CORHA

Principles and Practices for Healthcare Outbreak Response

Second Edition

The Council for Outbreak Response: Healthcare-Associated Infections and Antimicrobial-Resistant Pathogens

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Foreword

Despite significant progress, patients continue to experience preventable harms resulting from outbreaks of healthcare-associated infections (HAIs), emerging antimicrobial resistance (AR), and other breakdowns in patient and worker safety. Together, we can make healthcare safer, by detecting outbreaks sooner, responding faster and more effectively, achieving better outcomes for everyone.

The Council for Outbreak Response: Healthcare-Associated Infections and Antimicrobial-Resistant Pathogens (CORHA) was founded in 2015 to support this goal. CORHA's members bring expertise in healthcare epidemiology and infection prevention, environmental health, public health laboratory activities and HAI/AR reporting and regulation at the local, state and federal levels. We work to improve practices for the detection, investigation, and control of HAI/AR outbreaks.

The development of the CORHA Principles and Practices for Healthcare Outbreak Response represents a collective effort that began in 2018. Work on the 'P&P' was slowed by the COVID-19 pandemic, but progress continued. Recognizing the growing and urgent workforce training needs related to healthcare outbreak response, the council decided to release P&P materials on an as-available basis, beginning in 2021. This collection was recognized as a 'First Edition' and received a warm response, with materials subsequently adapted in the form of a free online training program on CDC TRAIN.

The completed Second Edition of the CORHA Principles and Practices consists of eight chapters and two supplements and benefits from a new and improved graphical design. We hope that the P&P will continue to serve as a useful resource for those trying to build, standardize, or improve upon their healthcare outbreak response capacities and practices.

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The Centers for Disease Control and Prevention (CDC)

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The Association for Professionals in Infection Control and Epidemiology (APIC)

The Society for Healthcare Epidemiology of America (SHEA)

The Association of Public Health Laboratories (APHL)

The Centers for Medicare and Medicaid Services (CMS)

The U.S. Food and Drug Administration (FDA)

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All individual contributor acknowledgements included in this document are presented alphabetically. The following organizations and agencies participate in CORHA, and their representatives participated in the development of the CORHA Principles and Practices for Healthcare Outbreak Response.

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CHAPTER 1

Overview

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CHAPTER 1

Overview

Preface

The field of healthcare epidemiology has expanded tremendously during the last few decades. What was once a specialty area, narrowly focused within hospital walls, has now grown to an extensive network of healthcare and public health professionals working collaboratively across a wide variety of healthcare settings, government agencies, and partner organizations to decrease healthcare-associated infections (HAIs) and antimicrobial resistance (AR).

One part of this partnership is rapid and efficient outbreak responses to prevent and halt the transmission of pathogens or spread of disease. The *CORHA Principles and Practices for Healthcare Outbreak Response* (hereafter referred to as the *CORHA Principles and Practices*) is intended to be a comprehensive reference comprised of chapters and materials that cover key areas related to HAI/AR outbreak detection, reporting, investigation, and control.

Introduction

Throughout the *CORHA Principles and Practices*, we use the terms "HAI/AR outbreak" and "response."

The term "HAI/AR outbreak" includes outbreaks involving infections that meet the definition of an HAI as well as infections or colonization with organisms typically associated with the receipt of healthcare, including pathogens demonstrating resistance to antimicrobial treatment (AR pathogens). Public health agencies often respond to outbreaks that extend beyond traditional HAIs and AR pathogens, and beyond exposures found solely within healthcare settings. Therefore, the CORHA Principles and Practices includes content applicable to response activities involving noninfectious chemical and other toxic agents as well as outbreaks that include both healthcare-associated and community cases.

"Outbreak response" (or simply "response") refers to efforts made to assist with the assessment and investigation of specific, acute HAI/AR risks. The types of hazards addressed by healthcare outbreak response include overt outbreaks, clusters of infections, sentinel cases (e.g., indications of an uncommon HAI or emerging AR threat), and serious breaches in infection control practice. As this list suggests, response activities often extend to cover *potential* outbreaks: situations that portend danger and may require action to assess risk, prevent exposure, or avoid harm. As used in the

Chapter 1 Overview

CORHA Principles and Practices, "healthcare outbreak response" is inclusive of this broader array of event types and activities.

The primary intended audience of the *CORHA Principles and Practices* consists of personnel at public health agencies at the federal, state, and local levels; however, the information presented here can also be useful to healthcare professionals, employees at healthcare facilities, and other partners involved in a healthcare outbreak response. It is important to acknowledge that the work involved in responding to and preventing HAI/AR outbreaks occurs across the healthcare–public health continuum. Healthcare institutions, public health and government agencies, and other partners working in this arena comprise a large community of professionals collaborating on the same goal: rapid detection of HAI/AR risks and intervention to stop outbreaks. Below we offer brief overviews of the chapters contained in this document with references to chapter sections and subsections.

Overview of Chapter 2: Fundamental Concepts

In Chapter 2, the focus is on the background and basis for surveillance of healthcare-associated infections (HAIs) and antimicrobial-resistant (AR) pathogens as well as associated outbreak response activities. The chapter contains information on healthcare settings with which public health professionals may interact as part of an HAI/AR outbreak response; changes to healthcare delivery, regulations, funding, and public health capacity over time that have impacted HAI/AR surveillance practices and outbreak responses; and trends in surveillance, including descriptions of systems used to identify potential outbreaks as well as types of outbreaks and other events to which public health routinely responds.

OVERVIEW OF TOPICS COVERED IN CHAPTER 2

SECTION	SUBHEADING	COVERED TOPICS
Introduction (2.0)		• Definition and prevalence of HAIs • Definition and prevalence of AR pathogens • Types of HAI/AR outbreaks • Primary audience
Trends in Healthcare (2.1)	Healthcare Settings (2.1.1)	• Definition of a healthcare setting • Types of healthcare settings • Healthcare settings' influence on outbreaks • Definitions, characteristics, and staff with whom public health will interact stratified by specific healthcare setting
	Healthcare Delivery (2.1.2)	• Trends in healthcare delivery • Influence of healthcare delivery changes on outbreaks
	Regulation and Oversight (2.1.3)	• Trends in regulations related to the prevention of healthcare-related infections • Introduction to regulatory partners • Variations in regulation across healthcare settings • Infection prevention and antimicrobial stewardship regulation; resources for HAI rate comparisons

OVERVIEW OF TOPICS COVERED IN CHAPTER 2		
SECTION	**SUBHEADING**	**COVERED TOPICS**
Trends in Surveillance (2.2)	Overview (2.2.1)	• Definition of surveillance • Purposes of disease surveillance • HAI/AR program development (2.2.1.1) • Funding for public health HAI/AR initiatives • Reportable diseases and conditions (2.2.1.1.1) • Surveillance within healthcare facilities (2.2.1.2)
	Public Health Systems (2.2.2)	• Overview of public health surveillance • Description of a surveillance case definition • Population-based surveillance (2.2.2.1) • Healthcare facility–based surveillance (2.2.2.2) • Other surveillance systems and forms of surveillance (2.2.2.3) • Emerging Infections Program: Healthcare-Associated Infections Community Interface (2.2.2.3.1) • Antibiotic Resistance Laboratory Network (2.2.2.3.2) • Sentinel surveillance (2.2.2.3.3) • Syndromic surveillance (2.2.2.3.4) • Regulatory monitoring systems (2.2.2.3.5) • Administrative databases (2.2.2.3.6)
	Impact of Advances in Laboratory Methods on HAI/AR Surveillance (2.2.3)	• Trends in microbiological and molecular testing and their impact on HAI/AR surveillance • Introduction to the impact of polymerase chain reaction (PCR) and whole genome sequencing (WGS) on surveillance and outbreak detection • Culture-independent diagnostic testing (CIDT) and its impact on public health surveillance • Link to a laboratory protocol resource at the Centers for Disease Control and Prevention (CDC)
	Quality and Usefulness of Surveillance Data (2.2.4)	• Uses of surveillance data (2.2.4.1) • Reasons for incomplete surveillance data (2.2.4.2) • Methods to improve the quality of surveillance data (2.2.4.2) • NHSN validation (2.2.4.2)

OVERVIEW OF TOPICS COVERED IN CHAPTER 2		
SECTION	**SUBHEADING**	**COVERED TOPICS**
Trends in Outbreak Detection and Response (2.3)		• Overview of outbreak detection and response • Changes to public health HAI/AR programs leading to improvements in outbreak detection and response • Other factors contributing to improvements in outbreak detection and response • Overview of the wide span of a healthcare outbreak response
	Modes of Transmission (2.3.1)	• Overview and examples of point-source and person-to-person spread of disease • Relationship of pathogens to mode of transmission
	Outbreak Types Based on Etiology (2.3.2)	• Importance of outbreak types • Outbreak detection and response based on pathogen, including when to suspect an outbreak and the importance of laboratory testing (2.3.2.1) • Outbreak detection and response based on infection type, including frequency and considerations (2.3.2.2) • Noninfectious causes of HAI/AR-related outbreaks (2.3.2.3)
	Outbreak Types Based on Setting (2.3.3)	• Impact of healthcare setting on the type of outbreak • Examples of types of outbreaks based on the healthcare setting • Single-facility outbreaks including typical causes (2.3.3.1) • Introduction to multifacility outbreaks, including typical causes and detection (2.3.3.2) • Local multifacility outbreaks (2.3.3.2.1) • Widespread multifacility outbreaks (2.3.3.2.2) • Outbreaks related to international travel (2.3.3.2.3) • Healthcare facility role in detection of outbreaks outside the facility and in the community (2.3.3.3)
	Investigation of Serious Infection Control Breaches (2.3.4)	• Introduction to serious infection control breaches • Centers for Medicare and Medicaid Services (CMS) requirement to report serious infection control breaches • Core infection control practices
Tables and Box		• Box 2.1 Reporting to the National Healthcare Safety Network (NHSN): Conditions and Healthcare Settings • Table 2.1 Selected Healthcare Settings Where Public Health May Conduct HAI/AR Outbreak Response Activities: Definitions, Characteristics, and Key Staff • Table 2.2 Outbreak Examples Based on Healthcare Setting or Procedure Type

Overview of Chapter 3: Planning and Preparation

In chapter 3, strategies for planning and preparation before an outbreak occurs are discussed. Background information on agencies and partners that may be involved in an outbreak response is provided, and their respective roles and responsibilities are described, including considerations for a coordinating agency and the composition of outbreak response teams. Other topics include planning and preparation for resource identification and record management, communication considerations, understanding legal authorities, and preparation for escalation, recovery, and follow-up, including potential implementation of an incident command system (ICS).

OVERVIEW OF TOPICS COVERED IN CHAPTER 3

SECTION	SUBHEADING	COVERED TOPICS
Introduction (3.0)		• Advantages of advanced preparation • Enumeration of tasks for public health agencies prior to an outbreak
Agency Roles (3.1)	Overview (3.1.1)	• Overview of the importance of understanding roles and responsibilities • Centralized and decentralized governance and relationship to public health agencies
	Local, State, and Federal Agencies (3.1.2)	• Description of local public health agency experience and capacity (3.1.2.1) • The local public health agency role in planning for HAI/AR outbreaks (3.1.2.1) • Local public health agency roles, responsibilities, and resources (3.1.2.1) • Description of state public health agency experience and capacity (3.1.2.2) • The state public health agency role in planning for HAI/AR outbreaks (3.1.2.2) • State public health agency roles, responsibilities, and resources (3.1.2.2) • Role of the state survey and facility licensing agency and strategies for coordination (3.1.2.3) • Role of the state provider licensing agency and strategies for coordination (3.1.2.4) • Role of CDC and coordination with state and local public health agencies and healthcare facilities (3.1.2.5) • Role of the Food and Drug Administration (FDA) in HAI/AR outbreak investigations (3.1.2.6)
	Healthcare Facilities (3.1.3)	• Roles and responsibilities of healthcare facilities • Role of the team tasked with preventing infections, including the infection preventionist and the medical epidemiologist within healthcare facilities • General information about facility planning for an outbreak • Variations in resources among healthcare facility types
	Patients and Other Agencies/Partners (3.1.4)	• Professional member organizations for healthcare professionals and healthcare facilities (3.1.4.1) • Tribal entities and the Indian Health Service (IHS) (3.1.4.2) • Law enforcement (3.1.4.3)

OVERVIEW OF TOPICS COVERED IN CHAPTER 3		
SECTION	**SUBHEADING**	**COVERED TOPICS**
Outbreak Response Team (3.2)	Overview (3.2.1)	• Basic composition of an outbreak response team • Introduction to roles and responsibilities of outbreak response team members
	Roles of Team Members (3.2.2)	• Introduction to the coordinating agency • Roles of the public health outbreak response team members • Role and responsibilities of the public health team leader (3.2.2.1) • Roles and responsibilities of the epidemiologist(s) on the public health team (3.2.2.2) • Role and responsibilities of the infection preventionist on the public health team (3.2.2.3) • Roles and responsibilities of public health laboratorians (3.2.2.4) • Other team members, who may include administrative staff, statisticians, public health information officers, legal staff, and emergency preparedness staff (3.2.2.5)
	Outbreak Response Team Model Practices (3.2.3)	• Pre-identified dedicated outbreak response teams (3.2.3.1) • Scaling up additional support (3.2.3.2) • Establishing outbreak response plans and protocols (3.2.3.3) • Training for outbreak response team members (3.2.3.4)
Resources (3.3)		• Introduction to resource components needed during the response to an outbreak
	Equipment and Supplies (3.3.1)	• List of equipment and supplies to consider in preparation for an outbreak response
	Outbreak Investigation Documents and Toolkits (3.3.2)	• Investigation documents, tools, and protocols to consider preparing ahead of an outbreak
	Reference Materials (3.3.3)	• Reference materials to consider compiling ahead of an outbreak
	Tracking Time and Resources (3.3.4)	• Advantage of setting up processes to track time and resources during large-scale investigations
Records Management (3.4)	Overview (3.4.1)	• Overview of systematic information management during an outbreak response
	Records Management Model Practices (3.4.2)	• Standardized information collection (3.4.2.1) • Considerations for sharing information across agencies (3.4.2.1) • Tracking data during an outbreak investigation, including what situations to track and data system considerations (3.4.2.2)

OVERVIEW OF TOPICS COVERED IN CHAPTER 3		
SECTION	**SUBHEADING**	**COVERED TOPICS**
Communication (3.5)		• Importance of communication across all partners • Considerations for communication preparation ahead of an outbreak
Escalation (3.6)	Overview (3.6.1)	• Notifying leadership within your agency • Obtaining help within your agency • Considerations for transferring coordination responsibilities to another agency
	When to Ask for Help (3.6.2)	• Considerations for when to ask for help from another agency
	How to Obtain Help (3.6.3)	• Whom to ask for help • Contact information for CDC
Incident Command System (3.7)		• History and description of the incident command system (ICS) • ICS in government agencies • ICS in healthcare organizations • Considerations for ICS activation
Other Aspects of Preparation (3.8)	Legal Preparedness, Authorities, and Litigation (3.8.1)	• Understanding legal authority • Anticipating legal situations and preparing in advance
	Ethics (3.8.2)	• Consideration of potential ethical dilemmas in advance
	Privacy (3.8.3)	• Understanding privacy laws and regulation • Maintaining confidential information • Preparing for protection versus disclosure of information
	Permissions and Approvals (3.8.4)	• Considerations for the need for permissions or approvals • Preparation for accessing medical records
Planning for Recovery and Follow-Up (3.9)	Overview (3.9.1)	• Planning for recovery and follow-up
	Recovery and Follow-Up Model Practices (3.9.2)	• Model practices to assist in planning for recovery and follow-up
Tables, Boxes, and Keys to Success		• Box 3.1 Selected Training Resources • Box 3.2 Selected Resources from Federal Regulatory Agencies • Box 3.3 Types of Facilities Required by CMS to Develop Emergency Preparedness Plans • Table 3.1 Additional Agencies and Partners that Public Health Agencies Interact with During an Outbreak Response • Table 3.2 Partners to Consider Involving by Type of Event • CORHA Keys to Success: Developing Relationships Prior to an Outbreak

Chapter 1 Overview

Overview of Chapter 4: Outbreak Detection and Reporting

Chapter 4 examines the detection and reporting of potential outbreaks, including detection via reports and through use of surveillance data. Definitions of sentinel cases, clusters, and outbreaks are described. The section on direct reporting of outbreaks includes information on reporting within a healthcare facility and reporting to public health, entities that can report to public health, and types of events that may be reported. This is followed by an overview of the use of routine surveillance systems for cluster and outbreak detection. Strengths and limitations, key determinants of successful detection, and model practices are described for both types of detection methods.

OVERVIEW OF TOPICS COVERED IN CHAPTER 4

SECTION	SUBHEADING	COVERED TOPICS
Introduction (4.0)		• Description of what is covered in Chapter 4 • Purpose of detecting clusters and outbreaks • Benefits of detecting outbreaks
Overview (4.1)		• Overview of methods of detection
	Outbreak Detection Pathways (4.1.1)	• Introduction to outbreak reporting • Introduction to detection of clusters and outbreaks using surveillance data • Other activities that may lead to outbreak detection
	Definitions (4.1.2)	• Definition of a cluster • Considerations for defining an outbreak • Threshold levels and outbreak definitions • General principles for determining when a situation warrants investigation and reporting
Reporting Sentinel Cases, Clusters, and Outbreaks (4.2)	Purpose (4.2.1)	• Importance of reporting as a method to detect outbreaks
	Background (4.2.2)	• Reporting potential outbreaks within healthcare facilities (4.2.2.1) • Reporting potential outbreaks to public health (4.2.2.2) • Public health processes to receive reports of potential outbreaks (4.2.2.2) • Requirements for reporting to public health (4.2.2.2) • Strategies to encourage reporting potential outbreaks to public health and perceived barriers to reporting (4.2.2.2) • Perceived barriers for reporting potential outbreaks (4.2.2.2)
	Reporting Entities (4.2.3)	• Sources of outbreak reports • Healthcare facility and provider reports (4.2.3.1) • Clinical and public health laboratory reports (4.2.3.2) • Public, patient, and media reports (4.2.3.3) • Other government agencies that may report, including state facility licensing agencies (4.2.3.4) • Other partners that may report (4.2.3.5)

OVERVIEW OF TOPICS COVERED IN CHAPTER 4		
SECTION	**SUBHEADING**	**COVERED TOPICS**
Reporting Sentinel Cases, Clusters, and Outbreaks (4.2)	Epidemiology Process (4.2.4)	• Importance of a pre-established process • Determining if cases, clusters, and outbreaks are linked
	Laboratory Process (4.2.5)	• Importance of communication between epidemiology and laboratory staff upon report of a potential outbreak
	Strengths and Limitations of Outbreak Reporting Systems (4.2.6)	• Strengths of outbreak reporting systems (4.2.6.1) • Limitations of outbreak reporting systems (4.2.6.2)
	Key Determinants of Successful Outbreak Reporting Systems (4.2.7)	• Definition of a successful outbreak reporting system • Factors impacting the sensitivity of outbreak detection (4.2.7.1) • Impact of the prevalence of disease on outbreak detection (4.2.7.2) • Impact of relationships among reporting entities and public health agencies (4.2.7.3)
	Model Practices for Outbreak Reporting Systems (4.2.8)	• Establishing requirements for reporting (4.2.8.1) • Ensuring timeliness of reporting (4.2.8.2) • Establishing a clearly defined reporting process methodology (4.2.8.3) • Useful tools to apply to outbreak reporting systems (4.2.8.4) • Importance of tracking outbreaks (4.2.8.5)
Detecting Sentinel Cases, Clusters, and Outbreaks through Surveillance (4.3)	Purpose (4.3.1)	• Importance of use of surveillance data as a method to detect outbreaks
	Background (4.3.2)	• Basic surveillance principles impacting detection of sentinel cases, clusters, and outbreaks • Techniques to assist with detecting patterns in surveillance data • Detection of clusters and outbreaks within a healthcare facility using surveillance data (4.3.2.1) • Surveillance data typically collected by public health that can be used to detect clusters and outbreaks (4.3.2.2)
	Types of Surveillance Data (4.3.3)	• Types of surveillance data used for cluster detection
	Epidemiology Process (4.3.4)	• General epidemiology process for collection of surveillance data • Manual review of surveillance data for cluster detection • Automated processes for cluster detection using surveillance data
	Laboratory Process (4.3.5)	• General laboratory process for conditions under surveillance • Methods for support of cluster detection using laboratory data

OVERVIEW OF TOPICS COVERED IN CHAPTER 4		
SECTION	**SUBHEADING**	**COVERED TOPICS**
Detecting Sentinel Cases, Clusters, and Outbreaks through Surveillance (4.3)	Strengths and Limitations of Surveillance for Outbreak Detection (4.3.6)	• Strengths of outbreak reporting systems (4.3.6.1) • Limitations of outbreak reporting systems (4.3.6.2)
	Key Determinants of Successful Outbreak Detection via Surveillance Systems (4.3.7)	• Surveillance system components that support outbreak detection • Factors impacting complete reporting of conditions under surveillance (4.3.7.1) • Effect of sensitivity of surveillance on cluster detection (4.3.7.2) • Impact of the prevalence of disease on cluster detection (4.3.7.3) • Influence of the speed of reporting diseases and conditions under surveillance on outbreak detection (4.3.7.4)
	Model Practices for Detecting Outbreaks through Surveillance (4.3.8)	• Strategies for rapid case detection (4.3.8.1) • Advantages of submission and characterization of isolates (4.3.8.2) • Standardized processes for cluster detection using surveillance data (4.3.8.3) • Communication practices supporting cluster detection (4.3.8.4) • Tools that can be used for cluster detection using surveillance data (4.3.8.5) • Importance of tracking outbreaks (4.3.8.6)
Multifacility and Multijurisdictional Considerations (4.4)		• Importance of complete reporting to identify multifacility and multijurisdictional outbreaks • Factors influencing multifacility and multijurisdictional cluster and outbreak detection
Table and Keys to Success		• Table 4.1 Potential Methods of Outbreak Detection by Healthcare Facilities and Public Health Agencies • CORHA Keys to Success: Maximizing Outbreak Detection

Overview of Chapter 5: Investigation and Control

Chapter 5 contains a review of the key elements and steps involved in the investigation and control of outbreaks involving HAIs and AR pathogens. The chapter is arranged to follow steps typically followed in an outbreak investigation, recognizing that such steps may indeed not occur in linear order and will depend on the precise nature and needs of the response. The chapter also reviews the goals of a healthcare outbreak investigation and includes collections of resources to support and improve the HAI/AR outbreak response.

OVERVIEW OF TOPICS COVERED IN CHAPTER 5

SECTION	SUBHEADING	COVERED TOPICS
Introduction (5.0)		• Description of what is covered in Chapter 5 • Overall function of public health in an outbreak investigation • Collaboration between public health and healthcare • Importance of a systematic approach
Perform an Initial Assessment (5.1)	Initial Information to be Gathered (5.1.1)	• Initial information to be gathered when an outbreak is detected or use of surveillance data
	Initial Control Measures (5.1.2)	• Initial control measures at the time of outbreak detection
	Determining the Level of Response (5.1.3)	• Considerations for determining the level of response: full investigation and response following a facility investigation or receipt of a report
	Developing Hypotheses (5.1.4)	• Development of an initial hypothesis
Verify the Diagnosis (5.2)		• Information review to aid in diagnosis verification • Importance of the laboratory in diagnosis verification
Assemble and Brief the Outbreak Response Team (5.3)		• Composition of the outbreak response team • Introduction to team roles • Introduction of the concept of a coordinating agency
	Partners (5.3.1)	• Partners' outbreak response teams, including healthcare facilities and regulatory partners • Escalation of response and partner roles
	Public Health Team Communication (5.3.2)	• Considerations related to public health team communication
	Communication Among Partners (5.3.3)	• Considerations related to communication among partners • Coordination among public health agencies and regulatory agencies

OVERVIEW OF TOPICS COVERED IN CHAPTER 5		
SECTION	**SUBHEADING**	**COVERED TOPICS**
Establish a Plan and Prepare for Fieldwork (5.4)		• Determination of missing information and steps to gather that information • Gathering of information on similar outbreaks, including information on the pathogen or type of infection • Considerations for utility and burden of planned steps during preparations • Considerations for on-site investigations • Onsite preparation steps including gaining access to medical records, preparing for data collection (including tool development), and infection control preparation
Confirm the Presence of an Outbreak (5.5)		• Factors involved in verifying outbreaks • Pseudo-outbreaks
Establish Case Definition and Classification Criteria (5.6)		• Components of a case definition • Creation of a useful case definition • Stratified case definitions and classification criteria
Identify and Count Cases (5.7)		• Retrospective and prospective case counting • Methods to retrospectively identify cases • Methods to prospectively identify cases • Consideration of cases in healthcare workers, visitors, and community residents • Importance of systematic case counting and application of case definitions and classifications
Collect, Organize, and Analyze Data (5.8)	Data Collection (5.8.1)	• Data sources for collection of data • Importance and components of a standardized data collection tool • Protecting information that could be used to identify a patient
	Organizing Data and Perform Descriptive Epidemiology (5.8.2)	• Organizing data into a line list • Descriptive epidemiologic analysis • Other data organization tools including maps, timelines, and epidemic curves
	Refining the hypothesis (5.8.3)	• Considerations related to refining the hypothesis
	Analytic Epidemiology (5.8.4)	• Considerations for use of analytic epidemiology • How to conduct an analytic study

OVERVIEW OF TOPICS COVERED IN CHAPTER 5		
SECTION	**SUBHEADING**	**COVERED TOPICS**
Perform an Infection Control Assessment (5.9)		• Considerations for performing on-site infection control assessments • Areas of focus during infection control assessments • Considerations for staff interviews
Consider an Environmental Assessment (5.10)		• Determining possible environmental factors that may have contributed to an outbreak • Environmental assessment as part of the infection control assessment • Determining when environmental sampling is appropriate • Laboratory considerations for environmental testing
Recommend Control Measures (5.11)		• Recommendations for infection control measures throughout the investigation • Providing written recommendations • Importance of follow-up after recommendations • What to do when there is imminent potential harm to patients
Interpret Results (5.12)		• Considerations for interpretation of results following the investigation
Monitor the Outbreak Until Completion (5.13)	Monitoring the Outbreak (5.13.1)	• Considerations related to monitoring the outbreak
	Re-evaluate Hypotheses and Case Definitions (5.13.2)	• Re-evaluation of hypotheses and case definitions during the monitoring phase
	Ending the investigation (5.13.3)	• Determining when to end an investigation • Post-outbreak and after-action meetings as a strategy for improvements
Other Follow-Up Activities (5.14)	Summarize Investigation Findings, Conclusions, and Recommendations (5.14.1)	• Writing a final report
	Distribute the Report (5.14.2)	• Considerations related to distribution of the final report
	Policy Action (5.14.3)	• Policy action that could result from an outbreak investigation

OVERVIEW OF TOPICS COVERED IN CHAPTER 5		
SECTION	**SUBHEADING**	**COVERED TOPICS**
Tables, Boxes, Figure, and Keys to Success		• Figure 5.1 Sample Timeline • Box 5.1 Selected HAI/AR Outbreak Investigation Resources • Box 5.2 Goals of an Outbreak Investigation • Box 5.3 Steps of an Outbreak Investigation • Box 5.4 Example Case Definitions • Box 5.5 Healthcare Facility Records to Consider Reviewing During an Outbreak Investigation • Table 5.1 Investigation Activities for Outbreak Response Objectives • Table 5.2 Immediate Control Measures for Healthcare Outbreak Management • CORHA Keys to Success: Initial Steps in the Investigation of Outbreaks • CORHA Keys to Success: Communication During an Investigation
Appendix		• Appendix A: Cohort and Case-Control Studies

Overview of Chapter 6: Laboratory Best Practices

Chapter 6 expands on the basic concepts presented in previous chapters to highlight the roles and contributions of laboratory partners. This chapter further develops concepts, explanations, and processes, while adding examples and emphasizing best practices.

OVERVIEW OF TOPICS COVERED IN CHAPTER 6

SECTION	SUBHEADING	COVERED TOPICS
Introduction (6.0)		• Description of what is covered in Chapter 6 • Overall function of public health laboratories • Collaboration between laboratories and public health partners
Types of Laboratories and Roles (6.1)	Public Health Laboratories (6.1.1)	• Structure and relationships of state public health laboratories • Coordination among state, regional, and CDC labs • Regional support network for sequencing • Role of Association of Public Health Laboratories (APHL)
	Clinical Laboratories (6.1.2)	• Role of clinical laboratories • Importance of collaboration with clinical laboratories
	Reference Laboratories (6.1.3)	• Role of reference laboratories • Development and structure of the AR Lab Network
Laboratory Functions in Support of a Healthcare Outbreak Response (6.2)	Surveillance (6.2.1)	• Laboratory role in surveillance • Discussion of National Healthcare Safety Network (NHSN) and associated federal regulatory agency reporting requirements
	HAI and AR Pathogen Detection and Confirmation (6.2.2)	• Testing assays that can support early detection • Phenotypic testing (6.2.2.1) • Genotypic testing (6.2.2.2) • Next generation sequencing (6.2.2.3) • Terminology (6.2.2.4) • Saving specimens and isolates (6.2.2.5) • Characterization testing (6.2.2.6)
	Reporting to Epidemiology and Other Partners (6.2.3)	• Role of laboratories in reporting data indicating a potential concern • Use of antibiograms for detection • Review of organisms that require immediate public health notification for action/intervention • Processes and partnerships involved in laboratory reporting

OVERVIEW OF TOPICS COVERED IN CHAPTER 6		
SECTION	**SUBHEADING**	**COVERED TOPICS**
Laboratory Functions in Support of a Healthcare Outbreak Response (6.2)	Detection of HAI Outbreaks by the Laboratory (6.2.4)	• Overview of how laboratories can support detection through characterization of isolates/organisms • Impact of next generation sequencing and the implications for data collection and interpretation that support detection • Pathogens that may be of concern at varying levels (e.g., single detection vs. cluster) and the public health systems for reporting, which include facilities/hospitals, localities/states, regional networks, and the CDC • Chain of reporting and importance of coordinated communication and awareness among key partners
	Environmental Testing (6.2.5)	• Value of environmental testing in support of clinical investigations • Types of environmental samples that might be considered and the kind of resources and expertise that should accompany those efforts
	Healthcare Worker Testing (6.2.6)	• Elements related to healthcare worker testing including available methods, potential implications, and legal/policy considerations
Safety, Quality Control, and Validation (6.3)		• Importance of following safety precautions including use of appropriate personal protective equipment • Role of FDA in review of evolving techniques
Laboratory Data Management (6.4)	Ensuring Chain of Custody (6.4.1)	• Overview of laboratory information systems and currently available national networks • List of suggested best practices for using laboratory data • Chain of custody processes and procedures
Epidemiology-Laboratory Communication (6.5)	Other Testing (6.5.1)	• Coordination among epidemiology and laboratory personnel for sample collection, investigation, monitoring, etc. • Consider available expertise, resources, and potential need for training or assistance • Utility of other types of testing such as toxin detection
Quality Control and Assurance (6.6)		• Mechanisms for quality control and assurance including validation protocols and regular testing of reagents in accordance with clinical laboratory standards
Tables, Boxes, Figure, and Keys to Success		• Figure 6.1 Antimicrobial Resistance Laboratory Network Map of Regional Laboratories • Table 6.1 Phenotypic and Genotypic Tests • Table 6.2 Common MDROs • Table 6.3 Tips for Collecting Environmental Samples • CORHA Keys to Success: Laboratory as a Key Team Member • CORHA Keys to Success: Appropriate and Rapid Testing

Overview of Chapter 7: Multifacility and Multijurisdictional Outbreaks

Chapter 7 focuses on the unique aspects of multifacility and multijurisdictional healthcare outbreak responses. Compared with single facility outbreaks, those that involve multiple facilities or multiple jurisdictions are more complex and are often more difficult to detect, coordinate, and investigate.

OVERVIEW OF TOPICS COVERED IN CHAPTER 7

SECTION	SUBHEADING	COVERED TOPICS
Introduction (7.0)		• Description of what is covered in Chapter 7 • Definition of multifacility and multijurisdictional outbreaks
Overview (7.1)		• Risks for and contributors to multifacility and multijurisdictional outbreaks • Description of outbreak complexities and considerations for coordination and communication
Example Scenarios (7.2)	Multifacility Outbreak within One Jurisdiction (7.2.1)	• Contributions of infection control breaches and poor communication between the transferring and receiving facilities • Considerations regarding facilities in one jurisdiction accepting patients with residences in other jurisdictions
	Outbreaks that Span Multiple Jurisdictions (7.2.2)	• Detection and coordination of multi-jurisdiction outbreaks • Implications of international travel and healthcare exposure
	Outbreaks Involving Medical Tourism (7.2.3)	• Considerations for outbreaks involving major infection control breaches
	Contaminated Products (7.2.4)	• When to consider medical product contamination • Potential for multifacility and multijurisdictional outbreaks associated with contaminated medical products
Coordination of Multifacility and Multijurisdictional Outbreaks (7.3)	Initial Detection of a Multifacility or Multijurisdictional Outbreak (7.3.1)	• The role of clinicians in detecting multifacility and multijurisdictional outbreaks • The role of public health agencies in detecting multifacility and multijurisdictional outbreaks
	Initial Notification Upon Detection (7.3.2)	• Notification of potentially affected and/or collaborating agencies • List of potentially impacted entitie
	Coordinating Agency (7.3.3)	• Importance of promptly identifying investigation partners • Considerations for identification of a coordinating agency

OVERVIEW OF TOPICS COVERED IN CHAPTER 7		
SECTION	**SUBHEADING**	**COVERED TOPICS**
Coordination of Multifacility and Multijurisdictional Outbreaks (7.3)	Interagency Outbreak Response Team (7.3.4)	• Suggested practices for establishing interagency outbreak response teams
	Communication and Collaboration (7.3.5)	• Highlighted key communication considerations for multifacility and multijurisdictional outbreaks
	Data Collection and Dissemination (7.3.6)	• The role of the coordinating agency or designee in data collection and dissemination • Data sharing considerations
	Regular Assessment of the Scope of the Outbreak and Resources Needed (7.3.7)	• List of questions that should be periodically considered throughout the investigation
Concluding a Multifacility or Multijurisdictional Investigation (7.4)		• Identifying opportunities to narrow the scope of a response • Considerations for monitoring processes • Considerations in concluding interagency responses
Tables, Boxes, Figure, and Keys to Success		• Box 7.1 Examples of How Healthcare Outbreaks Can Affect Multiple Facilities and/or Multiple Jurisdictions

Overview of Chapter 8: Notification and Communication

Chapter 8 describes the rationale and "who, what, how, and when" for the notification of patients and other stakeholders, along with information on risk communication principles and strategies, to support effective healthcare outbreak response. Incorporating notification into an outbreak response can be challenging, particularly when not all information has been collected or analyzed. Nevertheless, public health agencies and healthcare providers should consider this type of communication part of their missions to protect health and serve their populations.

OVERVIEW OF TOPICS COVERED IN CHAPTER 8

SECTION	SUBHEADING	COVERED TOPICS
Introduction (8.0)	Patients' Stories (8.0.1)	• Patient A case scenario as an example • Description of what is covered in Chapter 8
	Considerations for Notification (8.0.2)	• Utilitarian and ethical frameworks for considering patient notifications • Duty of public health agencies in making notifications • Notifications to aid patients and stakeholders in understanding and managing risk
Notification of Patients, Stakeholders, and the General Public (8.1)		• Overview and description of three potential triggers to perform patient notifications
	Immediate Notification (8.1.1)	• Affected and exposed patients (8.1.1.1) • Healthcare providers and personnel (8.1.1.2) • Visitors (8.1.1.3) • Other healthcare facilities (8.1.1.4)
	Expanded Notification (8.1.2)	• Affected and exposed patients (8.1.2.1) • Healthcare providers and personnel (8.1.2.2) • Visitors (8.1.2.3) • Other healthcare facilities (8.1.2.4)
	Public Notification (8.1.3)	• When to notify the public (8.1.3.1) • How to notify the public (8.1.3.2)
Communication Techniques (8.2)	Risk Communication Principles (8.2.1)	• Crisis and Emergency Risk Communication (CERC) • Identification of a spokesperson • Advanced planning of communications and considerations for media engagement
	Managing Differing Opinions Between Public Health Agencies and Healthcare Facilities (8.2.2)	• Considerations regarding public perception and trust • Considerations for the public health agencies when a facility holds a different opinion on notification

OVERVIEW OF TOPICS COVERED IN CHAPTER 8		
SECTION	**SUBHEADING**	**COVERED TOPICS**
Communication Techniques (8.2)	Tailoring Communication to the Audience and Setting (8.2.3)	• List of key considerations for the audience, method and content of the message
	Tools (8.2.4)	• List of tools and materials to consider developing prior to a patient notification event
Media (8.3)		• Advanced planning for media attention and engagement
	Types of Media (8.3.1)	• Types of media and communication methods
	Engaging the Media (8.3.2)	• Early involvement of public information officer (PIO) and other key staff • Information accuracy • Considerations for the method of engaging with the media
	Proactive versus Reactive Media Communication (8.3.3)	• Proactive vs reactive media engagement
Tables, Boxes, Figure, and Keys to Success		• Box 8.1 Additional Considerations for Immediate and Expanded Notification and Communication • Box 8.2 Tools and Materials to Develop When Planning for a Patient Notification • Box 8.3. Example of Patient Notification: Legionella Outbreak in a General Medicine Ward • Box 8.4. Example of Patient Notification: New Delhi Metallo-Beta-Lactamase-Producing Carbapenem Resistant Enterobacteriaceae (NDM-CRE) In A Long-Term Care Facility • Table 8.1 Framework for Healthcare-Associated Infection Outbreak Notifications: Immediate and Expanded Notifications

Overview of Supplement A: Medical Product Investigations

SECTION	COVERED TOPICS
Introduction (A.0)	• Unique challenges associated with medical product contamination events
Background: Intrinsic and Extrinsic Contamination (A.1)	• Definitions of intrinsic and extrinsic contamination
Detection and Reporting (A.2)	• Considerations for when to report infections and potential outbreaks linked to medical products • Channels through which to report, including FDA MedWatch
Investigation (A.3)	• Noted similarities to other types of investigations • Considerations for simultaneous exploration of hypotheses • Noted importance of engaging relevant experts early • Unique product testing considerations
Concluding a Medical Product Investigation (A.4)	• Noted potential for unique lessons learned in medical product investigations
Summary (A.5)	• Summary of the unique role and potential risks associated with medical products
Tables, Boxes, Figure, and Keys to Success	• Figure A.1 Opportunities for Intrinsic Contamination or Extrinsic Contamination, from Production through Patient Use and Reprocessing • Box A.1 Resources for Investigations of Blood, Biologic, Tissue, and Organ Contamination • Box A.2 CORHA Potential Medical Product-Related Outbreak: Assessment Questions • CORHA Keys to Success: Medical Product Investigations • Table A.1 Groupings of Organ Systems and Infection Types with Contaminated Medical Products and Pathogens
Appendix	• Appendix A: Key Resources & Additional Reading

Overview of Supplement B: Infection Control Breach Investigations

SECTION	COVERED TOPICS
Introduction (B.0)	• A brief discussion of how investigation of infection control breaches fits into the overall mission of public health agencies
Investigation of Infection Control Breaches (B.1)	• Overview of resources public health agencies and healthcare partners can reference to assist with investigations of infection control breaches • List of select publications detailing infection control breach investigations
Selected Infection Control Resources and References (B.2)	• List of generally relevant infection control resources, as well as resources specific to some of the more commonly reported infection control breaches
Investigation of a Drug Diversion Event (B.3)	• Guidance and background for responding to reports of healthcare drug diversion

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Disclaimers: The findings and conclusions in this document are those of the authors and do not necessarily represent the official views of the CDC nor those of other CORHA member organizations.

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CHAPTER 2

Fundamental Concepts

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CHAPTER 2

Fundamental Concepts

CORHA

Preface

In Chapter 2, we review fundamentals concepts related to healthcare and public health surveillance as well as trends in outbreak detection and response. As healthcare-associated infection and antimicrobial resistance (HAI/AR) surveillance improves and outbreaks are recognized earlier, the public health and healthcare communities are better positioned to reduce patient harm from HAIs, AR pathogens, and healthcare outbreaks. The ultimate goals of the healthcare outbreak response are to rapidly detect and respond to potential outbreaks, ensuring that any unsafe practices are discovered and corrected before further harm can occur.

2.0 Introduction

Healthcare-associated infections (HAIs) are infections acquired within a healthcare setting or related to the receipt of medical care. They are a leading cause of unnecessary death and are a serious threat to public health. Each year, millions of patients are affected by HAIs worldwide. Although significant progress has been made in preventing HAIs, data published by the Centers for Disease Control and Prevention (CDC) indicate there is much more work to be done.[1]

The term "healthcare-*associated* infection" reflects that the infection had its onset in a specific healthcare setting or following a healthcare exposure; it does not necessarily reflect with certainty where a pathogen was *acquired*. This uncertainty is due to the fact that patients may become colonized (i.e., microorganisms may appear on the skin of or inside a person without causing a disease) following exposure to a pathogen within the community or at a different healthcare facility.[2] Identifying HAIs and attributing them to a specific healthcare setting can be complicated, as some HAIs may not become apparent until after discharge from a healthcare facility.[3]

Antimicrobial resistance occurs when pathogens develop the ability to defeat antimicrobial agents designed to kill them. Infections caused by antimicrobial resistant (AR) pathogens can be difficult and sometimes impossible to treat. Both patients who are colonized and those who are infected with an AR pathogen can serve as a source of transmission. In many cases, AR infections result in extended hospital stays and may require use of more costly and more toxic alternative treatments. More than 2.8 million AR infections occur in the US each year, and at least 35,000 people die as a result.[4] As novel AR pathogens emerge, new and innovative detection and response strategies will be needed.

Protecting patients from acquiring an HAI or AR pathogen is a critical aspect of patient safety. Patients seek healthcare as a means of maintaining or improving their health. When, as an unintended consequence of healthcare, an infection occurs or colonization with an AR organism results, it can be a significant event for the patient—one shaped by the patient's health status, understanding, emotions, and social context.[5]

HAI/AR pathogen outbreaks in healthcare settings usually stem from breakdowns in practices designed to prevent transmission of disease. Often, these outbreaks are the result of a failure to follow basic ("core") infection control practices. Outbreaks also result from exposure of patients to contaminated medical products.

The evolving landscape of healthcare outbreak response has been shaped by changes in healthcare delivery, advances in laboratory techniques, and emerging pathogen resistance to antimicrobial agents. Health department expertise and capacity have grown dramatically. Increasingly, public health agencies, healthcare providers, and partner organizations are working together to identify and respond to potential HAI/AR outbreaks.

2.1 Trends in Healthcare

2.1.1 Healthcare Settings

The term "healthcare setting" represents a broad array of services and places where healthcare occurs, including but not limited to acute care hospitals, urgent care centers, rehabilitation centers, nursing homes and other long-term care facilities, outpatient clinics, specialized outpatient services (e.g., hemodialysis, dentistry, podiatry, chemotherapy, endoscopy, and pain management clinics), outpatient surgery centers, pharmacies, and any other location where medical care is provided. In addition, some healthcare services are provided in private offices or homes.

Within each type of setting, specific locations or services may be the focal point of an epidemiologic investigation. Acute care hospitals are complex organizations that can have multiple specialized areas for triage and emergency care, inpatient and outpatient surgical procedures, management of immunosuppressed populations (e.g., oncology or transplant recipients), rehabilitation services, and intensive care units. The type of healthcare delivered within a healthcare setting can vary widely depending on the community. For example, rural areas may have different services and expertise available than urban areas.

An understanding of the types of patients and clinical services provided helps investigators recognize infectious disease transmission risks. Selected healthcare settings, definitions, and characteristics, as well as the staff with whom public health agencies will typically interact, can be found in Table 2.1.

Table 2.1 | Selected Healthcare Settings Where Public Health May Conduct HAI/AR Outbreak Response Activities: Definitions, Characteristics, and Key Staff

SETTING	NATIONAL QUALITY FORUM (NQF) AND CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS) DEFINITIONS [6,7,8]	ADDITIONAL CHARACTERISTICS	KEY STAFF CONTACTS
Ambulatory Care Settings	**NQF:** Healthcare services that do not require hospital admission. These may be provided in an ambulatory surgery center, clinician's office, or clinic/ urgent care setting.	This broad designation includes any outpatient medical care setting where a patient is not admitted.	For clinics, public health often interacts with an office manager or clinical staff. For outpatient procedure centers, public health may interact with clinical staff, with a manager, or in some cases with an infection preventionist.

Table 2.1 | Selected Healthcare Settings Where Public Health May Conduct HAI/AR Outbreak Response Activities: Definitions, Characteristics, and Key Staff

SETTING	NATIONAL QUALITY FORUM (NQF) AND CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS) DEFINITIONS [6,7,8]	ADDITIONAL CHARACTERISTICS	KEY STAFF CONTACTS
Ambulatory Surgery Centers (ASCs)	**NQF:** Setting in which outpatient surgical services are provided. **CMS:** A facility where certain surgeries may be performed for patients who are not expected to need care for longer than 24 hours.	A type of ambulatory care site where surgical services are provided. Some centers are located within a hospital or hospital complex but are licensed separately. Others are stand-alone centers. Public health authorities usually reserve the term "ambulatory surgery center" for Medicare-certified facilities. The term "office-based surgical practice" is usually applied to less-regulated entities such as oral or plastic surgery practices.	Public health may interact with an infection preventionist when one is on staff; sometimes this person is a hospital-based or other infection preventionist affiliated with the center. Public health may also interact with center administration personnel (manager or executive level) or with clinical staff.
Critical Access Hospitals (CAHs)	**CMS:** A small facility located in a rural area more than 35 miles from another hospital or critical access hospital (15 miles away if the area has mountainous terrain or only secondary roads). This facility provides 24/7 emergency care, has 25 or fewer inpatient beds, and maintains an average length of stay of 96 hours or less for acute care patients.	Critical access hospitals are acute care hospitals that meet specific criteria defined by CMS.	Typically, public health interacts with a clinical staff member who fulfills several duties, including that of an infection preventionist. Other staff members may include those found in an acute care hospital (see Acute Care Hospital).
Urgent Care Centers	**NQF:** Setting in which urgent care services are provided. Urgent care services are medically necessary services required for illnesses/injuries that will not result in further disability or death if not treated immediately, but require professional attention and have the potential to develop such a threat if treatment is delayed longer than 24 hours.	Urgent care centers are a type of ambulatory care.	Often public health interacts with an office manager or clinical staff.

