooked meats, and raw milk or milk products. However, any food contaminated with the bacteria can be a source of infection. The incubation period can vary from 6 to 72 hours but is usually about 12 to 36 hours, although incubation periods longer than three days have been documented. The most common symptoms of salmonellosis are diarrhea, stomach cramps, fever, nausea, and vomiting.

October 20, 2016

The Division receives lab results of two suspected cases of salmonella infection. Swabs and cultures of the bacteria collected from the two cases are sent to the DOH State Laboratories Division for confirmation. The cases are assigned to the Disease Investigation Branch investigators who interview the patients to obtain illness history.

October 25, 2016

The DOH State Laboratory reports that the salmonella serotypes are the same for the two cases, indicating a potential outbreak.

006

CONFIRMED CASES

October 28, 2016

The Disease Investigation Branch receives DOH State Laboratory reports confirming that all six of the cases have matching pulsed-field gel electrophoresis patterns. As a result, the foodborne coordinator performs food frequency distribution analysis and determines that 87 percent of the infected patients ate poke containing ogo (also called limu or seaweed). The Disease Investigation Branch investigators begin traceback analyses by requesting distributor information from grocery stores identified by patients during interviews for all ingredients used to make poke.

A Break in the Case

Disease Investigation Branch determined the food source of this outbreak in less than two weeks.

October 31, 2016

Investigators determine that one ingredient, ogo, has a common distributor located in Kahuku.

November 2, 2016

The DOH Sanitation Branch inspects the farm with Disease Investigation Branch investigators.

November 4, 2016

The DOH State Laboratory reports that the initial screen of samples taken from the farm contain salmonella.

Lax Procedures (Finding No. 3)

The Division did not follow the disease-specific investigation protocols that it has in place.

We tested 15 salmonella cases and noted the following required forms and info were missing:

- 12 communicable disease reports
- 1 Salmonella interview form
- 7 casefiles did not have a completed workflow review, indicating required reviews may not have been performed.

According to DOH Sanitation Branch: "Farms of this type are not required to be permitted and are not under any inspection program as they are equivalent to any vegetable farm, and are considered by DOH to be raw agricultural commodity. Consumer health is protected by thoroughly washing [the product] prior to being used. All food establishments are required to thoroughly wash raw agricultural commodities prior to use as an ingredient in food products like any other ready-to-eat salad product."

November 5, 2016

DOH Sanitation Branch orders a cease and desist order to the farm to halt the sale and distribution of ogo. The branch works with the farm to obtain distribution records.

014
CONFIRMED CASES

November 7, 2016

DOH releases a medical advisory warning healthcare providers of the potential for salmonella infection in patients with a history of consuming ogo. DOH requests that providers report cases as soon as they are suspected. DOH issues a press release informing the public of the tainted ogo, two days after a cease and desist order was issued.

The Disease Investigation Branch and DOH Sanitation Branch continue site visits, pulling more samples from the farm.

November 10, 2016

DOH Sanitation Branch issues another cease and desist order to the farm to halt the sale of all products grown by the farm, including all ogo products and sea asparagus. Later that day, DOH issues a press release of the cease and desist order.

015
CONFIRMED CASES

December 5, 2016

DOH lifts the cease and desist order after the farm completes the remediation recommendations issued by the DOH Sanitation Branch. The farm may resume sale of ogo and sea asparagus products.

January 20, 2017

The final summary report of the outbreak is drafted and submitted for internal review. However, as of the end of our audit fieldwork, the report had yet to be approved.

Communication Breakdown
(Finding No. 1)

The public was officially notified two days after the cease and desist order was issued. According to the DOH Environmental Health Program manager, the reason for the delay was that they wanted to make sure that any press release put out to the public was as complete and accurate as possible, especially regarding distribution, and such information was not available at the time of the cease and desist order. However, the press release that was issued on November 7, 2016, had limited information regarding distribution.

According to the Division chief, there was no urgency to notify the public because any potential risk for further infection had been removed. However, the Division did not provide documentation that such a determination had been made.

Inconsistent Reports
(Finding No. 2)

The final summary report was not finalized and approved as of the completion of our audit fieldwork. We were provided a draft that generally followed the reporting format as recommended by CDC; however, it did not detail information on the effectiveness of the investigation and did not include recommendations for governing the Disease Investigation Branch's processes to identify, monitor, and control the outbreak. Debriefings to determine lessons learned and areas of improvement were not performed.