Table 2.1 | Selected Healthcare Settings Where Public Health May Conduct HAI/AR Outbreak Response Activities: Definitions, Characteristics, and Key Staff

SETTING	NATIONAL QUALITY FORUM (NQF) AND CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS) DEFINITIONS [6,7,8]	ADDITIONAL CHARACTERISTICS	KEY STAFF CONTACTS
End-Stage Renal Dialysis Facilities/ Dialysis Centers	**NQF:** Setting in which dialysis services are provided to patients.	Dialysis facilities may be stand-alone centers or associated with a hospital complex. Often dialysis facilities are part of large corporations.	Public health may interact with an infection preventionist (who may have other duties), clinical staff or managers, office managers, administrators, or corporate representatives.
Home Health Agencies	**NQF:** Limited part-time or intermittent skilled nursing care and home health aide services; physical therapy, occupational therapy, speech-language therapy, and medical social services organizations; and providers of durable medical equipment (such as wheelchairs, hospital beds, oxygen, and walkers), medical supplies, and other services that are provided to patients in their home or place of residence. **CMS:** An organization that provides home health care, defined as healthcare services and supplies that patients receive in their homes under a plan of care established by a provider.	Many but not all home health agencies are designated Medicare-certified by CMS.	Public health typically has fewer interactions with home health agencies than other healthcare settings. When public health does interact, it will typically be with a clinical manager.
Hospice	**NQF:** Palliative services provided to terminally ill patients and their families/ caregivers in the patient's place of residence or in an inpatient facility. **CMS:** An organization that is primarily engaged in caring for people who are terminally ill. Hospice care involves a team-oriented approach that addresses the medical, physical, social, emotional, and spiritual needs of the patient.	Many but not all hospice practices are designated Medicare-certified by CMS.	Public health typically has fewer interactions with hospice than other healthcare settings. When public health does interact, it is typically with a clinical or facility manager.

Table 2.1 | Selected Healthcare Settings Where Public Health May Conduct HAI/AR Outbreak Response Activities: Definitions, Characteristics, and Key Staff

SETTING	NATIONAL QUALITY FORUM (NQF) AND CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS) DEFINITIONS [6,7,8]	ADDITIONAL CHARACTERISTICS	KEY STAFF CONTACTS
Acute Care Hospitals (ACHs)	**NQF:** Setting in which healthcare services (including but not limited to diagnostic, therapeutic, medical, surgical, obstetric, and nursing) are provided by or under the supervision of physicians to patients admitted for a variety of health conditions.	A variety of hospital types including specialty hospitals (e.g., cancer hospitals, orthopedic hospitals, and pediatric hospitals, academic hospitals, community hospitals). Two hospital types are specifically described in this table: critical access hospitals and long-term acute care hospitals.	Typically, public health initially interacts with an infection preventionist or healthcare epidemiologist. Other staff may include quality and risk management, clinical staff (e.g., nurses, physicians, pharmacists, or therapists), executive administrative staff (e.g., chief medical or nursing officer), laboratory staff, administrative staff (e.g., medical records staff), facilities management (e.g., environmental services), and other specialty staff depending on the type of outbreak.
Inpatient Rehabilitation Facilities (IRFs)	**CMS:** A hospital or part of a hospital that provides an intensive rehabilitation program to inpatients.		Public health often interacts with the infection preventionist initially but may also interact with other staff members, similar to acute care hospitals.
Long-Term Acute Care Hospitals (LTACHs)	**CMS:** Acute care hospitals that provide treatment for patients who stay, on average, more than 25 days. Most patients are transferred from an intensive or a critical care unit. Services provided include comprehensive rehabilitation, respiratory therapy, head trauma treatment, and pain management.		Public health often interacts with the infection preventionist initially but may also interact with other staff members, similar to other acute care hospitals.

Table 2.1 | Selected Healthcare Settings Where Public Health May Conduct HAI/AR Outbreak Response Activities: Definitions, Characteristics, and Key Staff

SETTING	NATIONAL QUALITY FORUM (NQF) AND CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS) DEFINITIONS [6,7,8]	ADDITIONAL CHARACTERISTICS	KEY STAFF CONTACTS
Nursing Homes (NHs)/ Skilled Nursing Facilities (SNFs)	**NQF:** Setting in which healthcare services are provided under medical supervision and continuous nursing care for patients who do not require the degree of care and treatment that a hospital provides and who, because of their physical or mental condition, require continuous nursing care and services above the level of room and board. **CMS:** A nursing facility with the staff and equipment to provide skilled nursing care and, in most cases, skilled rehabilitative services and other related health services.	Although there are technical differences between the terms "nursing home" and "skilled nursing facility," these terms are sometimes used interchangeably. Some skilled nursing facilities can provide additional highly specialized skilled care, such as ventilator or central line care. Skilled nursing facilities that provide ventilator care are sometimes referred to as vSNFs.	Public health typically interacts with the infection preventionist or a staff member who fulfills some duties of an infection preventionist. Public health may also interact with nursing home facilities management (e.g., environmental services), administrators, nursing managers, and other specialty staff, depending on the type of outbreak.
Residential Care Facilities	Not applicable. While some healthcare services may be delivered on-site, residential care facilities are typically licensed under a social services model.	Residential care is an umbrella term that encompasses board and care homes, assisted living facilities (ALFs), and continuing care retirement communities. Medical care delivery in ALFs is highly variable and entails models that include on-site staffing, home health agencies, and individual resident arrangements with community-based clinics and providers. Group homes are another example in the residential care spectrum, where persons, many with chronic medical needs, live in a congregate setting.	Depends on facility type, but public health typically interacts with the facility manager.

Table 2.1 | Selected Healthcare Settings Where Public Health May Conduct HAI/AR Outbreak Response Activities: Definitions, Characteristics, and Key Staff

SETTING	NATIONAL QUALITY FORUM (NQF) AND CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS) DEFINITIONS [6,7,8]	ADDITIONAL CHARACTERISTICS	KEY STAFF CONTACTS
Outpatient Clinics		Outpatient clinics (such as a medical practice) are not typically licensed as a facility. A rural health clinic is a type of outpatient clinic that is licensed through CMS and/or state regulatory bodies.	Often public health interacts with an office manager or clinical staff.
Dental Settings		Dental settings encompass outpatient locations where oral and dental care is provided. Typically, dental settings are not licensed, but the providers are licensed through the appropriate state agency.	Public health most often interacts with an office manager or clinical staff.

2.1.2 Healthcare Delivery

Healthcare delivery has changed dramatically in recent decades. Hospital stays have decreased,[9] and healthcare is moving more toward outpatient settings. Between 2000 and 2016, the number of traditional institutional providers, such as hospitals and skilled nursing facilities, decreased or remained flat despite a growing and aging US population. Meanwhile, there was substantial growth and increased specialization among outpatient providers and certain forms of residential care such as assisted living facilities.[10]

Many types of surgeries have shifted from inpatient settings to ambulatory surgery centers, hospital outpatient departments, or office-based surgical practices.[11] Also, as healthcare improves and people needing critical care live longer, the number of long-term acute care facilities and skilled nursing facilities specifically offering ventilator care services has grown. Additionally, cost and access issues have led some patients to seek care outside the US (e.g., medical tourism); care provided in these settings may result in exposures to pathogens not commonly found in patients' local communities.[12]

The changing healthcare delivery landscape requires public health agencies to be nimble when responding to outbreaks; each healthcare setting has unique characteristics, and its patient population carries unique risks that can result in a wide variety of outbreaks. Infection prevention needs for healthcare settings have similarly changed over time, and infection prevention resources available for healthcare facilities can vary widely.[13,14]

2.1.3 Regulation and Oversight

With growth and changes in healthcare delivery, regulations related to the prevention of healthcare-related infections have also expanded. Federal agencies, such as the Centers for Medicare and Medicaid Services (CMS), Food and Drug Administration (FDA), and Occupational Safety and Health Administration (OSHA), play significant roles from a regulatory point of view. Other agencies, such as the Centers for Disease Control and Prevention (CDC), generate recommendations and standards that heavily influence healthcare regulation. Of note, core infection control practices are established by CDC's Healthcare Infection Control Practices Advisory Committee (HICPAC) and can be found on the following web page: https://www.cdc.gov/infection-control/hcp/core-practices/index.html.

State-level agencies license many types of healthcare facilities and take an active role in enforcement. Accrediting organizations provide participating healthcare facilities with a structure for achieving regulatory requirements and other quality standards. Although regulations and requirements for infection prevention are established for some healthcare settings, not all settings have clear requirements or active oversight. Likewise, some facilities that are generally subject to federal and state regulations may lack clear standards governing the organization or staffing of their infection prevention and control programs, and some facilities with clear standards may still be working toward meeting newly established requirements (e.g., CMS implemented requirements for infection prevention and antibiotic stewardship in nursing homes in November 2016 with a rolling 3-year set of requirements[15]). Regulations affecting infection prevention, HAIs, antimicrobial resistance, and antimicrobial stewardship can be found on the following web page: https://apic.org/policy-priorities/regulations/.

Increasing calls for transparency and expansion of reporting requirements and regulatory oversight have resulted in additional resources being directed toward HAI detection and prevention in healthcare facilities and public health agencies. For example, HAI rates by specific hospital and nursing home are now publicly available and can be found on the following web pages: https://www.medicare.gov/hospitalcompare/ and https://www.medicare.gov/nursinghomecompare/, respectively.

2.2 Trends in Surveillance

2.2.1 Overview

In 1963, Alexander Langmuir defined disease surveillance as "the continued watchfulness over the distribution and trends of incidence through the systematic collection, consolidation and evaluation of morbidity and mortality reports and other relevant data"; dissemination of data should involve "all who need to know".[16]

The World Health Organization (WHO) definition of public health surveillance is "the continuous and systematic collection, orderly consolidation and evaluation of pertinent data with prompt dissemination of results to those who need to know, particularly those who are in a position to take action."[17]

Public health agencies, healthcare facilities, and many other partner organizations conduct disease surveillance for the purposes described by Langmuir and the WHO. Here we describe trends in HAI/AR surveillance for public health agencies and healthcare settings that have influenced outbreak detection and response.

2.2.1.1 Public Health Surveillance, Healthcare-Associated Infections, and Antimicrobial Resistance Program Development

Widespread public health surveillance of HAIs and healthcare-associated pathogens, including AR organisms, is a relatively new endeavor. Historically, healthcare facilities performed their own surveillance and responded to outbreaks within their walls. In recent years, public health has taken a greater interest in the surveillance of infections that occur within healthcare settings. Technologic advancements in medical care have introduced new types of infection-related healthcare risks.

Dramatic improvements in HAI/AR surveillance and outbreak response have been made within the last decade, including increased health experience and expertise.[18] In addition, state public health reporting laws

have expanded to include additional HAI/AR reportable conditions over the last decade.

Support for state and local public health HAI and AR pathogen activities grew substantially beginning in 2009. Funds from the American Recovery and Reinvestment Act were used to establish HAI programs as part of CDC's Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infections Diseases Cooperative Agreement (ELC). This initial funding, which also established HAI surveillance activities as part of CDC's Emerging Infections Program (EIP), resulted in a foundation for health departments to support and coordinate efforts with healthcare partners, engage in HAI prevention efforts, and expand HAI surveillance (as described in the following section).

Greater levels of funding for HAI/AR program activities have been added to ELC in recent years. For example, approximately $85 million for healthcare Infection Control Assessment and Response (ICAR) was added as part of the Domestic Ebola Supplement in 2015[18] and further investments were made because of the AR Solutions Initiative beginning in 2016. During the SARS-CoV-2 pandemic, HAI/AR programs received several substantial funding supplements, further enhancing their capacities for surveillance, prevention, and outbreak response.

2.2.1.1.1 Reportable and Notifiable Diseases and Conditions

State, territorial, tribal, and local public health agencies establish lists of diseases and conditions for public health surveillance that are reportable by healthcare providers, healthcare facilities, and/or laboratories, including HAI and AR pathogens. Reporting is mandatory, involves use of personal identifiers, and enables states to identify cases in which immediate disease control and prevention are needed.

Each state has its own laws and regulations defining what diseases and conditions are reportable. Reporting criteria include how to report, to whom to report, and the time frame within which reporting should occur. Reports may be pathogen-specific or based on infection type or other criteria. Most public health agencies also include a broad requirement for reporting suspected outbreaks (which covers all pathogens and is not limited to those pathogens already required to be reported as individual cases).

Reporting to public health agencies ideally takes place via a web-based reporting system and/or automatic generation from electronic medical records or laboratory information systems. Systems that rely on phone calls, mail, or fax are still used in some circumstances (e.g., a phone call may be required for urgently reporting a condition in redundancy with web-based or electronic reporting) but can be slower and more labor-intensive. Isolates or clinical material are often required to be submitted in conjunction with the report; required samples are sent to public health laboratories for storage and/or additional testing.

Lists of reportable diseases and conditions vary among states and over time; public health agencies typically evaluate these lists periodically for needed changes to be responsive to emerging pathogens and shifting priorities. Note that reporting requirements by state can be found on the following web page: www.cste.org/group/SRCAQueryRes.

Public health agencies share de-identified data with CDC based on the nationally notifiable disease list found on the following web page: https://ndc.services.cdc.gov/. Data are reported voluntarily via CDC's National Notifiable Diseases Surveillance System (NNDSS). Lists of notifiable diseases vary among states and over time. The list of national notifiable diseases is reviewed and modified annually by the Council of State and Territorial Epidemiologists (CSTE) and CDC. Every national notifiable disease is not necessarily reportable in every state. In addition, not every state's designated reportable disease or condition is nationally notifiable. While NNDSS has limited utility for healthcare outbreak detection, it generally supports monitoring of trends and developing public health policies and prevention strategies for select conditions and diseases.

Most HAI conditions and some pathogen-specific data are reported separately from the NNDSS into a long-standing CDC-developed surveillance system, the National Healthcare Safety Network (NHSN). Reporting requirements and definitions for the NHSN have been

established by CMS and CDC, respectively. Additional state requirements vary among states; some states require reporting and others do not. Definitions for reportable conditions may differ from those of the NHSN. See section 2.2.2.2 for more information regarding NHSN.

2.2.1.2 Surveillance within Healthcare Facilities

Many healthcare facilities perform their own facility-specific surveillance in addition to performing surveillance activities to meet reporting requirements (e.g., CMS requirements for NHSN reporting[19]). How surveillance is performed within a facility varies widely. In hospitals this is typically performed by infection preventionists or infection prevention teams, whereas in other types of facilities surveillance may be performed by healthcare personnel with multiple duties.

In recent years, many healthcare facilities have moved toward using data mining within electronic health records to identify conditions of interest to infection prevention. Modules within electronic health record systems designed to monitor possible infections are available; these can show useful aggregate information on dashboards, save time, and assist with flagging infections for staff to review. However, these systems are not always feasible for all healthcare systems and facility types, and in some situations manual reviews may be more effective or necessary. Some healthcare facilities rely heavily on notification of outbreaks by clinicians.

Public health agencies should be aware of surveillance systems used within healthcare facilities in their jurisdiction, including barriers that facilities may experience in implementing surveillance systems as well as the systems' various limitations. As public health surveillance has improved, the burden on healthcare facilities for reporting to public health has increased. It is critical that infection prevention programs have adequate resources to complete necessary infection prevention tasks, including surveillance, outbreak detection and response, and active prevention of infections.

2.2.2 Public Health Systems

Public health surveillance systems rely on surveillance case definitions to identify cases systematically and consistently. Surveillance case definitions may differ from case definitions developed during an outbreak, which can be more specific for the purposes of counting outbreak cases. (Outbreak case definitions are described in Chapter 5.) A surveillance case definition is a set of uniform criteria used to define a disease for public health surveillance; it enables public health officials to classify and count cases consistently across reporting jurisdictions. Surveillance case definitions are not intended to be used by healthcare providers for making a clinical diagnosis or determining how to meet an individual patient's health needs.[20]

Reporting of conditions associated with healthcare settings can be population-based or facility-based. Reporting of HAIs is usually facility-based; reporting of AR pathogens may be population- or facility-based. Other surveillance systems not described here may be used in limited jurisdictions. Employees involved with HAI/AR programs should understand the capabilities and limitations of surveillance systems used within their agency and explore ways to partner or capitalize on opportunities to use other surveillance and monitoring systems.

2.2.2.1 Population-Based Surveillance

Population-based surveillance involves identifying cases that meet a specific surveillance definition within a defined population. Typically, in public health the population under surveillance is the population of residents of a certain jurisdiction such as a state or county. Often in public health HAI/AR programs, population-based surveillance is often laboratory-based (e.g., presence of carbapenem-resistant Enterobacterales [CRE] or *Clostridioides difficile*). Reporting of these conditions within a population is typically performed by clinical laboratories when the pathogen of interest is identified during testing of clinical specimens, either by submitting each individual case or lists of cases, often via electronic laboratory reporting. In some jurisdictions, providers and healthcare facilities may also report cases.

Routine public health surveillance of HAI/AR conditions is relatively new. With respect to foodborne surveillance, AR surveillance has been in place since 1996, following the establishment of the National Antimicrobial Resistance Monitoring System for Enteric Bacteria (NARMS), which

tracks changes in the antimicrobial susceptibility of selected enteric bacteria found in ill people (CDC), retail meats (FDA), and food animals (US Department of Agriculture [USDA]) in the US.[21] Tracking of healthcare-related AR pathogens was established much more recently.

Pathogen-specific surveillance may be performed as facility-specific surveillance (i.e., reported only by specific healthcare facility types, as described in the next section) or at a population level. Increasing the capacity of public health laboratories to receive isolates and clinical material, and to perform additional specialized testing (e.g., polymerase chain reaction [PCR] to identify mechanisms of resistance or whole genome sequencing) has allowed public health agencies to focus surveillance and prevention efforts on specific subsets of AR organisms such as carbapenemase-producing (CP)-CRE.

In 2016, CDC established the Antibiotic Resistance Laboratory Network (AR Lab Network), which includes laboratories in 50 states, four cities, and Puerto Rico, including seven regional labs and the National Tuberculosis Molecular Surveillance Center. The AR Lab Network is integrated with ELC-supported HAI/AR Program activities and supports a nationwide lab capacity to rapidly detect antimicrobial resistance.[22]

With increases in funding, as described above, state and local public health agencies have drastically increased their capacities to perform pathogen-specific surveillance of AR pathogens and other organisms associated with healthcare, such as carbapenem-resistant organisms (CRE, carbapenem-resistant *Pseudomonas aeruginosa* [CRPA], and *Acinetobacter baumannii* [CRAB]), methicillin-resistant *Staphylococcus aureus* (MRSA), *Candida auris*, and *Clostridioides difficile*.

Surveillance of other organisms that are of interest to HAI/AR programs but do not fall into the category of AR organisms are often tracked using population-based surveillance practices (e.g., using NNDSS). Such organisms may include nontuberculous mycobacteria (NTM), *Legionella* spp., hepatitis B and C viruses, and group A *Streptococcus*. These organisms often lie within the purview of HAI/AR programs when they intersect with healthcare (i.e., manifest as HAIs). As a result, HAI/AR programs may coordinate with other public health communicable disease programs for surveillance and outbreak response within healthcare facilities. Note that these surveillance activities may identify cases or outbreaks in need of investigation in settings other than healthcare, such as nail salons, tattoo parlors, and other community sites.

2.2.2.2 Healthcare Facility–Based Surveillance

For some conditions, surveillance occurs at the healthcare facility level rather than the population level. HAIs are typically reported using healthcare facility–based surveillance practices, which means that individual healthcare facilities will report conditions specific to their facility. Pathogens may be reported using healthcare facility–based surveillance or population-based surveillance, as described above. The system most often used for reporting healthcare facility–based surveillance is the CDC-developed NHSN.

In 1970, CDC launched the National Nosocomial Infections Surveillance System (NNIS), a collaborative surveillance system connecting CDC and hospitals that voluntarily reported “nosocomial” infections (now termed HAIs) into the system.[23] In 2005, NHSN was established, combining NNIS with the Dialysis Surveillance Network and the National Surveillance System for Healthcare Workers (NaSH).[24] NHSN facilities report HAI surveillance data for aggregation into a single national database.

NHSN now encompasses data from tens of thousands of medical facilities including acute care hospitals, long-term acute care hospitals, outpatient dialysis centers, ambulatory surgery centers, and nursing homes. Infections can be risk-stratified based on facility type, including specific hospital types such as pediatric, cancer, teaching, or others. Facilities report HAIs based on state mandates, CMS requirements, or voluntarily, and usually use NHSN for reporting; 34 states and the District of Columbia, as well as CMS, mandate reporting to NHSN.[19,25] See Box 2.1 for conditions that can be reported to NHSN.

Some jurisdictions may choose to implement both healthcare facility–based and population-based surveillance for some conditions; for example, acute care hospitals

may be required to report CRE via NHSN and clinical laboratories may report all cases of CRE throughout a jurisdiction on a population level. Population-based surveillance will capture all cases; facility-based surveillance will capture only cases within that facility type and will miss community cases. However, the benefit of facility-based surveillance is that analyses can focus on a particular facility type or a specific facility, allowing for the development of more directed infection prevention efforts. Both surveillance methods have their advantages, and use of both methods can provide a clearer picture of the HAIs and pathogens associated with healthcare within a jurisdiction and facility.

State and local health departments can access NHSN data based on local authority for regional, state, and local surveillance purposes, including identifying facilities in need of prevention assistance. Information on NHSN can be found on the following web page: https://www.cdc.gov/nhsn/.

NHSN data are used for national-, state-, and local-level analyses, as well as for targeted prevention initiatives by healthcare facilities, states, regions, quality groups, and national public health agencies.[26,27] Nationally, CDC has used NHSN-reported HAIs to develop the AR dataset of the Patient Safety Atlas, which allows the user to quickly customize maps and tables by filtering datasets to show AR data by geographic area, facility type, phenotype, HAI type, and time period.[28] Position statements from CSTE established *C. auris* and carbapenemase-producing carbapenem-resistant Enterobacterales (CP-CR: *Escherichia coli*, *Klebsiella* spp., and *Enterobacter* spp.) as nationally notifiable conditions in 2017 and 2018, respectively; CSTE position statements can be found on the following web page: https://www.cste.org/page/PositionStatements.

Box 2.1 | Reporting to the National Healthcare Safety Network (NHSN): Conditions and Healthcare Settings

Examples of conditions that can be reported to NHSN

Healthcare-associated infections
- Central line–associated bloodstream infections
- Surgical site infections
- Catheter-associated urinary tract infections
- Ventilator-associated events
- Dialysis events (e.g., bloodstream infection, antibiotic starts)

Pathogens
- *Clostridioides difficile*
- Carbapenem-resistant Enterobacterales
- Methicillin-resistant *Staphylococcus aureus* (bloodstream infections)
- SARS-CoV-2

Antimicrobial use and resistance

Blood safety errors

Healthcare process measures
- Healthcare personnel influenza vaccine status

Infection control adherence rate

Healthcare settings that can submit reports to NHSN

Acute care hospitals

Critical access hospitals

Inpatient rehabilitation facilities

Long-term acute care hospitals

Nursing homes

Outpatient dialysis facilities

Ambulatory surgery centers

Inpatient psychiatric facilities

2.2.2.3 Other Surveillance Systems and Forms of Surveillance

Although the two main types of surveillance systems for HAI and healthcare-associated pathogen reporting are population-based and healthcare facility–based, there are other systems that can support monitoring and outbreak detection. Each system or form of surveillance has advantages and limitations, may be employed in some jurisdictions but not others, and is not a replacement for population-based and healthcare facility–based surveillance systems.

2.2.2.3.1 Emerging Infections Program: Healthcare-Associated Infections Community Interface

The Healthcare-Associated Infections Community Interface (HAIC) component of CDC's Emerging Infections Program (EIP) engages a network of 10 state health departments and their academic medical center partners to help answer critical questions about emerging HAI threats, advanced infection tracking methods, and antibiotic resistance in the US. Data gathered through the HAIC play a key role in better understanding the epidemiology of targeted HAIs and pathogens.

HAIC differs from NHSN in that it tracks infections both inside and outside healthcare settings; typically, case ascertainment utilizes data from a variety of laboratories serving the population within surveillance catchment areas. Activities include surveillance of invasive *Staphylococcus aureus* infections, AR Gram-negative organisms (Multi-Site Gram-Negative Surveillance Initiative [MuGSI]), *Candida* bloodstream infections, and *C. difficile*, as well as HAI and antibiotic use prevalence surveys across healthcare settings. For more information on HAIC activities within the EIP, please visit the following web page: www.cdc.gov/hai/eip/index.html.

2.2.2.3.2 Antibiotic Resistance Laboratory Network (AR Lab Network)

As described previously, lab capacity in both clinical and public health laboratories is critical for the detection of AR organisms. The AR Lab Network includes public health laboratories in all 50 states, several cities, and Puerto Rico, as well as seven more comprehensive regional laboratories and the National Tuberculosis Molecular Surveillance Center.

This network infrastructure provides the capacity to detect emerging AR threats, respond at state and local levels to slow transmission, and increase understanding of AR trends and emerging threats.[21] Regional laboratories provide additional testing when state or local laboratories have limited capacity. At the time of this writing, this includes advanced testing for *Acinetobacter, Candida, C. difficile,* CRE, colistin resistance among extended-spectrum beta-lactamase (ESBL)–producing organisms, *Mycobacterium tuberculosis, Neisseria gonorrhoeae, Aspergillus fumigatus,* and *Streptococcus pneumoniae.*

The AR Lab Network assists each local jurisdiction with AR surveillance, and the network functions as a surveillance entity with the ability to provide information on several important pathogens. Regional laboratories that detect organisms and mechanisms of public health interest alert laboratories and epidemiologists who can implement public health actions to address transmission. More information on the AR Lab Network can be found on the following web page: https://www.cdc.gov/drugresistance/solutions-initiative/ar-lab-network.html.

2.2.2.3.3 Sentinel Surveillance

Sentinel surveillance is a form of surveillance that occurs among a group of healthcare facilities or settings (or other reporting entities) that have been selected to report cases of a specific disease. This contrasts with population-based surveillance, in which data are collected across an entire population. In sentinel surveillance, reporting occurs from only a carefully selected group of healthcare facilities. It is typically used when population-based surveillance is not feasible or practical.

Healthcare facilities selected for this purpose should have a high probability of encountering cases of the disease under surveillance as well as the clinical expertise and laboratory capability needed to detect the disease. Data collected can be used to monitor trends and disease burden, and, if the facilities selected are most likely to encounter the disease, can also be used to detect emerging diseases. Emerging diseases can be missed if they occur outside the sentinel system.[29] Sentinel surveillance has been used for AR pathogens in limited circumstances, such as AR pneumococcal disease,[30] and has the potential to be applied in other situations as well.

2.2.2.3.4 Syndromic Surveillance

Syndromic surveillance is a form of surveillance that was developed in the context of a need for early detection of a large-scale release of a biologic agent. It has also found application in situations of seasonal respiratory illnesses such as influenza. Increasingly, syndromic surveillance has been used for a variety of other surveillance activities—often short-term event–based surveillance, although it is also used for sustained surveillance activities.[31]

Syndromic surveillance definitions rely on a constellation of symptoms (hence the modifier "syndromic") for reporting. For this reason, syndromic surveillance is often a sensitive but not specific surveillance system. Since HAI/AR surveillance relies heavily on a laboratory component, syndromic surveillance is not often used in HAI or AR pathogen surveillance. Jurisdictions that perform syndromic surveillance can consider how such systems may complement or enhance their standard approaches to healthcare-related outbreak detection.

2.2.2.3.5 Regulatory Monitoring Systems

Public health communicable disease staff should consider collaborating with regulatory partners to understand their unique surveillance systems and reporting requirements. Regulatory partners, including state licensing agencies and CMS and FDA at the federal level, typically have systems in place to receive reports of adverse events; information gathered through these systems can help identify risks for communicable diseases in healthcare settings. For example, agencies and professional boards that receive reports of drug diversion events record these events in systems that ideally could be used by public health communicable disease staff to identify situations needing investigation to assess patient infection risks. Starting in 2014, CMS issued expanded guidance requiring accrediting organizations and state survey agencies to report serious infection control breaches to state health departments.[32] In addition, FDA monitors medical product safety, operating a variety of post-marketing surveillance and adverse event reporting programs, many of which help support outbreak detection and response (as described in subsequent chapters).

2.2.2.3.6 Administrative Databases

Some jurisdictions have access to administrative databases, such as hospital discharge databases, which can be used for surveillance purposes including case finding. These types of databases may be used to supplement other surveillance systems, such as comparisons with population-based or facility-based systems, to ensure complete case finding.

2.2.3 Impact of Advances in Laboratory Methods on HAI/AR Surveillance

The progress of microbiological and molecular testing technology over recent decades has dramatically impacted HAI/AR surveillance. Advances in testing have led to increased detection of specific organisms of interest to public health as well as to implementation by healthcare facilities of specific infection control measures to prevent transmission. Over the years, the expansion and refinement of DNA-based molecular techniques such as pulsed-field gel electrophoresis (PFGE), PCR typing, and multilocus sequence typing (MLST) have been applied to the surveillance of healthcare-associated pathogens, enhancing the detection of cases as well as the detection and investigation of outbreaks.

The use of nucleic acid amplification testing (NAAT) to identify resistance mechanisms and resistant organisms has impacted public health activities. Surveillance of carbapenem-resistant organisms relies on the detection of carbapenemases to identify cases of the highest public health import; with the advent of the AR Lab Network, the capacity to detect CP-CRE has expanded. In some jurisdictions, carbapenemase-producing organisms that rely on advanced laboratory testing for detection may be the only reportable carbapenem-resistant organisms.

Screening of patients for AR organisms as part of antibiotic resistance prevention efforts also relies on NAAT. Whole genome sequencing and related technological advances (referred to collectively as next generation sequencing [NGS]) can detect differences between organisms down to a single nucleotide. The application of NGS to timely surveillance data can identify related organisms and outbreaks and, when coupled

with epidemiologic data, pinpoint the spread of specific strains through healthcare and community settings. See Chapter 6 for more details.

Another area of laboratory advancement is the increasing use of culture-independent diagnostic testing (CIDT) in healthcare settings, often as part of a panel of tests. CIDT is performed directly on clinical material, leading to rapid and sensitive identification of organisms and mechanisms without generating an isolate. However, positive CIDT results (e.g., those for *Klebsiella pneumoniae* carbapenemase [KPC], MRSA, vancomycin-resistant *Enterococcus* [VRE], or *C. difficile*) may compromise efforts to perform additional identification, characterization, and typing for case linkage.

CDC laboratory protocols for the detection of antimicrobial-resistant and healthcare-associated pathogens can be found on the following web page: https://www.cdc.gov/hai/settings/lab/lab_settings.html.

2.2.4 Quality and Usefulness of Surveillance Data

2.2.4.1 Uses of Surveillance Data

HAI surveillance data help identify prevention priorities, including specific facilities that may need additional support to prevent infections, guide resource allocation, and be used to evaluate the effectiveness of prevention efforts over time. Surveillance data can be used to examine long-term patterns and trends for HAIs and AR organisms as well as to identify sudden changes in disease occurrence that may signal an outbreak that needs investigation. Public health and healthcare partners can act on surveillance data to rapidly respond to individual cases of high-consequence organisms, leading to immediate infection prevention interventions to prevent transmission. When additional epidemiologic information is collected on cases, data can be used to characterize groups at greatest risk for a disease, thus informing prevention efforts.

2.2.4.2 Completeness and Quality of Data

Although national, state, territorial, and local capacities for detection and surveillance of HAIs and AR organisms have improved throughout the past decades, surveillance of every case is incomplete for a variety of reasons, including the following:

- Case definitions may not be 100% sensitive.
- Case definitions may not be applied uniformly or interpreted correctly.
- HAIs may not be identified post-discharge.
- HAIs identified post-discharge (regardless of whether they are identified by another facility or in the community) may not be reported.
- Patients and community residents may be colonized with an organism that is not detected, and therefore they are not recognized as case-patients.
- Not all types of pathogens can be diagnosed with routine laboratory testing.
- Laboratories and health-care providers may fail to report to a public health agency.

The scope of possible underreporting for population-based healthcare-associated pathogens is often unknown. Since the syndromes as well as the signs and symptoms of infections can be quite varied, even for a specific pathogen, and because asymptomatic colonization is often included in pathogen-based surveillance, it is challenging to determine what proportion of cases are missed. It can be helpful to validate complete reporting by conducting laboratory audits or requesting line lists of all cases periodically to compare with reported cases. Electronic laboratory reporting can also be used to help assess data quality and completeness.

HAIs reported to NHSN are validated in some jurisdictions to enhance data completeness and quality. Validation usually includes systematic identification of facilities and medical records for review, comparison to other data sources when available, and review of facility processes for reporting. CDC provides guidance to public health departments embarking on validation efforts, which is provided on the following web page: https://www.cdc.gov/nhsn/validation/index.html. Healthcare facilities can also perform their own validation efforts, and CDC guidance for facilities can also be found on this web page. Despite the resources and expertise required, correcting errors identified during validation (in particular, underreporting) can be critical for establishing and maintaining accurate HAI reporting.[33,34]

2.3 Trends in Outbreak Detection and Response

Improvements in HAI/AR surveillance and the expansion of public health HAI/AR programs have increased the detection of and capacity to respond to healthcare-related outbreaks. For example, $85 million of increased funding to 55 state/local public health agencies, as part of domestic Ebola response activities in 2015, led to the expansion of state and local HAI/AR programs, including increased staffing for an outbreak response (96% of funded programs hired staff for this purpose), performance of on-site infection control assessments (83% of programs gained staff and expertise in this domain), development of investigative tools (78% of programs developed new tools), and increased outbreak-related laboratory capacity (91% of programs expanded the size of their laboratory space).[18]

As noted in section 2.2.3, healthcare outbreak detection and response have benefited from the increased capacity of public health and clinical laboratories to detect organisms of public health interest and provide laboratory testing which leverages advances in molecular testing methods. Healthcare outbreak detection and response have also benefitted from increased collaboration among public health, healthcare facilities, and partners, such as was necessary during the COVID-19 Public Health Emergency. As this field continues to evolve, collaboration between public health agencies and healthcare settings remains critical to the success of outbreak response.

Infection risks can vary widely across various healthcare facilities, reflecting the types of care the facilities deliver, differing patient characteristics, and pathogens most likely to be present in specific communities or settings. As described in section 2.1.1, healthcare settings range from acute care hospitals with broad variability among internal care locations (e.g., operating rooms, neonatal intensive care units, oncology wards, and burn units) to long-term care facilities as well as a diverse array of outpatient facilities covering everything from doctor's offices to ambulatory surgery centers.[10]

Outbreaks can be related to medical products, encompass multiple facilities and healthcare settings, span healthcare and community settings, or result from drug diversion and other unique circumstances. A vast number of infectious agents have been implicated in HAI transmission scenarios; these include a constantly evolving list of bacteria, fungi, viruses, parasites, and prions. HAI outbreaks can be caused by pathogens that are common throughout the community or by pathogens that are rarely observed outside healthcare environments and specific patient populations.[4]

Health department tracking of healthcare outbreak response activities is relatively new and still evolving. One recent assessment found that ELC-funded state and local health departments reported conducting 6,665 response activities in calendar year 2016, with the majority (78%) of activities involving long-term care facilities.[18] Much of this routine outbreak response pertained to the investigation and control of gastrointestinal and influenza-like illnesses in nursing homes. Superimposed on this baseline, we see a wide range of more complex and challenging healthcare outbreak response activities.[35-40]

2.3.1 Modes of Transmission

Classically, outbreaks have been characterized based on the mode of transmission and using terms such as "point-source" or "person-to-person." Often the pathogen identified provides a clue to the most likely method of transmission. For example, a group A *Streptococcus* outbreak is more likely to be person-to-person, whereas an unusual pathogen identified as part of a cluster of bloodstream infections across multiple units in a hospital is more likely to be point source.

In healthcare-related outbreaks, person-to-person is often the most common mode of transmission and can occur directly from one patient to another patient, from a patient to a healthcare worker and vice versa (often resulting in patient-to-patient spread), or from one person to another person via contamination of the environment or shared equipment. Poor adherence to hand hygiene and environmental cleaning contribute to person-to-person spread within healthcare facilities.

Examples of point-source outbreaks include those caused by contaminated medical equipment or medical products, including situations in which contamination occurs at the

point of manufacture, the point of distribution, or within the facility, and those caused by environmental point sources (such as *Legionella* contamination of a water feature).

The healthcare setting's physical environment is an important source for pathogen transmission that can result in infection or colonization among patients. The environment can be conducive to certain pathogen types (such as molds in water-damaged walls or ceilings), and human interactions with the environment can result in the transfer of pathogens between healthcare workers or patients and environmental surfaces.

In some cases, point-source and person-to-person transmissions can overlap—for example, when a healthcare worker with group A *Streptococcus* colonization spreads infection to patients during wound care or peripartum care or delivery. Likewise, a healthcare worker infected with a bloodborne pathogen (human immunodeficiency virus [HIV], hepatitis B, or hepatitis C) can spread the infection to patients when diverting medications (usually opioids) due to reuse or tampering with medications and injection equipment. A thorough epidemiologic investigation is needed to confirm a healthcare worker as a point source; this situation may need to be managed delicately, in close collaboration with the healthcare facility.

2.3.2 Outbreak Types Based on Etiology

Specific pathogen types, infection types, the involved body site, and relationships to procedures can all provide clues to investigators about possible modes of spread and sources of an outbreak. These clues can inform potential control measures that can be implemented even prior to completion of the investigation, as described in more detail in Chapter 5.

2.3.2.1 Outbreaks Based on Pathogen

Most HAI/AR outbreaks are identified based on a specific pathogen cluster. When an increase in a specific pathogen is identified, this can indicate the presence of an outbreak, and reporting and further investigation are usually warranted. One should suspect a possible outbreak when cases of a specific pathogen are clustered based on epidemiologic links between cases, such as when cases occur within the same medical unit, following the same procedure, or close in time.

When the pathogen is rare enough that it is unlikely to have caused multiple sporadic infections without a common source, an outbreak should also be considered. An outbreak may also be signaled by the presence of a single case when it involves a unique, unexpected pathogen. For example, in Colorado in 2012, investigation of a single case involving the first locally identified New Delhi metallo-beta-lactamase (NDM)–producing CRE revealed a much larger hospital outbreak.[41]

As laboratory techniques for assessing isolate relatedness have improved, outbreaks have been able to be identified based on specific pathogen characteristics, as illustrated in the previous paragraph. Whole genome sequencing has allowed for greater discrimination and more accuracy when confirming the relatedness of isolates of the same pathogen; this information can help confirm or refute the presence of an outbreak or determine if individual cases appear related to a larger outbreak. As NGS techniques become more available, they will likely play a larger role in the identification, investigation, and responses to outbreaks (See Chapter 6 for more details).

The regional and even global spread of specific pathogens forces public health and healthcare to consider outbreak responses not only on a local level but also on regional, national, and global scales. Understanding transmission of emerging pathogens provides context for local communities to determine outbreak investigation priorities. What is endemic in one region may be novel upon appearance in another region; public health agencies and healthcare facilities should understand their regional epidemiology as well as the wider epidemiology of emerging pathogens that could enter their region. For example, examination of clonal lineages of carbapenem-resistant *Klebsiella pneumoniae* in Europe identified four clonal lineages with high transmissibility within hospital environments and showed that spread among hospitals within a country was more frequent than between countries.[42] Likewise, understanding the global spread of *Candida auris* provided context for the emergence of *C. auris* within the US, which informed recommendations and guidance for *C. auris* among US jurisdictions.[43]

2.3.2.2 Outbreaks Based on Infection Type

Outbreaks identified based on the type of infection, such as bloodstream infections or surgical site infections, when the pathogen is unknown or multiple pathogens are involved, are less common than outbreaks identified based on a specific pathogen. Although both etiology and infection type are clues to the reason for an outbreak, in some cases both clues may not be available. Examples of this type include outbreaks of an unknown respiratory infection or an undiagnosed gastrointestinal illness.

An outbreak based on infection type should be considered when the overall rates of specific infection types are higher than expected or when infection occurs within a defined patient population known to be susceptible to certain types of infections, such as patients receiving dialysis or patients undergoing a specific procedure. An example of this type of outbreak was identified in dialysis patients from three hemodialysis facilities during 2015–2016, when increases in bloodstream infections due to *Serratia marcescens* and *Pseudomonas aeruginosa* were noted. The cause was recorded as pooling and regurgitation of waste fluid at recessed wall boxes that housed connections for dialysate components and effluent drains located at dialysis treatment stations, along with infection control practices that allowed healthcare workers' hands to become contaminated at the wall boxes.[44]

Another clue to identifying a mixed-pathogen outbreak can be the type of pathogen involved; in the example given, both pathogens frequently contaminate water and, therefore, investigation of possible water sources can help direct the course of the investigation.

2.3.2.3 Outbreaks Based on Other Etiologies

Noninfectious etiologies may also result in an outbreak within a healthcare setting and should be investigated with the same investigative steps described in the *CORHA Principles and Practices* for infectious disease outbreaks.

For example, toxic anterior segment syndrome (TASS) is an uncommon postoperative inflammatory reaction following eye surgeries involving the anterior segment, such as cataract extraction; the cause is a noninfectious substance that enters the anterior segment of the eye causing inflammation and damage to intraocular tissues. Investigations of TASS outbreaks have resulted in the identification of poor infection control practices and endotoxin contamination of shared products as possible causes of some outbreaks.[45,46]

Other examples of noninfectious outbreaks within healthcare settings include infant morbidity and mortality following intravenous administration of vitamin E,[47] aluminum toxicity following use of dialysis machines with electric pumps whose parts contain aluminum,[48] and carbon monoxide poisoning during surgery related to anesthesia circuits.[49]

2.3.3 Outbreak Types Based on Setting

The specific healthcare or non-healthcare setting of the outbreak has a substantial impact on the investigation and response. Some healthcare settings are more prone to certain types of outbreaks than others. Additionally, the need for public health assistance among healthcare facilities and other settings can vary. For example, dialysis facilities are more likely to have bloodstream infection–related outbreaks than gastrointestinal outbreaks, due to the nature of the healthcare provided. The changing landscape of healthcare discussed earlier in this chapter impacts the trends of types of outbreaks that occur. Understanding these different settings when investigating HAI/AR outbreaks is crucial to understanding likely risk factors and etiologies.[4] Examples of healthcare settings and types of outbreaks are shown in Table 2.2.

Table 2.2 | Outbreak Examples Based on Healthcare Setting or Procedure Type*

SETTING OR PROCEDURE	EXPOSURE OR RISK FACTOR	PATHOGENS OR CONDITIONS	INVESTIGATION AND RESPONSE CONSIDERATIONS
General	Infected or colonized persons (healthcare personnel, patients, or visitors); contaminated environmental surfaces	Organisms spread by contact (e.g., *Staphylococcus aureus*, AR Gram-negative bacteria, *Clostridioides difficile*, and group A Streptococcus)	AR prevention strategies as per CDC guidance†
	Serious, high-risk infection control breaches	Bloodborne pathogens (HIV, hepatitis B, and hepatitis C)	Consideration of patient notification, including possible bloodborne pathogen testing and prophylaxis
	Contaminated water sources (e.g., sinks, ice machines, whirlpool bathtubs, and hydrotherapy locations), aqueous medication preparation areas, or any device that generates mist	Hydrophilic organisms (*Legionella, Pseudomonas, Acinetobacter, Serratia, Stenotrophomonas,* and nontuberculous mycobacteria)	Epidemiologic investigation and infection control assessment focusing on water sources
General/ injections	Contamination of medications at the point of production (manufacture or compounding)	Environmental organisms (Gram-negative bacteria and fungi)	Syndromes often reflect the mechanism of transmission (e.g., infections at an injection site)
	Contamination of medications at the point of delivery (healthcare facility)	Gram-negative bacteria, Gram-positive bacteria, fungi, and bloodborne pathogens (HIV, hepatitis B, and hepatitis C)	Assessment of injection safety practices
	Diversion of medications (narcotics and related medications) by healthcare personnel	Bloodborne pathogens (HIV, hepatitis B, and hepatitis C), environmental bacteria	Assessment of medication handling practices; epidemiologic investigation focusing on healthcare personnel
General/point-of-care (POC) testing involving capillary blood sampling	Reuse of single-patient lancing devices or contaminated monitoring devices	Bloodborne pathogens (HIV, hepatitis B, and hepatitis C)	Assessment of infection control practices focusing on blood glucose monitoring or other POC testing
General/ surgical procedures	Contamination of surgical wounds from the following sources: healthcare workers, environment, or inadequately sterilized instruments	Varied, includes environmental pathogens (Gram-negative bacteria, fungi, and mycobacteria), colonized healthcare workers (*Staphylococcus aureus* or group A *Streptococcus*), and antimicrobial-resistant pathogens	Assessment of infection control practices related to surgical procedure, sterilization, and perioperative practices

Table 2.2 | Outbreak Examples Based on Healthcare Setting or Procedure Type*

SETTING OR PROCEDURE	EXPOSURE OR RISK FACTOR	PATHOGENS OR CONDITIONS	INVESTIGATION AND RESPONSE CONSIDERATIONS
General/ endoscopy	Endoscope reprocessing errors or device design problems that prevent adequate cleaning and disinfection	Gram-negative bacteria (particularly with duodenoscopes); upper- and lower-respiratory tract infections (e.g., bronchoscopes); and pseudo-outbreaks of nontuberculous mycobacteria	Infection control assessment focusing on endoscope use and reprocessing
Transplant units	Dust exposure or air-handling problems for severely immunocompromised patient populations (e.g., during building construction or renovation)	Fungi including *Aspergillus* and mucormycetes	Review of air handling systems and construction processes; typical scenario is invasive mold infections in a bone-marrow transplant unit
Hemodialysis clinics	Lapses in injection safety, maintenance of dialysis machines, or vascular access care	Bloodborne pathogens and bloodstream infections with varied bacterial or other pathogens	Review all dialysis infection control processes
Dental clinics	Biofilm formation in inadequately maintained dental unit waterlines; inadequate cleaning and sterilization of dental surgical instruments	Nontuberculous mycobacteria infections; bloodborne pathogens	Review of dental clinic infection control processes, water sources, and sterilization practices
Laboratory	Specimen collection, handling, or testing-related activities that may put laboratory workers at risk	Brucellosis, tularemia, coccidioidomycosis, and bloodborne pathogens (HIV, hepatitis B, and hepatitis C)	Evaluation of unintentional laboratory staff and other healthcare personnel exposures to bloodborne pathogens through needlesticks and splashes to mucous membranes; evaluation of specimen handling practices
Laboratory	Contamination of microbiological specimens during collection, handling, or culture	Pathogens vary	Pseudo-outbreaks resulting in inappropriate invasive diagnostic procedures, antibiotic prescriptions, or extended hospitalizations

*Adapted from Christensen BE, Fagan RP. Healthcare settings. In: Rasmussen SA, Goodman RA, eds. *The CDC Field Epidemiology Manual*.[4]

†See https://www.cdc.gov/healthcare-associated-infections/php/preventing-mdros/index.html

2.3.3.1 Single-Facility Outbreaks

Most healthcare outbreaks involve a single facility. This type of outbreak is easier to identify than a multifacility outbreak. Single-facility outbreaks may stem from infection control lapses that facilitate person-to-person transmission or contamination of shared equipment and supplies that function as point sources; environmental reservoirs can also play a role. In a review of outbreak investigations occurring in outpatient settings in Los Angeles County, it was found that 16 (57%) of 28 outbreaks were suspected to be due to lapses in infection control.[50] In an example of a point-source outbreak related to lapses in infection control, contamination of laundry with *Rhizopus microsporus* (a zygomycete) due to substandard washing, drying, and storage resulted in cases of pulmonary and cutaneous infections.[51]

2.3.3.2 Multifacility Outbreaks

Multifacility outbreaks can result from person-to-person transmission when patients are transferred between healthcare facilities or from a point source such as medical product contamination. Multifacility outbreaks can be challenging to identify unless there is timely and complete reporting to public health and recognition of the potential for patient sharing, common healthcare staff providing care across multiple facilities, or contamination of a medical product. This type of outbreak is typically identified when public health agencies receive similar outbreak reports from multiple facilities, when public health agencies identify an outbreak across facilities using surveillance or laboratory data, or when a healthcare facility performs its own outreach to other healthcare facilities.