Office of the Auditor's Comments on the Department of Health's Response

WE MET WITH DEPARTMENT OF HEALTH (DOH) director and deputy director for health resources administration as well as Disease Outbreak Control Division (Division) chief and her branch chiefs on December 19, 2017, to discuss our audit findings and recommendations. We had provided DOH and the Division with our draft report on December 12, 2017. DOH subsequently provided a written response to the draft report on December 22, 2017, which is Attachment 1.

DOH appears to generally agree with our recommendations. DOH acknowledges there is always room for improvement in a response effort and represents that, subsequent to the period of our audit, it has taken steps that address certain of our recommendations. For example, with respect to our recommendation that DOH continue to develop the All Hazards Preparedness Plan or an alternative strategy that establishes a defined chain of command, communication guidelines, and roles and responsibilities for responding to significant outbreaks, DOH reports that, on the same day as its response to us, the Governor approved a reorganization plan, shifting certain responsibilities for disease outbreak response from the Division to the DOH director.

We note that, in its response to Recommendation #2a, DOH provides numbers of investigations that it conducted in 2016. More specifically, DOH states that it conducted "1,459 dengue investigations, 3,177 hepatitis A investigations, and 357 Salmonella investigations." We understand these numbers to represent *total* reported cases that the Division investigated that year, including cases that were not related to the outbreaks selected in our audit.[1] The fact that the various investigation numbers provided by the Division and DOH are so markedly different – especially, in the case of hepatitis-A which was such a serious outbreak – highlights the importance of our recommendation that the Division develop procedures to better and more accurately document its work in investigating disease outbreaks.

[1] In our draft report, we reported the number of dengue fever, hepatitis-A, and Salmonella investigations for our selected outbreaks to be 1,643, 735, and 15, respectively. Those numbers were based on the information that was provided to us during our audit, including the data that we obtained from Maven. During our meeting on December 19, the Division chief questioned the numbers and, subsequently, provided us with her count of the investigations relating to those outbreaks. For the three outbreaks, she said that there were 2,136 dengue fever investigations, 1,211 hepatitis-A investigations, and 43 salmonella investigations. However, she did not provide us with documents or records to support these numbers.

DAVID Y. IGE
GOVERNOR OF HAWAII

VIRGINIA PRESSLER, M.D.
DIRECTOR OF HEALTH

STATE OF HAWAII
DEPARTMENT OF HEALTH
P. O. BOX 3378
HONOLULU, HI 96801-3378

In reply, please refer to:
File:

December 22, 2017

Mr. Leslie Kondo
State Auditor
Office of the Auditor
465 South King Street, Room 500
Honolulu, Hawaii 96813-2917

Dear Mr. Kondo:

Thank you for sharing the findings of your recent audit of the Hawaii Department of Health's Disease Outbreak Control Division. We understand the rationale for the audit's conclusion and recommendations, and appreciate the opportunity to provide you with an update and clarifications.

Protecting the health of Hawaii's people is our top priority. As a publicly funded entity, this is a responsibility the Department of Health takes very seriously. We share the same objectives as the Office of the Auditor: to have plans, policies, and protocols in place to ensure we can respond appropriately to any future disease outbreak.

We recognize there is always room for improvement in a response effort; and adopting best practices identified and established by federal organizations, such as the U.S. Centers for Disease Control and Prevention, will enhance our efforts going forward.

In post-outbreak debriefings conducted on our own following the dengue fever outbreak that concluded in April 2016, the Department of Health recognized the need to improve our response efforts. The audit, based on interviews of Department of Health staff and a review of internal documents, validated our own findings.

Audit Recommendations

Recommendation #1a:
The Office of the Auditor recommended the Department of Health continue to develop the All Hazards Preparedness Plan or an alternative strategy that establishes a defined chain of command, communication guidelines, and roles and responsibilities for responding to significant outbreaks.

Mr. Leslie Kondo
December 22, 2017
Page 2

The audit was conducted from November 2016 to May 2017. The Department of Health began its own self-assessment in the spring of 2016 and our findings served as the impetus to develop a reorganization plan, a process that took about a year to complete.

This reorganization is a major shift. It takes the response to disease outbreak from a divisional responsibility and elevates it to one that has direct oversight and involvement by the Director of Health. In addition, the reorganization broadens the focus from being singularly focused on disease outbreak to all crises affecting the health and well-being of Hawaii's people.

A reorganization of this magnitude requires the approval of the Governor, and we are pleased to report the Governor gave his approval on December 22, 2017 for the Department of Health to proceed with the reorganization.