2.3.3.2.1 Local Multifacility Outbreaks

Local multifacility outbreaks are more likely to be caused by person-to-person spread related to the transfer of patients between facilities within a jurisdiction. These types of outbreaks often result from the combination of infection control breaches and poor communication between transferring and receiving facilities. Less common scenarios may include local product contamination when a medical product is locally distributed, such as with a local compounding pharmacy; drug diversion by a healthcare worker who works at multiple facilities; or medical equipment contaminated locally and shared across multiple facilities.

2.3.3.2.2 Widespread Multifacility Outbreaks

In some situations, multifacility outbreaks can spread across multiple jurisdictions, states, or countries. This may occur when a pathogen is transmitted across multiple facilities, often related to patients being transferred between facilities that have poor infection control practices and no facility-to-facility communication; when an outbreak source moves across jurisdictions, such as the case of a healthcare worker infected with hepatitis C virus (HCV), who abused narcotic drugs intended for patients and transmitted HCV to patients across multiple healthcare facilities and states[52]; or when a contaminated medical product is distributed to facilities across a wide region.

As laboratory techniques, public health agency–healthcare facility relationships, and HAI/AR surveillance have improved over recent decades, the chance of finding an outbreak from product contamination has similarly improved. Reports of large-scale, high-profile outbreaks due to product contamination have increased in recent years, including outbreaks of fungal meningitis resulting in severe morbidity and mortality[53] and fungal endophthalmitis[54] leading to severe vision complications, both associated with widespread distribution of compounded medications, and an outbreak of invasive *Mycobacterium chimaera* associated with contaminated heater-cooler devices following cardiac surgeries.[55,56]

2.3.3.3 Healthcare Facilities as Sentinels for Community Outbreaks

A healthcare facility, such as an acute care hospital, may identify a suspected outbreak in which the source lies outside the facility. Broadly speaking, healthcare facilities can serve as sentinel sites for detecting outbreaks occurring in the larger community. For example, an emergency room or urgent care center may detect multiple cases of gastrointestinal illness associated with a community setting (e.g., at a school or restaurant) or an event. A healthcare facility may detect an outbreak in an assisted living residence or independent living center that has limited capacity to recognize an outbreak on its

own. A hospital may detect an outbreak associated with outpatient care, such as multiple infections following a procedure performed in a clinic setting. Healthcare facilities may also experience or be affected by outbreaks (e.g., hepatitis A or measles) that reflect unique circumstances in the communities they serve.

2.3.3.4 Outbreaks Related to Medical Tourism

The term "medical tourism" is commonly used to describe international travel for the purpose of receiving medical care.[12] Outbreaks related to medical tourism have been identified following reports from healthcare settings where patients have been evaluated and treated upon their return to the US. Detection of outbreaks related to medical tourism is challenging. This type of outbreak typically manifests with sporadic cases appearing across multiple states. Reporting such cases to CDC (email: medicaltourism@cdc.gov) can help facilitate outbreak recognition.[12]

An example of an outbreak associated with medical tourism involved Verona integron–encoded metallo-beta-lactamase (VIM)–producing carbapenem-resistant *Pseudomonas aeruginosa* infections; 11 cases of this infection were identified in medical tourists who traveled to a hospital in Mexico for bariatric surgery and subsequently presented for care in multiple facilities throughout the US.[57] Other examples include surgical site infections caused by nontuberculous mycobacteria in patients who underwent cosmetic surgery in the Dominican Republic and Q fever in patients who received fetal sheep cell injections in Germany.[12]

2.3.4 Investigation of Serious Infection Control Breaches

Conditions or practices that may lead to transmission of a pathogen are sometimes identified in the absence of identified infections. Following some types of infection control breaches, patients may develop an infection that could have long-term consequences but may not be immediately apparent. A prime example is the reuse of a syringe for multiple patients, which carries the risk for transmission of bloodborne pathogens with long incubations and symptoms that can be subtle, variable, or altogether absent.

Serious infection control breaches can be identified from internal audits and observations or from survey activities conducted by state survey agencies or accrediting organizations. CMS introduced a policy in 2014 that indicates that surveyors who identify serious infection control deficiencies should relay their concerns to public health agencies for evaluation, including considerations about the need for patient notification.[32] Investigations of infection control breaches should involve taking action to halt further exposures and correct deficient practices, as well as consideration of patient notification. See Supplement B for additional information.

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CHAPTER 3

Planning & Preparation

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CHAPTER 3

Planning & Preparation

Preface

Preparations made ahead of a healthcare-associated infection (HAI) or antimicrobial-resistant (AR) pathogen outbreak lay the groundwork for actions taken during the outbreak response. Activities that prepare public health agencies to respond to outbreaks involving healthcare delivery include developing the capacity to rapidly collect and analyze large amounts of information, take rapid action to stop transmission, and communicate effectively with stakeholders.

3.0 Introduction

Adequate preparation fosters a systematic approach to HAI/AR outbreak detection and response, accelerating the evaluation of the problem and minimizing the response time. In this chapter, we lay out the roles, resources, processes, and relationships that should be in place before an outbreak is detected. Although most activities discussed in this chapter are directed toward public health agencies, other groups can also use the information provided here as a guide to understand their roles and to inform their interactions with public health.

Prior to an outbreak, public health agencies should strive to 1) engage with entities that may become partners in an outbreak response; 2) understand the roles of these partners during an outbreak; 3) develop scalable and flexible plans for all aspects of healthcare outbreak response, including the potential for incorporating an incident command system (ICS) when needed; 4) establish processes for records management and data analysis; and 5) assemble resources and tools that can be quickly accessed and used during an outbreak response.

3.1 Agency Roles

3.1.1 Overview

Before an outbreak, public health agencies should have a clear understanding of their anticipated roles and responsibilities. Since states organize their governmental public health systems in diverse ways, the relative roles of local and state health departments will vary. In states where governance is centralized, responsibility for conducting outbreak investigations rests primarily with state health departments. Conversely, in jurisdictions where governance is decentralized (“home rule” states), this responsibility may rest primarily with the local health department.[1] Developing an understanding of individual agencies’ responsibilities and establishing strong working relationships is one of the most important preparation activities for any public health agency.

3.1.2 Local, State, and Federal Agencies

3.1.2.1 Local Public Health Agencies

Local public health agencies have extensive knowledge of local healthcare networks, providers, and facilities. As such, local public health agencies are well-positioned to actively engage partners across the continuum of care through activities such as routine surveillance of reportable conditions; bidirectional communication with healthcare organizations; hosting, attending, and presenting at meetings and educational events involving healthcare facilities and organizations; and including evaluation of the potential for HAI/AR outbreaks in annual risk assessments.

The capacities of local public health agencies vary considerably in accordance with the populations they serve—from small, rural communities to large, metropolitan areas. Local public health agencies, along with state public health agencies, have roles and responsibilities, which will be described later in this section. When resources are limited, local public health agencies should obtain support from their state public health agencies, as necessary. In some jurisdictions (for example, those with centralized governance structures), the state public health agency may already fulfill these roles.

Planning for outbreaks:

An understanding of endemic rates of disease can be helpful when planning an outbreak response. Public health agencies should establish methods for routine monitoring of baseline rates of HAIs, AR organisms, and other pathogens commonly associated with outbreaks. Local epidemiology varies across jurisdictions, and understanding local trends is necessary to determine when an outbreak may be occurring. Personnel who are responsible for performing surveillance should be trained to recognize scenarios indicating an outbreak. They should understand levels of urgency and know whom to contact when an outbreak is suspected. Local public health agencies should be aware of the local laboratory capacity and where to obtain advanced laboratory services, which may be needed to confirm outbreaks. Public health agencies should plan to engage in enhanced assessment and monitoring of infection prevention measures as part of an outbreak response.

Roles and Responsibilities:

The roles and responsibilities of local public health agencies include conducting surveillance, ensuring reporting of outbreaks by facilities within their jurisdiction, receiving and evaluating outbreak reports, providing recommendations to healthcare facilities to halt an outbreak, and notifying the public and media when warranted. Public health agencies detect HAIs, AR pathogens, and related conditions through surveillance and identify outbreaks via surveillance or receipt of outbreak reports.

Local public health agencies have a more granular view of the local population and may recognize characteristics, such as global travel patterns, that place some healthcare settings at increased risk for outbreaks. Local public health agencies may also recognize community transmission of pathogens that increase the opportunity for outbreaks within healthcare settings.

Local public health agencies should maintain a list of contacts at healthcare facilities and have a system to communicate health concerns, regularly disseminating information about local patterns of illnesses that may increase the opportunity for HAI/AR transmission in healthcare settings. Public health agencies also have the role of providing general advice to the public in their jurisdiction. Depending on resources, a local public health agency may also perform advanced laboratory testing.

Resources:

Resources of a local public health agency vary by agency but can include expertise in epidemiologic investigation, infection control, local healthcare provider outreach, and health education. The local public health agency also has a unique, in-depth knowledge of its local population, community, and healthcare facilities and organizations that is critical to leverage during an outbreak investigation and response. The local or state public health agency may serve as the coordinating agency during an outbreak investigation.

3.1.2.2 State Public Health Agencies

Compared to local public health agencies, state public health agencies generally hold a broader situational awareness of HAIs, AR pathogens, and other healthcare-

associated pathogens across their state. Often HAI and AR pathogen surveillance is mandated at the state level, which in turn provides information to local jurisdictions and other partners. Typically, much of this surveillance activity, as well as healthcare outbreak response and HAI/AR prevention, is coordinated or conducted under the auspices of the state health department's HAI/AR program.[2,3]

Most HAI/AR programs have multidisciplinary HAI advisory groups, which include members who furnish extensive healthcare expertise, provide input on state HAI/AR action plans, and offer consultative advice to the state HAI/AR program. State HAI/AR action plans typically include outbreak detection and response activities, reflecting findings from infection control assessments conducted at healthcare facilities and lessons learned from previous outbreak investigations.

State public health agencies strive to develop engaged partnerships with organizations that facilitate information sharing at the state and federal levels (including organizations listed later in this chapter) to support outbreak detection and response. State public health agencies may advise local public health agencies during a single jurisdictional outbreak or may take a coordinating role if the local public health agency does not have jurisdiction, lacks resources, or requests this type of assistance. Multifacility and multijurisdictional HAI/AR outbreaks are typically led by state public health agencies.

Planning for outbreaks:
State public health agencies monitor baseline rates of HAIs, AR pathogens, and other healthcare-associated pathogens to understand the baseline rates of transmission and local epidemiologic trends. Similar to employees at local public health agencies, personnel at state public health agencies who are responsible for performing surveillance should recognize scenarios that may indicate an outbreak. They should understand levels of urgency and know whom to contact when an outbreak is suspected. State public health agencies should plan for notification of other agencies, healthcare facilities, and the public.

The state public health agency, working with the state public health laboratory, the Centers for Disease Control and Prevention (CDC), and/or other partners, has the ability to coordinate advanced laboratory services (e.g., next generation sequencing to determine clonality of a cluster) during outbreaks of AR pathogens and when other specialized testing is needed; it is important to maintain knowledge of which labs are available to perform advanced testing and how to interact with those laboratories to obtain testing rapidly (see Chapter 6 for more information).

Roles and Responsibilities:
The roles and responsibilities of state public health agencies are similar to those of local public health agencies, including conducting surveillance, ensuring reporting of suspected outbreaks by facilities, receiving and evaluating outbreak reports, providing recommendations to healthcare facilities to halt an outbreak, notifying the public and media when warranted, and facilitating advanced laboratory testing.

State public health agencies also set policies for HAI and AR pathogen reporting, which facilitates detection of HAIs and AR pathogens through surveillance. State public health agencies may have a greater capacity than local public health agencies to detect clusters or outbreaks using surveillance data. State public agencies also hold a key role in providing health advisories and prevention messaging to the public throughout the state.

State public health agencies may assist local public health agencies with training as part of building preparedness for outbreaks. Responsibility for coordinating or leading the investigation of more complex (e.g., multifacility and multi-jurisdictional) outbreaks often lies with the state public health agency.

Resources:
State public health agencies have expertise in epidemiologic investigation, infection control, laboratory testing, and health education, as well as other more specialized expertise (e.g., clinical, pharmacy, and antimicrobial stewardship). State public health agencies often have more resources to respond to outbreaks than local public health agencies. Clear and frequent

communication between state and local public health agencies, as well as with the healthcare provider community and other partners, fosters an effective healthcare outbreak response.

3.1.2.3 State Agencies — Healthcare Facility Survey and Licensing

The role of the state survey agency includes overseeing state-level healthcare facility licensing requirements and Medicare certifications. To accomplish this, state survey agency personnel conduct surveys (inspections) of many types of healthcare facilities to assess adherence to the minimum health and safety standards established by the Centers for Medicare & Medicaid Services (CMS) as well as to any state-specific criteria. The state survey agency may become actively involved in an outbreak response (e.g., when regulatory assistance is deemed necessary to assure compliance with infection control requirements).

State public health agencies should possess knowledge of policies and procedures for bidirectional sharing of information with the state survey agency both routinely and during an outbreak. Beginning in 2014, CMS issued expanded guidance requiring accrediting organizations and state survey agencies to report serious infection control breaches to the relevant state health department.[3] Conversely, state public health agencies should establish thresholds for the notification of the state survey agency when outbreaks are being investigated. Involving regulatory partners in outbreak response training can help clarify roles and enhance legal preparedness during an outbreak, including identifying the conditions or criteria that warrant joint investigations by the state public health agency and state survey agency.

3.1.2.4 State Agencies — Provider Licensing

The role of professional licensing agencies (e.g., medical, nursing, dental, and pharmacy licensing boards) is to oversee licensing and credentialing of healthcare providers and other licensed professionals and to ensure that competency requirements are met. State professional licensing agencies may get involved in an outbreak response when regulatory assistance is needed for situations that involve licensed healthcare providers in healthcare settings that are not licensed or Medicare-certified at the facility level, such as a typical doctor's office or dental practice.[3] Likewise, licensing boards may receive or investigate complaints involving patient infections that could signal an outbreak, warranting attention from public health agencies.

State public health agencies should have processes in place that address bidirectional sharing of information with professional licensing agencies when needed, and thresholds and limitations for sharing this information should be established in advance. During outbreaks involving licensed healthcare providers, it can be helpful to involve professional licensing agencies if egregious practices are found or questions arise regarding a particular scope of practice, particularly when a healthcare facility is not operating as a state-licensed healthcare facility.

Involvement of the professional licensing agency can be as simple as providing information or it may rise to the level of a joint investigation. This situation is generally less common than those involving licensed healthcare facilities and, therefore, it is important for state public health agencies to have appropriate contact information and processes for contacting professional licensing boards, sharing information and conducting joint investigations when needed. As with state survey agencies, involving regulatory partners in outbreak response training can help clarify roles and enhance legal preparedness during an outbreak, including identifying conditions or criteria that may warrant joint investigations.

3.1.2.5 Federal Agencies — Centers for Disease Control and Prevention (CDC)

CDC works with public health agencies at state and local levels as well as with other federal agencies, such as the US Food and Drug Administration (FDA), to provide support during an outbreak response and to coordinate multistate outbreak investigations. CDC routinely provides consultation and laboratory assistance to healthcare facilities and health departments that are working to solve outbreaks or investigate infection control breaches and other adverse events. During some outbreak situations, CDC sends experts to work side-by-side with facility and state or local public health agency staff. For example,

state health departments may contact CDC and request assistance through a process known as an Epi-Aid.[4] Typically, these efforts include on-site assistance, laboratory support, and additional consultation with experts at CDC headquarters (see section 3.6.1 for more information).

Specific to HAI/AR surveillance, prevention, and outbreak response, CDC holds a continually active role supporting state and local public health agencies. For example, HAI/AR programs receive funding, technical assistance, and direction from CDC as part of its Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases Cooperative Agreement (ELC) with health departments. CDC also directly advises members of the public about what they can do to protect themselves, provides recommendations to the medical and public health community about how to prevent future outbreaks, and collaborates closely with policymakers, regulatory agencies, and industry to learn how to prevent outbreaks.

3.1.2.6 Federal Agencies — Food and Drug Administration (FDA)

FDA regulates and monitors the safety of drugs and medical devices. This agency conducts investigations of outbreaks suspected to be related to medical products. It is important that public health agencies and healthcare facilities notify FDA about products potentially implicated in outbreaks and that they do so early, even if the association is not yet clear. Healthcare facilities and providers can report suspected product issues to FDA via MedWatch, a voluntary web-based adverse event reporting program found at the following website: https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program.

Public health agencies can report directly to a regional FDA contact; this helps ensure that preliminary investigation findings and MedWatch reports are received and acted on in a timely manner. Determining the regional FDA contact ahead of an outbreak can facilitate timely communication. To foster bidirectional communication, state public health agencies can establish an information sharing agreement with FDA.[5] This is regulated by 21 CFR 20.88 and allows FDA to share nonpublic information (NPI) when it is in the interest of public health. Confidential Commercial Information (CCI) about commodities regulated by FDA may be disclosed when a 20.88 agreement is in place.

3.1.3 Healthcare Facilities

Roles and Responsibilities:

Healthcare facilities have the primary responsibility for ensuring the safety of patients under their care as well as their employees and visitors. When an outbreak is suspected, facility staff have the responsibility to report the outbreak to appropriate groups within the facility (typically to the infection prevention or quality team). Additionally, the facility has the responsibility to immediately report all suspected or confirmed outbreaks to the appropriate local or state public health agency. Often the healthcare facility will begin the investigation at the same time the outbreak is reported to public health. Whereas the healthcare facility has the responsibility for ensuring the safety of patients within the facility, the public health agency has an overlapping responsibility to protect the public from disease transmission, including within healthcare facilities in their jurisdiction. It is critical that healthcare facilities and public health agencies collaborate to detect and respond rapidly to suspected outbreaks, sentinel events, and serious infection control breaches.

Within a healthcare facility, there should be at least one person designated to oversee measures to prevent transmission of infections, including the detection of and response to outbreaks. In hospitals and larger healthcare facilities, this person is usually a credentialed infection preventionist (IP); a healthcare epidemiologist and other team members may support the IP. The roles and responsibilities of this team include conducting surveillance, facilitating laboratory testing, detecting clusters, ensuring reporting of potential outbreaks internally and to public health, communicating with public health during the course of an outbreak investigation, performing investigations to understand the cause of an outbreak in collaboration with public health, implementing changes in infection prevention practices to halt an outbreak, and assisting with notifying patients or media when warranted.

Planning for outbreaks:
Healthcare facilities should develop systems to ensure that there are adequate personnel to oversee implementation and monitor adherence to control measures in response to an outbreak. The facility IP should have completed competency-based training related to outbreak prevention and response (including auditing adherence to infection control measures, such as transmission-based precautions; staff and patient cohorting practices; and AR pathogen screening processes). The IP should establish processes for communicating with internal and external partners, including public health agencies.

Resources:
Resources within a healthcare facility to detect and respond to an outbreak vary greatly. Facilities with extensive resources and expertise in outbreak investigations may require little direct support from public health. Conversely, those lacking resources or expertise will be largely dependent on public health agencies to perform primary investigative functions. Regardless, personnel at every healthcare facility have unique, in-depth knowledge of their facility that is critical during outbreak investigation and response. Public health agencies should be prepared to work collaboratively with healthcare facilities during an outbreak response. Similarly, healthcare facilities should be prepared to assist public health with the investigation, including gathering information needed during the investigation and implementing disease control measures.

3.1.4 Patients and Other Agencies/Partners

Healthcare outbreaks primarily affect patients. Chapter 8 of the *CORHA Principles and Practices* provides detailed considerations for informing and engaging patients as part of healthcare outbreak response. Additional federal, state, territorial, tribal, local, and partner organizations, beyond the examples detailed above, may become involved in healthcare outbreak investigations. In advance of (or early in) an outbreak response, it is important to think through the array of stakeholders and partners needing to be involved or informed. Selected partners are described in this subsection in more detail, and abbreviated information about other partners is listed in Table 3.1. Table 3.2 details partners to consider based on the type of outbreak or event.

3.1.4.1 Professional Member Organizations
Although not typically involved in outbreak detection and response directly, member organizations such as the local and national chapters of the American Professionals for Infection Control and Epidemiology (APIC), the Society for Healthcare Epidemiology of America (SHEA), and the Infectious Disease Society of America (IDSA), as well as organizations representing medical, surgical, dental, nursing, and other types of specialized healthcare professionals, can be valuable partners when public health needs to understand the local healthcare landscape and communicate to targeted groups. Organizations representing professional specialties may have their own infection control guidelines; they may also offer useful venues (conferences, journals, and websites) for outbreak investigators to reach their constituents (e.g., for assistance with case finding or to disseminate prevention messaging).

National organizations that represent healthcare facility types, such as the American Hospital Association (AHA) and the American Health Care Association (AHCA), can be helpful partners to engage for messaging and coordination at the national level. These organizations also have local chapters in some jurisdictions; forming relationships with local chapters, such as the state hospital association, healthcare association, and healthcare professional or quality improvement organizations, can improve outbreak reporting and assist communication to healthcare partners during an outbreak or a time of increased transmission of a particular infectious disease. Developing relationships with these organizations helps ensure collaboration without overlap, so that organizations and agencies can mutually support an outbreak response as well as general prevention and quality improvement efforts.

3.1.4.2 Tribal Entities and the Indian Health Service (IHS)
Tribal governments generally have complete sovereignty and autonomy over reservation lands, and nontribal

groups can join an investigation only at the tribe's request. Investigations of outbreaks may be led by the tribal health staff, the Indian Health Service (IHS), or state health departments. Typically, public health and the IHS can implement investigation measures and control only with authorization of the tribal government.[6] Healthcare organizations operating on tribal lands have a variety of configurations.

Many healthcare facilities within tribal nations are autonomous and not bound by regulations that are applicable to other healthcare settings. Some facilities are owned by tribes and operated by the IHS, a federal agency within the US Department of Health and Human Services (HHS); other facilities are run entirely or in part by a tribal corporation that is independent of the IHS. Additional information about the IHS can be found in Table 3.1.

Engaging tribal entities as partners requires awareness of the local healthcare structure and the types of services offered. State public health agencies should develop an understanding of the structure of healthcare facilities operated by tribal entities within the state. Local healthcare providers may have the most extensive knowledge of care patterns within tribal nations and, in some cases, the local public health agency may be the most effective agency for engaging tribal partners.

3.1.4.3 Law Enforcement

Under circumstances in which criminal activity is suspected, appropriate law enforcement personnel should be notified. This may include situations in which an outbreak investigation identifies persons who are suspected of committing fraud and/or providing medical care without appropriate credentials, or persons who have stolen or tampered with controlled substances or other medications. The law enforcement agency to be notified depends on the scenario. For example, medication tampering or other aspects of drug diversion may require notification of local and state law enforcement, the Drug Enforcement Administration (DEA), and the FDA Office of Criminal Investigations (see Supplement B for more information). Public health agencies should maintain awareness of law enforcement reporting requirements; a contact list of law enforcement agencies can be developed in advance.

Table 3.1 | Additional Agencies and Partners that Public Health Agencies Interact with During an Outbreak Response

AGENCY OR PARTNER	ROLE IN OUTBREAK RESPONSE	EXAMPLES OF INTERACTIONS WITH STATE AND LOCAL PUBLIC HEALTH AGENCIES	FOR MORE INFORMATION
Centers for Medicare & Medicaid Services (CMS)	CMS is a federal agency that provides health coverage through Medicare, Medicaid, the Children's Health Insurance Program, and the Health Insurance Marketplace. CMS promulgates standards, regulations, policies, and guidance (some of which pertain to infection control) that are applicable to many healthcare facilities and provider types.	CMS may report infection control breaches or suspected outbreaks to state facility licensing agencies or state public health agencies. CMS may become involved in outbreak investigations that affect Medicare-certified facilities either through the state survey agency or directly via federal surveyors or regional office staff.	CMS: www.cms.gov CMS Health and Safety Standards: www.cms.gov/medicare/health-safety-standards/conditions-coverage-participation/

Table 3.1 | Additional Agencies and Partners that Public Health Agencies Interact with During an Outbreak Response

AGENCY OR PARTNER	ROLE IN OUTBREAK RESPONSE	EXAMPLES OF INTERACTIONS WITH STATE AND LOCAL PUBLIC HEALTH AGENCIES	FOR MORE INFORMATION
Veterans Health Administration (VHA)	A federal agency and one of the largest US healthcare systems, VHA provides healthcare to US veterans. Healthcare facilities within the system function as other healthcare facilities and may investigate any healthcare-related outbreaks occurring within their system. VHA has medical epidemiologists and infection prevention professionals within their facilities.	State and local public health agencies should receive information on outbreaks directly from VHA facilities as well as information on reportable diseases and conditions for surveillance. Additional information on HAIs in VHA facilities may be available via the National Healthcare Safety Network (NHSN). Public health agencies should work with VHA facilities within their authority to investigate outbreaks.	VHA: www.va.gov/health VA Hospital Compare: www.accesstocare.va.gov/Healthcare/HospitalCompareData?s=AL&f=679&m=FLU VHA Directive 1131, Management of Infectious Diseases and Infection Prevention and Control Programs: www.va.gov/vhapublications/ CSTE position statement 16-SI-03, Veterans Health Administration Reporting of Diseases, Conditions, and Outbreaks to Local and State Public Health Authorities: https://cdn.ymaws.com/www.cste.org/resource/resmgr/2016PS/16_SI_03.pdf
Indian Health Service (IHS)	IHS is a federal agency that provides health services to members of federally recognized tribes. IHS has public health professionals on staff.	Reporting of diseases and conditions, as well as reporting of outbreaks, occurs within the IHS system. State public health agencies that have tribal lands within state borders work with IHS and tribal leaders and often collaborate on outbreak responses.[6]	IHS: www.ihs.gov/
Federal Bureau of Prisons (BOP)	BOP is a federal agency that oversees federal prisons. BOP is responsible for prisoner health, has jurisdiction over federal correctional facilities, and employs a health services division.[6]	BOP and the federal correctional facility may request public health assistance in an outbreak response, typically from CDC and/or the state public health agency.[6]	BOP: www.bop.gov

Table 3.1 | Additional Agencies and Partners that Public Health Agencies Interact with During an Outbreak Response

AGENCY OR PARTNER	ROLE IN OUTBREAK RESPONSE	EXAMPLES OF INTERACTIONS WITH STATE AND LOCAL PUBLIC HEALTH AGENCIES	FOR MORE INFORMATION
State and local correctional facilities	State and local governments run correctional facilities within their jurisdictions. They are responsible for prisoner health.[6]	State and local correctional facilities are insular, and their individual department of corrections may request public health assistance in an outbreak response.[6]	See websites for specific state departments of corrections and local correctional facilities.
US Department of Defense (DoD)	Military commanders have authority over their bases and facilities. DoD and the branch of the military involved (e.g., the Department of the Navy) has its own public health responsibilities including response to suspected outbreaks. DoD has established the position of Public Health Emergency Officer (PHEO); the person holding this job is a clinician and member of a military service medical department having relevant training in emergency management and experience in public health.[6]	If a state or local public health agency is involved in an outbreak investigation of a branch of DoD, the public health investigators must communicate and cooperate with the military base commander. The PHEO works with installation and medical treatment facility emergency managers, who also communicate with local and state health departments.[6]	DoD: www.defense.gov
US Department of the Interior	The Department of the Interior oversees and has jurisdiction over federal lands and natural resources. Scientists, including members of the Public Health Service (PHS), are employed in the National Park Service Office of Public Health.[6]	When federal lands are involved in an outbreak, state and local public health agencies should collaborate with the National Park Service Office of Public Health.[6]	Department of the Interior: www.doi.gov/ National Park Service Office of Public Health: www.nps.gov/orgs/1735/index.htm

Table 3.1 | Additional Agencies and Partners that Public Health Agencies Interact with During an Outbreak Response

AGENCY OR PARTNER	ROLE IN OUTBREAK RESPONSE	EXAMPLES OF INTERACTIONS WITH STATE AND LOCAL PUBLIC HEALTH AGENCIES	FOR MORE INFORMATION
Accrediting organizations	Accreditation is a review process of a healthcare organization performed by accrediting bodies. Accreditation is typically voluntary and allows for a demonstration of the ability to meet requirements and standards (e.g., CMS Medicare certification) and an assurance of quality for healthcare consumers and payors.	Accrediting organizations may report outbreaks or infection control breaches to CDC or state or local public health agencies.[3]	CMS quality, safety, and oversight: www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/ CMS-approved accrediting organization list: www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Accrediting-Organization-Contacts-for-Prospective-Clients-.pdf

Table 3.2 | Partners to Consider Involving by Type of Event*

TYPE OF EVENT	AGENCIES
Single facility outbreak	Local public health agency, state public health agency, and healthcare facility/setting
Multifacility outbreak	Local public health agencies, state public health agency, and healthcare facilities/settings
Multistate outbreak	Local public health agencies, state public health agencies, healthcare facilities/settings, and CDC
Potentially contaminated medical product	Local public health agencies, state public health agencies, healthcare facilities/settings, FDA, CDC, and product manufacturer
Infection control breach in licensed healthcare setting	Local public health agency, state public health agency, state survey agency, and healthcare facility/setting
Infection control breach in private practice setting	Local public health agency, state public health agency, healthcare setting, and professional licensure board
Drug diversion (e.g., theft or tampering)	Local public health agency, state public health agency, healthcare facility/setting, professional licensure board, state survey agency, FDA, and law enforcement agencies
Outbreak related to healthcare outside the US	Local public health agencies, state public health agencies, and CDC

*State and local laws differ, and additional notifications may be applicable depending on laws and the situation. Public health agencies should be prepared by understanding reporting requirements prior to an outbreak.

3.2 Outbreak Response Team

3.2.1 Overview

Prior to an outbreak, it is helpful for a public health agency to establish who will respond when an HAI/AR outbreak is detected; this is the outbreak response team. At its most basic level, an outbreak response team may consist of a single epidemiologist; larger or more complex events may need several staff members, including a more senior medical epidemiologist, an infection preventionist, and other personnel with specialized expertise. A scalable response may require the staff involved in the outbreak response to adapt to different roles during the investigation. Personnel designated as part of an outbreak response team should receive ongoing training in outbreak investigation and response.

Roles and responsibilities for each team member should be clear and assigned early. Although public health agencies may designate roles in protocol documents and assign individuals to fill each role as the team is assembled at the beginning of a response, these roles should be flexible throughout the course of an outbreak investigation, and team members may fill more than one role.

3.2.2 Roles of Team Members

An entire outbreak response likely involves multiple entities (e.g., one or more public health agencies and one or more healthcare facilities), each with their own response team. The overall coordinating agency may serve as a traditional lead or may function as a facilitator and convener. Regardless of which agency is in the lead, each team must appreciate the importance of considering multiple points of view across the various entities involved in the response.

Public health team members, their roles, and their primary responsibilities are described in this section. The purpose is to make it easy for public health agencies to quickly assign roles to team members and ensure that key tasks are covered; however, responsibilities can be modified and transferred to other team members as needed.

Consider designating a single point of contact for the public health team to communicate with other involved entities. The point of contact can be any team member, but consideration should be given to keeping the point of contact consistent throughout the investigation. Points of contact should have excellent communication skills and experience working in or with healthcare facilities.

3.2.2.1 Team Leader

During any response to a suspected outbreak, a team leader should be designated. In small outbreaks, one epidemiologist may be sufficient to respond; however, as soon as additional team members have been added, it is helpful to have a clear team leader. During multi-agency responses, it is similarly helpful to designate an overall lead, or coordinating, agency. The team leader at the coordinating agency may hold the primary role of facilitator and convener, with other entities having their own team leaders for their jurisdiction or facility. The team leader should make a concerted effort to understand the roles and expertise of members of the team and those of members of other teams working across other entities. The team leader sets the tone for the investigation and should be an individual who can maintain a calm demeanor during stressful situations.

Responsibilities:

Responsibilities of the team leader include the following: overall organization; setting priorities; leading meetings and conference calls, including preparing clear agendas; coordinating all activities associated with the investigation; assigning roles and tasks to team members; modifying team roles and requesting additional staff when needed; coordinating messaging to other involved agencies, communication staff, and the outbreak response team; ensuring open communication among entities including communication with agency decision-makers; and ensuring each team member and involved agency has needed information.

3.2.2.2 Epidemiologists

Epidemiologists usually have a central role in healthcare outbreak investigations. One or more epidemiologists may be needed to support the outbreak response team with sound epidemiologic approaches—ranging from descriptive epidemiology to complex analytic methods—to help determine possible modes and sources of transmission and to rapidly implement control measures.

Responsibilities:
Epidemiologists identify cases; develop case definitions; develop hypotheses and strategies to test them; obtain information about the cases and other patients via interviews, medical record reviews, and observations; perform descriptive analyses using collected data; plan epidemiologic studies; analyze investigation data using statistical analyses; present results to make interpretations; coordinate testing of specimens and samples; and coordinate with other team members.

3.2.2.3 Infection Preventionists

HAI/AR outbreaks are unique in that infection control breaches of some kind are often the cause of, or contributors to, an outbreak. Infection preventionists (IPs) have specific skills and training related to the prevention of transmission of infections in the healthcare setting. IPs are adept at assessing care practices and the environment of care; many IPs have clinical experience and can contribute additional knowledge and context during an investigation.

Responsibilities:
An IP obtains and interprets information about the healthcare facility and cases related to infection prevention practices, reviews and interprets policies and procedures, performs observations on site to identify infection control gaps or breaches, provides infection control recommendations to the team and the healthcare facility to stop disease transmission, and provides additional clinical context during the investigation.

3.2.2.4 Laboratorians

Laboratorians provide expertise and advice related to the performance of laboratory testing. Laboratorians may also contribute specialized knowledge related to environmental reservoirs of HAI/AR pathogens. It is best practice for laboratorians to attend team meetings and be included in overall communications (not limited solely to laboratory aspects of the investigation). Excellent communication ensures that epidemiologists understand laboratory testing, and laboratorians should be kept informed about the epidemiologic investigation.

Responsibilities:
Laboratorians advise the outbreak team on appropriate laboratory testing methods, including the collection, handling, storage, and transport of clinical or environmental specimens; test clinical specimens or isolates; analyze environmental samples when obtained; interpret and report results; communicate laboratory testing methods and results; and maintain chain of custody when required. See Chapter 6 for more information.

3.2.2.5 Additional Team Members

Administrative staff: Planning efforts should include support personnel to make phone calls, answer inquiries from concerned members of the public, perform data entry and assist with information management, and conduct other administrative work.

Statistician: A statistician should be added to the team when advanced epidemiologic methods are employed that require additional analytic skills. Some public health agencies may not have a statistician available. Consider requesting help from other agencies when additional statistical help is needed.

Subject matter experts: Planning efforts should include identifying subject matter experts who can be called upon to assist with commonly encountered assessment needs that arise as part of healthcare outbreak investigations. Examples include engineers or environmental scientists with experience evaluating healthcare facility ventilation or water systems.

Public information officer: Public information officers (often referred to as “PIOs”) and communications experts should be involved early as a part of the outbreak response team when an outbreak is anticipated to be large enough to gain media attention; when communication assistance is needed among agencies; when developing messaging, such as for facilities or for the public; or if other communication needs occur.

Legal support: Like public information officers, legal staff should be involved early as a part of the outbreak response team when legal questions are anticipated to arise. Legal staff can help with interpreting public health authority and assist in interactions with legal staff in other agencies and healthcare facilities.

Emergency preparedness: When a response to an outbreak or infection control breach requires large amounts of agency resources, when media attention can occur, or when establishment of an incident command system (ICS) is under consideration, public health agencies should consider involving emergency preparedness staff. Emergency preparedness staff can provide expertise in the emergency response and the ICS as well as additional logistical support with resource requests (e.g., staffing or supplies).

3.2.3 Outbreak Response Team Model Practices

3.2.3.1 Outbreak Response Unit

Entities that routinely respond to healthcare outbreaks should establish a team that can be dedicated to that purpose. Ideally, outbreak response team members will be skilled in outbreak responses and have knowledge of healthcare settings. Team members may have other responsibilities when outbreaks are not occurring, particularly in smaller agencies. Having a dedicated team allows for team members to gain experience collaborating with each other and ensures consistency across investigations.

3.2.3.2 Additional Support

In large-scale events, it may be necessary to expand the outbreak team to include additional support for medical record reviews, interviews of patients, or other tasks such as data entry. Identification in advance of additional people to assist with these tasks can help an investigation proceed rapidly without taxing agency resources. Additional persons to be identified could include staff within other areas of an agency (some may have medical record review experience or experience in interviewing patients) or personnel from other organizations (e.g., medical students, residents and fellows, or public health students) with minimal levels of expertise. Inclusion of trainees in an outbreak response can be beneficial for both the team (helping with staffing and resource limitations) and trainee (providing valuable experience). Develop just-in-time training for additional support staff and provide directed training to allow for rapid incorporation of these staff members into the team.

Public health agencies should identify possible external sources of expertise to assist the outbreak response team when such sources are not internally available. Part of planning includes identification of gaps in expertise within an agency and identification of other entities that have this expertise; often needed expertise may be found at the state health department or CDC. Building relationships with a variety of healthcare facility and community partners can be advantageous when additional expertise is needed beyond the capacity of public health, particularly in areas not typically found within public health agencies, such as respiratory therapy, industrial hygiene, and pharmacy, to name a few.

3.2.3.3 Outbreak Response Plans and Protocols

Outbreak response plans should be scalable, adaptable, and flexible, so that they can be implemented when an outbreak is limited to a few cases and rapidly expanded if the scope of the outbreak broadens. Plans should be flexible, so that they can be used in any healthcare setting or unit, including specialized units within facilities. It is helpful to have general outbreak response plans as well as pathogen- or condition-specific response protocols for the types of outbreaks that are seen frequently. Established plans and protocols allow for a rapid response, provide support for less-experienced team members, and offer consistency across similar outbreaks.

Plans can include contact lists (including lists of outbreak response team members and people within the agency to inform, outside agency contact lists, and contact lists for additional support team members), steps to follow during an outbreak, scientific publications and other key reference texts, draft agendas for meetings and conference calls, draft emails for situational updates, medical record review forms, interview forms, on-site facility infection control assessment tools, laboratory testing information, and any other pieces that are common across outbreaks. Additional information about assembling documents and toolkits for a healthcare outbreak response are described in section 3.3 Resources.

3.2.3.4 Training for the Team

Didactic and operational training for the team should be provided for all personnel who may be tasked with

responding to an outbreak on a regular basis. Consider training on agency protocols, specific subjects (e.g., pathogens seen routinely, healthcare settings commonly worked with, and infection control practices), and general outbreak response. Since the healthcare outbreak response is specialized, public health staff responding to outbreaks should have training or experience in healthcare settings and understand the roles of healthcare facility staff, in particular infection preventionists.

Consider shadowing opportunities within facilities when available and internal training sessions for staff who have never worked in a healthcare setting given by staff members who have. Staff unfamiliar with an outbreak response in healthcare settings can be paired with more experienced and knowledgeable staff members, when needed, to provide on-the-job training. Specific just-in-time training can also be conducted when a new situation is encountered or it is necessary to add team members with less experience to an ongoing outbreak response. Training in the ICS can also be helpful (the ICS is discussed later in this chapter). Additional training is available for public health staff from a variety of resources; some examples relevant to a healthcare outbreak response are listed in Box 3.1.

Conducting simulated exercises is another way to prepare for an outbreak response. Exercises may be discussion-based or operations-based.[7] Examples of discussion-based exercises include seminars, workshops, tabletops, and games simulating operations—many of which can be found online. Operations-based exercises include drills, functional exercises, and full-scale exercises. Regional training conducted with multiple agencies can help identify problems that may arise during outbreaks involving multiple entities.

3.3 Resources

Part of preparing for the investigation of an HAI/AR outbreak is assembling the necessary resources—supplies, equipment, and personnel—to support the outbreak response team and ensure that everything needed for the investigation and response is readily available. In this section we describe resources that can be assembled prior to an outbreak.

Personnel resource needs were discussed in the previous section. The following lists of equipment, supplies, documents, and reference materials will help public health agencies identify resources in preparation for outbreak

Box 3.1 | Selected Training Resources

- Infection control training through CDC can be found at the following links:
  - CDC/STRIVE Infection Control Training: https://www.cdc.gov/infection-control/hcp/training/strive.html
  - Project Firstline: www.cdc.gov/infectioncontrol/projectfirstline/index.html
  - Infection prevention training for nursing homes and assisted living facilities: https://www.cdc.gov/long-term-care-facilities/hcp/training/index.html
- Healthcare epidemiology trainings offered by the Society for Healthcare Epidemiology of America (SHEA) can be found at learningce.shea-online.org
- SHEA/CDC Outbreak Response Training Program (ORTP) can be found at https://learningce.shea-online.org/content/sheacdc-outbreak-response-training-program-ortp
- Infection prevention training resources offered by the Association for Professionals in Infection Control and Epidemiology (APIC) can be found at https://apic.org/education-and-events/online-learning.
- Manufacturers of medical devices sometimes offer free or low-cost online or in-person training in device-specific reprocessing and infection prevention measures, such as online courses related to endoscope reprocessing.

investigation; outbreak training should include methods to obtain resources specific to a particular outbreak as needed during the investigation.

3.3.1 Equipment and Supplies

List of equipment and supplies to consider in preparation for an outbreak response:

- Communication equipment: Consider the capability and equipment for conference calls and online meeting platforms that can support large numbers of users.
- Electronic equipment: Computers, including laptops for fieldwork as well as needed software (e.g., data entry and statistical programs), should be available in advance, and portable printers can be considered. Also consider the need for secure internet access; a secure personal hotspot can be helpful.
- Data storage and transportation devices: An encrypted, portable, data storage device (e.g., an encrypted thumb drive) can help facilitate secure information sharing of electronic files too large to be emailed.
- Photography: It can be helpful to take photos during a field investigation. Ideally, personal cell phones should not be used. Be aware of your agency's policy for taking photographs or shooting videos during an outbreak. In general, avoid including people in photos unless permission has been obtained; consult with the healthcare facility about applicable policies. If photographing the environment of care, ensure that photographs do not contain identifying information. Educate personnel about policies for producing, storing, and sharing photographs or videos.
- Laboratory supplies: Consider what will be needed depending on the specimens to be collected, including appropriate specimen collection materials, containers, and transport materials (e.g., coolers and ice packs). Ensure appropriate shipping materials are available when needed. Prior to collecting samples, consultation with laboratory experts at the testing laboratory is advised. Environmental sampling should only be considered under specific conditions; in Chapters 5 and 6 we discuss additional considerations for environmental testing.
- Specialized instruments for the assessment of the environment of care, such as
  - Ultraviolet gel and a portable black light device to help evaluate environmental cleaning
  - Flutter strips, smoke tubes, or velocimeters for evaluating positive or negative air flow
  - Moisture meters to detect moisture in dry wall following exposure to water leaks

  Many acute care facilities have these instruments available, but public health agencies may find these items useful if assessing the environment of care in other healthcare settings.

3.3.2 Outbreak Investigation Documents and Toolkits

As noted in section 3.2.3, forms, information sheets, tools, plans, and protocols can be created in preparation for an outbreak response and modified as needed for specific situations. Public health agencies may consider developing outbreak investigation protocols for specific pathogens or settings, reflecting national guidelines while taking into account other considerations including local epidemiologic conditions. Information sheets, sample patient letters, and any other materials intended for dissemination to the public should be easy to read and understand, with clear instructions for ease of implementation. Public health agencies can develop tools in advance that healthcare facilities can use to report outbreaks and respond to informational needs from public health agencies. Likewise, it may be useful to establish protocols to guide involvement of communication teams and leadership as well as to advise how to notify external partners, patients, and the public.

Outbreak investigation documents to consider in preparation for an outbreak response include the following:

- Outbreak intake forms, which may be general or disease-specific
- Laboratory test requisition forms
- Standardized outbreak line lists or a database to collect case data
- Forms to assess adherence to infection prevention and control measures (e.g., Infection Control Assessment and Response [ICAR] tools and checklists)[8,9]
- Patient interview forms
- Staff interview forms

- Medical record review forms
- Facility maps
- Timeline templates
- Line-list templates and samples
- Template emails for information gathering
- Template meeting or conference call agendas
- Template letters of recommendation that public health agencies can use when recommending interventions in writing to healthcare facilities, including infection control recommendations
- Template letters to patients (e.g., letters for patient notifications)
- Templates for final outbreak reports and after-action reports
- Talking points on common pathogens or outbreak types for media inquiries
- Patient information sheets

3.3.3 Reference Materials

It is not possible to compile specific references for every outbreak that may be encountered. Having some common reference materials on hand in advance of an outbreak, however, can save the team response time. Reference materials to consider reviewing or compiling in preparation for a healthcare outbreak response include the following:

- CORHA Resources and Products for Healthcare Outbreak Response: www.corha.org/resources-and-products/
- CDC HAI prevention toolkits: https://www.cdc.gov/healthcare-associated-infections/php/toolkit/index.html
- CDC resources for Outbreak Investigations in Healthcare Settings: https://www.cdc.gov/healthcare-associated-infections/about/outbreak-investigations-in-healthcare.html
- CDC and Healthcare Infection Control Practices Advisory Committee (HICPAC) infection control guidance documents: www.cdc.gov/infectioncontrol/guidelines/index.html
- Latest version of the American Public Health Association's Control of Communicable Diseases Manual[10]
- Selected resources from federal regulatory agencies (found in Box 3.2)
- Published medical literature specific to commonly encountered outbreaks
- Resources compiled from outbreaks previously investigated by the agency

3.3.4 Tracking Time and Resources

Public health agencies should consider tracking time and resources during anticipated large-scale investigations. When processes are set up in advance of a response, tracking staff time and resources can be implemented rapidly, providing valuable information for future outbreaks and resource allocation.

3.4 Records Management

3.4.1 Overview

A tremendous amount of information can be collected during an outbreak response. Information needs to be collected and managed systematically to allow for easy access, analysis, and interpretation.

3.4.2 Records Management Model Practices

3.4.2.1 Information Collection and Sharing

Standardized data collection forms (paper or electronic) can help ensure that data are collected uniformly and systematically. If forms are not already developed ahead of an outbreak, they should be developed before data collection. Standardized forms can be modified from those used in previous outbreak investigations. Types of data collection forms include medical record review forms, patient interview forms, and healthcare facility staff interview forms. Staff collecting data should be trained in the use of forms to ensure data are collected in a consistent and appropriate manner (see section 3.8.1, Legal Preparedness, Authorities, and Litigation).

Forms, data, and information should be shared among team members in a secure manner. Methods for sharing information and types of information to be shared across agencies should ideally be determined prior to an

Box 3.2 | Selected Resources from Federal Regulatory Agencies

Centers for Medicare & Medicaid Services (CMS)
- Conditions for Coverage (CfCs) & Conditions of Participation (CoPs) (health and safety standards including infection control) that healthcare organizations must meet to begin and continue participating in Medicare and Medicaid programs: www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs

Food and Drug Administration (FDA)
- MedWatch Online Voluntary Reporting Form: https://www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting
- Medical Device Recalls: https://www.fda.gov/medical-devices/medical-device-safety/medical-device-recalls
- MAUDE — Manufacturer and User Facility Device Experience: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm
- National Drug Code Directory: https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory

Environmental Protection Agency (EPA)
- Selected EPA-Registered Disinfectants: https://www.epa.gov/pesticide-registration/selected-epa-registered-disinfectants
- Pesticide Product and Label System (PPLS): https://ordspub.epa.gov/ords/pesticides/f?p=PPLS:1

Occupational Safety and Health Administration (OSHA)
- Healthcare Standards and Enforcement: https://www.osha.gov/healthcare

outbreak. Public health agencies should be aware that each entity involved in an outbreak response may have its own policies and limitations with respect to methods for sharing information (e.g., messages sent via encrypted email and/or shared documents on a secure website), and it is best practice to have several options available for sharing information to allow for flexibility.

3.4.2.2 Data Management and Investigation Tracking

Standardized databases and line lists should be used to collate data during an outbreak. General databases and line list templates can be developed ahead of time and standardized tools used in previous outbreaks can be modified. Data should be entered as soon as possible to allow for rapid interpretation and analysis. Identify software tools to be used to analyze outbreak data (e.g., Epi Info, SAS, or R) and have staff who are trained to use these tools. Ensure data are routinely backed up and kept in a secure environment.

Each investigation, whether it involves a detected cluster, suspected or confirmed outbreak, AR containment, infection control breach, or other sentinel event, should be tracked in an information management system or database. The investigation tracking system should be flexible to accommodate the various types of events and provide information to allow authorized users to do the following[3]:

- Summarize overall investigation findings
- Evaluate the effectiveness of local reporting requirements
- Inform prevention efforts by identifying facilities, settings, and issues that may benefit from proactive prevention
- Inform prevention and response guidance and tools
- Understand local resources needed for an outbreak response

A best practice for public health agencies and larger healthcare facilities or systems is to use an outbreak investigation tracking system. CORHA has developed an HAI/AR Outbreak Investigation and Response Tracking System and associated data dictionary for this purpose, available at www.corha.org/resources/corha-hai-ar-outbreak-and-response-tracking-system/. HAI/AR programs receive specific guidance on response tracking from CDC as part of the ELC.

Information that can be captured in this type of tracking database includes the following: intake information (entity reporting, dates of interest, and basic description of the situation), healthcare facility information, public health agency information, investigation information (dates of testing and onset, case definition, numbers and characteristics of cases, investigation methods, and suspected source), on-site visits conducted, laboratory information, control measures implemented, and summary and conclusions.

3.5 Communication

Effective communication is one of the most essential elements for a successful outbreak investigation. It is essential that there be processes in place for communication among the outbreak response team members, between the team and leadership within the agency, among involved agencies, with the healthcare facility or facilities involved, and with media, patients, and the public. To make communication as smooth as possible, prepare in advance and consider the following:

- Establish communication best practices for your outbreak team; strive for daily email updates or calls, with the responsibility for organizing this assigned to one team member selected at the start of the investigation.
- Take partners' needs into account when sending external updates, including those of the involved facility, regarding frequency of communication, level of information, and content (e.g., summaries of findings to date).
- Develop guidelines for when to involve public information officers and communication experts, emphasizing the need to involve them as early as possible.
- Designate an outbreak response team member as the point of contact for each communication pathway.
- Create and use contact lists for partners and personnel; in some cases, contact lists can be developed in advance.
- Have clear agendas during meetings and calls; develop template agendas and meeting invitations that include an agenda; and follow up with meeting minutes and/or a summary of key action items.
- Do not underestimate the importance of ongoing discussions during the investigation, either in person or via conference calls. It is extremely helpful to have scheduled meetings (in person or by calls) during the investigation to make sure communication pathways are established and partners are kept up to date.
- Develop procedures for presentations and publications, including procedures for early discussions internally and with partners regarding leads for any reports, papers, or other products.
- Establish mechanisms for obtaining input and opinions from leaders in other communicable disease disciplines, such as foodborne and vaccine-preventable diseases, who can provide useful ideas for how to approach communications during an outbreak investigation.
- Plan regular meetings across disciplines and among healthcare partners as part of the preparation; this can aid the outbreak response later.

3.6 Escalation

3.6.1 Overview

The public health outbreak team should periodically assess the need for obtaining additional assistance and escalating the response. Internally, there should be a communication protocol in place that includes triggers for notifying leadership and involving additional expertise (e.g., communication, emergency response, and legal expertise).

Thresholds for escalation to another agency should be considered in advance. Conversations with leadership and other internal experts can be helpful ahead of a possible escalation; they should involve preparing and educating leadership about the general course of an HAI/AR outbreak response and discussing when an outbreak may require involvement of outside agencies.

Leadership should also be knowledgeable about CDC's Epi-Aid request process. An Epi-Aid is an investigation of an urgent public health problem such as infectious or noncommunicable disease outbreaks, unexplained illnesses, or natural or manufactured disasters. When a public health authority, usually the state epidemiologist, requests assistance from CDC, an Epi-Aid allows rapid, short-term (1–3 weeks), generally on-site technical assistance by Epidemic Intelligence Service (EIS) officers and other CDC subject-matter experts. The focus of an Epi-Aid investigation is to assist partners in making rapid, practical decisions for actions to prevent and control the public health problem.[4]

3.6.2 When to Ask for Help

A cardinal rule for all HAI/AR outbreak response teams: Ask for help earlier rather than later. A seemingly small or local outbreak may signal a much larger problem. Preparations should include discussions internally regarding when the agency should seek help from another agency.

Consider asking for help when

- The pathogen is novel or is of high consequence, or transmission appears to occur by novel means.
- The scale of the outbreak seems likely to overwhelm agency resources.
- Initial remediation attempts fail.
- The outbreak is known or suspected to affect multiple counties, states, or countries, or expands beyond the original jurisdiction.
- The investigation points to a regulated or widely distributed medical product.
- The nature of the outbreak (e.g., agent, affected population, or scale) or response is beyond the experience of the agency staff.
- Specific technical support or expertise is needed.
- Specialized laboratory services or support is needed.

3.6.3 How to Obtain Help

Knowledge of how to obtain help when needed is a key aspect of a public health agency's preparation and planning for a healthcare outbreak response. To receive prompt assistance and ensure that adequate patient protections are quickly put in place, healthcare facilities should be reminded of requirements and thresholds for reporting potential outbreaks as soon as the outbreak is suspected and not wait for an outbreak to grow.

In general, public health agencies should begin escalation by requesting assistance from the public health agency at the next jurisdiction level (e.g., local public health agencies should contact the state and state public health agencies should contact CDC). State public health agencies have communicable disease or HAI/AR programs that can be contacted directly; if unable to locate contact information directly, call the general agency number or the 24/7 on-call person for the agency. Public health agencies can contact CDC for technical assistance related to healthcare outbreak investigations via email (haioutbreak@cdc.gov) or by phone using the CDC 24/7 emergency response number (800-CDC-INFO).

3.7 Incident Command System (ICS)

Originally developed in the 1970s to coordinate activities to control wildfires, the Incident Command System (ICS) is a scalable structure that states may adapt to meet their needs during an outbreak, including within a single jurisdiction. The system has been expanded and integrated into the Federal Emergency Management Agency's (FEMA's) National Incident Management System (NIMS) to aid intra-agency and interagency coordination, especially during large-scale emergencies that involve multiple jurisdictions. The ICS features a clearly defined chain of command with common nomenclature for key management positions, defined management sections, and a modular organizational structure.

The ICS uses specifically defined emergency response function roles. Public health agencies at the local and state levels may use the ICS as part of an all-hazards plan to mitigate threats to health and safety. Federal agencies are required by executive order to use the ICS to address outbreaks that are considered public health emergencies, so that all relevant federal agencies, as well as state and local governments, are appropriately coordinated and connected during emergencies. The CMS Emergency Preparedness Rule[11] has mandated that 17 different types of healthcare organizations develop all-hazards plans, listed in Box 3.3.

Box 3.3 | Types of Facilities Required by CMS to Develop Emergency Preparedness Plans[11]

1. Hospitals
2. Religious Nonmedical Health Care Institutions (RNHCIs)
3. Ambulatory Surgical Centers (ASCs)
4. Hospices
5. Psychiatric Residential Treatment Facilities (PRTFs)
6. Program of All-Inclusive Care for the Elderly (PACE) Organizations
7. Transplant Centers
8. Long-Term Care (LTC) Facilities
9. ntermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID)
10. Home Health Agencies (HHAs)
11. Comprehensive Outpatient Rehabilitation Facilities (CORFs)
12. Critical Access Hospitals (CAHs)
13. Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services
14. Community Mental Health Centers (CMHCs)
15. Organ Procurement Organizations (OPOs)
16. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)
17. End-Stage Renal Disease (ESRD) Facilities

Most HAI/AR disease outbreak investigations do not require formal activation of the ICS, but elements of it are frequently utilized in outbreaks. For larger investigations or investigations that may lead to media attention, early use of the ICS can be beneficial by providing additional structure and support to the outbreak response team.

3.8 Other Aspects of Preparation

3.8.1 Legal Preparedness, Authorities, and Litigation

Agencies should understand their legal authority to conduct an outbreak investigation and steps that can legally be taken to halt an outbreak; all relevant laws related to disease surveillance, reporting (including reporting of outbreaks), detection, investigation, and control activities should be understood in advance.[6,12] Specific authority and the basis for that authority, particularly when working in healthcare facilities, varies among states and jurisdictions; staff involved in outbreak investigations should understand the authority of their specific agency. If there are legal agreements that need to be in place for information sharing across agencies, these should be identified and put into place ahead of an outbreak. The agency should have legal staff available to provide advice and to join the outbreak response team when needed.

Outbreaks can result in litigation and have broad financial and public relations implications for affected facilities.[13] As a result, there may be increases in scrutiny and the number of stakeholders interested in the investigation. There may be increased pressure to investigate rapidly or implement necessary control strategies quickly. In addition, public health records frequently are the subject of Freedom of Information

Act requests. Agencies should prepare their outbreak response staff regarding procedures for documenting the steps taken in an investigation and advise them to exercise care and discretion in using emails and other communications, recognizing that investigation records might become publicly available or used as part of litigation proceedings.[13]

3.8.2 Ethics

Ethical dilemmas may arise during investigations of outbreaks or infection control breaches, particularly regarding decisions about patient notification. In advance of an outbreak investigation, public health agencies should consider what standards and conventions to apply as well as criteria for arranging consultations and obtaining guidance. Although it is not always possible to anticipate ethical questions in advance, agencies should consider establishing guidelines in advance. For example, agencies can consider what questions may need to be addressed to make the decision to notify patients about an outbreak at a healthcare facility or notify patients about deficient medical care practices or possible infection risks (e.g., bloodborne pathogens) following an infection control breach.

3.8.3 Privacy

Public health agencies should be familiar with laws related to protecting the confidentiality of patients and healthcare facilities. Protocols similar to those used in the collection of routine surveillance data may guide records management protocols that are compliant with the Privacy Act, the Federal Information Security Modernization Act (FISMA), the Healthcare Insurance Portability and Accountability Act (HIPAA), and state laws. Plan to collect the minimum amount of data needed. The privacy rule allows healthcare entities to share protected information directly with public health agencies that are legally authorized to receive reports for the purpose of controlling disease, injury, or disability.[14,15]

Methods aimed at maintaining the confidentiality of information collected during the outbreak should be instituted and adhered to consistently. Examples of methods to maintain confidentiality include the following: assigning a unique non-personal identifier to patients (such as when transporting forms with medical information or when sharing information with agencies that do not need personal identifiers); encrypting emails when confidential information is shared between agencies; and limiting the number and type of personal identifiers collected as far as possible. Identifiers include direct identifiers (such as name, date of birth, and address) and indirect identifiers (such as dates of admission and discharge).[14,15]

Protection or disclosure of the name of a healthcare facility depends on state laws. In general, when there is a public health need to share the name of the healthcare facility in order to protect patients and the public, this need takes precedence.

3.8.4 Permissions and Approvals

The outbreak response team should consider if there are permissions and approvals that need to be obtained within their agency or across agencies. Understanding required permissions and approvals ahead of an outbreak can reduce miscommunication and speed up a response. Make sure there is an understanding with leadership within the agency of any necessary permissions and approvals.

Public health agencies should explore options and approaches for accessing facility medical records in advance of outbreaks. Often access to an electronic system of health records takes time to acquire, and valuable time can be saved if members of the outbreak team already have access; this accommodation may already be in place due to public health surveillance activities. In some cases, access may be given at the level of the health system. Gaining access to facility electronic medical records can be challenging but worth the initial effort in advance of, or very early in, an outbreak investigation.

3.9 Planning for Recovery and Follow-Up

3.9.1 Overview

Public health agencies should establish processes for completing an outbreak investigation, ensuring that gap

mitigation is maintained, and capturing lessons learned for applying them to future outbreaks. See Chapter 5 for additional details. When recovery and follow-up are planned ahead of an outbreak, information related to these activities can be recorded during the course of the outbreak investigation, saving time when wrapping up investigations.

3.9.2 Recovery and Follow-Up Model Practices

Model practices to plan for recovery and follow-up include the following:

- Establish criteria at the start of an outbreak to determine actions that must happen, or endpoints that must be met, before de-escalating enhanced surveillance or prevention measures. As the outbreak evolves, these criteria can be modified. In some situations, general criteria can be established ahead of an outbreak.
- Ensure that lessons learned are recorded throughout the outbreak investigation, and that these are available for informing and improving future outbreak response activities. Establish procedures for process improvement based on lessons learned.
- Identify final outbreak report templates and processes ahead of, or early in, the outbreak and consider populating information as the investigation progresses. This enhances recall and saves time at the end of an investigation.
- Consider after-action discussions following the investigation to identify successes, challenges, and any gaps that can be mitigated. Discussions should include agencies, facilities, providers, and other stakeholders involved in the response. It is often helpful to have discussions moderated by someone with expertise in facilitation. Preparation steps can include template after-action reports, template agendas for after-action meetings, and identification of facilitation experts.

CORHA Keys to Success

Developing Relationships Prior to an Outbreak

An outbreak is not the time for first introductions. Partners within the public health and healthcare community should recognize the importance of mutually supporting capabilities during outbreak investigations.

Relationships

- Relationships among public health agencies, regulatory agencies (e.g., state survey agency and state licensing boards), member organizations, law enforcement agencies, and healthcare facilities should be developed at and across local, state, and federal levels.
- Public health and healthcare facility relationships can be developed by attendance of public health agency staff at local meetings such as the Association for Professionals in Infection Control and Epidemiology (APIC), holding educational events or conferences for healthcare facility partners, and attendance and presentations at facility-offered events such as grand rounds.

Continued on following page.

CORHA Keys to Success

Relationships

- Public health agencies should collaborate with local healthcare industry associations such as the local hospital association, long-term care association, quality improvement organization, and professional societies. These organizations possess valuable knowledge from their stakeholders and can assist public health agencies in outreach efforts.
- Relationships are strengthened when public health agencies have established procedures for working with other agencies and organizations during an outbreak response, and when public health staff understand the roles of their agency and partner agencies. Public health agencies can also develop tools to help healthcare facilities respond to public health requests during an outbreak response.
- Use local epidemiology, newly published guidance, and lessons learned from previous outbreak investigations to identify opportunities for outreach.
- Relationships with healthcare facilities are strengthened when public health understands and acknowledges the expertise of the healthcare facility. One way to accomplish this is to ask for assistance from facilities or providers with expertise in areas in which public health is working.

Communication

- Procedures should be in place that describe general communication plans during an outbreak among involved partners. These procedures can be modified or specified in greater detail for individual outbreaks. Established communication plans can ensure clear communication is present from the initiation of an outbreak response.
- Plan for frequent communication among the outbreak response team and involved agencies; it is better to over-communicate than under-communicate. Prepare for communication using a variety of methods, including in-person or virtual meetings, conference calls, and email updates.
- Establishing methods and schedules for communication with facilities at the first stages of an investigation can help alleviate trying to communicate during busy schedules.
- Outbreak team members should practice excellent communication skills. Consider effective communication as one aspect of team member training in advance of an outbreak.

Flexibility

- Public health can assess the needs of healthcare facilities and provide services in advance (e.g., tools for outbreak response and advanced laboratory services). Flexible collaboration at all stages of preparation will enhance relationships and facilitate a nimbler outbreak response if the investigation changes course.
- All involved agencies and healthcare facilities should understand that the outbreak investigation can change course quickly, and staff should remain flexible during an outbreak response. Preparation should not be so rigid that this need for flexibility is overlooked.

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CHAPTER 4

Outbreak Detection & Reporting

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CHAPTER 4

Outbreak Detection & Reporting

Preface

Detection and reporting provide the foundation for healthcare outbreak response. Potential outbreaks may be detected and reported by healthcare facilities and astute clinicians, and occasionally from other partners and the public. Routine surveillance provides another important avenue to identify sentinel cases, clusters, and outbreaks of healthcare-associated infections (HAIs) and antimicrobial resistant (AR) pathogens.

4.0 Introduction

Detection represents the first and most essential step in the response pathway, triggering activities aimed at assessing the situation, implementing control measures, and halting disease transmission. In this chapter, we describe methods to detect outbreaks and ways in which HAI/AR outbreak identification can be improved. Section 4.1 provides an overview of healthcare outbreak detection and reporting; section 4.2 offers a description of communication pathways and systems to support direct reporting of potential outbreaks; and section 4.3 focuses on the use of routine surveillance systems for outbreak detection. The chapter concludes with section 4.4, which provides some considerations for detecting and reporting multifacility and multijurisdictional outbreaks.

4.1 Overview

Outbreaks can be detected by a variety of entities, including public health agencies, healthcare facilities, healthcare providers, laboratories, and other partners. Public health agencies and healthcare facilities share responsibility for outbreak detection and investigation, and, as described earlier in Chapter 3, relationships and communication among partners that detect and respond to outbreaks are essential to protecting the health of patients as well as that of the public. In this section, we review the definitions of the terms “cluster” and “outbreak” that will be used throughout the chapter and describe methods to detect outbreaks.

4.1.1 Outbreak Detection Pathways

Outbreaks can be detected by public health agencies and healthcare facilities via direct reporting (section 4.2), using routine surveillance data (section 4.3), or other means (Table 4.1). Reporting of potential outbreaks should occur internally within healthcare facilities as well as externally to public health agencies; in general, outbreak reporting is required by law (see Chapter 3 for more information).

Table 4.1 | Potential Methods of Outbreak Detection by Healthcare Facilities and Public Health Agencies

ENTITY	SOURCES OF OUTBREAK REPORTING	DATA SOURCES FOR OUTBREAK DETECTION	ADDITIONAL ACTIVITIES THAT MAY RESULT IN OUTBREAK DETECTION
Healthcare Facility	• Healthcare providers • Infection preventionist • Other healthcare facilities • Clinical laboratory • Hospital epidemiologist • Public health agencies • Patients • Members of the public • Media and social media	• Facility tracking systems (e.g., electronic medical records) • Admission, readmission, and transfer reports • Automated cluster detection systems • Clinical laboratory data	• Infection prevention rounds • Microbiology rounds
Public Health Agency	• Healthcare facilities • Healthcare providers • Clinical laboratories • Public health laboratories • Other public health agencies • Members of the public • Other agencies (e.g., state survey agency, Centers for Medicare & Medicaid Services [CMS], and accrediting organizations) • Media and social media	• Reportable conditions (including pathogens and HAIs) as well as general outbreak reporting requirements • Public health laboratory data • Other public health surveillance systems (e.g., sentinel surveillance systems and disease registries) • Other data sources (e.g., hospital discharge data)	• Infection control assessments • Prevention collaboratives • Other public health initiatives and stakeholder engagement

Outbreak reports may be directed to local, state, territorial, or tribal public health agencies. Public health agencies typically have protocols for communicating these reports to partner agencies (e.g., local health departments may report to a state public health department and vice versa).

One of the primary reasons for systematic collection of selected HAI and AR pathogen data via surveillance is to identify outbreak activity. Surveillance data can be used by healthcare facilities and public health agencies to detect sentinel cases and recognize patterns indicative of clusters or outbreaks. Identification of clusters or outbreaks may be accomplished by identifying similar cases within a facility, across multiple facilities, within the community, or across a region.

Understanding the endemic rates of a disease via surveillance, which can vary across institutions and jurisdictions, is often a key component of determining if an outbreak is occurring. In general, outbreak detection efforts benefit from a regular and systematic approach to reviewing surveillance data; the use of software programs can help automate this process.

Public health agencies may also learn about potential outbreaks as a result of infection control assessments and surveys or audits. For example, serious infection control breaches are now more likely to be reported to public health agencies when detected by state survey agencies or by accreditation partners, due to a requirement from the Centers for Medicare & Medicaid Services (CMS) to do so.[1]

4.1.2 Definitions

The term “cluster” can be defined as an unusual grouping of two or more instances of a disease or similar pathogen that occur together in time and space or share some other unique characteristic. A cluster is often the initial signal of possible transmission of disease and serves as a threshold to trigger further investigations to determine if the cluster represents an outbreak.

Chapter 4 Outbreak Detection & Reporting

When initial epidemiologic or laboratory evidence indicates possible transmission, we consider this a "potential" or "suspected" outbreak. This is the threshold for additional investigation and reporting to public health. The Centers for Disease Control and Prevention (CDC) *Field Epidemiology Manual* defines the terms "outbreak" and "epidemic" as follows:

> An outbreak is defined as "the occurrence of more cases of disease than expected in a given area or among a specific group of people over a particular period of time." When there are clearly many more cases than usual that are distributed across a larger geographic area, the term epidemic can be used.[2]

In healthcare settings in which certain types of infections are common and may even be the reason for a patient's admission, it can be challenging to recognize an increase in the number of cases above what is considered endemic or above the baseline of disease.[3] First, baselines vary from facility to facility, among various healthcare settings, and among regions of a state or country. Second, baseline levels within a particular healthcare setting may reflect inadequate control of ongoing transmission of pathogens.

Baselines may not be available for all pathogens and infection types; in some instances, the occurrence of even a solitary case can reflect a departure from baseline or expected levels. These may serve as sentinels (i.e., unexpected occurrences that require immediate attention) and are referred to in the *CORHA Principles & Practices* as "sentinel cases." For example, a solitary case of a bloodborne pathogen infection, such as the hepatitis C virus or human immunodeficiency virus (HIV), occurring as a result of a healthcare exposure exceeds the expected level; this is often sufficient to prompt an investigation.

Reports of unusual pathogens, unexpected infection types, or unusual combinations of pathogens and infections can all be useful in revealing a larger issue or outbreak. Examples of unusual situations that were reported to public health agencies and were the initial signals of larger outbreaks include nontuberculous mycobacteria (NTM) infections following cardiothoracic surgeries using heater-cooler devices,[4] a cluster of *Elizabethkingia anophelis* infections,[5] and fungal meningitis primarily due to *Exserohilum rostratum* among patients following injections of a compounded medication.[6]

Determining a single definition for "outbreak" that fits all HAI/AR situations can be challenging. Often it is beneficial to have established pathogen-specific reporting thresholds and outbreak definitions. A number of CORHA's pathogen- and condition-specific materials (available on the CORHA website) have been structured to include categories covering the threshold for facilities to begin an investigation, the threshold for facilities to report the situation to public health, and the definition of an outbreak. Note that confirmation of the presence of an outbreak, as part of an investigation, is discussed in Chapter 5.

Thresholds for investigation and reporting are critical for triggering a rapid response. For pathogens or conditions that do not have specific thresholds for reporting to public health, consideration should be given to the following general principles:

- There is a reasonable suspicion that pathogen transmission occurred between two or more individuals, based on preliminary epidemiologic and laboratory evidence.
- There is a reasonable suspicion that two or more cases of disease were acquired from a common source, based on preliminary epidemiologic and laboratory evidence.
- Single cases of unusual pathogens, unexpected infection types, and novel or rare conditions should be treated as sentinel cases so that they may be investigated as potential outbreaks. A similar rationale applies to suspected medical product contamination and serious infection control breaches (e.g., syringe reuse). The aforementioned criteria may also be applicable to illnesses due to noninfectious conditions (such as toxins or chemicals).

4.2 Reporting Sentinel Cases, Clusters, and Outbreaks

4.2.1 Purpose

Nearly every type of outbreak that can occur in the community can also occur within healthcare settings. On the other hand, healthcare settings are unique and complex settings that lend themselves to types of outbreaks that can only occur within healthcare venues. Many types of HAI/AR outbreaks can occur, and many of these are not routinely detected via public health surveillance because surveillance is usually limited in scope (e.g., specific infections or pathogens). The types of hazards addressed by healthcare outbreak response include overt outbreaks, clusters of infections, sentinel cases (e.g., an uncommon HAI or emerging AR threat), or serious breaches in infection control practice. Therefore, direct reporting of outbreaks, clusters, sentinel cases and serious breaches is a critical pathway for public health to become aware of potential outbreaks within healthcare settings.

4.2.2 Background

Reporting internally within a healthcare facility and externally to the public health agency as soon as a potential outbreak is detected is critical to ensuring an effective and timely outbreak response. See Table 4.1 for a list of possible reporting sources for each organization type. Although this chapter focuses primarily on public health outbreak detection, understanding the components of outbreak detection within healthcare facilities is also discussed to some extent for context.

4.2.2.1 Reporting within a Healthcare Facility

Healthcare facilities of all types should strive to have systems in place for staff to notify a designated person or team when a potential outbreak is recognized. Outbreaks are usually reported to an infection control team. In some facilities this may be a large team composed of infection preventionists, healthcare epidemiologists, and other experts. In other facilities it may be one person with multiple duties, including infection prevention. Within a healthcare facility, clinicians, staff, and laboratories are typically the most common sources of outbreak reports.

The culture of the healthcare facility should be such that internal reporting is an open process, wherein staff feel empowered to make a report and be supported when a notification is made. Public health agencies may detect an outbreak within a facility that the facility is not aware of, either by using surveillance data or based on a report from outside the facility. When this situation occurs, public health should contact administrators at the healthcare facility as soon as possible, to ensure that the facility can immediately respond to the situation and gather additional information.

4.2.2.2 Reporting to Public Health

Entities that report to public health are described in the next section and in Table 4.1. Processes should be established to receive, triage, and respond to reports of potential outbreaks.[7] These processes should be clearly communicated to outside partners that report as well as internally to staff members who respond to outbreaks. The easier it is for entities to report, the more likely they are to do so.

In general, all outbreaks are reportable to public health, including potential outbreaks, outbreaks occurring within a healthcare setting, and any situation that may indicate illness from a common exposure, including within healthcare. Increasingly, this includes requirements for reporting single cases of novel or rare conditions that may be sentinel events.[7] Healthcare facilities and other reporting entities should report potential outbreaks and should not wait until an outbreak is confirmed before doing so. However, not all outbreak reports will require an active response or extensive investigation; passive monitoring may be sufficient in some instances and is itself a form of surveillance (this topic is covered in additional detail in Chapter 5).

Public health agencies should collaborate with healthcare facilities and other reporting entities to improve outbreak reporting.[7] Some strategies that public health agencies can use to increase reporting include the following:

- Encouraging healthcare facilities to report anything that they believe is unusual, and maintaining open communication between the public health agency and the facility to allow for discussion of unusual situations

- Implementing an effective triage and prioritization process that allows for reporting of potential outbreaks with a full public health investigation only when indicated
- Striving for increased visibility among healthcare facilities and partners, such as through educational outreach on HAI/AR topics and reporting requirements and pathways
- Establishing and maintaining relationships among public health agencies and reporting entities

Perceived barriers to reporting potential outbreaks can include the following:

- Concern on the part of the facility that reporting may trigger additional work or regulatory action
- Uncertainty regarding reporting requirements or procedures
- Uncertainty about the thresholds for reporting
- Previous negative experiences with reporting

Public health agencies should be familiar with reporting barriers in their jurisdiction and collaborate with facilities to overcome these reporting barriers.

4.2.3 Reporting Entities

Reporting to public health can come from a variety of sources, including from the healthcare facility (from the infection prevention team, directly from staff, or from a clinical laboratory), from laboratories (public health laboratory, reference laboratory, or community laboratory), or from community sources (the public, the media, other government agencies, or other organizations). The public health agency receiving the report could be situated at the local, state, territorial, tribal, or federal level, and public health agencies that receive these reports should notify other impacted agencies as appropriate. If healthcare facility personnel contact CDC directly, CDC staff members will advise them of the need to coordinate with a state or local public health agency. Entities reporting outbreaks and those required to report may vary across jurisdictions.

4.2.3.1 Healthcare Facilities and Providers

In general, most HAI/AR outbreak reports are made to public health agencies by healthcare facilities and providers, who are on the front line for identifying reportable conditions, pathogens, and potential outbreaks. See Table 4.1 for information on how outbreaks come to the attention of facilities and public health.

4.2.3.2 Laboratories

Clinical laboratories and public health laboratories may detect potential outbreaks when, for example, similar test results indicate commonalities and possible linkages between specimens or patients. Laboratories may detect sentinel cases or identify clusters using automated processes and laboratory information systems, or astute laboratorians may identify these during specimen testing or record reviews. Laboratories that identify potential outbreaks should notify appropriate healthcare facility contacts (e.g., the infection prevention department), if applicable, and the public health agency. See sections 4.2.5 and 4.3.5 for more details.

4.2.3.3 Public, Patients, and Media

Less often, members of the public, including patients within a healthcare facility, may experience and report a sentinel case. Members of the public may call the health department directly, and public health agencies may also identify outbreaks based on information gleaned from social media. Initial reports may come to public health via the media, including posts on social media. In these situations, public health should initiate a brief investigation to see if there is a potential outbreak that has not yet been reported.

4.2.3.4 Other Government Agencies

Various other government agencies at the local, state and territorial, and federal levels may become aware of and report outbreaks to public health agencies.[7] For example, state facility licensing agencies may learn about an outbreak during a routine survey of a healthcare facility or an investigation of a complaint. Likewise, serious infection control breaches also may be identified by state facility and provider licensing agencies or other regulatory partners.[1,7] State healthcare facility and professional licensing agencies should report potential outbreaks to the public health agency. In turn, public health agencies should have protocols and the appropriate authority to receive and share information on potential outbreaks, including infection control breaches, with these entities.

4.2.3.5 Other Partners

Other partners working with healthcare settings may also be positioned to identify outbreaks.

- Accrediting organizations may identify and report a significant infection control breach or outbreak to public health authorities.
- Law enforcement personnel may identify concerns that they report to public health during criminal investigations.
- Other organizations with roles in HAI/AR prevention, such as hospital and long-term care associations, member organizations, and quality improvement organizations, may be the first to learn about an outbreak.

These partners may not have specific requirements to report; however, public health agencies should develop relationships with these entities, opening the door to communication when partners identify concerns.[7]

4.2.4 Epidemiology Process

When an initial report of an outbreak is received, there should be a pre-established process for intake as well as for assigning an appropriate staff member to the initial assessment. Information should be gathered from easily available sources to make a preliminary assessment and triage an appropriate level of response; see Chapter 5 for a detailed discussion of information to be gathered and how to determine the level of a response.

For each report received, consideration should be given to the possibility that the report may be linked to other reports or surveillance data. Linking clusters, outbreaks, and single cases of public health interest that have been detected can be done within the jurisdiction and is aided by having an outbreak investigation tracking system (see section 4.2.8.5) in place along with regular communications between surveillance and response staff. This can also be accomplished nationally via communication through CDC's Epi-X, listservs such as the Infectious Diseases Society of America's (IDSA's) Emerging Infection Network (https://ein.idsociety.org), or direct communication with CDC. These sources can be utilized to help ensure that the outbreak is not larger or broader than anticipated (e.g., due to distribution of a contaminated medical product).

4.2.5 Laboratory Process

When epidemiology staff members first receive a report of a potential outbreak, they should communicate with their public health laboratory colleagues to share initial information and allow them to prepare for upcoming laboratory activities appropriate for the investigation. In some instances, the public health laboratory will receive the first communication regarding a potential outbreak. For example, a hospital may contact the laboratory for assistance with specialized testing to assess the relatedness among isolates or samples as part of the hospital's internal investigation of a cluster of infections. At other times, a public health laboratory may detect a possible healthcare outbreak as part of its regular testing activities. In either case, laboratory staff should relay this information to their epidemiology colleagues. The key is to ensure clear communication and coordination between epidemiology and laboratory staff.

4.2.6 Strengths and Limitations of Outbreak Reporting Systems

4.2.6.1 Strengths

Strengths of outbreak reporting systems include the following:

- A healthcare outbreak reporting system provides the surest and fastest method for public health to learn about potential outbreaks.
- All types of outbreaks and infection control breaches can be reported, including outbreaks in which the pathogen is unknown or in which the pathogen or condition was not included in surveillance.
- During the reporting process, additional communication can occur between the reporter and public health staff.
  - Public health gains information quickly about the outbreak scope and infection control measures already in place.
  - Initial recommendations for prevention measures can be communicated during the initial report when appropriate, allowing for rapid intervention to prevent new cases. See Chapter 5 for additional details.
  - Healthcare facilities and providers have overlapping expertise with public health professionals, leading to a widespread system of experts who can identify clusters and outbreaks across the continuum of care.

4.2.6.2 Limitations

Outbreak reporting systems also have limitations.

- Defining and communicating clearly what should be reported can be challenging.
- Reporting systems depend on a wide variety of reporters with inconsistent understanding, interpretation, and practice related to surveillance and reporting.
- Signal fatigue can occur.
- Recognition of multifacility outbreaks can be delayed or missed if not all facilities involved make reports.

4.2.7 Key Determinants of Successful Outbreak Reporting Systems

A successful outbreak reporting system is one in which the reporting criteria are defined as clearly as possible, the entities reporting are clear about when and what to report, reporting is systematic and complete, processes for handling reports have been pre-established, and, when indicated, rapid investigation is initiated as a result.

4.2.7.1 Sensitivity of Detection

The sensitivity to detect outbreaks using an outbreak reporting system is highly dependent on the reporter's ability to recognize the significance of a sentinel case or to identify a cluster or other evidence of a potential outbreak, as well as awareness of and ease of using outbreak reporting mechanisms and procedures. Sensitivity of detection may also be dependent on the availability of resources at the public health agency, including staff with HAI/AR experience. Multifacility and product-related outbreaks can prove more difficult to detect than other types of outbreaks, because several individual reports may need to be linked together by the public health agency or agencies.

4.2.7.2 Prevalence of Disease

The prevalence of a pathogen or infection (or a pathogen-infection combination) impacts the ability of a healthcare facility, provider, or public health agency to identify a cluster. When the background prevalence of a disease is low, it is generally much easier for a sentinel case or cluster to stand out and be recognized. Conversely, when the background prevalence of a disease, infection, or pathogen is high (e.g., methicillin-susceptible *Staphylococcus aureus*), it can be challenging to discern a potential outbreak from background rates of sporadic disease occurrence. This can lead to delayed recognition and underreporting, along with missed opportunities for intervention and outbreak control. It can also lead to overreporting (due to decreased specificity), additional work for healthcare facilities and public health, and depletion of resources. Similarly, during an investigation involving a pathogen with a higher background prevalence, inclusion of cases that are not actually part of the outbreak (i.e., misclassification) can lead to challenges in finding the cause of the outbreak.

4.2.7.3 Relationships

The quality of relationships between the reporting entity and the public health agency can impact the willingness of the entity to report. If there is trust, mutual respect, and an understanding of the expertise and importance of each entity, the partners are much more likely to actively engage in reporting and joint investigations. It is critical to develop relationships prior to an outbreak, as discussed in detail in Chapter 3. Each outbreak response experience can have an impact on future reporting. Public health agencies can improve reporting by demonstrating sensitivity to the burden experienced by healthcare facilities and providers during a public health response to an outbreak; however, this should not be at the expense of a complete investigation when warranted.

4.2.8 Model Practices for Outbreak Reporting Systems

4.2.8.1 Required Reporting

Public health agencies benefit from establishing and communicating clear outbreak reporting requirements. Ideally, these will encompass HAI/AR response needs broadly, including confirmed outbreaks, clusters, sentinel cases (e.g., a novel or rare HAI or an emerging AR threat), and serious infection control breaches.[7] The method for setting forth requirements for reporting varies among states and territories. In addition, public health agencies should also have clear authority to initiate an outbreak investigation, including those occurring in healthcare settings, as well as authority to conduct all activities needed to stop the outbreak (as outlined in Chapter 3).

4.2.8.2 Ensuring Timeliness

Potential outbreaks should be reported to public health upon initial identification. Reporting entities should not wait until an outbreak is "confirmed" or an internal investigation has been completed before reporting to public health. Public health agencies should have a clear and easy reporting process (described below) and develop relationships with reporting entities to maintain open lines of communication.

4.2.8.3 Clear Reporting Process

Public health agencies should work toward ensuring that reporting entities understand reporting requirements in their jurisdiction;[7] toward this end, reporting requirements should frequently be communicated to reporting entities. Thresholds for reporting can be challenging to define and challenging for public health agencies to clearly communicate.

Public health agencies can remove barriers to reporting by helping interpret guidance, communicating expectations, and making the reporting process as simple as possible. When possible, the processes for reporting potential outbreaks should be clearly written and easily available, and include the following:

- Clear guidance on timing of reporting
- Description of what information is needed when making a report
- Clear, easy-to-locate information on the reporting method, which could be via phone (with numbers that are easy to locate, including a 24/7 after-hours number) and/or via systems for electronic reporting such as a web- or text message–based system
- Guidance on what to expect during and after the reporting process

Public health staff should have a clear understanding of the reporting process for entities that report, and there should be a clear, written internal process for standardized intake and triage of reports. Ideally, the reporting intake process should be centralized, so that one or only a few people conduct the intake or one person reviews reports to identify commonalities.

4.2.8.4 Useful Tools

Useful tools for an effective outbreak reporting system include clear written processes for intake, recording, and reviewing outbreak reports to guide the systematic collection of reports. An intake form can be helpful to ensure that information is collected systematically each time. Alternatively, an electronic system with required fields for filing outbreak reports can make it easy for the entity charged with reporting, as outlined in the following section.

Depending on the type of outbreak, reports of outbreaks can be checked against data collected in other systems, including state survey reports on the facilities involved; CDC's Epi-X, the IDSA Emerging Infection Network listserv (https://ein.idsociety.org), and other reports of ongoing national outbreaks; and public health surveillance systems that may identify additional cases.

Knowledge of healthcare facility systems and patient transfer patterns can be a useful tool to detect multifacility outbreaks and understand the potential scope of an outbreak. If public health agencies have the expertise and resources, a model practice is to create and maintain a network analysis of facility transfer patterns to apply to detected outbreaks.

4.2.8.5 Outbreak Tracking

As described in Chapter 3, each agency should strive to track all forms of outbreak reports and response activities, inclusive of clusters, sentinel events, and infection control breaches.[7] CORHA developed an HAI/AR Outbreak Investigation and Response Tracking System and associated data dictionary for this purpose; they are available on the CORHA website (www.corha.org/resources-and-products/?filter_cat=data-management). Health department HAI/AR programs also receive specific guidance on response tracking from CDC.

4.3 Detecting Sentinel Cases, Clusters, and Outbreaks through Surveillance

4.3.1 Purpose

By using surveillance data, public health agencies can systematically detect sentinel cases, clusters, and outbreaks of pathogens and conditions that are currently under public health surveillance. This is an essential public health activity that complements the direct outbreak reporting pathways reviewed in section 4.2. Patterns suspicious for an outbreak can be recognized not only within a single facility but across multiple facilities and throughout the community. Pattern recognition can occur via manual review of surveillance or laboratory data or automatically using specific software for data mining and cluster detection.

Public health agencies that rely on the detection of outbreaks using both surveillance data and outbreak reporting systems will detect more outbreaks than agencies relying on either system alone. Of note, while this section primarily takes the point of view of public health surveillance, many of the activities and principles reviewed here can also apply to healthcare facilities, especially larger hospital-based systems.

4.3.2 Background

Disease surveillance is an established practice in public health (as detailed in Chapter 2). By receiving reports of every case of a specific condition or pathogen, surveillance can be comprehensive, and by using various techniques, patterns in data can be recognized. In some situations, a review of case information in an electronic health record or health information exchange can be helpful to identifying characteristics indicative of a cluster or sentinel case. Public health agencies may adjust their approaches to performing surveillance and analyzing the data based on local epidemiology and priorities.

Two techniques that can assist with detecting patterns within surveillance data are routine laboratory typing and the use of automated systems to detect clusters. For example, when all *Salmonella* isolates undergo whole genome sequencing (WGS), a technique now used routinely in foodborne surveillance, clusters are identified based on the similarity of the isolates, which is determined by examining single nucleotide polymorphism (SNP) differences. A cluster of three *Salmonella* isolates with no SNP differences may lead to an investigation to find a link between cases.

HAI/AR programs within the U.S. have begun to implement similar laboratory testing approaches for pathogens related to healthcare settings, particularly those that represent emerging AR threats (see section 4.3.5). When available, innovative laboratory technologies provide powerful methods for enhancing outbreak detection. The use of automated systems, such as cluster detection software tools, applied to surveillance data is another method by which clusters and outbreaks may be detected. This method is described in greater detail in section 4.3.4.

4.3.2.1 Detection within a Healthcare Facility

Public health agencies should be aware of surveillance systems in place in healthcare facilities in their jurisdiction, including barriers that facilities may experience in implementing surveillance systems. Surveillance systems may vary widely across facilities and healthcare settings, and can include electronic health records, infection prevention systems, laboratory systems, or even basic line lists in small or low-resource facilities. Facility surveillance systems cross paths with public health when such systems are used to collect and report conditions under public health surveillance and when a system results in the detection of a cluster or outbreak that triggers public health reporting requirements.

Healthcare facilities should have surveillance systems in place for selected pathogens, conditions, and syndromes; an essential function of facility surveillance systems is to detect situations that indicate disease transmission within the facility. There is no single approach to surveillance that fits all healthcare facilities, and facilities should design surveillance procedures and systems based on their populations, priorities, and objectives, as well as on any applicable regulatory requirements.[8]

Recommendations for surveillance within healthcare facilities are outside the scope of this chapter, but other resources are available for this purpose.[7]

4.3.2.2 Detection by Public Health

HAIs and healthcare-associated pathogens, including AR pathogens, are reported to public health agencies according to state or territorial, tribal, and local regulations. Public health agencies establish lists of conditions for public health surveillance that are reportable by healthcare providers, healthcare facilities, and/or laboratories. Conditions to report may be pathogen-specific or based on infection type (described later in this chapter), or based on some other criteria. Isolates or clinical material are often required to be submitted in conjunction with the report. Additional information on surveillance practices can be found in Chapter 2. Reporting requirements by state are available at www.cste.org/group/SRCAQueryRes. Conditions that are notifiable to CDC on a national level can be accessed at https://www.cdc.gov/nchs/hus/sources-definitions/nndss.htm.

4.3.3 Types of Surveillance Data

It is important to understand the distinct types of HAI/AR surveillance data collected by public health agencies as well as their advantages and limitations. The two types of surveillance used extensively by health department HAI/AR programs are population-based surveillance and healthcare facility–based surveillance. Population-based surveillance involves identifying cases that meet a specific surveillance definition within a defined population, typically residents of a certain jurisdiction such as a state or a county.

For some conditions, surveillance occurs at the healthcare facility level rather than the population level; each healthcare facility may be expected to report conditions for their facility either to a local or state public health agency or to a national system such as CDC's National Healthcare Safety Network (NHSN), which in turn may transmit back to or be accessed by a local or state public health agency. See Chapter 2 for additional information on these surveillance practices.

When a cluster is detected using a specific data source, understanding the strengths and limitations of the surveillance system will lead to a more accurate interpretation of the significance of the cluster. An outbreak may be detected using population-based surveillance, healthcare facility–based surveillance, or other surveillance systems in use. One example of the latter may be a review of local or regional antibiogram data, when available, to understand the resistance pattern for organisms that are not selected for routine surveillance and to monitor for increasing levels of a particular pathogen or resistance pattern.

4.3.4 Epidemiology Process

Once reports of cases of a condition under surveillance are received by the public health agency, individual cases may be reviewed to gather additional epidemiologic data, depending on the priorities of the public health agency and local epidemiology as well as on the characteristics of the condition. Gathering additional epidemiologic information may be accomplished via discussions with the healthcare facility, medical record reviews, and/or interviews with patients. The level of additional data gathered for each case and the methodology employed is highly variable among jurisdictions and among specific pathogens or conditions; broadly speaking, it covers the epidemiologic "who, what, where, and when" and sometimes also includes aspects of the "why and how."