The reorganization clearly defines the roles and responsibilities of Department of Health employees to respond more effectively to outbreaks, eliminating any ambiguity and providing clarity on the chain of command. Using the widely accepted incident command organizational structure and protocols, we believe this will enhance future responses to public health emergencies, including natural disasters and major disease outbreaks at a time when other government partners and the public are counting on the Department of Health to lead.

Breakdown in communications was one of the recurring issues identified in the Office of the Auditor's review of the three disease outbreaks cited in the audit. The Department of Health understands that during an outbreak, communication within our department, with other response agencies and the public is essential. Under the reorganization, keeping the public informed by providing accurate, timely information is identified as a response objective. This addresses the shortcomings that we and the Office of the Auditor identified.

Recommendation 1b:
Determine the type of information that can/should be shared with external agencies and parties involved in jointly responding to an outbreak and develop procedures for sharing such information (e.g., HIPAA/confidentiality agreement). DOH may consider seeking advice and counsel from the Department of the Attorney General and oversight agencies such as the CDC.

In most cases, the Hawaii Department of Health prefers to publicly disclose as much information as possible, particularly with outreach response partners. At the same time, we are cognizant we must honor the Health Insurance Portability and Accountability Act (HIPAA) and patient privacy to avoid any violations of patient confidentiality. We are seeking guidance from the Attorney General's office to pre-determine what we are allowed to disclose so that we can be confident about what we can and cannot offer during an outbreak response.

Mr. Leslie Kondo
December 22, 2017
Page 3

Recommendation 2a:
Develop and enforce administrative procedures related to the opening, investigating and closing of cases, clusters, and outbreaks. Such procedures should include review and recordkeeping requirements, reporting requirements, responsible parties involved with each process, and established deadlines.

The Disease Outbreak Control Division will retain oversight of the investigation of disease outbreaks. This will not change as a result of the reorganization. This will free up the Disease Outbreak Control Division to concentrate its efforts on recordkeeping and other administrative procedures.

The Division currently carries out a broad range of activities to support these investigations. The Division's field investigations supervisors are responsible for reviewing incoming electronic laboratory reports; making determinations as to what requires an investigation; assigning such cases to program investigators; providing consultation and guidance in conducting investigations; reviewing completed investigations or completeness of data elements; and meeting reporting requirements.

In 2016, the Division noted that 17,312 reports required an investigation, including 1,459 dengue investigations, 3,177 hepatitis A investigations, and 357 *Salmonella* investigations. A single dengue investigation requires a review of 153 data elements, 904 data elements for hepatitis A, and up to 838 data elements for *Salmonella*. It is important to note these are only three types of the 66 reportable diseases the Division has investigated.

Recommendation 2b:
Continue to develop and implement guidelines for the summary report and after-action assessments for epidemiological investigations. These should include input from responsible parties, established deadlines, and a scientific format as recommended by CDC. We note that Epidemiological Investigation Summary Report Guidelines have been drafted by the Disease Investigation Branch.

The Department of Health agrees with this recommendation in the audit. The Epidemiological Investigation Summary Report includes the key elements expected in a scientific paper format, and this is applied to all investigations conducted by the Disease Outbreak Control Division. Both the Guidelines and Report continue to be revised to incorporate input from program staff, CDC colleagues, and other partners to improve the usefulness of the report.

Recommendation 2c:
Complete summary reports and after-action assessments for each significant outbreak, including documentation of key activities to ensure accountability.

Mr. Leslie Kondo
December 22, 2017
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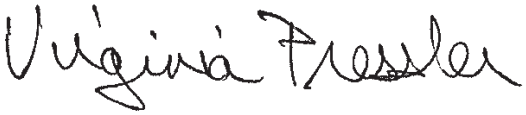
Guidelines are being developed and implemented for conducting formal after-action assessments following disease outbreak investigations. However, the after-action assessments may not always be able to be conducted immediately after all outbreaks. By their nature, outbreaks are unpredictable; and when they are large in scale or protracted, routine duties must be reprioritized to focus all attention on the outbreak to protect the public's health. For example, the dengue outbreak created a 40-fold increase in dengue investigation volume compared with the same timeframe from 2014 to 2015. The hepatitis A outbreak represented a 10-fold increase compared to the same timeframe in 2015.

On behalf of the Department of Health, I would like to thank you for your support in strengthening our disease outbreak capabilities. I hope these responses address your concerns and conclusions. If you have any follow-up questions, please feel free to email or call me.

Thank you very much.

Sincerely,



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