Resource limitations typically do not allow for complete data collection on every case for every pathogen and condition for which reports are collected. Public health agencies prioritize individual case investigations based on local epidemiology and priorities. Routine collection of selected information should occur as soon as possible after public health receives a case report to maximize the possibility of cluster detection. For more information on descriptive epidemiology, see Chapter 5 and *CDC's Principles of Epidemiology in Public Health Practice, 3rd Edition*.[3]

As epidemiologic information accrues, these data can be reviewed for possible linkages among cases in etiology, person, time, and place. Manual review of cases is one method to identify clusters in need of additional

investigation. Reviews may identify clusters associated with a particular facility or facility network among patients with similar healthcare conditions or exposures to procedures, or among patients with similar community exposures or other unique exposures. This works well if the condition under surveillance has a fairly low prevalence and the reviewer has a solid understanding of the data. If the prevalence of the condition is high, manual review of cases may be too labor-intensive and subjective to perform routinely.

More automated methods can be used to detect clusters using surveillance data, particularly when a high prevalence of disease is too cumbersome for manual review. Some public health agencies and hospital systems use automated methods, such as application of data mining and cluster detection software, to identify clusters among surveillance data. Automated technologies can speed up the process of detecting clusters and can combine data across data sources. Advantages of using automated cluster detection include speed, efficiency, accuracy, reduction of staff time, and the potential to detect more clusters and prevent more disease.[9,10] Additional resources are needed to implement such processes, such as information technology support, staff training, and software acquisition.

Use of automated systems by public health agencies to detect clusters currently varies greatly by jurisdiction; in a 2017 survey, 36% of respondents indicated that their agency did not use automated methods for cluster detection.[11] The most commonly reported barriers to automated methods for cluster detection include lack of resources, perceived lack of timeliness, lack of access to data, and lack of expertise.[11] It can be challenging to set parameters that provide enough sensitivity to detect every cluster that truly represents an outbreak without being so sensitive that more clusters are identified than can be investigated practically (including many that are not true outbreaks, representing a poor signal-to-noise ratio); a recent review found that the sensitivity of detection algorithms can vary between 17% and 100%.[12]

4.3.5 Laboratory Process

Electronic laboratory reporting for conditions under public health surveillance supports complete and accurate reporting. When unusual pathogens, testing results, and pathogen-specimen combinations are detected, astute laboratory staff are in a prime position to detect clusters and report potential outbreaks to clinical and public health partners. Laboratory information systems and other laboratory databases also can be sources of data to detect sentinel cases, clusters, and potential outbreaks.

Clinical laboratories forward isolates or clinical specimens to the public health laboratory according to local regulations as part of the surveillance process. For AR pathogens, as well as for other healthcare-associated pathogens (such as group A *Streptococcus*), it is important to receive isolates for confirmation (e.g., by identifying an organism's genus and species as well as its antimicrobial susceptibility) and additional testing to further characterize the isolate (e.g., by molecular testing).

For example, identification of mobile genetic elements of interest to public health, such as carbapenemase and *mcr-1* genes,[13] may be important to identify potential outbreaks; this additional characterization helps focus epidemiologic investigations on selected cases that truly may be related and avoid case misclassification. Additionally, some jurisdictions may prioritize AR pathogens with specific characteristics such as carbapenemase-producing carbapenem-resistant Enterobacterales (CP-CRE).

Epidemiologists should be aware of what testing is performed routinely on isolates submitted to the public health laboratory, what is the turn-around time, and how results are communicated to healthcare facilities. Communication of results to epidemiology and the healthcare facility should be timely and part of an established process. Laboratory processes that support surveillance also support the detection of clusters; epidemiology should be able to act quickly on single cases and clusters that have been detected.

In 2016 CDC established the Antibiotic Resistance Laboratory Network (AR Lab Network), which led to the expansion of capabilities of facilities and public health agencies to detect emerging AR threats and support coordinated local responses to prevent their spread. It also functions as a surveillance entity with the capacity to provide information on national trends and detect outbreaks. More information on the AR Lab Network can be found in Chapter 2 and at this website: https://www.cdc.gov/antimicrobial-resistance-laboratory-networks/php/about/index.html.

4.3.6 Strengths and Limitations of Surveillance for Outbreak Detection

4.3.6.1 Strengths

Using surveillance data to detect sentinel cases, clusters, and outbreaks has several strengths, namely

- Use of surveillance data has the potential to be thorough and systematic.
- When epidemiologic information is available on cases, the signal-to-noise ratio and sensitivity can be high.
- Surveillance data collection supports complementary processes—both manual and automated. The manual process of outbreak detection relies on personnel to review surveillance data and make connections among cases. With experienced personnel and less common conditions, this methodology should identify most outbreaks of diseases and conditions under surveillance. Using data mining and cluster detection software can supplement and automate this process.

4.3.6.2 Limitations

Limitations of outbreak detection using surveillance data include the following:

- Reliance on surveillance data to detect outbreaks only works for conditions under surveillance.
- Outbreak detection based on using surveillance data is typically slower than that based on direct outbreak reporting to public health. It is dependent on the timing and completeness of individual case reports, reports on results of additional testing, and the time it takes for staff or automated processes to flag a cluster (see section 4.3.7).
- Manual review of surveillance cases can miss clusters, is subject to human error, can be limited to a set of prespecified organisms (e.g., multidrug-resistant organisms [MDROs]), and can be very time-intensive.
- Automated cluster detection minimizes risk of human error; however, adjusting thresholds to achieve an effective signal-to-noise ratio can be tricky when the condition is common. Signal fatigue could occur if the signal-to-noise ratio is low.
- Using software for automated detection requires information technology resources and staff expertise.

Incorporating both outbreak reporting systems and use of routine surveillance data to detect outbreaks capitalizes on their complementary strengths and minimizes the limitations of each system. Public health agencies should consider options for improving and optimizing their use of both types of systems to detect potential outbreaks.

4.3.7 Key Determinants of Successful Outbreak Detection via Surveillance Systems

Successful use of surveillance to detect outbreaks is dependent on rapid surveillance with complete data, targeted and specific information collected on cases that supports epidemiologic linkage and cluster detection, and rapid and systematic identification of clusters using the data collected. The key determinants are discussed in this section.

4.3.7.1 Completeness of Reporting

To use surveillance data to detect clusters, cases must be reported in a complete, accurate, and timely fashion. Public health agencies can support this by ensuring that requirements for reporting within their jurisdictions are clear, there are rapid time frames for reporting, and there is clear communication with entities reporting cases for surveillance. Electronic laboratory reporting is systematic; it ensures complete and timely reporting on the part of the entities using it and should be employed when possible.

Additional epidemiologic information gathered on each case should be limited to what is needed and specific to assisting the detection of outbreaks; superfluous

information should not be included because that may divert resources. Laboratory testing performed by the reporting entity should be communicated to public health. The capacity of the public health laboratory to perform additional laboratory testing (e.g., confirmation of clinical laboratory test results and advanced laboratory testing including molecular testing) may determine if cases can be linked based on laboratory data; any testing performed by the public health laboratory should be completed in a timely manner and shared with epidemiologic staff responsible for performing cluster detection.

4.3.7.2 Sensitivity of Detection

Depending on the pathogen or condition, surveillance may identify only a sampling of the true number of cases in the population, and the completeness of reporting the true number of cases directly impacts the ability of public health to detect a cluster. With some HAI conditions, underdiagnosis and underreporting can decrease the sensitivity of case detection. Pathogen-specific surveillance, particularly that for AR pathogens, may provide an incomplete picture because of the presence of colonized individuals in the population or because of differential approaches to testing. Similarly, if isolates and clinical material are not routinely submitted for confirmation and additional testing, the included cases may not represent the true scope of an outbreak. WGS and other forms of next generation sequencing are extremely promising to help define the scope of outbreaks, particularly as these techniques become applied more widely. See Chapter 6 for more information.

4.3.7.3 Prevalence of Disease

As described previously, the prevalence of a disease often has an inverse relationship to the ease with which an outbreak can be detected. When the prevalence of disease is high, determining additional characteristics of the pathogen (e.g., by resistance mechanism testing or molecular typing such as WGS) and collecting additional epidemiologic data can be helpful in distinguishing cases that may be part of a cluster. For example, if a healthcare facility identifies two cases of carbapenem-resistant Enterobacterales (CRE) in an intensive care unit, it may be difficult to determine if this is a likely outbreak. However, if additional testing is performed and both isolates harbor a carbapenemase that has not yet been identified in the facility, it is much more likely that this will be identified as a cluster and possible outbreak.

4.3.7.4 Speed of Detection of Diseases and Conditions under Surveillance

It is advantageous to detect outbreaks as soon as possible so that, if warranted, an investigation can proceed and provide opportunities for swift implementation of control measures. Rapid outbreak detection and response depend on the speed of the reporting, which can be affected by local reporting requirements, time spent reviewing records and collecting information, and ease of use of reporting processes.

4.3.8 Model Practices for Detecting Outbreaks through Surveillance

4.3.8.1 Case Reporting

To support rapid detection of outbreaks, surveillance requirements and processes should reflect the need for timely case detection and reporting. Public health agencies can do the following:

- Create local timelines for reportable conditions that are commensurate with the urgency to detect outbreaks involving a specific disease or condition
- Put processes in place to make reporting easier for reporting entities (e.g., support electronic laboratory reporting) and support those entities by providing education, being available for questions, and communicating frequently and clearly the methods for reporting
- Ensure that case information that is collected is limited to what is needed for effective surveillance, outbreak detection, and other public health needs, ensuring judicious use of resources

4.3.8.2 Submission and Characterization of Isolates

Public health agencies often issue requirements for submission of isolates and clinical material in connection with case reports of communicable disease. This is especially useful when agency-directed testing for confirmation and characterization may assist with the identification of clusters and outbreaks. Clearly communicating the rationale and mechanisms for isolate submission helps ensure that this process happens

quickly and reliably. Providing additional guidance, as needed, to affected laboratories helps ensure that case reporting and isolate submission can occur simultaneously.

Awareness of local epidemiology, supported by communication between epidemiologists and public health laboratorians, allows laboratories to prioritize testing of pathogens as needed. Outbreak detection should be a strong consideration for prioritization of testing. Epidemiology staff should understand the testing practices and timelines of their laboratory partners.

When detecting clusters using surveillance data, establishment of etiology is a critical component. Laboratory testing frequently plays a key role in determining and confirming the diagnosis. For example, public health laboratories often will confirm test results performed at the clinical laboratory, especially when the etiology is in question. It is best practice to enlist the assistance of a reference laboratory with the capacity to perform advanced laboratory testing, such as the public health laboratory, when attempting to determine if isolates or specimens are related.

Resources do not always allow for every isolate or specimen to undergo advanced laboratory testing. When resources do not allow for typing of all submitted isolates, it is important for epidemiologists and public health laboratories to coordinate on prioritization strategies. The ideal practice would be to perform molecular typing on all isolates that are submitted. Detection of clusters via assessments of relatedness (e.g., sequencing and isolate typing) and confirmation of relatedness of isolates when suspected transmission is occurring would add to the ability of public health to detect clusters, confirm outbreaks, and ensure that cases identified as part of an outbreak investigation are not misclassified. Routine typing of isolates that are submitted as part of surveillance is gaining ground and remains an important long-term goal for the HAI/AR field.

4.3.8.3 Standardized Processes for Cluster Detection

Processes to identify clusters using surveillance data should be as rapid as possible, regardless of whether they are conducted manually or using an automated method. Public health entities may choose to implement manual cluster identification or automated cluster detection, depending on the pathogen or condition and available resources. As often as possible, public health agencies should have processes in place, preferably written, that are standardized to ensure consistent identification of clusters and outbreaks.

4.3.8.4 Communication

Laboratory staff should understand local epidemiology and be kept informed of clusters and outbreaks; epidemiology staff should understand the testing practices, constraints, and timelines of the laboratory. It is critical that laboratory and epidemiology staff communicate regularly to accomplish this. Routine procedures for communicating general practice information (such as regular meetings) should be established, as should procedures for rapidly communicating the day-to-day work of surveillance data, test results, cluster and outbreak detection, and local epidemiology patterns.

4.3.8.5 Useful Tools

The use of software programs to automate cluster detection is increasing, particularly in conjunction with antimicrobial resistance surveillance. Free software is available. One such tool is SaTScan™, which can be used in combination with data sources to detect clusters of disease using space, time, and space-time data. WHONET was developed to manage microbiology data by focusing on antimicrobial susceptibility test results; it has the capability to develop descriptive statistics and graphs that can be reviewed to detect possible clusters. WHONET can be used in combination with SaTScan. For further information or use, click on whonet.org and www.satscan.org.

Knowledge of healthcare facility systems and patient transfer patterns can be a useful tool to detect multifacility outbreaks and understand the potential scope of an outbreak. Public health agencies can consider creating and maintaining network analyses of facility transfer patterns to apply to detected outbreaks. Surveillance data can be applied to facility network maps to understand patterns that may indicate clusters or to identify facilities that may be at risk.

4.3.8.6 Outbreak Tracking

As discussed in Chapter 3, each agency should strive to track all outbreak responses, including investigations related to confirmed outbreaks, clusters, sentinel events, and infection control breaches. 7 As mentioned earlier, CORHA has an HAI/AR Outbreak Investigation and Response Tracking System and associated data dictionary for this purpose: www.corha.org/resources-and-products/?filter_cat=data-management. In addition, health department HAI/AR programs receive specific guidance on response tracking from CDC.

4.4 Multifacility and Multijurisdictional Considerations

Multifacility and multijurisdictional outbreaks can result from contaminated medical devices or drugs, a common healthcare provider, or other shared infection source that is present in multiple facilities or jurisdictions. Recognizing this type of outbreak is challenging because initial signals can manifest as a collection of seemingly isolated case reports. Recognition also may depend on a high index of suspicion and benefits from the use of direct reporting mechanisms. In fact, major multifacility and multijurisdictional outbreaks with high incidences of morbidity and mortality have been detected due to reports of a nonreportable condition that originated from a single healthcare facility or provider.[6,14,15]

While healthcare facilities and healthcare providers play important roles in helping identify multifacility outbreaks, public health agencies have the advantage of being able to monitor and link reports across facilities and even across jurisdictions. Cluster detection using surveillance data can help identify multifacility and multijurisdictional outbreaks that would otherwise go undetected.

Public health agencies should employ methods to detect outbreaks via reporting and use of surveillance data, as described throughout this chapter, to detect multifacility outbreaks; these agencies should maintain a low threshold for sharing concerns regarding a potential multijurisdictional outbreak with other state public health agencies or relevant federal agencies including CDC and the US Food and Drug Administration (FDA). Detection and investigation of multifacility and multijurisdictional outbreaks will be covered in additional detail in Chapter 7.

CORHA Keys to Success

Maximizing Outbreak Detection

Receiving Reports

- Perform surveillance for HAIs and AR pathogens that includes mandatory reporting and submission of isolates and clinical material when applicable.
- Ensure mandatory reporting includes reporting of potential outbreaks and novel or rare conditions that may represent sentinel events.
- Establish processes for reporting that are clear to reporting entities, easy to follow, and allow for rapid reporting.
- Establish thresholds for reporting potential outbreaks that are clearly defined; make guidelines for reporting as clear as possible.
- Ensure that entities that do not report regularly can easily find methods for reporting when they do identify a potential outbreak; build relationships with a variety of partners that may report.

Detection of Clusters and Outbreaks

- Use multiple methods to detect HAI/AR outbreaks, including, at a minimum, receiving reports of clusters and outbreaks and using surveillance data to detect clusters.
- Ensure processes are in place to detect clusters and outbreaks by using surveillance data; this may include review of surveillance data by experienced personnel, data analysis to identify clusters and outbreaks, or automated processes involving data mining and cluster detection methods.
- Ensure public health laboratory testing practices support the detection of outbreaks, including prioritization of testing based on local epidemiology and the ability to perform advanced laboratory testing, with regular communication between epidemiology and laboratory staff.

Communication

- Ensure that reporting entities receive detailed communication on reporting requirements with a frequency that maximizes sharing of information without overload.
- Clearly communicate thresholds and guidelines for reporting potential outbreaks to reporting entities.
- Ensure clear and regularly scheduled communication on local epidemiology and laboratory testing practices between epidemiology and laboratory public health staff. Processes for rapid communication of test results should be in place.

Evaluations

- Use an outbreak tracking database to monitor reports and investigation activities in a comprehensive manner. Use this information to identify areas for improvement.
- Periodically evaluate processes for outbreak detection and refine and enhance them when needed.

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CHAPTER 5

Investigation & Control

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CHAPTER 5

Investigation & Control

Preface

Chapter 5 offers a review of the key elements and steps involved in healthcare outbreak response. The chapter is arranged according to the steps typically followed in an outbreak investigation, recognizing that such steps may not occur in linear order and will depend on the precise nature and needs of the response. Chapter 5 also presents a review of the goals of a healthcare outbreak investigation and includes collections of resources to support and improve the healthcare-associated infection and antimicrobial resistance (HAI/AR) outbreak response.

5.0 Introduction

Collaboration between public health and healthcare is essential for an effective outbreak response. While healthcare settings are responsible for disease prevention and infection control practices on their premises, public health officials are generally responsible for ensuring the health and safety of the entire population within their jurisdiction, including patients, visitors, and employees in healthcare settings. During an outbreak investigation, public health authorities may conduct (or assist with) data collection, epidemiologic analyses, laboratory testing, and infection control and environmental assessments, as well as provide recommendations to prevent disease transmission.[1,2] The level of public health involvement and support will vary depending on the nature of the outbreak and available resources.

During an outbreak investigation, a systematic approach is necessary to determine the nature and scope of the problem, identify the etiologic agent, establish the existence of an outbreak, define the population at risk, determine risk factors and routes of transmission, implement appropriate control measures, and develop strategies to prevent future occurrences. For example, outbreaks of invasive *Mycobacterium chimaera* infections among cardiothoracic surgical patients exposed to heater-cooler devices identified a newly recognized HAI risk and resulted in new recommendations to prevent these life-threatening infections from being transmitted during surgical procedures.[3,4]

See Box 5.1 for HAI/AR outbreak investigation resources. The overall goals of an outbreak investigation are listed in Box 5.2. Objectives for healthcare outbreak response and associated activities to be performed by epidemiology, infection prevention, and public health laboratory staff are listed in Table 5.1. Investigation-specific objectives can be developed based on the goals and objectives listed in Box 5.2 and Table 5.1.

Box 5.1 | Selected HAI/AR Outbreak Investigation Resources

CDC Healthcare-Associated Infections (HAIs). Outbreak Toolkit: https://www.cdc.gov/healthcare-associated-infections/php/toolkit/outbreak-investigations-toolkit.html

CDC Healthcare-Associated Infections (HAIs). About outbreak investigations in healthcare settings: https://www.cdc.gov/healthcare-associated-infections/about/outbreak-investigations-in-healthcare.html

CORHA: www.corha.org

Outbreak response and incident management: SHEA guidance and resources for healthcare epidemiologists in United States acute-care hospitals[5]: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7113030/

Box 5.2 | Goals of an Outbreak Investigation

- Stop the outbreak as quickly as possible to protect patients
  - Ensure a rapid response with accurate information
  - Implement control measures that will halt transmission of disease and prevent additional cases
- Maintain the public's confidence
  - Recognize that patient and staff safety is the primary focus
  - Consider how decisions may impact patient care and public perception
- Recognize new and underappreciated risks associated with healthcare delivery
- Prevent future outbreaks
  - Identify systemic problems that may lead to additional patient harm
  - Mitigate gaps in infection control when identified and support mitigation of such gaps both within the facility and more broadly

What follows is a step-by-step guide for the investigation of an HAI/AR outbreak. Steps can be applied to other investigations such as suspected transmission events, sentinel cases of emerging pathogens, infection control breaches, and noninfectious toxin or chemical exposures. Although most steps in an outbreak investigation follow a logical process—from determining whether an outbreak exists to identifying and controlling the source of the outbreak—multiple steps often occur concurrently and not necessarily in a specific order. The steps covered here are from the perspective of the public health agency (see Box 5.3).[2] The healthcare facility may be concurrently implementing its own outbreak response activities, and coordination between that facility and the appropriate public health agency should occur with each step. A response should be appropriately rapid, but it is important also to ensure accuracy. Take the time needed to gather information, conduct background research, and gather initial data.

Table 5.1 | Investigation Activities in Support of Outbreak Response Objectives

OBJECTIVE	EPIDEMIOLOGY	INFECTION PREVENTION	PUBLIC HEALTH LABORATORY
Identify mode of transmission and vehicle.	• Obtain information on individual cases using any or all of the following: - Surveillance data - Medical records - Healthcare facility staff interviews - Patient interviews • Establish outbreak case definition based on clinical profile or characteristics of the pathogen, agent, or infection. • Characterize cases by person, place, and time, and evaluate this descriptive epidemiology to identify patterns. • Analyze exposure information by comparing cases to develop hypotheses.	• Obtain information about healthcare practices and infection control practices that may help characterize the outbreak.	• Obtain and store clinical material or isolates. • Perform confirmatory laboratory testing to confirm pathogen and/or antimicrobial resistance. • Perform molecular testing when applicable and available to assess relatedness.
Identify persons at risk and determine size and scope of outbreak.	• Look back at clinical laboratory records and other relevant facility records to identify cases. • Talk to facility staff to identify cases. • Depending on the nature of the outbreak, take additional steps as warranted; examples include contacting other facilities, healthcare providers, and/or public health agencies to ask if they have similar cases (“call for cases”) and directly asking members of the public to contact the health department.	• Communicate/alert key stakeholders.	• Contact clinical laboratories to identify additional cases. • Coordinate rapid referral and additional testing of outbreak specimens.

Table 5.1 | Investigation Activities in Support of Outbreak Response Objectives

OBJECTIVE	EPIDEMIOLOGY	INFECTION PREVENTION	PUBLIC HEALTH LABORATORY
Identify the cause of outbreak.	• Complete descriptive analysis using summary statistics, timelines, maps, epidemic curves, and other techniques to develop a list of possible causes. • Review descriptive epidemiologic results combined with any analytic epidemiology results to develop the most likely explanation for the outbreak.	• To determine any contributing gaps in infection control, perform an on-site infection control assessment to include - On-site observations - Facility staff interviews - Review of infection control policies	• Evaluate results of all outbreak-associated testing to highlight possible relations among isolates from clinical, environmental, and healthcare worker samples. • Work with the appropriate regulatory authority to ensure that samples are collected and maintained with appropriate chain of custody. This will help the regulatory authority take appropriate regulatory action.
Identify contributing factors and antecedents.	• Summarize information to identify confirmed or suspected contributing factors.	• Evaluate results of infection control assessment, taking into account identification of the agent and results of the epidemiologic investigation, to identify contributing factors and antecedents.	• Summarize information including appropriate metadata about testing results from clinical, environmental, and healthcare provider samples.
Determine the potential for ongoing transmission and need for control measures.	• Perform ongoing surveillance of the pathogen, agent, or infection using public health surveillance systems, clinical laboratory data, and facility prospective surveillance. • If the outbreak appears to be ongoing, continue surveillance and consider additional investigation and gap mitigation.	• Re-assess infection control practices after gap mitigation has occurred. • If deficient infection control practices are identified or if additional cases are identified following gap mitigation, consider re-assessment of infection control practices.	• Maintain stored sample using established specimen retention criteria, in case a comparison to newly identified cases is needed.

CORHA Keys to Success

Initial Steps in the Investigation of Outbreaks

Initial Steps That Should Be Performed Rapidly

- Complete initial steps in the investigation within a brief time. Use this information to develop plans for a more in-depth investigation when warranted.
- Confirm the diagnosis by obtaining and verifying clinical and laboratory information. Alert and communicate with key stakeholders.
- Begin by gathering readily available data from the affected healthcare facility(ies), laboratories, and applicable public health surveillance systems.
- Determine how the implicated agent was identified and request that specimens or microbial isolates be saved and made available for further testing. This should be done as soon as possible to avoid unintentional loss of the specimen(s).
- As needed, perform a literature review to understand the clinical features, host factors, exposure pathways, environmental factors, and other characteristics associated with the pathogen, infection, or condition; for novel or unfamiliar situations, consult experts and partners (e.g., the Centers for Disease Control and Prevention [CDC]).
- Develop a preliminary hypothesis.
- Establish objectives for the investigation that reflect overall goals of an outbreak investigation to identify hazards, stop the outbreak, maintain the public's confidence, and prevent future outbreaks.
- Determine the investigation authority based on local regulations.

Preliminary Control Measures

- Consider the need for instituting preliminary control measures based on initial information and descriptions of potentially hazardous conditions or practices (e.g., reuse of single-dose vials or other injection supplies).
- Perform a site visit and an on-site infection control assessment early in the process when warranted, including when there is
  - High potential impact to patients (e.g., high morbidity, mortality, or ongoing exposure) should this be ongoing cases instead of exposure; you probably do not know exposure at this point.
  - Involvement of an outpatient facility or other setting that lacks internal resources for conducting a reliable assessment.

Requests for Assistance

- Request assistance as soon as the need is recognized to allow for a rapid investigation at the level determined to be appropriate.

Evaluations

- Frequently re-evaluate outbreak response objectives, methods, and approach as findings accumulate. Questions to consider include:
  - Do the data support the hypothesis?
  - Does the hypothesis need to be revised?
  - Is there a need for additional resources?

Box 5.3 | Steps of an Outbreak Investigation

1. Perform an initial assessment.
2. Verify the diagnosis.
3. Assemble and brief the outbreak response team.
4. Establish a plan and prepare for fieldwork.
5. Confirm the presence of an outbreak.
6. Establish preliminary case definition and classification criteria.
7. Identify and count cases.
8. Collect, organize, and analyze data.
9. Perform an infection control assessment.
10. Consider an environmental assessment.
11. Recommend control measures.
12. Interpret results.
13. Monitor the outbreak until completion.

Not all steps may be performed in every outbreak response. There is no rule that steps should be performed in order, and some steps may take place concurrently.

5.1 Perform an Initial Assessment

5.1.1 Initial Information to be Gathered

When a cluster or potential outbreak is detected, collect as much of the following information as possible, knowing that some information may not initially be available. Initial data gathering may include conversations with personnel at the facility; a brief review of medical records, if easily accessible; and a brief review of public health surveillance data. Initial information can include the following:

- Specific pathogen, infection, or syndrome
- Number of cases identified, types of cases (e.g., infections vs. colonization and/or occurring primarily in patients vs. patients and staff), and outcomes (e.g., number of deaths)
- Known or expected background rate of cases, if known
- Date of detection of the potential outbreak
- Characteristics of the patients or affected population (e.g., basic demographics and/or underlying conditions); timing and details of potential exposures such as visits, procedures, surgery, and admission/discharge; timing and details of symptoms, testing, diagnosis, hospitalization, or other follow-up care; and death
- Type of setting and setting characteristics (e.g., if a skilled nursing facility, does the facility have multiple units, care for ventilated patients, etc.?)
- Location of the cases (e.g., facility-wide vs. confined to a single unit or type of unit)
- Any testing information available (e.g., laboratory name, dates of culture/testing, additional testing performed, and methodology[ies] used)
- Information related to any possible medical product involvement (more information is available at https://corha.org/wp-content/uploads/2019/06/CORHA-Medical-Product-Assessment-Questions.pdf)
- Descriptions of relevant care delivery practices to help gauge whether accepted infection control standards are being followed (e.g., for an outbreak involving injections, determination of whether single-dose vials are reused for multiple patients as well as other injection preparation and administration practices)
- Measures already implemented (e.g., infection control measures, additional testing, and notification of patients)

5.1.2 Initial Control Measures

A brief assessment of infection control practices should be performed when the initial information is gathered, often during the first phone call with the facility. If there are practices that need to be corrected immediately, this recommendation should be given to facility personnel as part of the initial assessment. Table 5.2 shows immediate control measures that could be followed. See Chapter 2, Table 2.2 for more examples that can inform initial steps; based on past experiences, specific interventions to address various situations are often known and should be considered for implementation, in advance of a more detailed investigation. Put another way, it is often not necessary to wait for a detailed on-site assessment for initial recommendations to be given. Infection control assessments and control measure recommendations are discussed in greater detail later in this chapter.

TABLE 5.2 | Immediate Control Measures for Healthcare Outbreak Management*

TYPE OF TRANSMISSION SUSPECTED	SUGGESTED ACTION
Cross-transmission (transmission between persons)	Patient isolation and transmission-based precautions determined by infectious agent(s); certain scenarios may require closure of locations to new admissions
Airborne infection (e.g., tuberculosis or emerging viral pathogens)	Triage, detection, and patient isolation with recommended ventilation type (positive or negative air pressure)
Agent present in water, waterborne agent	Assessment of the premises' water system, liquid products, or medications; use of disposable devices in which reusable equipment is suspected
Contaminated medical product	Sequestering of product and a switch to an alternate product or suspension of affected procedure(s); file MedWatch report to FDA
Environmental reservoir	Review and enhancement, as needed, of cleaning and disinfection processes; interruption of suspected mode of delivery from environment to patient
Colonized or infected healthcare personnel	Review of facility policies and discussion of work restrictions, duty exclusions, treatment, personal hygiene, or other steps
Infection control breach posing risk of bloodborne or other pathogen transmission	Immediate cessation of risky practice until corrective action can be instituted; patient notification; assurance that occupational health staff are aware

*Adapted from Christensen BE, Fagan RP. Healthcare Settings. In: Rasmussen SA, Goodman RA, eds. *The CDC Field Epidemiology Manual,* Table 18.3.[2]

5.1.3 Determining the Level of Response

Information gathered in the initial assessment will guide the next steps, including determining if an investigation is warranted. Levels of response for a public health agency may include a full investigation and response, investigation by the facility with public health being kept informed, or other approaches. An effective triage process should be established to determine an appropriate level of response and to ensure public health investigations proceed when needed; furthering the investigation is not necessary for all reports of potential outbreaks, although all should be tracked by public health.

Full investigations can be resource-intensive for the public health agency and the facility, and are not needed for all potential outbreaks. On the other hand, resource limitations should not be the sole factor in determining the appropriate level of response during an outbreak; additional staffing and expertise are usually available when a situation needs them (e.g., from other jurisdictions or departments within state or local public health, or from federal public health partners such as CDC). Local regulations and the authority to investigate may also need to be considered when determining the level of response, as noted in Chapter 3.

A more comprehensive investigation and public health involvement should be considered when

- Risk to patients may be elevated and ongoing due to a potentially hazardous, unusual, or unsafe situation.
- Failure to intervene could result in preventable exposures, patient harm, or spread.
- There is potential for greater levels of harm (e.g., morbidity and mortality) due to vulnerability of the population at risk or involvement of a considerable number of persons.
- Early implementation of proven control measures is time-sensitive (e.g., prophylaxis).
- Resources and the experience level at the facility to conduct its own investigation is limited, such as in healthcare settings with less infection control capacity such as outpatient settings.
- The facility involved has a history of struggling to manage outbreak response activities in an independent or reliable manner.
- There is a sentinel event, such as an unusual or novel organism or an organism-infection combination, the suspected involvement of a medical product, or other situation in which even a single case warrants additional follow-up.

Ensure the triage and prioritization process is established in advance and applied equally. A best practice is to have at hand criteria for the investigation and apply them as uniformly as possible, realizing that some judgment is needed and situations vary. The level of response may change as the investigation proceeds, and public health agencies should remain flexible.

5.1.4 Developing Hypotheses

To focus response activities, it helps to develop an initial hypothesis about potential sources of the outbreak early in the investigation. As noted in section 5.1.2, after gathering initial information, it is often possible to determine likely causes based on previous outbreak reports and experiences. Key steps to developing hypotheses include a review of what is known about the pathogen or infection, including results of previous outbreak investigations involving similar settings or procedures. Consider possible infection control breaches and medical product involvement early in hypothesis development, which can inform early control measures. Initial hypotheses can help direct the course of the investigation. Hypotheses should be re-evaluated, refined, and narrowed as the investigation proceeds.

Meanwhile in the Healthcare Facility…

Initial Assessment

At this point in the investigation, public health should be working with the healthcare facility. The facility may have already performed the following (levels of investigation performed at this point may vary among facilities and healthcare settings):

- Collection of initial information and development of hypotheses about the cause of the outbreak
- Implementation of infection control measures based on preliminary information and previous experiences involving similar types of outbreaks
- Notification of the facility leadership of the potential outbreak and reporting to the public health agency

5.2 Verify the Diagnosis

At the time a potential outbreak is detected, diagnosis of the disease may not yet be clear or, in some cases, may be incorrect. Early in the investigation, identify as accurately as possible the specific nature of the disease by ensuring that the diagnosis is correct; this can be done by investigating possible laboratory error or contamination as a basis for increased diagnoses, evaluating possible changes in surveillance and case definitions, and reviewing clinical findings and microbiological test results.[2] Information to be reviewed should include clinical features of the disease, timing of symptom onset, laboratory test results as they relate to the suspected source, and biologic plausibility.

The laboratory serving the facility or healthcare setting should be involved in the investigation as soon as an outbreak is suspected. Any clinical material, specimens, microbial isolates, environmental samples, and medical products (including medications and devices) should be saved; the public health team should prioritize contact with the laboratory to ensure that samples are saved and, if needed, forwarded to the public health laboratory as soon as possible. Retention of anything that may be tested as part of the investigation is increasingly important in the face of widespread use of culture-independent methods to detect specific microorganisms and drug-resistant genes. If an unusual microorganism is suspected in the outbreak, it is essential to confirm laboratory test results via a review of test methods or additional testing. Additional testing to confirm a diagnosis, identify possible resistance mechanisms, or assess relatedness via molecular methods should be considered and can be done at the state or local public health laboratory or another reference laboratory.

5.3 Assemble and Brief the Outbreak Response Team

The number and composition of members of the public health outbreak response team will depend on the nature of the outbreak. Consider the need for staff with epidemiology, data analysis, laboratory, infection prevention, and medical expertise. If multiple public health agencies are involved,

Meanwhile in the Healthcare Facility…

Verify the Diagnosis

The facility may be concurrently performing the following:

- Reviewing its own laboratory results and medical record information to verify the diagnosis
- Requesting assistance from public health to contact the laboratory, if external to the facility, to save isolates; and requesting assistance from the public health laboratory to perform additional testing
- Proceeding with infection control measures to protect patients, including saving suspected medical products and cessation of their use, if applicable

there will likely be multiple public health teams. A lead agency should be determined, and this agency will provide facilitation and coordination for the response. The leading agency is referred to as the "coordinating agency" in this chapter. Roles assigned should include designation of the team lead. During the investigation, the composition of the team may need to be modified. For complex or lengthy investigations, assess the availability of additional staff to backfill team members' routine work. For specific information on team member roles, see Chapter 3.

Each entity involved in an outbreak response may have its own team. The leading team may be from the healthcare facility, when public health is not directly involved, or from a public health agency that coordinates with the healthcare facility team. Similar strategies for team composition can be applied to teams from the healthcare facility and other agencies, although specific members and roles may vary. Close collaboration and coordination are needed when multiple teams are involved during a multifacility or multijurisdictional outbreak; this is described in additional detail in Chapter 7.

5.3.1 Partners

Multiple partners are likely to participate during an outbreak investigation. It is common for investigations to involve at least one public health agency along with the healthcare facility in which the potential outbreak occurred. Each involved entity may have its own response team. In addition to public health and the healthcare facility, other partners may include state facility licensing agencies (supervisory staff and surveyors from the involved healthcare setting); law enforcement (local, state, or federal), if criminal action could be involved; professional oversight organizations such as pharmacy boards or clinician licensing boards (staff from the licensing organization); or regulatory agencies such as the US Food and Drug Administration (FDA).[2] Representatives from the facility and public health may participate in investigative activities on a daily basis and be involved in many aspects of the outbreak response; other partners may participate as team members less frequently or provide assistance for specific parts of the investigation.

If the investigation cannot be managed with local resources alone due to its scale, complexity, or limited agency expertise, help should be requested sooner rather than later. Escalation may move from the local public health agency to the state public health agency to CDC; in some cases, escalation may be helpful to obtain additional opinions or perspectives; in other cases it may be helpful to request additional resources and expertise. A specific type of escalation involves Epi-Aids, investigations of an urgent public health problem led by CDC. Epi-Aids can be requested by a state, tribal, or territorial public health authority—often a state epidemiologist.[2,6]

5.3.2 Public Health Team Communication

Public health team members should participate in regular briefings. As an investigation evolves, consider bringing in additional team members as needed and as early as possible, such as communication staff, if media attention is anticipated, or legal staff, if legal questions are anticipated. The team lead should be open to assessing how team members are managing their workloads; team members should be open with their team lead about workloads and priorities. Consider implementing an incident command system (ICS) to formalize roles and communications when a large response is anticipated, See Chapter 3 for more information on the ICS. Should the investigation lead to media attention, ensure that public information officers are added to the team.

5.3.3 Communication Among Partners

The public health outbreak response team should coordinate with other entities involved in the response, including the healthcare facility, regulatory agencies, and other entities involved. It is essential to consider the roles and responsibilities of staff members at the affected healthcare facility and to communicate early and regularly with them, including sharing details of the outbreak response team's approach. The public health team should be aware of the multiple responsibilities of a healthcare facility outbreak response team, including ongoing surveillance and other roles. It is helpful for the public health team to consider the following regarding communication with the healthcare facility:

- Determine the frequency and method of communication with the healthcare facility early in the investigation. In some cases, daily calls can be helpful. Consider when to include healthcare facility staff members on public health calls, such as calls with staff at CDC.
- Methods for sharing information should be discussed early, as some entities may have restrictions on methods of sharing.
- An early discussion of priorities, objectives, and steps of the investigation can help prepare teams across entities.
- Value expertise across the partners.
- Determine methods that can help support staff members at the healthcare facility in their response.
- When giving recommendations, consider including methods for implementation.

Public health and regulatory investigations should be coordinated. When both public health and regulatory agencies are involved in an investigation, it may be helpful to consider establishing two coordinating agencies—one public health and the other regulatory—with management responsibilities shared between the two coordinating agencies. Because investigations can occur in parallel, it is critical that information be shared rapidly and fully between public health and regulatory agencies. In infection control breach investigations, a regulatory agency, such as the state survey agency or a professional licensing board, is often brought into the investigation early and, in fact, may be the initial investigating agency that notifies public health (see Supplement B for additional information regarding infection control breach investigations).

Information sharing is usually guided by local and state regulations, and the coordinating public health agency should be familiar with these regulations. If needed, legal staff should also be added to the team early to ensure that information-sharing regulations are followed. Typically, the regulatory agency is at the state level; coordination with public health may necessitate a specific role for the state public health agency, even if a local public health agency is designated as having the coordinating role. When sharing information with federal regulatory agencies, consider the necessary authority and procedures for sharing.

Drug diversion investigations are a subset of major infection control breaches that involve notification of and coordination with law enforcement, including local and state law enforcement agencies, the Drug Enforcement Administration (DEA), and FDA. Given coordination with multiple state and federal agencies, unless the local public health agency has broad expertise and capabilities, these investigations are usually led by a state public health agency. Coordination at the CDC level may occur if the drug diversion has a national component, such as a healthcare worker who has worked at healthcare facilities in multiple states. For more information on drug diversion investigations, see Supplement B and the CSTE Drug Diversion Toolkit: https://www.cste.org/general/custom.asp?page=Drug-Diversion-Toolkit.

CORHA Keys to Success

Communication During an Investigation

General Communication Strategies

- Develop agendas for meetings and calls with clear objectives and action items.
- Establish clear lines of communication internally and among points of contact for each partner involved.
- Train team members on basic communication skills. Communication during outbreaks is an opportunity to develop relationships; use this opportunity to be respectful and consider middle ground options. Establish an atmosphere of collaboration from the beginning.
- Establish a schedule of regular status updates across involved partners based on the needs of the partners.

Within the Agency

- Establish a system of regular briefings with the investigative team and others within the agency.
- Inform leadership early when an investigation begins and establish a plan for updating leadership.
- Involve experts, such as those involved in communication and emergency preparedness, as soon as it is determined that their expertise may be needed.

With the Involved Healthcare Facility(ies)

- Determine with the facility a clear plan for communication as early as possible, including frequency and method.
- Develop and clarify expectations of public health agency and facility roles and responsibilities early.
- During each communication, establish a detailed plan for next steps, including roles and responsibilities.
- Frequently update the facility with the progress of the investigation, including aggregate data summaries; facility staff often have epidemiology experience and can offer expertise.
- Consider in-person communication when tension is high. Public health agencies can improve relationships and help dispel tension through face-to-face meetings with involved healthcare facilities.

With Other Partners

- Determine a plan for communication during the investigation with all involved partners, including their roles and the frequency and method of updates. These plans may differ from communication among public health agencies and healthcare facilities.
- Communicate early with agencies, healthcare facilities, and partners if a publication or presentation is anticipated to result from an investigation and may lend itself to communication with a wider audience upon the investigation's conclusion. Establish leads for each potential product early in an investigation to avoid difficult conversations later in the investigation.

With Patients and the Public

- Consider early in the investigation the need to inform patients and the public, and to re-evaluate this need frequently. This is described in detail in Chapter 9.

Meanwhile in the Healthcare Facility…

Assemble and Brief the Outbreak Response Team

The facility may be concurrently performing the following:

- Assembling its own outbreak response team, depending on the healthcare setting, which could include a medical epidemiologist, an infection preventionist, environmental services department staff, clinical staff, laboratory staff, administrative leaders, communication staff, legal staff, and department leads for the affected facility areas
- Communicating with its corporate staff, which in some cases includes a medical epidemiologist and infection preventionist who may be an integral part of the outbreak investigation
- Developing or refining internal communication protocols specific to this outbreak investigation
- Communicating directly with state and federal regulatory partners

5.4 Establish a Plan and Prepare for Fieldwork

Based on data gathered in the initial assessment, determine what information is still lacking and what steps should be followed to gather that information. The team should be prepared to formulate a plan quickly for the next steps. Assign tasks to team members. Gather information on the pathogen or infection and similar previous outbreaks; typically, this is done via a review of the medical literature, review of previous outbreak reports, and consultation with experts.

When thinking through the steps of an investigation, consider the utility and burden of each task. For example: will additional laboratory testing change the course of an investigation? Consider for each step whether the results could impact the investigation; if a task will not impact the investigation or change public health recommendations, evaluate whether that task is absolutely necessary.

Depending on the severity, scope, and potential for spread of the outbreak, decide whether a site visit to the healthcare facility should occur and how soon that visit should be scheduled. Also consider the size of the public health team attending the site visit based on both the needs of public health and the facility. During infection control observations, deployment of small, more experienced teams may be prudent to minimize disruption to facility functions. Infection control visits can be paired with epidemiologic investigations, medical record reviews, and in-person public health–facility team meetings. Consider pairing trainees with more experienced team members. If multiple facilities are involved, consideration should be given to visiting all facilities involved; see Chapter 7 for more information on multifacility outbreaks.

Some preparatory actions may need to take place early, ahead of the site visit, to avoid delays, including the following:

- Access to medical records: This often takes time if not already established, and steps should be taken as early as possible to begin the process of gaining access to medical records. In some facilities this requires the help of information technology professionals. It can be helpful to involve infection preventionists, medical epidemiologists, or clinical staff partners to help communicate the urgency of an outbreak investigation. Requesting other types of records (such as infection or transmission-based precautions logs, facility maps, patient lists, or staff lists) can be done in advance of a site visit.
- Data collection tool development: As discussed in Chapter 3, it can be helpful to develop data collection tools in advance of an outbreak; the tools can be modified for specific outbreak and pathogen types. Using standardized tools during an outbreak response ensures uniform data collection and supports case definition development and case finding efforts (as described in sections 5.6 and 5.7). Final versions of data collection tools specific to an outbreak should be created for the collection of any data—onsite or otherwise. This should be done in advance of a site visit when possible.

- Determination of specific infection control observations: Depending on the type of outbreak, areas of the facility that should be visited for infection control observations will vary. Determine specific observations to be performed ahead of a site visit, allowing for flexibility during the visit itself as new information is discovered.

For anticipated large responses, consider tracking staff time spent, as this information can be used to understand resource needs for future investigations.

Meanwhile in the Healthcare Facility…

Establish a Plan and Prepare for Fieldwork

As the public health outbreak response team prepares for possible fieldwork, facility staff members are preparing to host public health authorities at their facility. It is important that the public health team understand the burden of preparation involved for the facility. The facility may be doing the following:

- Preparing its team and staff for a possible visit from public health authorities
- Preparing for a possible regulatory visit from state licensing agencies, although it is worth noting that these visits are usually unannounced
- Responding to public health requests for information, records, and access to records

5.5 Confirm the Presence of an Outbreak

Just as the diagnosis needs to be verified, it is important to confirm the presence of an outbreak. Keep in mind the following:

- Some cases may be part of the outbreak, whereas others may be unrelated.
- Increases in cases indicating a potential outbreak may be due to increased or changed local reporting procedures, changes in case definition, increased interest reflecting local or national awareness, or improvements or other changes in diagnostic procedures.
- A single case may be treated as a potential outbreak for response purposes if the pathogen, pathogen-infection combination, or situation is unusual or is a sentinel event.

Healthcare-related outbreaks may be a smaller part of a larger community-wide outbreak, which can be identified using public health surveillance data.[2] In these situations, possible community-associated or other explanations for illness not associated with healthcare should also be investigated.

Pseudo-outbreaks can manifest as an increase in diagnosed infections, often without clinical illness, which stem from laboratory processing errors or contamination of clinical diagnostic equipment such as bronchoscopes. Likewise, changes to surveillance methods can result in a spike in disease reports for a particular condition or pathogen. These situations are important to investigate. For example, an incorrect diagnosis can lead to unnecessary procedures, antibiotic prescriptions, and other potentially harmful or costly interventions. Consider a pseudo-outbreak when the pathogen identified does not match the clinical picture (e.g., patients do not have typical symptoms or compatible imaging findings). If a pseudo-outbreak is suspected, investigations may identify improper selection or contamination of materials used for specimen collection or deficiencies associated with reprocessing equipment involved in obtaining specimens (e.g., bronchoscopes or endoscopes).[2] Substandard laboratory practices or changes to surveillance practices should also be considered.

Meanwhile in the Healthcare Facility…

Confirm the Presence of an Outbreak

The facility may be concurrently performing the following:

- Reviewing its own surveillance data
- Communicating with colleagues at other facilities to determine whether other facilities are experiencing a similar situation
- Communicating with its laboratory to rule out the possibility of a pseudo-outbreak

5.6 Establish Case Definition and Classification Criteria

An outbreak case definition is a set of standardized criteria used to categorize patients. For outbreak investigation purposes, case definitions can be different from surveillance case definitions and different from clinical criteria for a diagnosis. A case definition typically includes:

- Clinical information relevant to the disease or condition (e.g., symptoms and signs) and/or laboratory information (e.g., diagnostic test results)
- Information about the location of possible exposure (e.g., intensive care unit, radiology suite, operating room, or ward)
- A defined time period during which exposure or onset occurred[2]

In some situations, demographic characteristics of affected patients may also be a part of a case definition.

Initially, consider using broad criteria for the case definition, making it more sensitive. As additional evidence accumulates, the case definition can be refined and made more specific; avoiding cases that might be unrelated is important when trying to identify causes. The case definition should be based on the etiologic agent, if known, and can include clinically infected and colonized patients. It is important to remember that the "case" designation references the set of defined criteria based on person, place, time, and other characteristics in the case definition and classifications (see below). The term "case" does not reference the patients themselves; in fact, in rare situations a single patient can represent more than one case (e.g., if the patient becomes infected serially within the outbreak period). When counting cases, it is important to distinguish the number of cases and the number of patients, as these may differ, and both sets of information can be useful to understand the outbreak. See Box 5.4 for example case definitions.

A stratified case definition (e.g., confirmed vs. probable vs. possible [i.e., suspect] or confirmed vs. probable) can be applied to account for the degree of uncertainty.

- Confirmed: Usually must have laboratory verification
- Probable: Usually has typical clinical features and an epidemiologic link to confirmed cases but lacks laboratory confirmation
- Possible (suspect): Usually has fewer of the typical clinical features or weaker epidemiologic links to confirmed cases[2]

Cases may move from one classification to another as additional information becomes available. For example, a case may be temporarily classified as *probable* or *possible* while laboratory results are pending.

Box 5.4 | Example Case Definitions

- *Pseudomonas aeruginosa* isolated from a blood culture with a culture date after January 1, 2019, collected from a patient who spent at least one night in the ICU in Hospital X, with <10 single nucleotide polymorphism (SNP) differences from the outbreak strain based on whole genome sequencing (WGS).
- Presence of at least two of the following symptoms: cough, sore throat, shortness of breath, or increased need for oxygen in a resident while residing in Nursing Home X between February 1 and March 31, 2022.
- A positive PCR test for *Klebsiella pneumoniae* carbapenemase in a specimen collected at any clinical site from a patient admitted to Hospital Y in November 2021.

Meanwhile in the Healthcare Facility…

Establish Case Definition and Classification Criteria

Although in some situations, a healthcare facility may be working to develop a case definition, in most circumstances this task is performed by public health. When a healthcare facility has the capacity to develop a case definition, the public health agency should work with the healthcare facility to develop a case definition that can be used by all partners.

5.7 Identify and Count Cases

Identification (and classification) of cases is important for several reasons. Case finding helps investigators confirm the presence of an outbreak, formulate accurate hypotheses for its cause, and direct resources to affected patients and institutions. The approach to finding and enumerating cases can reflect the stage of the investigation, similar to how a case definition can be adjusted over time to make it broad initially and then more specific (see previous section). Finding and counting cases in a comprehensive manner can support efforts to identify and evaluate potential risk factors. Once the cause of the outbreak has been determined, it may be less important (and could pose an unnecessary burden) to identify and account for every single related case.

Cases can be identified both retrospectively and prospectively. Retrospective case identification may involve the following methods:

- Reviewing laboratory records (e.g., microbiology logs to identify a specific pathogen or histopathology logs to identify invasive fungal infections)
- Reviewing facility surveillance records (e.g., infection prevention logs and/or National Healthcare Safety Network [NHSN] surveillance data)
- Reviewing other facility records, such as scheduling records, billing records, occupational health records, pharmacy records, radiology reports, admission/discharge records, or logs specific to the infection type (e.g., operating room logs to identify surgical site infections)
- Reviewing public health surveillance data (e.g., reportable condition and public health reports)
- Interviewing facility staff (e.g., infection preventionists, medical epidemiologists, clinicians, and laboratorians)
- Reaching out to clinicians, other facilities, or public health agencies (a "call for cases")—applicable to both retrospective and prospective case identification

Prospective case identification involves identifying new cases as the outbreak unfolds. Methods to consider for prospective case identification include:

- A call for cases, as described above
- Notification of clinicians to raise awareness, ensure appropriate testing, and encourage reporting to the infection prevention or outbreak team when suspected cases are identified
- Notification of laboratory staff to raise awareness, ensure appropriate testing, encourage reporting of cases, and ensure storage of clinical specimens or isolates appropriately to ensure further testing can be performed
- Testing of patients at risk who may be colonized or infected with specific pathogens (e.g., carbapenemase-producing carbapenem-resistant Enterobacterales, group A *Streptococcus*, or hepatitis C virus) to identify additional cases

Note that the pool of potentially exposed individuals may extend to healthcare workers, visitors, and even community residents, depending on the pathogen or syndrome and likely exposures. In general, testing of healthcare workers is only done when consistent with the epidemiologic picture and biologic plausibility.

Meanwhile in the Healthcare Facility…

Identify and Count Cases

The healthcare facility and public health agency should be collaborating to identify and count cases. At this step, the healthcare facility should be doing the following:

- Determining and implementing methodology to identify cases retrospectively and prospectively, including consideration of screening via testing when applicable
- Notifying clinicians and laboratory staff within the facility to be alert for cases meeting the case definition
- Considering whether other facilities within the facility's network need to be notified
- Considering a call for cases among networks depending on likely hypotheses
- Tracking cases within the facility and being prepared to share information with public health

Cases should be counted systematically, uniformly applying the developed case definition, stratification, and classification. As noted earlier, in some instances the approach can be adjusted (e.g., made less meticulous) after the cause of the outbreak has been determined. It can also be helpful to track all reported or detected cases, including those not meeting the case definition. In that way, if the case definition is refined and additional cases meet the case definition, this information will already be available. Methodology for tracking cases can be found in the following section.

5.8 Collect, Organize, and Analyze Data

5.8.1 Data Collection

Data collection refers to all information gathered during an investigation, including patient-specific data gathered from medical records, information amassed during the review of logs and other facility records, data collected during the case identification process, infection control assessments, laboratory results, and any other pieces of information relevant to the investigation. Data sources used to identify cases (listed in the previous section) can also be used to collect data during the investigation; types of records are listed in Box 5.5. Information can be entered into a line list or database to allow for easy review.

Box 5.5 | Healthcare Facility Records to Consider Reviewing During an Outbreak Investigation[4]

- Individual patient medical records
- Infection control dashboard
- Records that specify dates of precautions (e.g., contact or droplet)
- Central service or supply records
- Occupational health records
- Hospital billing records
- Operative notes
- Infection control assessment
- Pathology reports
- Interviews with physicians
- Pharmacy reports
- Logbooks
- Purchasing records
- Medical records
- Radiology reports
- Microbiology data
- Surveillance records

Information should be gathered systematically, maintained in a consistent format with appropriate security safeguards, and compiled in a way that is easy to store, review, and interpret. The use of standardized data collection forms ensures that pertinent information is collected from all patients, medical records, and other sources for subsequent systematic analysis. In addition, the use of standardized data elements (e.g., same variable names and attributes) will enhance data sharing and comparisons of exposures between cases and controls and/or within different healthcare facilities and/or jurisdictions, if indicated. Although a paper tool will suffice when a few cases are involved, the development and use of a readily accessible electronic database can be invaluable to ensure all critical team members across entities have timely and salient information during large, complex, or multijurisdictional investigations.

A standardized data collection tool will ensure that consistent, complete information is collected on all outbreak cases. This can be developed by the public health agency or adapted from a tool available from CDC (https://www.cdc.gov/healthcare-associated-infections/media/pdfs/Response-Toolkit-Abstraction-Form-508.pdf). If a case-control study is begun to test various hypotheses, the same tool can be used to collect information on control patients. A standardized data collection form should also be used in the event patients need to be interviewed. The data collection tool usually comprises the following components:

- Patient-identifying information such as name, medical record number, admission date, admission source (admitted from emergency department, home, another facility [name of facility], etc.), and discharge date and discharge status (discharged to home, transferred to another facility, deceased, etc.)

- Demographic information, such as age, sex/gender, and race/ethnicity
- Location information (e.g., room, unit, ward, floor, and building; facility type or healthcare setting; and single vs. multi-occupancy room)
- Clinical information focused on simple, objective criteria to the extent possible: disease signs and symptoms that allow investigators to verify that the case definition has been met; date of illness onset or specimen collection needed to chart the time course of the outbreak and, when applicable, the incubation period; supplementary clinical information, such as illness duration and rehospitalizations or patient death, which help characterize the spectrum of illness
- Risk factor information tailored to the specific disease and situation under investigation
- Other information (e.g., insurance status, socioeconomic characteristics) not covered above that could identify healthcare disparities or issues relating to health equity

As described in Chapter 3, section 3.8.3, information that can be used to identify a patient in some way (both direct and indirect identifiers, including names, addresses, dates of birth, dates of admission/discharge/death, and anything that can identify an individual) must be protected from public disclosure. All members of the outbreak response team—epidemiologists, laboratorians, environmental health specialists, and healthcare personnel—must follow data security practices and comply with relevant state and federal laws.

5.8.2 Organize Data and Perform Descriptive Epidemiology

Data collected using standardized methods should be organized systematically. Initially, this is accomplished with the aid of a line list,[2] which typically involves using a spreadsheet so that data can be organized and sorted easily during initial review and analysis. The line list helps guide the outbreak investigation and permits rapid examination of exposures. For each case, collect and array the following types of information encompassed by the case definition:

- Demographic information: age, sex/gender, race/ethnicity, and occupation, plus other relevant characteristics of the affected population or others at risk
- Location information: location within the facility (e.g., room number, bed number, and adjacent rooms)
- Temporal information: examples include dates of illness onset, diagnosis, admission, discharge, procedures
- Clinical information: symptoms, signs, and laboratory test results (e.g., culture, serology, or polymerase chain reaction [PCR] results)
- Risk factor information as it relates to the specific disease in question[2]

Once the information is collected and organized, performance of descriptive epidemiologic analysis is the first stage; this includes describing the data using tables, graphs, diagrams, maps, or charts to answer the basic questions of what, when, where, among whom, and how much. Descriptive epidemiology provides a critical assessment of the status of the outbreak and often serves as the basis for determining further actions such as implementing specific prevention and control measures, initiating environmental assessments, and conducting analytic studies to test specific hypotheses. In many investigations, descriptive epidemiology is sufficient to determine the likely outbreak cause with sufficient confidence.

The analytic approach used in any situation depends on multiple factors, including circumstances specific to the outbreak (e.g., the pathogen and number and distribution

Figure 5.1 | Sample Timeline

	1/1	1/2	1/3	1/4	1/5	1/6	1/7	1/8
Patient 1		**		*				
Patient 2	**	*						
Patient 3							**	*

Legend: Blue boxes = time in facility; * = date of positive culture; ** = date of procedure

of cases), staff expertise, structure of the investigating agency, and agency resources. Investigators are encouraged to use a combination of analytic approaches, as appropriate to the specific outbreak.

The first step in a descriptive epidemiologic analysis is to describe cases or case-patients, typically in a simple table that includes the numerator, denominator, and percent (or mean, median and range) for each characteristic (e.g., demographics, exposures, and risk factors). Additional tools used to organize data include maps and timelines. Facility maps are often extremely helpful and can be used to create spatial images of patients' locations and movements. Creating a timeline for each patient that includes exposures of relevance, testing dates, symptom onset, and patient locations can also be helpful to identifying common factors and overlaps. See Figure 5.1 for a sample timeline. All components of descriptive epidemiology, particularly when combined with infection control assessments, can be used to develop, refine, and evaluate hypotheses regarding the cause of the outbreak. As described in Chapter 3, tools can be developed during the preparation phase and stored ahead of the outbreak investigation.

In many outbreak investigations, it is helpful to prepare an epidemic curve (i.e., a histogram). The epidemic curve is used to depict the magnitude of the outbreak over time, provide clues about the pattern of spread, identify the current phase of the outbreak, evaluate the effectiveness of control measures, identify outliers that may provide clues, distinguish an epidemic from endemic disease, and deduce a probable time of exposure when an incubation period is known. Update the epidemic curve regularly to depict the status of the outbreak. Notable events, such as implementation of control measures, and specific characteristics of cases, such as genetic matches, can also be indicated on the epidemic curve.

5.8.3 Refining the Hypothesis

Development of the initial hypothesis should occur early in the investigation, using findings from the descriptive epidemiologic analysis to refine the hypothesis further. After an explanatory outbreak hypothesis has been developed, the next step is to evaluate its plausibility, typically by using a combination of epidemiology, laboratory, and environmental evidence. From the epidemiologic point of view, hypotheses are evaluated either by comparing a hypothesis with established facts or by using analytic epidemiology to quantify relationships and assess the role of chance.

The first method, simple comparisons, is likely to be sufficient when the leading hypothesis is supported by the accumulated evidence in an obvious manner and to the degree that formal hypothesis testing is unnecessary. Additionally, control measures are often clear and can be implemented without the need for further epidemiologic studies and analyses. Many outbreaks do not have a sufficient number of cases or a predicted cause of the outbreak is multifactorial; in these situations, more complex analytic epidemiology may not help advance the investigation. However, when there is a clear hypothesis to be tested in the presence of a sufficient number of cases and particular exposure(s) of interest, analytic epidemiology can be useful. Sometimes a case that has unique characteristics or risk factors can be helpful in developing or refining a hypothesis. Care should be taken in refining the case definition or hypothesis based on outliers; in some situations, outliers may provide useful clues to the cause of an outbreak, but they also can be red herrings that are not part of the outbreak at all.

5.8.4 Analytic Epidemiology

Analytic epidemiology can be used for hypothesis testing when conducting a healthcare outbreak investigation. The two most common types of analytic epidemiology studies used in field investigations are *retrospective cohort studies* and *case-control studies*. Additional information about each can be found in Appendix A.

In healthcare investigations, analytic studies typically take the form of a case-control study. The frequency of exposure to a risk factor among a group of case-patients (i.e., persons with the condition of interest) is compared with the frequency of exposure to that risk factor among a group of controls (i.e., persons without the condition of interest). Controls must be selected carefully to limit bias. Two or more controls for each case-patient may be needed to provide sufficient statistical power.

Analytic studies are labor-intensive and are not always necessary to identify the likely source of an outbreak or to institute control measures in healthcare investigations. For example, a combination of laboratory evidence and observations of serious lapses in infection control practices that are known to be associated with disease transmission are frequently sufficient to recommend and implement control measures. The following considerations can influence the decision to conduct an analytic study:

- Will an analytic study add to what is already known about the cause of the outbreak or contribute to the control recommendations?
- Is the necessary technical and statistical support available?
- Is the number of cases large enough to power the analysis and support statistical inferences?
- Can a sufficient number of controls be selected to minimize bias?
- Is information available for testing possible risk factors?

Meanwhile in the Healthcare Facility…

Collect, Organize, and Analyze Data

Different healthcare facilities and facility types may have different capacities to collect, organize, and analyze data. Some facilities may perform the collection and organization of data, whereas others may also be able to perform analyses such as timelines and epidemic (epi) curves. Some healthcare facilities rely on public health for all data collection and analysis. Public health should be sure to frequently communicate the results of analyses with the healthcare facility. The healthcare facility may be doing the following during this step:

- Collecting data on cases or assisting public health to do so
- Tracking information on cases within healthcare facility systems
- Performing data analysis or assisting the public health agency to do so
- Responding to public health requests for additional data, facility maps, or other additional information

A prerequisite to the conduct of an analytic study is having a sufficient sample of cases to power the statistical analyses. The key feature of analytic epidemiology is inclusion of a comparison group, which enables epidemiologists to quantify the relationships between exposures and disease by contrasting observed patterns (e.g., incidence rates and odds ratios) among case-patients or exposed persons with those among non–case-patients or unexposed persons. In this manner, investigators can test a hypothesis regarding the likelihood of those relationships being due to chance.

5.9 Perform an Infection Control Assessment

Infection control assessments offer the opportunity for public health to understand risk factors that may have contributed to or resulted in an outbreak. In some cases, infection control assessments may be brief and conducted over the phone; for example, as part of the initial assessment (section 5.1). In many cases, however, the best practice is for the public health outbreak response team to make a site visit to the facility that includes an on-site infection control assessment. If this is not feasible, consideration can be given to performing a virtual assessment using video meeting applications.[7] Unfortunately, limitations to this approach exist. Video views may be restricted to the selected camera angle, and potentially inaccurate assessments of true infection control practices may result if facility preparations are put in place prior to the virtual visit.

Interviews and discussions with both managers and frontline staff can help identify areas of concern and help focus infection control audits and other forms of assessment related to the environment of care, procurement and handling of equipment and supplies, or environmental factors that could have contributed to the outbreak. Direct observation of infection control practices and other conditions at the facility often results in the identification of infection control breaches or other exposures that contribute to patient harm. Considerations for performing an on-site infection control assessment include the following:

- On-site visits provide the opportunity to interact with and interview key staff, tour relevant areas of the

facility, and gain increased understanding of the conditions, layout, culture, and common practices within an affected facility.
- On-site observations can be combined with on-site medical record reviews.
- If a regulatory agency is also conducting on-site visits, visits could be consolidated into joint (public health–regulatory) agency visits, which would provide greater information to both agencies and the potential for decreased burden on the facility.
- Control measures can be recommended during an on-site visit.

Ideally, the outbreak response team will have expertise in infection prevention, which will aid the facility walk-through and infection control assessment. An infection control assessment should be tailored to the type of facility, the population affected, and common case-patient exposures or other potential risk factors. However, it can be helpful in some instances to broaden the assessment to aid with the identification of additional risk factors, unanticipated exposure pathways, and suboptimal practices. Consider the following areas of focus when preparing for and conducting on-site investigations:
- Prepare for the visit by reviewing scientific literature related to the key concerns involved with the outbreak.
- Assemble checklists and other audit tools in advance of the visit; maintain familiarity with locally available examples of such items (e.g., those used in previous investigations) as well as general and setting-specific tools made available on the CDC website: https://www.cdc.gov/healthcare-associated-infections/php/toolkit/icar.html.
- Assess whether actual practices deviate from recommended infection control practices and facility policies. Such discrepancies are best identified through a combination of direct observations and review of healthcare provider self-reported practices.
- Examine whether practices differ among healthcare providers; give priority to observing staff who were most closely involved in providing care for the case-patients.
- Observe key activities (e.g., medication preparation, care of vascular access, hand hygiene, adherence to isolation precautions, device and equipment reprocessing, environmental services, and respiratory therapy) related to suspicions about likely transmission pathways that may be involved in the outbreak.
- Consider taking photographs when possible. Be aware of facility and public health internal policies; photos should not contain anything that can identify a patient. Photos of medical products during medical product investigations can be extremely helpful; think about using photos to document lot numbers and specific product information.
- Review key concerns with facility staff to help generate hypotheses about the disease source and mode(s) of transmission. Review challenges with maintaining good infection control practices, facility staff members' thoughts on the root cause of the outbreak, and information that may not be documented in medical records.
- Review protocols and procedures to ensure that they are up-to-date and have been followed consistently. Assess if actual practice matches written and verbal protocols and what is expected.[2]

In addition to direct observations, it can be helpful to talk with multiple staff members about their routine infection control practices in detail, as sometimes it is not possible

Meanwhile in the Healthcare Facility…

Perform an Infection Control Assessment

Facilities with an infection preventionist or an infection prevention team will likely have performed an infection control assessment (or several) before the public health agency does. It is helpful for the public health agency team and the facility infection prevention team to work together to compare findings, and it is beneficial to have duplicate infection control assessments between the facility and the public health agency. Facilities that do not have infection control teams or an infection preventionist can benefit from an on-site public health assessment by receiving education during the visit. Facilities may prepare ahead of the arrival of the public health team; it may be beneficial to remind the facility that to help them, public health personnel need to observe actual, not optimal, infection control practices.

to observe each staff member; this additional step can identify gaps in infection control that may not be detected through observation alone. A good technique to approach observations and staff interviews is to emphasize that you would like to learn how different staff members perform the task of interest since approaches may vary.

5.10 Consider an Environmental Assessment

An environmental assessment is a systematic evaluation of environmental factors that may have contributed to an outbreak. The need for an environmental assessment is informed by epidemiologic and other findings from the investigation. Often, some form of environmental assessment is conducted as part of the on-site work and infection control assessment, such as an assessment of environmental cleaning practices that includes observations and interviews with environmental services staff. CDC has specialized tools available to help guide environmental assessments when investigating outbreaks involving waterborne pathogens or outbreaks caused by certain fungi such as *Aspergillus* and mucormycetes.[8,9] The overall goal of the environmental assessment is to identify possible environmental risk factors that contributed to the outbreak, such as:

- Possible points of contamination and contact between the disease agent and vulnerable persons
- Environmental conditions conducive to microbial survival, growth, and transmission

Environmental cultures are infrequently warranted and should only be obtained once a potential microbial source or reservoir has been identified and epidemiologically linked to the outbreak cases. For example, air sampling in an operating room that may be affected by its construction may be pursued during the investigation of an outbreak of surgical site infections with Aspergillus.[9] Since clinical laboratories may not be licensed or able to perform environmental testing, samples may need to be sent to a public health, environmental, or reference laboratory.

Additional information on the laboratory component of an environmental assessment can be found in Chapter 6. Methods used in the collection of environmental samples can influence the accuracy and interpretation of results, and therefore consultation with a laboratory experienced in environmental sampling is advised. Check with the laboratory regarding validated collection methods and supplies needed to collect environmental samples.

Meanwhile in the Healthcare Facility…

Consider an Environmental Assessment

Facilities with an infection preventionist or an infection prevention team will likely be able to perform an environmental assessment. When environmental sampling is performed, the facility will work with its laboratory to ensure that sampling procedures are correct and the laboratory has the capability to perform the testing. Often public health laboratories are needed for testing environmental samples, and coordination between clinical and public health laboratories is needed in this situation.

5.11 Recommend Control Measures

Effective control measures are critical for stopping the outbreak and preventing recurrence. If appropriate disease control measures are known and available, they should be initiated as soon as possible, even before a full investigation is launched. Control measures can be recommended at various times throughout an investigation, including during the initial assessment, when performing on-site assessments, and following the on-site assessment. In general, such measures are directed against one or more segments in the chain of transmission that are susceptible to intervention—agent, source, mode of transmission, portal of entry, or host. See Chapter 2, section 2.3, for example scenarios.

It is helpful to provide the facility with recommendations in writing, either as part of an infection control assessment form or as a letter of recommendation. In some cases, flexibility in implementation can be helpful to the facility when patient safety is not compromised. Follow up with the facility to ensure that recommendations have been followed and prevention measures are in place; this may be done in person or via phone or email communication, depending on the situation.

Keep in mind that regulatory partners (e.g., state professional boards or the state healthcare facility licensing agency) may need to be informed of the investigation's findings and recommendations, according to local regulations, and may exert oversight authority as part of the corrective actions. Practices can be difficult to change, and new practices may need to be used for a substantial time before they become routine. For independent outpatient offices or facilities, monitoring implementation of preventive controls typically warrants heightened levels of attention.

In situations in which there is the potential for imminent harm to patients, the on-site team should consider the following steps:

- Notifying leadership and legal staff within your agency
- Notifying the appropriate regulatory agency
- Taking immediate steps to ensure that patient risk is mitigated (e.g., poor practices are immediately corrected, procedures are suspended, or ward or unit is closed to new admissions)

Teams should be aware of laws that allow for notifying appropriate agencies as well as individual obligations for doing so; consult with legal staff when situations may be unclear. See Chapter 8 for more information related to notification of patients, stakeholders such as providers and healthcare facilities, and the general public.

Additional disease control measures beyond recommendations to the facility may also need to be implemented. In some situations, recommendations to the public, specific patient groups, or healthcare providers and healthcare facilities may be needed, such as product recalls, infection control recommendations to a broader group of facilities, or notification of the wider healthcare community, if there is an event of significance or a patient population at risk.

5.12 Interpret Results

The outbreak response team is responsible for ensuring that all available information is used to construct a coherent narrative of what happened and why.

Meanwhile in the Healthcare Facility…

Recommend Control Measures

Healthcare facilities will be working to implement recommended control measures once received. Some measures may be in the process of implementation following internal assessments conducted by the healthcare facility. Facility staff may find it beneficial to discuss methods to implement recommendations with public health agency staff.

Investigators should consider their data critically and question the strength of causal associations while considering timing, dose-response, plausibility, and consistency of findings. When data elements support the primary hypothesis, strong conclusions can be drawn. The most successful investigations are rigorous and evidence-based, but also adaptable, with investigators able to innovate as circumstances demand. Haphazard investigations are unlikely to yield meaningful results. However, even well-executed investigations can be inconclusive. HAI/AR investigations are often marked by small sample sizes as well as the absence of complete records and the presence of confounders and common exposures.

Meanwhile in the Healthcare Facility…

Interpret Results

Healthcare facilities may be interpreting their own results or reviewing results shared by the public health agency. Some facilities may have questions, other interpretations, or suggestions for additional analyses. Review of the results among the public health agency, healthcare facility, and other partners can result in discussion and, possibly, additional next steps. It is important to communicate findings and be open to discussion.

5.13 Monitor the Outbreak until Completion

5.13.1 Monitor the Outbreak

Assure that surveillance of ongoing cases continues, with information on any potential new outbreak-associated cases forwarded to epidemiologists in real time. Likewise, as investigators acquire information about similar cases, exposures or adverse conditions at other facilities, or transfers of case-patients to or from other facilities or across state lines, investigators should promptly update the appropriate health authorities and consider whether any information indicates that the outbreak may be multijurisdictional.

5.13.2 Re-evaluate Hypotheses and Case Definitions

Ongoing review of investigation findings, including current case-patient lists, new laboratory data, updated epidemic curves, and recent environmental assessment findings, can raise novel questions or help answer existing questions related to an outbreak. Investigators should re-evaluate hypotheses as well as case definitions and classifications as new information is gathered. This information, in turn, may lead investigators to modify existing prevention and control strategies or to adopt new strategies.

5.13.3 Ending the Investigation

When the likely cause of the outbreak has been determined and appropriate control measures have been put in place, the investigation can end and a monitoring period can begin. The duration of the monitoring period should be dependent on the specifics of the pathogen or infection type as well as the likelihood that prevention measures will be successful. Determining timeframes ahead of time can be helpful. Most outbreaks are considered to be over when two or more incubation periods of the etiologic agent have passed with no new cases. This arbitrary rule may be difficult to apply in some situations (e.g., infections with long or variable incubations).

Maintaining communication with the healthcare facility involved to make sure additional cases are not detected is critical for some time after the investigation is over. The duration of continued monitoring will vary depending on the type of outbreak. Often this monitoring can be accomplished by reviewing surveillance data reported to public health or through inclusion of a recommendation to the facility to report any new cases to public health for a defined time. Should additional cases be detected, additional investigation should be considered, beginning with an evaluation of the new cases. This may include assessing whether exposure(s) of these cases is consistent with previous patterns and conclusions, and whether control measures are being implemented in the manner recommended. Note that for outbreaks involving a common source, such as those involving a distributed medical product with a long incubation or nonspecific symptoms, it may not be feasible to continue counting cases. In these situations, emphasis should be placed on recall efforts (or implementation of other recommended control measures) to stop new exposures and on directing newly diagnosed case-patients to appropriate medical management. Ultimately, the decision to end an investigation depends on the gravity and scope of the outbreak and on the likelihood that it reflects an ongoing public health threat.

For larger or more controversial investigations, conducting a post-outbreak meeting among investigators to assess lessons learned and to compare notes on ultimate findings can be helpful. This is particularly important for multiagency investigations and is also discussed in Chapter 7. It is important for public health agencies to be open to feedback during and after the investigation. In smaller outbreak investigations or when agency resources do not allow for a post-outbreak meeting, public health agencies should still consider obtaining constructive feedback from partners as well as self-evaluation. A formal after-action meeting should include the following:

- Identify potential sources and contributing factors to the outbreak and control measures that may need to be addressed to prevent additional outbreaks at the facility or other facilities in general.
- Assess the effectiveness of outbreak control measures that were implemented, barriers and difficulties in implementing these measures, and opportunities for improvements in future similar outbreaks.

- Identify barriers or factors that compromised the investigation and identify areas for improvement.
- Identify necessary changes to current investigation protocols and practices.
- Clarify resource needs, structural changes, or training required to optimize future outbreak responses.
- Discuss any legal issues that may have arisen and identify options for addressing these.
- Assess whether further scientific studies should be conducted.

Meanwhile in the Healthcare Facility…

Monitor the Outbreak until Completion

During this step, the healthcare facility may be performing the following:

- Putting into place additional surveillance of the pathogen or infection
- Continuing to monitor for additional cases, which may involve communication with the laboratory and providers
- Continuing to communicate with public health when additional cases are detected
- Performing internal reviews of the investigation of the outbreak
- Participating in after-action reviews involving public health and other involved agencies

5.14 Other Follow-Up Activities

5.14.1 Summarize Investigation Findings, Conclusions, and Recommendations

Writing a final report of the investigation can be helpful to document your methods and findings, as well as any lessons learned that may inform future investigations and prevention needs. In some cases, this report can be brief or follow a standard format or template, such as in the case of a common outbreak type (e.g., influenza-like illness in a long-term care setting). Written reports should include the following components:

- Background: Including information about the outbreak setting, timing, and manner of detection
- Methods: Including agencies involved in the investigation, case definition, details of investigative methods (e.g., record reviews, patient interviews, and environmental assessments), types of patient specimens and environmental samples that were collected and tested, and a summary of laboratory testing methods
- Results: Including numbers of persons exposed, sickened, hospitalized, and deceased; key clinical findings; key laboratory findings, including numbers of patient specimens and environmental samples that were collected; key infection control findings; key environmental findings; any analyses that were performed; and any figures, graphs, and tables that supported the investigation
- Recommendations: Including those put in place for abatement of the outbreak under investigation, any enhanced surveillance, and prevention of similar outbreaks
- Conclusions: Including the etiologic agent, transmission route(s), contributing factors, successes and challenges, lessons learned, justifications for conclusions, and study limitations.

The complexity of the report will depend on the outbreak; for smaller outbreaks, a brief report may suffice. The final report is an excellent tool to provide education for newer staff and a resource for future, similar outbreak investigations. Given that outbreak reports can be subject to the Freedom of Information Act or local information release laws, they should be written with public disclosure in mind. The reports should not identify individuals or provide other legally nonpublic information unless absolutely necessary; care should be taken to follow local laws. It is simpler to refrain from including this information rather than redacting it later. For unusual situations, investigations that are large, complex, or highly consequential, or investigations that can contribute to general scientific knowledge, consideration should be given to submitting the report for publication in the medical literature, either in the *Morbidity and Mortality Weekly Report* or a peer-reviewed journal that reaches the intended audience—public health or otherwise.

5.14.2 Distribute the Report

Copies of the report should be shared with members of the investigative team, laboratories, healthcare facilities, and other partners involved in the investigation.

Consideration should be given to distributing the report more widely to help inform and educate the public health and healthcare community to help prevent future outbreaks. The report is a public record and should be made available to members of the public who request it.

5.4.3 Policy Action

Information gained during an outbreak may identify the need for new public health or regulatory policy at the local, state, or federal level. Establishment of different oversight (e.g., inspection) practices, infection control standards, manufacturing practices, source controls, or surveillance and reporting procedures may be necessary. Reports of past outbreaks should be analyzed to determine whether multiple outbreaks support the need for new policy. Other public health and regulatory agencies also should be consulted to determine whether concurrence exists on the need for new policy. If so, the issue should be presented to the appropriate jurisdictional authority by using the appropriate policy development processes.

Meanwhile in the Healthcare Facility…

Other Follow-Up Activities

The healthcare facility may be in the process of writing its own internal report, which could take the form of a report, root cause analysis, after-action document, or other. Public health agencies should share their report with the facility. If a published report in the medical literature is being considered, the healthcare facility and public health agency should work collaboratively.

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Appendix A: Cohort and Case-Control Studies

Retrospective cohort studies

A retrospective cohort study—in which the investigator calculates incidence rates for the exposed and unexposed—is the study of choice for an outbreak in a small, well-defined population. Generally, an exposure is strongly suspected if it meets the following criteria:

- The incidence rate is high among those exposed.
- The incidence rate is low among those not exposed, and thus the difference, or ratio, between incidence for the exposed and unexposed groups is high.
- Most case-patients were exposed, and thus the exposure could "explain" or account for most, if not all, cases.

Relative risk

Commonly, the investigator calculates the relative risk (a.k.a. the risk ratio) by dividing the incidence of disease in the exposed group by the incidence of disease in the unexposed group. When the two incidence rates are the same, the relative risk equals 1.0, and the exposure is not associated with disease. The larger the relative risk, the stronger the association between exposure and disease.

Statistical significance testing

When an exposure is found to have a relative risk different from 1.0, many investigators perform a chi-square or other test of statistical significance to determine the probability of finding an association as large or larger than that based on chance alone. This probability is called the *p*-value, and the smaller the *p*-value the less likely it is that the observed association is due to chance. (A purely chance association is considered the "null hypothesis," which must be disproved to demonstrate causality.) Generally, an acceptable *p*-value—commonly 0.05 or a 5% probability of a chance association—is specified in advance.

The chi-square test works well if the number of study participants is greater than about 30. For smaller studies, the Fisher exact test may be more appropriate. Although this statistic is tedious to calculate manually, it—like the other statistical tests described here—can be calculated electronically using Epi Info or another computer program.

The statistical association between exposure and illness may reflect a causal link, but it also may reflect confounding (interference by a third variable that distorts the association between cases and exposures), bias (any action that systematically distorts findings), or chance (a random, unpredictable occurrence that is not due to human intervention). Conversely, failure to achieve a *p*-value <0.05 due to a small number of cases, a faulty sampling method, an inappropriate selection of controls, or other factors cannot rule out an association with a potential source or exposure.

Confidence intervals

An alternative to the *p*-value is a confidence interval, a statistic that combines an interval estimate (i.e., a range of values estimated to contain the true value) with a probability statement that specifies the uncertainty associated with the interval estimate (i.e., the uncertainty associated with the investigator's sampling methods). The typical 95% confidence interval for a calculated relative risk, for example, indicates that use of the same sampling method to select different case-patients and controls will yield a confidence interval that contains the true relative risk 95% of the time. Less variable data and larger sample sizes will tend to yield narrower confidence intervals and, thus, more precise estimates of the true relative risk.

Because a confidence interval provides more information than a *p*-value, many medical and epidemiologic journals prefer confidence intervals to *p*-values. However, in the outbreak setting, the difference may be irrelevant. If the objective of an outbreak investigation is to identify the source of pathogenic exposure, a relative risk and *p*-value may serve as well as a relative risk and confidence interval.

Appendix A: Cohort and Case-Control Studies

Case-control studies

In a case-control study, the investigator compares the exposure status of case-patients with a comparable group of persons without the disease under study ("controls").

Choosing controls

When designing a case-control study, one of the most important tasks is selecting the individuals who will comprise the control group. As mentioned above, controls must *not* have the disease under investigation, but should otherwise represent the population in which the cases occurred.

Common control groups consist of

- Patients admitted to the same hospital unit within the same timeframe
- Patients undergoing the same medical procedure
- Patients with the same underlying diagnosis that prompted hospital admittance (but without, of course, the HAI or condition under investigation)

If the control group differs systematically from the case group, a true association between exposure and disease may be missed or a spurious association may be observed between a non-causal exposure and disease.

When designing a case-control study, other considerations include the number of controls to select per case and potential confounding due to factors associated with both the exposure and disease outcome that cause a spurious association. Sample size formulas are available to help determine the number of controls per case. Confounding can be controlled by matching cases and controls on the confounding factor during the selection process or during data analysis.

Often, the number of case-patients that can be enrolled in a study is limited by the size of the outbreak. For example, in a hospital, four or five cases may constitute an outbreak. Fortunately, potential controls are usually plentiful. In an outbreak of 50 or more cases, one control per case will usually suffice. In smaller outbreaks, two, three, or four controls per case may be feasible. However, including more than four controls per case is rarely worth the effort in terms of increased statistical power.

Odds ratios

In most case-control studies, the population is not well defined, and the total number of people exposed (or unexposed) to a suspected vehicle or source is not known. Without a proper denominator, incidence rates cannot be calculated. Thus, for a case-control study, the odds ratio is the preeminent measure of association. Fortunately, for rare events, such as HAIs and most other outbreak-associated diseases, the odds ratio from a case-control study approximates the relative risk that would have been found if a cohort study had been feasible.

The odds ratio—the ratio of the odds of exposure among cases to that among controls—is calculated as a/c ÷ b/d where:

a = the number of individuals who are both exposed and have the disease
b = the number who are exposed and do not have the disease
c = the number who are unexposed and have the disease
d = the number who are both unexposed and without the disease

To test the statistical significance of the odds ratio, a chi-square test can be computed. However, it is important to remember that statistical significance is not proof of causality, as the observed result may be due to chance, bias, or confounding.

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CHAPTER 6

Laboratory Best Practices

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CHAPTER 6

Laboratory Best Practices

Preface

The laboratory holds a unique role in healthcare outbreak response, providing key information to help initiate and guide investigations. Whereas in previous chapters we introduced and described some basic concepts regarding the role of laboratory partners, here we present more detailed explanations, examples, and considerations, with an emphasis on best practices.

6.0 Introduction

The role of the laboratory in healthcare-associated infection (HAI) outbreak response is critical, beginning with organism identification and routine antimicrobial susceptibilities. Given the availability of advanced technologies, communications, and networks, a laboratory may be able to provide information regarding novel resistance patterns and mechanisms, identify clusters of related illness, and generate data to be used by public health and healthcare partners to detect and respond to outbreaks.

Public health laboratories (PHLs) are required to notify public health authorities upon the identification of reportable diseases. PHLs are also well positioned for the early recognition of sentinel cases (those involving unusual pathogens or resistance patterns) or clusters. Additionally, PHLs are encouraged to promptly alert epidemiology partners after receiving a request from a healthcare facility or provider to perform typing of multiple isolates for an apparent cluster or outbreak.

Many aspects of outbreak response benefit from active collaboration and coordination between the PHL and other public health and healthcare partners. Examples include clarifying requirements and streamlining procedures for the reporting of potential outbreaks and the retention/submission of specimens and/or isolates by commercial, private, and academic laboratories—both in state and out of state (incorporating these into guidance or administrative codes). PHLs also may serve a key function in the support of outbreak response activities by developing and maintaining an inventory of specialized testing and characterization services available in house or in other laboratories and by providing guidance to partners regarding how to access these services.

This chapter begins with an overview of the various types of laboratories and their roles, followed by a description of laboratory functions that support outbreak response and the importance of reliable and clearly communicated data. For laboratory data to be meaningful and useful, they must be accurate, timely, of high quality, and presented

in a clear and concise manner. Specific to laboratorians, we also address safety practices to be followed when working with antimicrobial-resistant (AR) pathogens and the validation of AR and HAI test methods.

6.1 Types of Laboratories and Roles

6.1.1 Public Health Laboratories

At least one state public health laboratory is located in each state in the US; additional governmental laboratories are often found in large cities or counties. Despite diversity in discipline and range of capability, these laboratories are dedicated to promoting and protecting the health of citizens. As the national public health laboratory, the Centers for Disease Control and Prevention (CDC) offers a wide scope of testing, guidance, research, and development services.

In 2016, CDC established the Antimicrobial Resistance Laboratory Network (AR Lab Network), which serves to detect and characterize AR pathogens and communicate findings and resources to prevent infection. The seven AR Lab Network regional laboratories offer access to a wide variety of specialized testing including colonization testing, identification of resistance mechanisms, specialized susceptibility testing using reference methods, and next generation sequencing (NGS). Although some of these testing services may also be available at state or local public health laboratories, reference laboratories, or large clinical laboratories, the regional laboratories assure a centralized mechanism to access this testing for all facilities.

The national, non-profit professional organization dedicated to strengthening public health laboratory systems is the Association of Public Health Laboratories (APHL). As a representative of national, state, and local governmental health laboratories, APHL is positioned to capitalize on the available diversity in PHLs, foster communication, provide expert-derived guidance, and work with federal agencies to develop and execute national health initiatives such as those related to HAIs and AR pathogens. Related toolkits, guidance documents, offers of training opportunities, and various other resources are available at www.aphl.org.

6.1.2 Clinical Laboratories

Clinical laboratories, often based in hospitals, provide a wide range of laboratory procedures that aid clinicians in the diagnosis, treatment, and management of patients. Commercial laboratories, some of them quite large and national in scope, provide similar functions. Clinical laboratories serve an integral role in the detection and characterization of a wide array of HAIs and AR pathogens. More complex analyses of pathogens such as *Mycobacterium tuberculosis* complex (MTBC) and *Candida* spp., however, may require isolates to be transferred to a commercial or reference laboratory, or a state PHL.

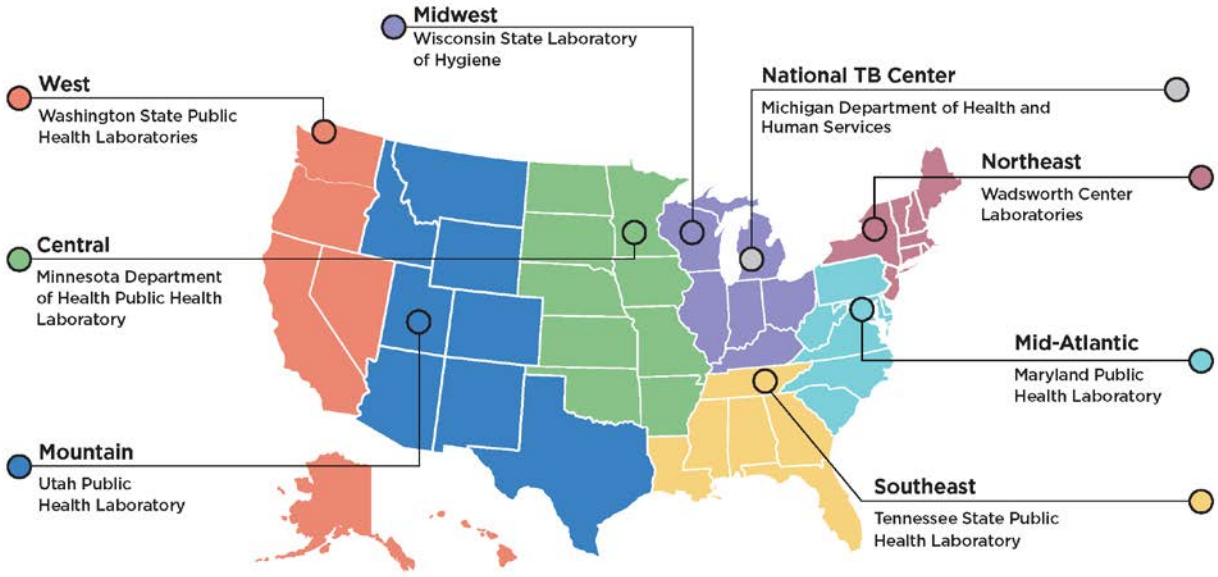
Antimicrobial susceptibility testing services in clinical laboratories may include growth and molecular-based analyses of some of the more common Gram-positive and Gram-negative bacteria. Clinical laboratory staff should be knowledgeable of applicable surveillance and reportable disease regulations or guidance material and consider these when deciding to proceed with AR testing.

6.1.3 Reference Laboratories

Reference laboratories may offer extensive and specialized testing to support surveillance activities. These facilities may be independent laboratories or associated with public health agencies or educational or research institutions. The same considerations described in the previous section regarding jurisdictional reporting requirements apply to reference laboratories.

In addition to its function as the US national reference laboratory, CDC established and supports the AR Lab Network (described in section 6.1.), greatly expanding the capacity of public health facilities to detect and respond to AR cases and outbreaks. The Network consists of laboratories in 50 states, four cities, and Puerto Rico, and includes seven regional laboratories and the National Tuberculosis Molecular Surveillance Center (Figure 6.1).[1] The Network aids the public health community in the quick detection of emerging AR threats in healthcare, food, and the community; rapid response at the state and local level to contain pathogen transmission; and increased understanding of emerging AR threats.[1]

Figure 6.1 | Antimicrobial Resistance Laboratory Network Map of Regional Laboratories[1]



The AR Lab Network assists each local jurisdiction with AR pathogen surveillance, but the Network as a whole functions as a surveillance entity with the capacity to provide information on national trends and to detect outbreaks. When state or local laboratories have neither the capability nor the capacity, the Network's regional laboratories can provide additional testing. At the time of this writing, this includes advanced testing for *Acinetobacter, Aspergillus fumigatus, Candida auris,* carbapenem-resistant Enterobacterales (CRE), colistin resistance among extended-spectrum beta-lactamase (ESBL)–producing organisms, *Mycobacterium tuberculosis, Neisseria gonorrhoeae, and Streptococcus pneumoniae*. Regional laboratories that detect organisms and mechanisms of resistance of public health significance routinely alert public health partners to trigger investigations and other actions to prevent transmission.

6.2 Laboratory Functions in Support of Healthcare Outbreak Response

6.2.1 Surveillance

Surveillance, as it relates to HAIs, involves collecting and analyzing health-related data to evaluate the quality of healthcare that is being provided, identifying opportunities for improvement and monitoring progress following intervention. Laboratories are integral to the surveillance process, as they generate, analyze, and submit data to surveillance programs, and may be the first healthcare partner to identify an unusual occurrence or frequency in their results. Laboratories serve as the first level of action in the surveillance process, and therefore, their staff should be cognizant of how, when, and to whom data can be shared to be most impactful.

Hospitals and clinical laboratories monitor and report certain drug-resistant organisms and HAIs to meet a variety of different regulatory requirements. The Centers for Medicare & Medicaid Services (CMS) mandates the reporting of certain HAIs through the National Healthcare Safety Network (NHSN).[2] States and counties may require that hospitals report certain pathogens, diagnoses, and/or multidrug-resistant organisms (MDROs). In addition, CDC provides guidance for the initial response to a novel or targeted MDRO or resistance mechanism. Such a response may involve a combination of prospective and retrospective laboratory surveillance, depending on the resistance pattern of interest. More information on surveillance, including reportable and notifiable diseases, is provided in Chapter 2.

6.2.2 HAI and AR Pathogen Detection and Confirmation

As described in Chapter 5, section 5.1.2, early detection of the causative agent is critical to appropriate treatment and the prevention of additional cases. The laboratory has numerous assays on hand to support the identification and confirmation of HAI and AR pathogen cases and to subsequently assist with the diagnostic aspects of these case definitions where needed. Tests involving the physical characteristics of a microorganism are known as phenotypic or growth-based (e.g., culture), whereas tests involving genetic properties are called genotypic or molecular-based (e.g., polymerase chain reaction [PCR] or sequencing). With regard to the detection and confirmation of new and emerging AR pathogens, each type of test displays advantages and limitations (Table 6.1).

Table 6.1 | Phenotypic and Genotypic Tests

TEST TYPE	METHOD, OUTPUT	EXAMPLES	ADVANTAGE	LIMITATION
Phenotypic	Zone of inhibition, Millimeters	Kirby-Bauer disk diffusion susceptibility test	• Simple to perform • Applicable to several antibiotics • Applicable for diverse organisms (e.g., *Haemophilus influenzae, H. parainfluenzae, Neisseria gonorrheae, and N. meningitides*)[7] • Standardized method • Cost-effective • Results correlate to known resistance/ susceptibility based on defined breakpoints for known resistance	• Detection may be limited to the growth rate of the organism (takes 16–24 hours for results) • May require a pure culture of an actively growing organism • Visual/manual data interpretation requires expertise and competency • Breakpoints are not defined for all organism/drug combinations
Phenotypic	MIC, reported concentration, µg/mL	Automated: Vitek®, MicroScan™, Sensititre™, Phoenix™ Manual/semi-automated: gradient strips (e.g., ETEST® or MTS™ strips), broth dilution, agar dilution	• Simple to perform if using an automated method • Applicable to several antibiotics • Applicable for diverse organisms (e.g., *Haemophilus influenzae, H. parainfluenzae, Neisseria gonorrhoeae, N. meningitidis*)[8] • Standardized method • Cost-effective	• Detection is limited to the growth rate of the organism (takes 16–24 hours for results) • May require a pure culture of an actively growing organism • Visual/manual data interpretation requires technical expertise and competency • High volume of reagents • Requires multiple dilutions • Requires expertise

Table 6.1 | Phenotypic and Genotypic Tests

TEST TYPE	METHOD, OUTPUT	EXAMPLES	ADVANTAGE	LIMITATION
Genotypic	PCR	Lab-developed tests, CDC-developed tests, Commercial platforms	• Can be culture-independent • Rapid • Sensitive • Specific • Detection of multiple targets simultaneously • High throughput	• Presence of resistance genes or mechanisms does not always confer phenotypic resistance • If performed without prior culture, there is no isolate for further investigation • Inability to distinguish viable from nonviable organism • Advanced technical skills may be required for some assays • High instrument and consumable costs • Risk of amplicon contamination
Genotypic	Nucleic acid sequencing	Targeted sequencing, NGS, Long read, Short read	• Novel resistance mechanisms can be detected • Novel pathogens may be detected • Identifies genetic relatedness among isolates • Mutations (e.g., single nucleotide polymorphisms [SNPs]) that confer new resistance or altered resistance patterns may be detected • Can be used to resolve discrepancies in other test results (e.g., mCIM+ / PCR-)	• Gene target associated with resistance must be known • May require pure culture of actively growing organism • Detection is limited to the processing time of sequencing and analysis, which can be time consuming • High technical skill is required • High instrument and consumable costs • Increased potential for cross-contamination (can be identified in analysis through pipelines) • Inability to distinguish between viable and nonviable organism • Presence of target does not always confer phenotypic resistance but may be relevant for clinical management; infectious disease consult may be warranted • New targets require additional validation

6.2.2.1 Phenotypic Testing

The emergence of matrix-assisted laser desorption/ionization–time of flight mass spectrometry (MALDI-TOF MS) greatly improved the ability of laboratories to identify organisms rapidly and efficiently down to the species level. This has contributed to the reporting of organisms with less familiar nomenclature, such as a unique species previously characterized as part of a group of organisms or a complex. For example, MALDI-TOF MS can be used to identify *Enterobacter asburiae*, which otherwise would have been labeled *Enterobacter cloacae* complex when using traditional biochemical tests.

Similarly, enhanced characterization of bacterial and fungal species through molecular techniques such as DNA sequencing has prompted reclassification or renaming of some species. The laboratory can be helpful in assisting infection preventionists and epidemiologists in navigating these changes in nomenclature, particularly when including former microbial names in case findings (e.g., the 2017 reclassification of *Enterobacter aerogenes* to *Klebsiella aerogenes*).[3] When relying on laboratories that identify organisms by applying more traditional methods, such as biochemical tests (e.g., API 20E), or use of older automated instruments with outdated software, it is important to bear in mind that discrepancies may occur when the organism identification is confirmed using newer technologies or more up-to-date software.

Phenotypic antimicrobial susceptibility testing (AST) describes conventional methods that establish antibiotic resistance or susceptibility by measuring growth (or lack thereof) of an organism in the presence of a drug. To interpret the results, phenotypic testing methods require that the organism be identified and grown in a pure culture. Several manual and automated tests are available, including disk diffusion, agar dilution, broth microdilution, broth dilution, and gradient strip diffusion. The Kirby-Bauer disk diffusion susceptibility test results in a zone of inhibition around a disk containing antibiotics of known concentration. The size of the zone correlates to the susceptibility or resistance of the organism to the drug and is inversely proportional to the minimum inhibitory concentration (MIC). Zone size alone is meaningless and should not be reported to clinical providers.[4] The MIC is the minimum concentration of antibiotic necessary to inhibit growth. It can be determined by both microdilution and the ETEST®. It can also be referred to as the minimum bacteriostatic concentration because growth is inhibited but the organism is not killed. In contrast to the MIC, the minimum bactericidal concentration (MBC) is the minimum concentration necessary to kill the organism. Both the MIC and zone sizes can be interpreted to be resistant, susceptible, or susceptible dose-dependent results based on breakpoints defined in the *Clinical & Laboratory Standards Institute (CLSI) M100*.[5]

Regardless of the test selected, laboratories should use the current interpretive breakpoints published by organizations that develop standards, such as CLSI or the European Committee on Antimicrobial Susceptibility Testing (EUCAST). These sources will have the most up-to-date recommendations for breakpoints and detection strategies. Often, Food and Drug Administration (FDA)–cleared products may not reflect current breakpoints and, therefore, validation studies may be necessary. Validation studies are also warranted when laboratory-developed tests (LDTs) or other methods selected have not been approved by the FDA, such as those labeled “for research use only (RUO),” which are not intended for use in patient diagnostics. Laboratories should be aware of the new College of American Pathologists (CAP) requirement[6] that all breakpoints should be identified and recorded, and that any breakpoints updated prior to 2021 must be current as of January 1, 2024. APHL and the AR Laboratory working group have developed a toolkit to assist laboratories in this transition.

6.2.2.2 Genotypic Testing

Molecular methods may be used to predict antibiotic resistance in vivo through the detection of specific genetic targets or mutations. Identification of a gene target or mutation may be useful in predicting antibiotic resistance in vivo. The primary benefit of molecular antimicrobial susceptibility tests (ASTs) is that they allow direct testing of clinical or environmental specimens without the need for culturing. When applied in this manner, genotypic ASTs are more rapid than phenotypic methods. However, these systems lack the ability to distinguish between viable and nonviable organisms, and genetic indicators of resistance do not always confer resistance phenotypically.

The intended use of the assay, whether for screening or identification, must be considered, because this dictates how the results are reported and the data are interpreted. Screening tests typically exhibit high sensitivity and low-to-moderate specificity since they are designed to quickly assess a specimen for the presence or absence of the target. Such tests allow for a presumptive result and should be reflexed to culture to isolate and identify the organism. Alternatively, identification tests usually possess characteristics of high sensitivity and specificity, and therefore are more accurate. Depending on the assay, additional testing may be necessary before reporting a confirmed result. Discerning a presumptive from confirmatory result is critical when reporting data to epidemiologists and other partners. Nevertheless, in many cases preventive action can still take place based on a presumptive or preliminary result to reduce the risk of transmission. Confirmed and final results should be reported as soon as they are available.

6.2.2.3 Next Generation Sequencing

During the past two years, advancements in next generation sequencing (NGS) technology have led to the use of NGS not only for identification purposes but also for the detection of drug-resistant markers. NGS can play an important role in HAI outbreak investigations, including those involving MDROs.

Currently, this technology may be cost-prohibitive due to the high upfront cost of equipment and the need for highly specialized bioinformaticians. In the near future, however, NGS equipment is expected to become affordable and trained personnel more widely available.

NGS is relevant and useful to antimicrobial resistance surveillance in two distinct ways. The first is in the detection of novel resistance genes that may not be detected using current molecular (PCR) assays. This is illustrated in a recent case of *Pseudomonas aeruginosa* infection. The organism proved to be nonsusceptible to most antibiotics evaluated, was deemed positive for carbapenemase using the modified carbapenemase inactivation method (mCIM), and was found negative for all PCR targets for which it was tested. NGS analysis detected the presence of the $bla_{\text{sim-1}}$ gene, which is the first time this target was detected in the US.[7]

The second use for NGS among antimicrobial resistance surveillance is to determine the relatedness between pathogen strains. This is particularly relevant to assess transmission within or between healthcare facilities. Strains that are highly related to one another are more likely to share a common source.

6.2.2.4 Terminology

Laboratories should remain current with the accepted definitions for various MDROs that are resistant either to a primary antimicrobial drug or to one or more drugs from different drug classes. Some common or targeted MDROs described by CDC are listed in Table 6.2.[9]

Table 6.2 | Common or Targeted MDROs

ORGANISM	DRUG RESISTANCE
Staphylococcus aureus	Methicillin-resistant *S. aureus* (MRSA) Vancomycin-intermediate *S. aureus* (VISA) Vancomycin-resistant *S. aureus* (VRSA)
Enterococci	Vancomycin-resistant Enterococci (VRE)
Escherichia coli *Klebsiella*	Extended spectrum cephalosporin-resistant
Proteus mirabilis	Extended spectrum cephalosporin-resistant *ampC* phenotype
Enterobacterales	Carbapenem-resistant Enterobacterales (CRE)
Pseudomonas aeruginosa	Carbapenem-resistant *P. aeruginosa* (CRPA)
Acinetobacter	Carbapenem-resistant *Acinetobacter* (CRAB)

No single list of MDROs is comprehensive, but standard terminology applies throughout.[5]

- Susceptible (S) indicates growth is inhibited by drug treatment.
- Intermediate (I) indicates growth is inhibited by a drug dose higher than that required by a susceptible MDRO.
- Resistant (R) indicates growth is not inhibited by treatment with at least one drug.

- Multidrug resistant (MDR) indicates acquired resistance; “not susceptible” to at least one drug in three or more drug classes.
- Extensively drug resistant (XDR) indicates acquired resistance; “not susceptible” to almost all drug classes but sensitive to at least one drug class.
- Pan-drug resistant (PDR) indicates acquired resistance to all drugs available.

6.2.2.5 Saving Specimens and Isolates

During an outbreak investigation, all relevant organism isolates should be retained by the clinical laboratory, PHL, or reference laboratory to ensure availability for strain typing. In the event culture-independent diagnostic tests (CIDTs) are used and an isolate is unavailable, laboratories should send CIDT-positive samples to the PHL within 24 hours after the positive result has been obtained. Clinical laboratories should coordinate with PHL staff prior to shipping. For circumstances outside outbreak management, laboratories should work with the infection prevention team to develop a routine laboratory policy for saving isolates. The policy should define which isolates are retained and for how long, and should also address the retention of original specimens, their derivatives, and any specimens with uncommon results.[10] Such a retention policy is valuable: specimens can be retained for repeated or additional testing when needed, further investigation for public health purposes, quality control purposes, and new test validation. Extended storage (up to 10 years) is ideal for specimens and isolates exhibiting unusual, emerging, and novel resistance mechanisms. An inventory system covering retained specimens and isolates should be in place for the biosafety and biosecurity of the laboratory. The laboratory must consider the needs of the patient, the storage capacity of the laboratory, and future test development.

6.2.2.6 Characterization Testing

Considerations and best practices for establishing a case definition and managing case findings are discussed in Chapter 5, section 5.1.6. This section provides information regarding laboratory testing that may be used to support an outbreak investigation through characterization and relatedness testing.

An outbreak response may require laboratory support beyond that associated with typical clinical specimens. Each clinical laboratory needs to be able to rapidly identify AR pathogens for subsequent referral to a PHL or reference laboratory for full characterization. Timely communication and collaboration between laboratories are critical. Outbreak investigation and response may include surveillance activities such as point prevalence surveys and admission screening, which can require substantial laboratory resources. These can involve processing a large number of samples using methods not routinely performed in that laboratory. They may require healthcare personnel testing or environmental testing if personnel or an environmental reservoir is potentially implicated in the outbreak during the investigation. During an investigation, it may be appropriate to perform molecular analyses such as PCR and NGS to identify mechanisms of resistance and to determine genetic relatedness between clinical isolates and/or environmental sources.

If it is determined through NGS that two or more organisms are genetically related, it is likely that they share a common source. This could be evidence of patient-to-patient transmission or a common reservoir of infection. Species identification and susceptibility results may provide evidence for or against an epidemiologic link. However, because many organisms have predictable resistance patterns, susceptibility patterns are not sufficiently discriminatory and additional tests are required. Thus, genotypic or DNA-based typing methods have replaced phenotypic typing methods that discriminate poorly among isolates. Given the dramatic reduction in cost and time needed to sequence a bacterial or viral genome, NGS has now become the gold standard for molecular typing of healthcare-associated pathogens and has largely replaced older genotypic methods such as pulsed-field gel electrophoresis (PFGE) and multilocus sequence typing (MLST). If a laboratory cannot perform strain typing when it is deemed necessary, isolates can be sent to the PHL for testing.

6.2.3 Reporting to Epidemiology and Other Partners

Detection of clusters and possible outbreaks can originate from a variety of sources, as described in Chapter 4. As epidemiology staff gather information, they rely on laboratory results to provide meaningful details relevant to a possible event. Thus, the laboratory plays a key role in outbreak detection through the generation of testing results and compilation of these results into reports. Laboratory testing should be performed accurately and in a timely manner, with reports made available upon completion. Laboratory results are crucial in identifying the true cases associated with an event. Data must be reported in a clear and concise manner so that it may be evaluated without interpretation biases, as is possible when technical details are provided without proper context or guidance.

Reports such as antibiograms, which include antimicrobial resistance surveillance data for a defined population, may be shared with epidemiologists, infection control practitioners, clinicians, and other stakeholders. Within a facility, antibiograms may be developed for specific areas such as an intensive care unit or infectious disease unit. Clinical laboratories should provide periodic summaries of selected microbiology results, such as antibiograms specific to HAI pathogens or trends in selected AR pathogen incidence over time. Hospital laboratory personnel may need to call infection prevention program personnel directly to report some results to ensure that timely control measures are implemented (e.g., transmission-based isolation precautions and prophylaxis of contacts). The list of results that require such urgent test reporting may vary based on federal, state, or local regulations and on requests or requirements from the facility; however, some examples of organisms requiring immediate notification follow:

- *Neisseria meningitidis* from a sterile site
- *Legionella*
- *Mycobacterium tuberculosis* (or a positive result from an acid-fast bacillus test of respiratory samples)
- Potential agents of bioterrorism (e.g., *Bacillus anthracis* or *Yersinia pestis*)
  - Note: If presence of a potential agent of bioterrorism cannot be ruled out in the laboratory, it is important to reduce access to the primary specimen or cultured isolate, and to contact the state or local PHL immediately.
- AR pathogens (e.g., carbapenem-resistant Enterobacterales, vancomycin-resistant *Staphylococcus aureus*, and *Candida auris*)

Epidemiologists and infection preventionists may be able to use these reports to support an investigation regarding the source and spread of disease within a facility. They may also collaborate with other partners to support the development of guidelines to prevent future outbreaks and reduce the incidence of antimicrobial resistance. It is important to establish and maintain good working relationships with partners in epidemiology and HAI programs, hospital infectious diseases and infection control departments, and microbiology laboratory directors. One way to do that is to establish a committee that meets two to three times each year. More information on communication among partners can be found in Chapter 5, section 5.1.3.3.

Reporting procedures must allow for the timely transmission of laboratory results to infection prevention personnel and relevant state and local reporting systems. Because different facilities often use highly variable methods for storing and tracking data, it is essential to allow for reliable data exchange so that relevant information is not lost during transmission. It is also beneficial to allow various options for reporting to be available. These options can include secure transmission via legacy systems such as fax and telephone as well as electronic submission such as secure email and electronic laboratory reporting (ELR).

In addition to the modes of reporting given above, hospital laboratory staff should meet regularly with infection prevention personnel to ensure that communication channels are direct and effective, and to discuss areas of mutual concern such as the status of all ongoing cluster or outbreak investigations. Together they can also determine whether supplementary testing, such as organism typing or environmental cultures, will be necessary. It may prove beneficial to bring in state and local public health partners as well.

Ensuring that the aforementioned reporting mechanisms are in place may be challenging if a hospital has outsourced laboratory services (such as to a commercial laboratory or a central laboratory within a large healthcare system), but reporting remains necessary to provide optimal HAI and AR pathogen outbreak detection and response.

6.2.4 Detection of HAI Outbreaks by the Laboratory

Chapter 4 established that detection of an HAI outbreak can occur at any level, but here we explore how the laboratory can support detection. Essentially, laboratories provide support through characterization testing, which may be used to guide outbreak response and monitor developments. The use of PHLs and the AR Lab Network regional laboratories can provide the necessary structured framework for improved communication, coordination, and tracking during an HAI outbreak.

Characterization of isolates may be performed to assist with identifying the source of an outbreak and to link clinical cases and/or environmental sources; however, data resulting from such analyses may be complex and require interpretation. Next generation sequencing is commonly used to investigate isolates at the genetic level and yields large amounts of data requiring subsequent analyses with sophisticated software programs. Multiple sequences can then be further examined to determine genetic relatedness, which is depicted using a phylogenetic tree. When data from multiple patients or sources are compiled and reported in such a manner, a description should be included to clearly indicate which isolates are and are not likely to be genetically related. These data, along with other epidemiologic findings, may be used to define the scope of the outbreak, the attributed source, and risk factors, or to otherwise link cases based on common features. For this to be successful, communication among partners in a timely manner is essential.

HAI outbreaks are defined by an increase in the number of cases of infections among patients or staff above the expected number of cases; this increase can be determined through ongoing surveillance. Pathogen-specific surveillance can be used to monitor select pathogens through reporting by healthcare providers and laboratorians, and should consider inclusion of information on patient exposure, risk, and underlying conditions. The full spectrum of specific pathogens under surveillance may be determined by infection prevention and control units within healthcare settings.

Pathogens may be reportable beyond the original facility, and this may require submission of a specimen from the laboratory serving the healthcare facility to an appropriate local or state public health laboratory. Notification to the CDC is required for nationally notifiable pathogens or for select reporting programs. Specimen submission to the CDC or an AR Lab Network regional laboratory may be a requirement or necessary when additional testing is requested.

As cases are identified and reported, a response could occur at multiple levels, beginning first with the infection prevention team at the healthcare facility, then followed by public health epidemiologists working closest with the reporting laboratory. A first response effort would include collection of additional follow-up data to help identify how acquisition or transmission occurred. These data can be used to link cases based on relevant findings. Specific metadata for each isolate are invaluable for epidemiologic study and could include basic details about the specimen (such as collection date, source, submitting facility, and test results), patient information (e.g., age, sex/gender, and residence), and patients' significant risk factors (e.g., comorbidities, recent travel, unique exposures, or behaviors).

Concurrent review of microbiology data remains the most common HAI and AR pathogen case-finding method used by hospital infection prevention programs, and requires prompt, accurate, and reliable reporting of positive laboratory test results. This communication may occur in a number of ways, but most hospital infection prevention programs have in place electronic surveillance systems that interface directly with the laboratory information system (LIS) or electronic medical record (EMR) system. Such electronic surveillance systems allow infection prevention teams to configure alerts and efficiently monitor test results in real time.

Detection may also occur at the local or state health department through regular systematic review of routine surveillance data, review of patient reports, or review

of reports from alert healthcare personnel. When an outbreak is identified at the public health level, an outbreak number is often assigned; this allows all related communications, laboratory findings, and reports to be connected. With adequate staff and expertise, the local health department can initiate and coordinate the responsibilities of the investigation to determine who will lead the response and what is needed from participating laboratories. If local public health capabilities are insufficient, the state health department will lead the response. Details such as laboratory testing methods and the facility at which testing will be performed, the timeframe of the investigation, and resources are agreed upon to effectively manage the investigation. Given the logistical challenges with analyzing large datasets, having electronic accessioning systems in place will result in a seamless linkage of isolate test results to epidemiology data, while allowing for additional laboratory or epidemiology data to be added.

Whether an increase in the number of cases is detected by healthcare personnel or the laboratory, public health officials and infection preventionists should be contacted to coordinate specimen submission and initiate the formal chain of reporting. Public health officials should also collaborate with healthcare personnel to assist the facility with coordination of effective control measures as well as additional specimen collection if further testing or confirmation is needed. If the laboratory providing testing is located offsite from the healthcare facility, enhanced coordination with the facility and health department may be needed in response to the greater logistical challenges associated with specimen collection, transport, testing, and data transmission between different systems.

To ensure the swift detection of outbreaks, effective communication of test results between the laboratory and the infection prevention program is key. In particular, electronic systems that communicate laboratory results to the infection prevention team in real time may help identify outbreaks as they happen. It is important to note, however, that concerns about a cluster or an outbreak are sometimes first raised by an astute laboratory technologist, nurse, or other member of the healthcare team. Outbreak detection should therefore be a multidisciplinary effort that encourages all personnel to report concerning nosocomial infections to the infection prevention program.

6.2.5 Environmental Testing

Environmental testing is an attractive addition to outbreak investigations because it can test hypotheses about transmission, identify pathogen reservoir(s) and later evaluate the efficacy of interventions. Environmental testing is generally not encouraged, however, except in circumstances in which an environmental source has been implicated or the literature supports environmental testing. In addition, it should be undertaken only after consulting with an epidemiologist experienced in outbreak investigations. Many clinical microbiology laboratories do not possess expertise in testing environmental samples, and most do not validate their existing tests for use on nonhuman specimens. When there is limited capacity in the laboratory to perform such testing, specimens should be referred either to laboratories that specialize in environmental microbiology or to the jurisdictional public health laboratory. Some PHLs may include environmental, food safety, or water quality testing laboratories that possess methods, equipment, and personnel that can enhance the environmental testing capacity of their HAI or AR pathogen laboratories.

Diverse environmental samples may be analyzed to support outbreak investigations. Samples from inanimate objects in the outbreak setting, such as hospital furniture, water fixtures and equipment, and water and cooling systems, may be collected using swabs. Air samples may be of interest during invasive fungal infections. Outbreak responders may want to consult with laboratorians regarding the ecology of the targeted organism to help develop epidemiologic hypotheses and guide sample collection. Additionally, identification of a laboratory's capacity not only to sample but also to process sampling devices is crucial to developing an environmental sampling strategy.

The selection of collection devices for environmental sampling depends on many factors, such as the size, porosity, hydrophobicity, and ease of downstream processing of targeted fomites and sampling devices. Swabs come in a variety of materials, such as foam, cotton, and rayon, and are ideal for sampling small surfaces and

crevices. For larger surfaces, use of a paddle, sponge, or wipe device increases the likelihood of recovering microbes. Premoistening the selected sampling device with a sterile buffer that also neutralizes any residual disinfectants will also improve the chances of recovering the outbreak organism (Table 6.3). It is ideal for environmental samples to be transported under refrigeration and processed within 24 hours after collection. Establishing and maintaining the chain of custody (COC) related to samples is especially important for outbreak investigations that may implicate medical products or devices.

Table 6.3 | Tips for Collecting Environmental Samples[11]

SAMPLE TYPE	SAMPLING DEVICE AND MECHANISM
Small surface	• Use premoistened swab.
Large surface	• Use premoistened paddle, sponge, or wipe.
Bulk water and ice	• Collect one liter.
Drinking water	• Collect one liter. • Add sodium thiosulfate to neutralize disinfectants.
Fluid from the medical device line	• Run device pumps before collection to suspend nonmotile organisms.
Medical device	• Consult with a biomedical engineer for the best collection strategy that does not adulterate the device. • Neutralize cleansers and disinfectants that may be present.

6.2.6 Healthcare Worker Testing

Healthcare workers occasionally are screened during outbreaks, particularly in those outbreaks involving methicillin-resistant *Staphylococcus aureus* or *Streptococcus pyogenes*. Screening methods are well established for these two organisms, but for many others (such as multidrug-resistant Gram-negative organisms), methods are still under development and will continue to evolve as more complex resistance phenotypes emerge.

Results may be difficult to interpret, because recovery of outbreak pathogens from screening cultures obtained from healthcare workers does not establish the direction of transmission or definitively implicate workers as the source of the outbreak. Also, culturing samples from healthcare workers is a fraught procedure and may be perceived as hostile if mandated. Healthcare worker testing may fall under human subjects testing, which requires institutional review board (IRB) approval and has potential legal ramifications. Healthcare workers should therefore be screened only after consultation with an epidemiologist experienced in outbreak investigation; and screening should ideally be made in groups of workers with similar roles to focus interventions on practices rather than individuals. Additionally, healthcare providers should be engaged and consulted, as appropriate, in addressing the health concerns or treatment needs of individual healthcare workers who are being tested.

6.3 Safety, Quality Control, and Validation

Quality testing in a safe environment is a primary goal in any laboratory, but the processing of AR, novel, and emerging pathogens contributes complexities that can increase turnaround time for reporting. The impacts of self-infection or laboratory contamination with these organisms can compromise health or the integrity of the testing space, respectively; laboratorians, therefore, may take extra precautions such as wearing additional personal protective equipment (PPE) and working in a laboratory with a heightened safety infrastructure. Donning, doffing, and decontaminating PPE and working in an enhanced safety environment all increase the amount of time required to safely process a specimen.

Similarly, working with AR, novel, and emerging pathogens requires the use of quality controls that may not be readily available to non-reference laboratories; additional time may be needed to acquire the proper control materials. Finally, laboratory testing of these organisms is rapidly evolving. Several tests have not received the required FDA approval or have been developed at a laboratory (laboratory-developed test [LDT]), which would require validation by the user prior to use, often requiring considerable time.

6.4 Laboratory Data Management

Laboratory data can play a significant role in detecting an outbreak that involves healthcare-associated drug-resistant pathogens. Laboratory information systems (LISs) are software systems used by most laboratories to process, manage, and store data. The electronic centralization of data provides a mechanism for rapid analyses of large datasets and identification of trends. Some LISs can be configured to send alerts to remind laboratory personnel to save an isolate when it meets predefined criteria and to generate reports that identify patients with specific test results. These reports can be used to help identify cases and isolates that should be saved for additional analysis such as sequencing. Some national networks and resources managed by CDC that may be of assistance in this area are found below:

- National Healthcare Safety Network (NHSN): One function of this system is to tracks HAIs.
- Emerging Infections Programs (EIP): This national resource provides surveillance, prevention, and control of emerging infectious diseases.
- Healthcare-associated infections – community interface (HAIC): This network of state health departments and academic medical center partners provides information on emerging HAI threats, advanced tracking methods, and AR pathogens in the US.

Other suggested best practices for using laboratory data include the following:

- Communicate routinely with state epidemiology/ healthcare-associated infection programs, hospital infectious diseases and infection control departments, microbiology laboratory directors, and other key partners.
- Compile and report significant and unusual findings of drug-resistant organisms to individual healthcare facilities' infection control departments on a regular (weekly/monthly) basis.
- Generate an annual statewide antibiogram that can be shared with healthcare facilities.
- Share characterization data (i.e., those provided by NGS) of highly drug-resistant or rare isolates.

6.4.1 Ensuring Chain of Custody

A chain-of-custody (COC) document should accompany all sample handling from receipt through disposition ("cradle to grave") with the goal of preventing any opportunity for tampering. In this section, we do not provide comprehensive guidance regarding chain of custody. Rather, our intention is to provide an awareness of the utility of a COC document in the context of AR pathogens and HAIs as well as general information for consideration.

A COC document may not be common practice for laboratorians primarily involved in clinical laboratory testing of AR pathogens and/or HAIs; however, there are situations in which it may be prudent to have one or one may be requested by a submitter. For example, if a pathogen with a novel resistance profile—one that has the potential to severely threaten the public's health—is identified, a laboratory may elect to implement an internal COC document to prevent theft and misuse. HAI investigations in which law enforcement is involved due to negligence, intentional harm, or otherwise, may prompt the submission of a sample already covered by COC documentation.

While each laboratory's resources and needs are unique, there are critical elements of COC documentation and procedures that are standard, including the following: 1) the submitter's contact information; 2) description of the evidence; 3) signatures for transfer of custody; and 4) documentation of final disposition of the sample. To strengthen recordkeeping in support of the chain of custody, laboratories may photograph the evidence, document and track aliquot transfers, document disposition, document communications, and compile all resulting records in a single "case file" for ease of retrieval. However, a laboratory decides to proceed, it is the quality, not the quantity, of documentation that is paramount in a COC document, and this is critical to the legal defensibility of the data generated.

6.5 Epidemiology-Laboratory Communication

Communication between laboratorians and epidemiologists during all stages of an outbreak is crucial for comprehensive and suitable public health action. Communication should begin as soon as possible to ensure proper specimen collection and accurate laboratory test results. Before specimen collection, laboratorians can advise on relevant factors

for consideration, including the sample type to be collected, specific storage medium and conditions, time constraints to ensure sample viability, and testing turnaround time. Clinical samples from residents or patients and environmental samples from the facility and equipment may be suitable; appropriate collection and storage guidance is vital because incorrect temperatures and inappropriate conditions may negatively influence laboratory results. Some outbreak investigations may require testing in specialized laboratories. The PHL will be able to facilitate specimen collection, testing, and reporting of results. The PHL can serve as the single point of contact for all partners throughout the investigation. Coordination and communication are critical, especially when multiple facilities and laboratories are involved. Thus, effective communication with testing laboratories at the outset is necessary to understand the specific needs of an outbreak investigation and to prepare for all potential challenges. Optimally, channels of communication should be established and relationships fostered prior to an incident to facilitate an expedited response.

The laboratory's ability to respond to an outbreak can vary depending on available reagents and supplies, and even on personnel. Once the scope of an outbreak has been determined, additional laboratory staff may need to be trained. Existing protocols may require modifications, including additional validation or verification. This highlights the importance of early communication between the laboratory and epidemiology. Laboratorians and epidemiologists should coordinate specimen collection and delivery to the lab as well as the expected timeline for the availability of results. For example, specimens collected on a Thursday and received by the lab on a Friday may require additional weekend staff for processing and testing. It may be better to collect specimens on a Wednesday, so that the results can be reported before the weekend. Thus, communication between epidemiology and the laboratory should occur through an open channel to ensure priorities are met without compromising testing quality and results.

6.5.1 Other Testing

There are occasions when it is necessary to investigate an outbreak or suspected outbreak of an organism other than those mentioned in this chapter. In those cases, it is again crucial to maintain the proper chain of custody of all samples and specimens, and to ensure the proper quality control of all testing. Communication is vital to ensuring a timely and accurate response to every outbreak. Other outbreak investigations may involve toxin testing for endotoxin using LAL and gel clot, *Staphylococcus* exfoliative toxin, or *Clostridioides difficile toxin*; sterility testing using USP 71 or USP 61 for non-sterile products; or histopathological analysis of samples.

6.6 Quality Control and Assurance

As with all laboratory testing, in addition to appropriate regulatory certifications, quality control and assurance are vital to ensuring actionable and timely results. Commercial reagents and FDA-approved kit-based tests need to be quality checked, as described in their package inserts. Before beginning any new method, proper validation or verification of the method must be completed. Methods can vary by jurisdiction, but general principles apply. There must be a written plan that includes the number of isolates or specimens evaluated, as well as the acceptance criteria for sensitivity and specificity, accuracy and precision, and inter- and intra-run variability. The plan and final report must be approved and signed by the laboratory director. All tests must include appropriate positive and negative controls, as described in the test package insert, following relevant CLSI guidance and in accordance with Clinical Laboratory Improvement Amendments (CLIA) standards. All tests must be performed in the manner described in standard operating procedures. Results must be checked for accuracy prior to reporting. When performing PCR and sequencing involving amplified material, best practice is to conduct "wipe tests" of the environment to rule out contamination. Unusual results or drug-resistance patterns as well as results that are not reproducible should be discussed with the laboratory director and quality manager before action is taken.

CORHA Keys to Success

Laboratory as a Key Team Member

- Perform clinical testing:
  - Support and/or confirm diagnosis; and
  - Detect outbreak.
- Perform environmental testing:
  - Determine the outbreak source.
- Perform organism identification.
- Perform AST.
- Identify novel AR patterns.
- Identify clusters of illness and potential outbreaks.
- Perform advanced testing, as able and appropriate, to determine the relatedness of clinical cases.
- Determine the mode of pathogen transmission.
- Collaborate with other laboratories (PHLs and reference laboratories), epidemiologists, and hospital infection prevention (IP) staff to ensure adequate capability and capacity to respond to HAIs and established as well as emerging AR pathogens.
- Provide sample collection and shipping materials, including any required requisition forms and guidance for specimen transport.
- Transport specimens to reference, environmental, or other specialized laboratory testing facilities, as necessary.
- Communicate reportable HAIs and AR pathogens to appropriate authorities, including local epidemiology centers.
- Participate in AR surveillance (local, state, and federal) to support rapid identification of novel AR pathogens and early outbreak identification in order to prevent additional illness and spread of infection.
- Provide interpretation of laboratory test results and technical consultation to epidemiologists, public health members, healthcare workers, hospital IP staff, and others
  - To guide/focus investigations;
  - To assist with the development of case definitions; and
  - To identify the appropriate number and type of specimens for collection.
- Host visiting epidemiologists and/or hospital IP staff during rounds.
- Store samples, as able and requested, to support additional testing requests.
- Maintain a chain of custody of samples, as necessary.
- Employ electronic laboratory reporting for rapid communication of quality data.
- Use LIS to mine data and assist epidemiologists and hospital IP staff in the identification of trends.
- Communicate routinely with other outbreak team members to understand the needs and roles of all participants.

CORHA Keys to Success

Appropriate and Rapid Testing

1. Communication between partners is crucial and must begin early.
2. Communications concerning the expected number of specimens, collection date, transport, and expected turnaround time should be clear.
3. Results and reports should be shared in real time.
4. Sequencing can play a pivotal role in the detection of novel resistance mechanisms and determination of relatedness between strains.

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CHAPTER 7

Multifacility & Multijurisdictional Outbreaks

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CHAPTER 7

Multifacility & Multijurisdictional Outbreaks

CORHA

Preface

Compared with single-facility outbreaks, those involving multiple facilities or multiple jurisdictions are more complex and often more difficult to detect, coordinate, and investigate. This chapter focuses on the unique aspects of multifacility and multijurisdictional healthcare outbreak response. See Chapter 3 for more information on public health jurisdictions and agency roles during outbreak response.

7.0 Introduction

A multifacility outbreak can be defined as any outbreak that affects more than one healthcare facility, including outbreaks that involve multiple types of healthcare settings such as a single outbreak across a hospital and an outpatient clinic. Multifacility outbreaks can involve multiple jurisdictions, and multijurisdictional outbreaks often involve multiple facilities. Multijurisdictional outbreaks can involve more than one county or city within a state, multiple states, or even multiple countries. As the numbers of involved facilities, agencies, and levels of organizations across jurisdictions increase, the need for special efforts to maintain effective communication and coordination also increases.

7.1 Overview

Multiple healthcare facilities (and multiple jurisdictions) may experience outbreaks that share the same underlying cause.[1-3] For example, this can happen when medical products are contaminated at the point of production and then distributed to multiple facilities (See Supplement A for more information on contaminated medical products). Another example is a healthcare provider who does not follow recommended infection control practices and works (and spreads infections) in multiple facilities. Another common scenario in multifacility and multijurisdictional outbreaks involves an emerging pathogen that spreads after a colonized or infected patient is transferred from one facility to another.[4-6]

As the ability of healthcare facilities and public health agencies to detect and respond to outbreaks involving healthcare-associated infections and antimicrobial resistance (HAI/AR) increases, multifacility and multijurisdictional outbreaks have the potential to be identified more frequently and rapidly. The healthcare and public health communities must be sensitive to potential regional or national implications of any local

outbreak, especially those that could have far-reaching consequences, such as when transmission stems from a contaminated medical product.

When there are multiple healthcare facilities or jurisdictions involved in an outbreak response, coordination and communication become more complicated. Two main points need to be considered: 1) recognition of an outbreak situation possibly affecting multiple facilities or jurisdictions should be accompanied by rapid communication; and 2) response activities will benefit from integration and coordination at the local, state, and national levels. Examples of categories of multifacility and multijurisdictional outbreaks can be found in Box 7.1; reviewing these examples to categorize an investigation can assist with ensuring that appropriate entities are promptly notified and effectively engaged.

Box 7.1 | Examples of How Healthcare Outbreaks Can Affect Multiple Facilities and/or Multiple Jurisdictions

1. Multiple healthcare facilities or settings within a single local jurisdiction
2. One healthcare facility serving patients across multiple local jurisdictions
3. One healthcare facility serving patients across multiple states or countries
4. Multiple healthcare facilities across multiple local jurisdictions within the same state
5. Multiple healthcare facilities across multiple states
6. Multiple healthcare facilities across multiple countries

7.2 Example Scenarios

7.2.1 Multifacility Outbreak within One Jurisdiction

A multifacility outbreak within a single jurisdiction may be detected via case reports, surveillance data, or other public health activities. It may initially be detected as a single-facility outbreak that is later determined to be multifacility. These types of outbreaks often result from a combination of infection control breaches and poor communication between transferring and receiving facilities. In New York City, a *Candida auris* outbreak investigation revealed a network of transmission involving hospitals and long-term care facilities in multiple boroughs, spurred on by infection control lapses and environmental contamination.[4] In Oregon, an outbreak of extremely drug-resistant *Acinetobacter baumannii* across multiple healthcare facilities was facilitated by the transfer of colonized patients without effective communication.[6]

If a medical product is locally distributed, such as with a local compounding pharmacy, a point-source outbreak among multiple local healthcare facilities is also possible. Scenarios that are less common but could result in local multifacility outbreaks include deficient infection control practices (or drug diversion) by a consultant or other healthcare worker who works at multiple facilities within a jurisdiction (see Supplement B), or medical equipment contaminated locally due to inadequate reprocessing practices and shared across multiple facilities (see Supplement A).

Multifacility outbreaks, even if the facilities are located within one jurisdiction, will usually involve patients from multiple jurisdictions (by address of residence) and may involve patients across state and national boundaries. Patient interviews may be performed by the jurisdiction where the facility is located or the jurisdiction where the patient resides, depending on the preferences of affected public health agencies.

7.2.2 Outbreaks that Span Multiple Jurisdictions

A multifacility outbreak may involve multiple jurisdictions. This type of outbreak can be detected via case reports, surveillance data, or other public health activities. It may originally be detected as a single-facility outbreak that is later determined to involve multiple facilities across jurisdictions. The outbreak mechanisms can resemble those presented in the previous section, with facility involvement that crosses jurisdictional boundaries.

When multiple jurisdictions are involved, effective outbreak response is supported by ongoing and regular coordination across jurisdictions. Coordination will usually be led by the public health agency that covers the multiple jurisdictions, such as the state public health agency, if multiple counties are involved, or the Centers for Disease Control and Prevention (CDC), if multiple states are involved. An example of the latter was the investigation of *Mycobacterium chimaera* contamination of heater-cooler devices used in cardiac surgeries.[7] In some cases, the state public health agency may have sufficient capacity, resources, and expertise to lead a multistate investigation. See section 7.3.3 for more details.

7.2.3 Outbreaks Involving Medical Tourism

Outbreaks related to medical care obtained outside the U.S. are another important example of multijurisdictional outbreaks, as patients receiving care at a single facility abroad may be returning home to various states across the U.S. Identification of outbreaks associated with medical tourism typically depends on astute clinicians who recognize that patients presenting with infectious complications following overseas healthcare procedures may represent a larger problem. Reporting single cases of infections related to medical tourism is critical to the identification of this type of outbreak; typically, CDC coordinates these investigations in close collaboration with state and local public health. Clinicians are advised to notify state and local public health as soon as medical tourism-associated infections are identified.[8] In coordination with state and local public health, cases may also be reported to CDC's Division of Global Migration and Health (DGMH) by emailing medicaltourism@cdc.gov.

7.2.4 Contaminated Products

Medical products can become contaminated during production or distribution. The possibility of intrinsic contamination should be considered when an unusual organism causes infection following a procedure, when there is widespread distribution of cases across multiple facilities and jurisdictions, and when it is biologically plausible that the pathogen identified could have caused this type of product contamination. When an outbreak related to an intrinsically contaminated medical product is detected, unless the product is contaminated locally within a specific facility (for example, during drug compounding or improper storage), the investigation and response is almost always multijurisdictional and multifacility. Since these investigations can be complex and involve multiple federal agencies, the coordinating agency is usually CDC, FDA, a state public health agency, or a large local public health agency with extensive capacity. For additional information on medical product investigations, see Supplement A.

7.3 Coordination of Multifacility and Multijurisdictional Outbreaks

7.3.1 Initial Detection of a Multifacility or Multijurisdictional Outbreak

A multifacility or multijurisdictional outbreak may be detected by an astute clinician or by examination of surveillance data that reveal a suspected outbreak across facilities. As described in Chapter 4, public health agencies fill a key role in the detection of multifacility outbreaks, since they receive case reports and surveillance data that can be reviewed for potential linkages. Sharing information across the public health and healthcare communities through open and regular communications—both formal and informal—can help detect multifacility outbreaks. For example, forums, local conferences, and listservs can provide opportunities to share information on current outbreaks that may lead to multifacility/multijurisdictional outbreak detection.

7.3.2 Initial Notification Upon Detection

After a potential multifacility/multijurisdictional outbreak has been detected, entities that may be affected and/or need to participate in the investigation should be promptly notified. As discussed in Chapter 3, section 3.1, notification should be considered for the following potentially impacted entities:

- Affected local public health agency
- State public health agency, including epidemiology and laboratory partners
- Surrounding local public health agencies (other counties, cities, or states) when these agencies may be affected (e.g., cases may be detected within their jurisdictions)

- Affected healthcare facilities (those with cases)
- Healthcare facilities that may receive or transfer patients from or to affected facilities
- Healthcare facilities that may be positioned to detect and report new cases (e.g., if patients go to their local clinic or hospital for care after being exposed at an affected facility)
- Facility or provider licensing entities
- Affected patients or members of the public
- CDC if the outbreak is unusual or involves organisms of national interest, if technical assistance or additional resources may be needed, or if the outbreak may extend across state lines
- Food and Drug Administration (FDA) if intrinsic medical product contamination is suspected
- Local, state, or federal law enforcement if criminal actions are suspected (see Supplement B for information on drug diversion and drug tampering)

Notification processes among local, state, and national public health agencies and healthcare stakeholders may vary depending on jurisdiction and how an outbreak is initially recognized. More information on notification and communication can be found in Chapter 8.

7.3.3 Coordinating Agency

Following notification of affected agencies and healthcare facilities, it is important to promptly identify investigation partners and to recognize or designate a lead or "coordinating" agency, to do the following:

- Organize a multiagency, multidisciplinary team
- Manage information collection and dissemination
- Facilitate communications
- Ensure a complete and rapidly progressing investigation

Depending on the scope and nature of the outbreak, the coordinating agency may be a local public health department, state public health department, or federal agency such as CDC. Identification of the coordinating agency should allow for rapid investigation and mitigation of the outbreak. In some cases, during a multijurisdictional outbreak involving a single facility, the entity coordinating the response may be the healthcare system or academic center. When there is a multifacility outbreak, however, typically the coordinating agency will be a public health agency rather than a healthcare facility. For the remainder of this chapter, the term "coordinating agency" will be used to imply a coordinating public health agency. Additional considerations for identification of a coordinating public health agency include the following:

- **In some situations, outbreak responses may be coordinated most efficiently by the public health agency nearest the source or index case; in other situations, it may make sense for the coordinating agency to be the one having the broadest jurisdictional authority.** An outbreak response involving multiple local public health agencies may be coordinated best by a local public health agency, if most cases or facilities are in that jurisdiction, or by the state public health agency, if cases or facilities are more widely dispersed throughout the state. A multistate outbreak may be coordinated best by a state public health agency or CDC. Outbreaks of widely geographically dispersed cases may be coordinated best by CDC. It is critical to have conversations early in the investigation regarding the role of each agency.
- **The coordinating agency should have sufficient resources, expertise, and legal authority. I**n some situations, a coordinating agency may be a state public health agency or CDC due to resource limitations within local or state public health agencies, respectively. FDA may be the coordinating agency in some situations involving widely distributed contaminated medical products. Federal, state, and local regulations may also dictate which agency or jurisdiction should assume the coordinating role.
- **Designation of the coordinating agency may change over time, depending on the cause, scale and phases of an outbreak.** If an outbreak expands geographically or evolves in a manner that creates resource demands that no longer can be met by the originally designated coordinating agency, consideration should be given to changing the coordinating agency.

7.3.4 Interagency Outbreak Response Team

Investigating a multifacility or multijurisdictional outbreak is a collaborative process and requires team effort. As noted in the previous section, the coordinating agency

plays a key role in helping assemble and manage a multidisciplinary outbreak response team. The team may comprise local, state, and federal agencies, as well as healthcare facilities and healthcare providers. Consider the following suggested practices for establishing interagency outbreak response teams:

- Clarify the roles and authorities of local and state public health agencies and other entities.
- Consider how, and to what extent, investigation team partners may need to, or be expected to, retain a lead role within their jurisdiction or agency.
- Discuss plans for incorporating (or communicating and coordinating with) regulatory agencies such as state healthcare facility and professional licensing agencies, the Centers for Medicare and Medicaid Services (CMS), and law enforcement agencies (local, state, and/or federal including the Drug Enforcement Administration (DEA); see Chapter 5 for more information.
- Review or designate specific roles for individual team members in each agency.
- Establish points of contact and communication pathways (see section 7.3.5).
- Share organizational charts.
- Refer to Chapters 3 and 5 for additional information relevant to assembling and managing outbreak response teams.

7.3.5 Communication and Collaboration

The success of a multifacility or multijurisdictional outbreak investigation often hinges on effective communication and collaboration. While Chapters 5 and 8 discuss these aspects in detail, some important considerations for multifacility and multijurisdictional outbreaks are highlighted below.

- The coordinating agency should establish regular communication with involved partners, which may involve regular meetings and email updates for all of the response team members, as well as smaller regularly scheduled group interactions for focused topics.
- The initial communication with all involved partners should include, at a minimum, introductions and roles, a summary of what is known to date, initial investigative steps that will occur (including any that have already taken place), jurisdictional responsibilities for case investigation (e.g., by facility location vs. resident address), and method and frequency of communication.
- In more complex investigations, use of the incident command system (ICS) can help formalize the roles and lines of communication. See Chapter 3 for a more detailed discussion of the ICS. Agencies involved in the outbreak response should evaluate and decide in advance how to apply ICS, including across agencies during a multifacility or multijurisdictional outbreak response.
- Healthcare facilities and providers should be engaged early in the investigation and should receive timely and regular communications; these entities may benefit from having clearly designated points of contact within the response team, especially when issues arise outside of regularly scheduled interactions.
- Consider the need to notify the wider public health and healthcare communities, including when calling for additional cases; CDC's Epidemic Information Exchange (Epi-X), listservs such as the Emerging Infections Network through the Infectious Diseases Society of America (IDSA), and other networks can be useful for this, depending on the nature of the outbreak.
- Regular updates should include reviews of the investigation's progress across all facilities and jurisdictions. Involved entities will all want to know the big picture, including case numbers, hypotheses, new findings, aggregate data summaries, and investigation progression.
- Consider and regularly reassess internal communication within each agency and partner, including the need to communicate with leadership, communication experts, legal counsel, emergency response personnel, epidemiology experts, and laboratory experts.
- Multifacility outbreak investigations often provide opportunities to improve facility-to-facility communication, which may not be well-established prior to the outbreak response.
- Releasing information to affected patients or members of the press should be discussed with (or coordinated through) the lead agency when feasible.

For media inquiries, having a unified message and communications plan developed ahead of time is advisable. This enables a rapid response that is consistent among the agencies. For additional information, see Chapter 8.

- Early in the investigation, consider the potential for scientific publications or presentations; discussing agency and individual roles, and agreeing on leads, contributors, and other aspects of attribution can help with collecting information and avoiding conflicts later on.

7.3.6 Data Collection and Dissemination

Data collection, organization, and analysis should ideally be managed centrally by the coordinating agency or through its designee (e.g., the coordinating agency may elect to engage a partner with more experience or authority for this activity). Data collection forms should be applied uniformly by all agencies involved in data collection. Data collection on cases may involve medical record reviews and patient interviews; data collection to determine possible sources of infection or infection control breaches may involve infection control observations, staff interviews, and review of other types of facility records. The coordinating agency should ensure that the entities performing data collection have the resources they need to complete the investigation in a timely manner. Consideration should be given to on-site observations for all involved facilities, and not just those facilities with the majority of cases. To maintain confidentiality, the coordinating agency should also ensure that proper approvals for collecting data have been obtained, including human subjects research determinations as needed.

Sharing of data among affected entities is regulated by local, state, and federal authorities. The coordinating agency should consider options to ensure that each jurisdiction and facility has access to their own data. In most cases, it is not appropriate for all involved entities to have access to all data; for example, it may not be appropriate for a healthcare facility to have access to confidential information on patients from another healthcare system. Maintaining patient confidentiality is essential, and any data sharing should be done in a secure and legal manner. Options to consider based on agency and local and state regulations may include sharing of data collection tools via secure methods or a secure shared database that allows for each entity to access their own data. A memorandum of understanding (MOU) or other formal agreement between agencies may be necessary for such arrangements. See Chapter 3, section 3.4.2.1 for more on information collecting and sharing.

Barriers to data sharing can include patient privacy regulations and internal policies. Awareness of all entities' barriers can help determine the best method for data-sharing practices throughout the investigation. When the response intersects with a criminal investigation or regulatory action, data collection and sharing are subject to additional layers of complexity, and the role of the coordinating agency may be further amplified.

The coordinating agency should ensure sharing of aggregate analyses as the investigation progresses. The coordinating agency should update descriptive analyses, timelines, maps, epidemic curves, and other analyses as needed, and ensure that communication to the entities involved includes dissemination of these data summaries. Aggregate analyses can often be shared more readily across the involved entities because they do not usually contain confidential information. Consideration should also be given to avoid sharing information that may identify an individual based on the detail of information given, even if that information is not typically considered confidential by the public health or healthcare agency.

7.3.7 Regular Assessment of the Scope of the Outbreak and the Resources Needed

The scope of an outbreak response will change over time, especially in the case of multifacility and multijurisdictional outbreaks. Typically, there is a growth period as the overall response process ramps up. Cases may accumulate, and the scope of the investigation may widen to include additional facilities and jurisdictions. Later, after control measures have been implemented, activities may decrease and resource demands may begin to decline. When the scope of an outbreak changes, entities involved in the response, resources needed for the response, and the ability of the coordinating agency to continue in the lead role should be reassessed. Questions that should be periodically considered throughout the investigation follow:

- Are there additional entities that became involved during the investigation that should be added to communication streams? Are there entities whose involvement may be reduced or initiated?
- Does the coordinating agency continue to have the capacity to lead the response or has the outbreak expanded or shifted in a way that may necessitate transitioning the role of coordinating agency to another agency?
- Are there other experts who may provide additional insight?
- Does it make sense to adjust the frequency of communications? Does the coordinating agency believe that meeting attendance can be narrowed? Are there opportunities to consolidate and decrease the footprint of activities and communications?
- Is it appropriate to consider decreasing the frequency of communications and transitioning to surveillance/maintenance activities?

7.4 Concluding a Multifacility or Multijurisdictional Investigation

Determining when to declare an end to a multifacility or multijurisdictional outbreak investigation can be challenging. As described in section 7.3.7, the scope of the response requires regular reassessment. The coordinating agency is often in the best position to gauge ongoing needs for active contributions from members of the interagency team. Generally, once the likely cause of the outbreak has been determined and appropriate control measures have been put in place, opportunities to narrow the scope of the response can be identified. The investigation may enter a maintenance or "monitoring" phase; this may include a process for confirming that transmission has been interrupted, continuing surveillance for additional cases, completing follow-up activities related to product recalls, case management, finalizing collection and analysis of data, and preparation of reports.

Considerations for a monitoring process can include the needs of the affected agencies (e.g., some organizations may still be detecting cases while others may not), the jurisdictions involved, and the types of tasks that should occur during the monitoring period. Determining timeframes and endpoints for involved entities during the investigation is very helpful. The duration of the monitoring period often depends on the specifics of the pathogen or the type of infection as well as the likelihood that control measures will be successful. For example, if the outbreak involves a pathogen with a long incubation period, there may be an extended period during which additional cases can be identified as a consequence of exposures that occurred before control measures were implemented (e.g., a product recall). On the other hand, when a multifacility outbreak stems from introduction of a novel multidrug-resistant organism (MDRO), control measures may be more diffuse (e.g., enhanced infection control) and require more vigilance to rule out ongoing transmission. If additional cases representative of ongoing transmission are detected during the monitoring period, it may be necessary to re-activate the response or extend the monitoring period in affected facilities or jurisdictions.

The decision to formally conclude an interagency response depends on many factors, including the gravity and scope of the outbreak, and on the likelihood that the current situation reflects an ongoing public health threat. For additional considerations, see Chapter 5, section 5.1.13. The conclusion of a multifacility/multijurisdictional outbreak represents an opportunity for reflection, assessment, and improvement. It is best practice to conduct an after-action review (i.e., a post-outbreak debriefing meeting) with all involved agencies to identify gaps in the outbreak response and to mitigate these gaps prior to the next outbreak.

In summary, multifacility and multijurisdictional outbreaks can involve multiple healthcare facilities, public health agencies at all levels, regulatory agencies, and other entities. While these investigations can be complex, nonlinear, and involve differences in perspectives and priorities, identification of a coordinating agency, delineation of roles, and establishment of regular and effective communication practices can all increase the likelihood of success.

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CHAPTER 8

Notification & Communication

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CHAPTER 8

Notification & Communication

Preface

When patients are placed at risk as a result of an outbreak in a healthcare setting, a serious infection control breach, or another situation that jeopardizes their health, they have a right to know what happened, the extent of their risk, and what they need to do. Incorporating notification into an outbreak response can be challenging, particularly when not all information has been collected or analyzed. Public health agencies and healthcare providers should consider this type of communication part of their missions to protect health and serve their populations. In this chapter, we describe the "who, what, when, how, and why" for notification of patients and other stakeholders, along with information on risk communication principles and strategies to be followed to support an effective healthcare outbreak response.

8.0 Introduction

8.0.1 Patients' Stories

Patient A was first admitted to a small local hospital for treatment of a minor ankle fracture. He was readmitted to the same hospital just two days after his discharge, experienced a prolonged and complicated hospitalization, and died 3 months after the initial admission from pneumonia caused by methicillin-resistant *Staphylococcus aureus* (MRSA). Patient A's daughter reported discovering two other deaths at the hospital related to MRSA infections in the month prior to her father's first admission. When Patient A's daughter expressed questions to hospital staff about her findings, she felt frustrated and talked down to with no empathy; she said that the staff responded with "expressed helplessness and 'I don't know' answers." Patient A's family was left with unanswered questions, making the traumatic loss of a loved one even more difficult.[1,2]

When a patient contracts an infection in a hospital or other healthcare setting, it can be a shocking and frightening experience. When infections spread, the experience can become more frightening and confusing for patients and their families, and may be upsetting for the staff as well. During an outbreak, healthcare providers and staff understandably feel urgency to stop the outbreak. However, in that urgency, we should not forget to inform the people affected most by the incident.

As in Patient A's case, patients and their families can be left in the dark in the midst of a known outbreak or similar situation. At a large hospital, Patient B delivered her baby, who was admitted to the neonatal intensive care unit (NICU). According to Patient B, she was not

informed before delivery that the NICU was in the midst of an ongoing MRSA outbreak, which the hospital had not yet been able to control. She remained uninformed of the outbreak when told that her child tested positive for MRSA while still in the NICU.[3]

There is great emphasis today on patient-centered care. Nevertheless, the process of informing patients and others needing to know about outbreaks has not always kept up with the current prevailing philosophy of transparency. Neglecting to inform can lead to speculation, misinformation, and distrust in the hospital, healthcare setting, and healthcare providers. Not only is lack of transparency poor patient care, but it also neglects an important part of the outbreak response, specifically gaining the patient's perspective. When patients and families are informed about outbreaks during the hospital stay and following discharge, they can become active participants in the outbreak investigation and can help identify risk factors and reasons for the outbreak.

The framework presented in this chapter acknowledges the importance of informing patients, families, providers, and, in some cases, the general public when outbreaks occur in healthcare settings. Considerations for notification of patients, their families, and the public should always include the experiences of people public health is entrusted to protect.

8.0.2 Considerations for Notification

Historically, there has been some debate about whether and when to notify patients, their families, and the public of suspected and confirmed outbreaks. More recent experience of public health agencies and healthcare facilities and providers has shifted the tide on the debate toward early notification.

A paper by Dudzinski and colleagues[4] on large-scale adverse events, which covers outbreaks and infection control breaches, described two ethical frameworks that often guide the decision to notify. Notifying patients at risk, even when the chance of physical harm is extremely low, is supported in both ethical frameworks.

The first framework, from the utilitarian perspective, focuses on minimizing risk and maximizing benefit. Under the utilitarian framework, notifications can benefit stakeholders by informing and empowering them, and can help mitigate harm (e.g., by facilitating diagnosis and treatment). However, a healthcare facility may believe that disclosure of a low-risk event has the potential to result in net harm (such as worrying patients or undermining public confidence). Taking a broader perspective on benefits and harms can help in these situations. For example, disclosure can help with the epidemiologic process (to identify the cause and control the spread of disease) and/or with diagnostic interventions (to determine which patients may have been exposed or harmed). In addition, the utilitarian framework may also support notification to ensure that the institutions involved build or maintain trust.

The second ethical framework, from a duty-based perspective, focuses on the duty to notify. It takes the stand that patients have a right to know and an expectation that they will be notified when delivery of healthcare has placed them at risk. This framework applies to situations in which the increased risk was not anticipated or was not recognized at the time of the incident. This duty-based framework is tied closely to transparency and supports disclosure in most situations.

The duty of public health agencies is to protect the health of the public. A part of this duty is to maintain the trust of the public; when the public senses that information is being withheld, this trust is undermined. It is critical to employ risk communication strategies, described later in this chapter, to convey information effectively and maintain trust. This is true for public health and healthcare alike. Difficulty in how to communicate messages should not be a barrier to the decision to communicate. Ensuring timely and accurate communication helps prevent misinformation from filling voids and establishes or maintains trust.

Patients and other stakeholders should be provided information in a manner that helps them understand and manage risk. Keep in mind that the actual risk may not match other people's perception of risk and that different people can experience different levels of risk in the same situation. According to Peter Sandman,[5] the amount of actual risk and the outrage experienced by people hearing about the risk do not always correlate. When

preparing for a patient notification, consider the following categories of risk and outrage:

- High risk and low outrage: communication should include messaging to alert people to potentially serious risks.
- Low risk and high outrage: communication should include messages of reassurance.
- High risk and high outrage: communication should include helping people cope with serious risks.
- Low risk and low outrage: communication may focus on providing information.[5]

Additional considerations for notification and risk communication are discussed throughout this chapter.

8.1 Notification of Patients, Stakeholders, and the General Public

In this section, we discuss notification of affected and exposed patients, stakeholders such as providers and healthcare facilities, and the general public both during and after an outbreak. CDC authors have described three potential triggers to perform patient notifications: 1) when patients have experienced a healthcare-associated infection (HAI; including colonization with an antibiotic-resistant pathogen); 2) when patients need to be able to mitigate risks (e.g., by identifying symptoms of an infection that is incubating or already present, or receiving screening for a pathogen present without symptoms); and 3) when patients have experienced an alteration in care due to an outbreak or infection control breach (such as receipt of care they otherwise would not have received or application of additional infection control precautions).[6]

For additional details on topics described throughout this section, please refer to Table 8.1. For examples of how to apply the table, see the examples in Box 8.3 (*Legionella pneumophila*) and Box 8.4 (New-Delhi metallo-beta-lactamase–producing carbapenem-resistant Enterobacteriaceae).

8.1.1 Immediate Notification

Immediate notification refers to a set of initial and critical communications that occur when an outbreak is first suspected. Healthcare providers should immediately report a suspected outbreak or infection control breach to designated internal team members (infection preventionists, hospital epidemiologists, patient safety officers, etc.) and to public health authorities following local, state, and/or federal requirements, where applicable. Refer to Chapter 4 for additional information on cluster and outbreak definitions and on reporting to public health agencies. Pathogen-specific outbreak definitions can be found on CORHA's website at www.corha.org/resources-and-products/.

Ideally, representatives of healthcare settings should take the lead on immediate notification. Public health staff may need to take this position when healthcare setting representatives do not or are unable to do so. It is best that the notification process begin as soon as possible—within 24 hours after an outbreak has been recognized. Sometimes notification must occur before all facts about the outbreak are known. In most cases, notification plans should prioritize infected patients, ensuring that they are notified and counseled promptly (by their healthcare providers whenever possible). Notification to other groups should follow as soon as possible and, at times, steps may occur simultaneously instead of sequentially. The same principles apply as new cases are identified.

8.1.1.1 Affected and Exposed Patients

When cases have been identified, those patients with an infection or a condition of interest should be notified immediately, ideally by their own healthcare provider. The rationale behind immediate notification of this group (those "directly affected") includes 1) fully informing patients of the event and implications for their health; 2) equipping patients with the knowledge to seek appropriate treatment; and 3) supporting the investigation and control of the outbreak. Affected patients can be notified verbally (in person or by phone, if they are no longer in the facility) or in writing, if verbal notification is not possible. If patients are incapacitated or have died, their designated healthcare proxies should be notified.

If other persons in the healthcare setting, such as healthcare workers or visitors, are deemed part of the outbreak, they should also be notified immediately with the same considerations described above for patients. Applicable counseling and information about the potential risk of transmission, infection, clinical illness, testing,

treatment, and additional care measures should be clearly communicated. Regardless of the initial method of communication, patients and other affected persons will benefit from receiving information in writing.

Patients and other persons who have been exposed (but are not yet known to be infected or share the condition of interest) should be notified as soon as possible after patients who are directly affected. The methods for notification should be the same, with the same considerations, as patients directly affected. Messaging is likely to vary, and additional counseling information regarding the risk of infection after exposure and post-exposure prophylaxis may need to be considered in addition to the information communicated to affected patients.

Patients and other persons who may be at risk of exposure in the future should also be notified before any potential exposure occurs. This may include patients about to undergo a procedure or patients admitted to a unit or area in a healthcare setting currently experiencing an outbreak; it may include persons with an intrinsic increased risk for the condition under investigation (such as persons who are elderly or immunocompromised). The methods for notification can be the same as those used with affected and exposed persons but may also include notification via postings at strategic locations in the healthcare facility, such as at the entryway into a unit or at handwashing stations. The primary purpose is to decrease the risk of exposure for this group of persons, with the understanding that risk tolerance varies between different people, even though the actual risk of exposure may be the same.

If many people require notification or a large volume of inquiries is expected, consider establishing a dedicated call line ("hotline") or other method to allow opportunities for questions. Ideally, the dedicated call line will be run by the facility since the facility is responsible for the direct care of the patients. However, in some circumstances, it may be beneficial for a public health agency to establish a line of communication, either in parallel to or in place of the facility (this typically occurs only when the facility does not have an established call line). A web page with the same information can be considered when inquiries are likely to be of high volume. Whenever possible, information should be presented in an easy-to-understand format, such as a frequently asked questions (FAQs) document.

Additional details and considerations can be found in Table 8.1, step 1.

8.1.1.2 Healthcare Providers and Personnel

Affected patients' healthcare providers should be notified as soon as possible, preferably according to the same timeline as affected patients. Providers should be made aware of and understand the current situation and what outbreak information is available as well as their patients' conditions and risk. In many cases, healthcare providers are the best persons to notify their patients, because a relationship between provider and patient already exists; providers can help answer their patients' questions and offer a level of trust and confidence to support them. It is important to give providers full information about the outbreak and condition, and not assume that they know how to proceed in an outbreak situation, which may differ from routine clinical care. The method of provider notification may depend on internal processes, and may include direct communication with each provider or more general messaging to healthcare providers facility wide.

Other provider groups who should be notified include those at the same healthcare facility who do not provide direct care to affected or exposed patients, as well as community providers who do provide care to those patients. These providers should be notified as soon as possible and should be given complete information about the outbreak so that they can counsel patients and answer questions. There are many methods by which this information may be communicated; for example, during team meetings, by group emails, or in written postings. The exact method of communication depends on the severity of the situation, the need for broader communication, healthcare facility internal policies, and recommendations of public health agencies.

When the need arises, a health alert may be issued by the public health agency to alert many providers at once to the situation. This is valuable when there is potential for wide-spread exposures; providers can aid in the identification of cases and receive recommendations for the next steps in the care of affected patents in the community. One

example showing the need for a health alert would be when a contaminated medication has been distributed broadly among healthcare facilities and providers.

It is important to note that employees in the healthcare facility who are not directly affected or exposed should also be notified of the outbreak. It is best to communicate early to ensure that all employees are accurately informed and feel safe, before rumors begin to circulate. Also, healthcare professionals and support staff often work in multiple settings, raising the prospect of exposure and spread to other healthcare settings (see section 8.1.1.4).

Finally, healthcare providers or other employees may themselves be affected or exposed persons or may have underlying illnesses placing them at risk for complications for the condition of interest. These people should be considered in a similar manner to affected and exposed patients discussed in the previous section. Employee health should be consulted and involved in the communication to and management of these employees.

See Table 8.1, step 1, for more information about communication with healthcare providers and employees.

8.1.1.3 Visitors

Visitors to the healthcare facility should be informed when they may be at risk of exposure, when underlying illnesses may increase that risk, and how a change in their behavior may be necessary at the location of the outbreak (such as additional handwashing or use of personal protective equipment [PPE]). Visitors who may have been exposed should receive messaging similar to other exposed persons, as described above. Methods for communication may include written postings, in-person communication at the time of a visit, or written or verbal communication prior to a visit. Remember that visitors are often family or friends; they will have questions not only about any risk to them but also any risk to the patient. For visitors who need to make behavioral changes or institute safety precautions (e.g., transmission-based precautions), the required changes must be conveyed clearly and directly as necessary via educational materials or demonstrations.

Communication should occur as soon as possible and prior to exposure when possible. Under some circumstances, suspension of visitation may need to be considered for a period of time if such visitation could pose a risk to patients or visitors.

Refer to Table 8.1, step 1, for more information about communication with visitors.

8.1.1.4 Other Healthcare Facilities

Information about an HAI outbreak may need to be shared with other healthcare facilities when affected or exposed patients receive care at multiple facilities or when other healthcare facilities' patients and healthcare workers could be exposed. Keep in mind that healthcare professionals and support staff sometimes move and work between facilities. Other facilities typically require notification when a patient at the primary affected facility is transferred and could pose a risk to healthcare workers and patients at the receiving facility. Public health should encourage thorough communication and documentation (e.g., in medical records) when transferring patients, especially when there is a risk for communicable disease spread and a need to implement transmission-based precautions. Resources such as transfer forms can be helpful for communicating this kind of key information. A template transfer form is available from CDC at: https://www.cdc.gov/healthcare-associated-infections/media/pdfs/Interfacility-IC-Transfer-Form-508.pdf.

Additionally, health alerts may be sent by the public health agency to notify multiple healthcare facilities and providers, often when there is potential for wide-spread exposures, for the purposes of case-finding, and when making recommendations to providers in the community.

More information on notifying other healthcare facilities can be found in Table 8.1, step 1.

8.1.2 Expanded Notification

As an investigation progresses and more information becomes available, notification procedures should be updated and may require expansion to other individuals, groups, or partners. This is especially true if the investigation grows to include additional units or additional healthcare settings. Previously notified individuals should also receive updated communications, as appropriate.

Coordination and frequent communications among involved partners is critical during this phase. As coordination and message timing become more complicated, public health may need to assume a coordinating role. This may include helping coordinate notification timelines or developing a shared media communication plan for healthcare facilities, public health and other government agencies, and other partners.

Anticipate media and public attention (see section 8.3). Public health staff should continue to defer to representatives of the primary affected healthcare setting to perform individual notifications whenever possible, unless surge capacity is needed or the facility is closed, uncooperative, or lacks capacity (as in the case of a small or outpatient facility).

8.1.2.1 Affected and Exposed Patients

Additional affected and exposed patients may be detected throughout the course of the investigation. Transparency and open communication remain critical in this context. These additional patients (or their designated healthcare proxies) should be notified as soon as the patients have been identified, ideally within 24 hours after identification or as soon as possible; do not wait for the investigation to be completed. All information discussed in section 8.1.1.1 on methods of notification and considerations apply to additional affected and exposed patients; consider providing additional information as to why notification may be coming later than for other patients who already have been notified. Additional details and considerations for expanded notification can be found in Table 8.1, step 2.

8.1.2.2 Healthcare Providers and Personnel

As additional affected or exposed patients and other people are identified, consider notifying their providers as soon as possible, as outlined in section 8.1.1.2. Often during the expanded notification stage, additional personnel (such as facility employees, facility providers who are not directly involved in care of affected patients, or community providers) might become more involved and benefit from being notified. See Table 8.1, step 2, for more information.

8.1.2.3 Visitors

Additional visitors beyond those targeted during the immediate notification phase may be identified and require outreach as the investigation progresses. For example, if during the outbreak investigation additional units are identified as being affected, additional signage may be posted in strategic locations within these units. If additional risk factors are identified during the investigation, these may have implications for visitors and should be communicated as appropriate to assist with prevention efforts. More details can be found in section 8.1.1.3 and Table 8.1, step 2.

8.1.2.4 Other Healthcare Facilities

During the expanded notification stage, additional healthcare facilities may need to be notified; for example, when other healthcare facilities care for affected or exposed patients, or when their own patients and healthcare workers may be at risk. The methods and considerations for notifying other healthcare facilities are described in section 8.1.1.4 and in Table 8.1, step 2.

8.1.3 Public Notification

Public notification in the context of a healthcare investigation should be considered when there is a need to communicate ongoing risks or advocate actions to a broader audience. Examples include very large-scale notification events or circumstances in which potentially exposed persons cannot be reached through other means. Public notification may also be required when the outbreak is located within a defined area of the healthcare setting and patients may have limited ability to make informed decisions once they have begun care elsewhere in the facility. For example, a woman entering a hospital to deliver a baby may not be aware of an outbreak in the NICU until after delivery, at which point, notification does not allow her to decide whether to have her child cared for in that NICU.

8.1.3.1 When to Notify the Public

Notification of the public can be beneficial under certain circumstances. The decision for public notification should be considered when any of the following apply:

- If the outbreak has already, or is likely to, become public through other channels
- To proactively provide accurate information, to clarify or correct wrong or misleading information already in the public sphere, and to more effectively communicate risks

Box 8.1 | Additional Considerations for Immediate and Expanded Notification and Communication

- Include language on what is known, what is not yet known, who is at risk, who is not at risk, how individuals can protect themselves, and how they can prevent infection or disease spread to others.
- For outbreaks limited to a specific unit (e.g., NICU, ICU, Hematology-Oncology ward):
  - Postings can be placed at entry doors to the unit, nursing stations, handwashing stations, waiting rooms, and staff break rooms.
  - Postings in patient rooms may indicate precautions to take, but one needs to be mindful of Health Insurance Portability and Accountability Act (HIPAA) regulations.
- For outbreaks that affect multiple floors/units (e.g., legionellosis or a pathogen affecting several units):
  - Postings can be placed in the lobby, at the visitor check-in desk, in elevators to floor(s) that are affected, and in each potentially affected unit, etc.
- Provide information on actions the healthcare setting is taking to prevent spread and future outbreaks.
- To ensure the quality and effectiveness of content to the targeted audience, consider there may be language challenges, making sure communication is available in multiple languages; determine the need for translators.
- Where applicable, refer to state or federal reporting and notification policies, which may require a more immediate notification and reporting timeline.
- NOTE: Postings within the facility may be inadequate if the outbreak is located in areas that patients cannot avoid accessing once they are admitted to the facility; these include the emergency room, ICU, or operating room. In this case, notification may have to occur before the person decides to seek services at the healthcare facility (see 8.1.3, Public Notification).

- To assist an active investigation by helping identify additional affected and exposed persons outside the current healthcare setting where the original cases were identified
- To inform healthcare providers in the community for the purposes of adjusting patient care, assisting with identifying cases, assisting with other aspects of an investigation, and preventing further transmission
- To advise the public and potential patients when the at-risk population is very large
- To provide information that people should receive to protect their health and prevent transmission to others. (This could include notifying patients who were exposed but who have not been reached through other means. Often this includes specific recommendations and actions to take, such as clinical evaluation, testing, symptom watch, or contacting the local public health authority.)
- To provide information to people considering visitation to affected healthcare settings when visitation may place them at risk
- When a novel pathogen is identified or emerging, or when an outbreak involves unusual or rare multidrug-resistant organisms for which there is limited treatment
- If the illness is severe or there are many cases or associated deaths
- To demonstrate commitment to transparency and ensure the organization's perspective is accurately represented in the media
- When the outbreak occurs in an area of a hospital or other healthcare setting that provides services that patients may require but cannot predict in advance of being admitted.

8.1.3.2 How to Notify the Public

Public notification often depends on collaboration between public health and healthcare. In general, it is preferrable that healthcare providers take the lead in notifying the public; ideally, they will inform public health and seek input on the messaging. Public health may need to take the lead in notifying the public in some circumstances, such as when the healthcare provider refuses or is unable to do so, or the outbreak

involves multiple facilities, settings, or communities. Considerations include the following (see sections 8.2 and 8.3 for expanded information on this topic):

- Message content and timing should be jointly developed or reviewed by healthcare and public health stakeholders.
- Designate a spokesperson to identify resources and staff to handle inquiries and follow up.
- Consider giving key stakeholders (e.g., neighboring public health areas) advance notice, as appropriate.
- Present as much relevant detail as possible regarding what is known and not known, who is at risk and who is not, what has been done so far, and what are the planned next steps.
- Show empathy: people will be concerned about their risk or may have experienced harm.
- Include action(s) that persons can take for protection.
- Describe where to find additional information, such as a website or call line.
- Prevent identification of affected persons (confidentiality breach). Establish clear guidelines with the media regarding privacy of individual information and what is protected health information.
- Acknowledge when investigation findings are not yet final to avoid drawing erroneous conclusions, such as implicating the wrong source or prematurely assigning blame.
- Clarify misinformation.
- Prevent stigmatization of persons or groups affected by the outbreak or investigation.
- Have a plan to communicate updates—frequently, if necessary—as knowledge expands.

8.2 Communication Techniques

It is critical that the correct information gets communicated in a way that reaches the intended audience. In the above sections, we discussed notification of patients, persons at risk, healthcare providers, and the public. Although a full discussion of risk communication is outside the scope of this guidance document, we describe the basic principles in this section.

Public health agencies should involve their communication experts and public information officers (PIOs) as soon as a notification event is considered; the assumption throughout this section is that these experts are already involved.

The reader should be aware of two important resources that are referenced throughout this section:

- For more information on communication during a crisis, see CDC's Crisis and Emergency Risk Communication (CERC) Manual: emergency.cdc.gov/cerc/.
- For more information to guide health departments and healthcare settings during notification events, see CDC's Patient Notification Toolkit: www.cdc.gov/injectionsafety/pntoolkit/index.html.

8.2.1 Risk Communication Principles

To help craft effective messages, we need to understand how a situation may be perceived. People's perceptions of risk vary depending on the type of information conveyed and how it is conveyed; not all risks are perceived equally. Risks that tend to be more accepted include those that are perceived to be voluntary, familiar, under an individual's control, naturally occurring, or generated by a trusted source; have clear benefits; or affect adults. Less accepted risks include those that are perceived to be imposed, controlled by others, manmade, generated by an untrusted source, or exotic; have little or no benefit; or affect children.[7]

CDC's Crisis and Emergency Risk Communication (CERC) Manual lists five key components of trust and credibility that make up the foundation of risk communication principles.[7]

- Empathy and caring
- Competence and expertise
- Honesty and openness
- Commitment and dedication
- Accountability

A spokesperson trained in these risk communication principles should be identified and chosen early, based on the person's ability to develop trust and credibility. The spokesperson should be involved in determining the information to be communicated and in developing key messages.[8] Refer to the CERC Manual for more information on the selection of a spokesperson and risk communication principles, available at emergency.cdc.gov/cerc/.

It is important to plan what needs to be communicated in advance. As messages are developed for targeted audiences (affected patients, exposed persons, healthcare providers, and the public), think about

communicating the following three things:

- What happened
- What you are doing to correct it
- What the audience needs to know, including steps people can take to protect themselves

When considering communications for the news media, it is important to plan as much as possible in advance. Anticipate possible media coverage when many patients are involved, the condition is new or rare, the persons affected are vulnerable, or the "story" may carry an emotional impact. Often public health can help the healthcare setting anticipate and plan for media coverage. In some circumstances, it may be necessary to approach the media proactively, such as when a wider audience needs to be notified. On the other hand, the media may be notified through other sources and approach public health agencies or the facility.

Considerations for planning for media communications include the following:

- Determining the extent of information to convey to the news media
- Determining when to convey that information
- Determining with whom you wish to coordinate to convey that information
- Being prepared if information is leaked to the media before it is formally announced[8]

The last item cannot be underestimated. When planning the timing of communication to patients and other affected parties, as described in earlier sections of this chapter, keep in mind that your timelines and plans (e.g., those related to notification of patients and families prior to public notification) can go awry if information is leaked to the media. Having on hand talking points, press releases, media statements, and messaging created ahead of a media leak are critical. For more information on the media, see section 8.3.

8.2.2 Managing Differing Opinions Between Public Health Agencies and Healthcare Facilities

It is not uncommon with notification events, which can be highly charged and stressful situations, to encounter differing opinions among public health agencies and healthcare facilities. Healthcare facilities and providers often have concerns about reputation, privacy, and potential legal fallout.[5] Both public health and healthcare facilities have interest in protecting involved patients and staff, but public health also needs to consider implications for the public's health at large. The media also has its own focus, which does not always match the focus of public health and healthcare facilities.

Reasons for not disclosing errors leading to outbreaks or risk of outbreaks include potential for psychological harm among patients when the risk is low and, as mentioned above, facility concerns for harmed reputation. However, in a study looking at low-risk errors, 94% of patients reported wanting to know about an error, even when the risk of harm was low.[9] Additionally, when patient notifications are delayed, the public's perception of and trust in the healthcare facility can suffer, even if disclosure is made at a later time. Paradoxically, a healthcare facility's concern about loss of trust or reputation, which can cause it to delay or withhold notification, can create just the situation that it wishes to avoid: a state of distrust or loss of reputation. Disclosure is often the better approach when concerns about public perception and trust are raised as a reason not to disclose.

When opinions differ about the need to notify patients or other stakeholders, it is best practice to seek an agreement and approach the notification jointly. Public health agencies should provide best practice information to healthcare facilities, as described above, to support notification if there are concerns about unduly worrying patients with low risk or concerns about the facility's reputation. Public health may be able to provide options that are acceptable to the facility that support public health's goals. When healthcare facilities and public health continue to maintain different perspectives, it is important to ensure that the public health agency is familiar with and following federal and state guidelines and recommendations. Consider using the opportunity to strengthen relationships. A successful example from Los Angeles involved the appointment of specific public health–healthcare facility liaisons to improve healthcare outbreak reporting, strengthen surveillance infrastructure, and enhance communication.[10] Also consider consultation with experts, such as those working at CDC. In advance

of notification events and outbreak investigations, it is important to develop relationships with healthcare facilities, infection preventionists, and other partners (See Chapter 3, CORHA Keys to Success: Developing Relationships Prior to an Outbreak).

When the public health agency and the healthcare setting hold steadfast with different opinions, an agreement cannot be reached, and public health determines that patients and others affected still need to be notified, the public health agency may need to perform notification directly or pursue legal orders for disclosure of information. This will require early and close collaboration with legal resources available to the public health agency. Considerations that public health agencies need to plan for include the following:

- The method of notification: When the communication will be issued by the health department, methods to consider can include phone calls, letters, press releases, media statements, and a combination of methods. When possible, notification in writing can be helpful so that patients have information at hand to refer to and take to their healthcare provider.
- Where patients can obtain more information: Public health agencies should consider a hotline and a website where patients can receive more information.
- Instructions for follow up: This information should be communicated to patients when they are notified. This can be more difficult for public health agencies if additional medical care is needed such as laboratory testing or treatment. Public health agencies can consider setting up an agreement with a laboratory or healthcare provider to provide the service, if public health is unable to do so directly, or they can provide instructions for patients to take to their own healthcare providers. Logistics need to be carefully considered.

8.2.3 Tailoring Communication to the Audience and Setting

When crafting communication messages, consider with whom you are communicating (the **audience**), how you will communicate (the **method**), and what information needs to be included (the content).

Before crafting any communication message, it is critical to consider the audience. Knowing whom you want to reach will determine the content, method, and wording of the message. Audience characteristics to consider include demographics, language, educational level, and cultural considerations. Issues of health equity should also be considered; more information on this topic can be obtained from the following web page: www.cdc.gov/coronavirus/2019-ncov/community/health-equity/index.html. Apply audience characteristics and health equity considerations when developing a message as well as when selecting a spokesperson. When tailoring communications to a specific audience, involve the public health communication experts and PIO for input.

Here are some important **audience** considerations:

- If the population is highly mobile (e.g., persons who move frequently with frequent changes of address, those experiencing homelessness, or those in temporary residential care), a letter may not be the best method of communication.
- Elderly and some other patients may have a caretaker or health care proxy who needs to receive the information. Similarly, with younger populations, parents need to be notified.
- All communication to patients and caregivers should be in plain language—written at no more than a seventh-grade reading level—and easily understandable.
- Information should be provided via channels and in formats and languages suitable for diverse audiences, including people with disabilities, limited English proficiency, low literacy, and people who face other challenges accessing information.
- Information should be provided in a manner that is culturally and linguistically appropriate.
- When notifying a demographic that may be difficult to reach through traditional methods, consider engaging with community leaders, religious leaders, and other trusted sources.
- Consider where patients and caregivers will go to obtain more information and have their questions answered, such as a website or phone number. Include this information in the notification.
- Remember that the audience may experience stress, which makes understanding the notification more difficult.

Additional considerations for the **method** of communication include the following:

- When notifying someone in person or by phone, consider following up with a handout or mailed letter so the person can refer back to the written information in hand.
- When communicating in writing, consider including a letter that the patient can take to their primary care provider. This will make it easier for the patient to explain what happened and any next steps their provider may need to take.
- Think about how the audience (patient) receives information. Is there a patient portal set up electronically that can help with disseminating information?
- Social media groups can be another avenue to reach certain groups or difficult-to-reach persons.
- Although not the preferred option, when unable to reach specific groups or specific individuals, or when broader communication to the general public is required, a press release can be considered.

Consider the following when developing your communication **content**:

- Remember to show empathy in the message, because people will be concerned about their risk of infection or may have experienced the infection already.
- Provide information that allows the audience to understand what happened as well as how it happened and where. If details are still unknown, communicate that the situation is still under investigation. Often communication is distributed before complete information has been procured. Notification should not be postponed until all information is known, but it is important to be clear and acknowledge when findings are not complete.
- Include information on corrective actions already taken to mitigate the current risk and any planned actions to mitigate future risks.
- Provide information on who is being contacted and why, including an assurance that the correct patients are being contacted.
- Include any instructions about what patients or others need to do to protect themselves, such as symptoms to watch out for, seeing their provider for an evaluation, or being tested.
    - The audience should understand what symptoms to expect, including any warning signs they may experience that would prompt them to contact their healthcare provider.
    - If evaluation by a healthcare provider is needed, make sure the audience has information to communicate to their provider.
    - If testing is needed, make sure the audience has all information required prior to testing, such as where to go to a specific laboratory or healthcare facility, and whether or not the cost of the test will be covered.
- Ensure there is a method by which additional questions can be answered, such as a website and/or a 24-hour contact number. Be prepared for many calls during the first 1 to 2 weeks at least.
- Include information on the planned next steps and what the audience can expect including any information on future updates.
- Make sure the content is consistent. Since messages may be repeated across multiple sources (e.g., the healthcare facility and the public health agency) or via multiple communication platforms, coordination among communicating entities is critical.
- When preparing reactive messaging, such as talking points in preparation for a media interview, consider the tough questions that patients may have and be prepared to address their concerns. This can include clarifying any misinformation associated with the event.

8.2.4 Tools

Similar to developing investigation materials ahead of an outbreak, as described in Chapter 3, it can be very helpful to develop template materials prior to a patient notification event. Box 8.2 provides a list of tools and materials to consider developing in advance.

8.3 Media

Anticipate and prepare ahead of time for possible media attention. Patients and individuals affected or at risk should hear about an outbreak, serious infection control breach, or other situation placing them at risk directly from their healthcare provider or facility. Ideally, the communication will come from someone they trust.

Box 8.2 | Tools and Materials to Develop When Planning for a Patient Notification

- Patient notification letters (including the disease transmission identified [e.g., outbreak] or no disease transmission identified [e.g., infection control breach], and their test results): Examples can be found in the CDC Patient Notification Toolkit, section 1, https://www.cdc.gov/healthcare-associated-infections/hcp/patient-notification-toolkit/developing.html
- Healthcare provider notification of testing recommendations letter: An example can be found in the CDC Patient Notification Toolkit, section 1 (see previous link)
- Media talking points: General talking points can be crafted with space to add disease- and situation-specific information; press releases and media statements for previous similar situations also can be recycled and revised
- Media statement: General media statement with space to add disease- and situation-specific information; press releases and media statements for previous similar situations also can be recycled and revised
- Frequently asked questions documents for posting on websites or use by hotline operators: Disease-specific questions are often reusable across multiple events; examples can be found in the CDC Patient Notification Toolkit, Example Q/A Resources, https://www.cdc.gov/healthcare-associated-infections/hcp/patient-notification-toolkit/communication.html

Though not ideal, in some situations, notification from a public health agency is necessary.

Patients do not want to hear about a problematic issue that involves or impacts their health first from the media. This can create a feeling of distrust in the healthcare facility as well as distrust in those in authoritative positions. Patients may feel like the facility was trying to hide the issue rather than inform the public. In one example of this, families of children who were part of a devastating mucormycosis outbreak were unaware of the outbreak for several years prior to publication of the incident in a medical journal.[11,12]

In certain situations, media-based notification may be the only viable option. Examples include very large-scale notification events or situations in which the healthcare provider, facility, or public health agencies cannot identify or contact at-risk individuals (e.g., due to poor record keeping or incidents involving over-the-counter medical products). Under those circumstances, healthcare and public health partners should plan carefully and proactively engage media. For the majority of situations, however, individuals at risk can be notified by the provider or facility, and it is important to do so as soon as possible, ensuring that the media is not the first to inform.

8.3.1 Types of Media

There are two broad types of media:

- Traditional media: newspapers, online news platforms, television, and radio
- Social media: communication platforms and applications that allow persons to create and share content and communicate

Types of media communication:

- Media statement: a response to an inquiry from the media, generally a reactive communication
- Press release: a method of providing information to the media to communicate information you want the public to know, generally a proactive communication
- Interview: involving a reporter from a media outlet and a spokesperson from the healthcare facility or public health; the interview may be live or recorded (for use in television or radio) or published in print media
- Press conference: a live statement or series of statements from the spokesperson or others involved communicated to the media; generally convened in high profile situations or for very large outbreaks

8.3.2 Engaging the Media

How you engage the media and how you craft your message determines whether the audience builds trust, understands, and accepts the message or becomes distrustful, suspicious, and angry. Some individuals in the media may start out distrustful of government messages. Be aware of this and do not inadvertently contribute to their distrust. Involve your communications staff and PIO as early as possible when a patient notification is first considered. If you do not have a PIO on staff, consider using an outside consultant. These subject-matter experts have the knowledge, relationships, and ability to guide epidemiologists and healthcare providers during their interactions with the media.

As described in previous sections, a trained spokesperson with the ability to develop trust and credibility should be identified early. Have a spokesperson who is well-spoken and knowledgeable about the topic. Being prepared and able to answer questions with confidence helps build credibility. For considerations in choosing a spokesperson, refer to the CERC Manual: emergency.cdc.gov/cerc/. When engaging the media through a spokesperson or via press releases and media statements, ensure that the information communicated is accurate. Once a story has been distributed in any format, it is difficult to get it changed or edited if there is inaccurate information.

The amount of information shared with the media varies and depends on a few factors. Personal health information must be protected, and HIPAA regulations need to be followed. Public health agencies need to balance confidentiality with ensuring accurate and complete information, which may necessitate releasing more information than normal.

Methods of engaging with the media can vary depending on the circumstances. Considerations include the following:

- A press release can be used when there is concern about incomplete notification (e.g., due to an inability to locate affected or at-risk persons) or when there is concern that the media may release the story ahead of patient notification. A press release should contain the same information as the patient notification letter.
- A media statement is generally a response to an inquiry from the press. Remember that this is an opportunity to get vital messaging out to the public that can extend beyond the specific question that was posed by the press.
- Performing a phone or on-camera interview often depends on receiving a request from the media, the situation's severity, and the spokesperson's availability.
- Sometimes a request from the media for a phone or on-camera interview can be modified to a written response if the severity of the situation does not warrant an interview or the spokesperson is unavailable.
- On-camera interviews can be challenging when the spokesperson is untrained in responding to the media. Note that just-in-time training may not work for on-camera media interviews, and a crisis situation is not the time to provide this training.
- Press briefings typically are only used for rapidly evolving situations (such as the COVID-19 pandemic or natural disasters). Patient notifications are generally not the best situations to hold press briefings.

8.3.3 Proactive versus Reactive Media Communication

Proactive media communication refers to contacting the media before they are aware of the story. As described in previous sections, an announcement (e.g., via a press release) should ideally come from the facility (or public health agency when indicated) and include information similar to that provided in a patient notification letter. If the disclosure is initiated by the healthcare facility, a public health representative will likely be asked to comment; thus public health needs to be prepared and, ideally, coordinate with the health facility in developing public messages. Be inclusive with the information shared; this will decrease the possibility that the public perceives a withholding of information. The benefits of proactive media interactions include the ability to control the message in relating the story and ensuring that accurate information is disseminated.

Reactive media communication refers to healthcare's response to a story told first by the media. In general, reactive media communication is not ideal; instead, early disclosure (getting ahead of the story) is recommended.

With reactive media communication, it is difficult for healthcare facilities or public health agencies to control the message. Inaccurate or misleading information can be presented and may be difficult to correct, particularly if it appears that, previously, information was withheld.

In this chapter, we have reviewed considerations for notification of patients, families, and the public, as well as methods for conducting a successful patient notification. For additional information, please see CDC's Patient Notification Toolkit: https://www.cdc.gov/injectionsafety/pntoolkit/index.html.

Table 8.1. | Framework for Healthcare-Associated Infection Outbreak Notifications: Immediate and Expanded Notifications

STEP 1: IMMEDIATE NOTIFICATION			
Case patients who have been infected (or their designated healthcare proxies and, if patients are deceased, their closest family member)			
How to Notify *(one or more of the following, as appropriate)*	**When to Notify**	**What to Notify** *(public health agency to be involved on an ongoing basis to ensure accuracy)*	**Justification** *(one or more of the following)*
Verbally, in person or by phone calls if the patient has already been discharged; provide the opportunity to ask questions. A written descriptive statement and FAQ responses should also be given or sent. If unable to reach patients, in person or by phone, a written communication should be sent. Depending on the situation, consider establishing a hotline or other opportunity for questions. With guidance from your legal team, consider establishing a central location such as an easily accessible 508 compliant web page that provides the same vetted information communicated in other correspondence, with FAQs and links to additional resources.	First tier	Applicable counseling and information about potential risk of transmission, infection, clinical illness, testing, treatment, and additional care measures may need to be communicated and implemented (e.g., isolation, personal protective equipment [PPE], cohorting, screening, and/or changes in antibiotics administered).	To prevent and control transmission and assist with outbreak investigation activities. To fully inform patients about the event and implications for their health. To allow patients to seek appropriate treatment.

Table 8.1. | Framework for Healthcare-Associated Infection Outbreak Notifications: Immediate and Expanded Notifications

STEP 1: IMMEDIATE NOTIFICATION			
Patients who have been exposed or potentially exposed (or their designated healthcare proxies and, if patients are deceased, their closest family member)			
How to Notify *(one or more of the following, as appropriate)*	**When to Notify**	**What to Notify** *(public health agency to be involved on an ongoing basis to ensure accuracy)*	**Justification** *(one or more of the following)*
Verbally, in person or by phone calls if the patient has already been discharged; provide opportunity to ask questions. A written descriptive statement and FAQ responses should also be given or sent. If unable to reach patients in person or by phone, a written communication should be sent. Depending on the situation, consider establishing a hotline or other opportunity for questions. With guidance from your legal team, consider establishing a central location such as an easily accessible 508 compliant web page that provides the same vetted information communicated in other correspondence, with FAQs and links to additional resources.	After patients have been infected or colonized, but then as soon as possible.	Applicable counseling and information about potential risk of transmission, infection, clinical illness, testing, treatment, post-exposure prophylaxis, and additional care measures may need to be communicated and implemented (e.g., isolation, PPE, cohorting, screening, and/or changes in antibiotics administered).	To prevent and control transmission and assist with outbreak investigation activities. To fully inform patients about the event and implications for their health. To allow patients to seek appropriate treatment.

Table 8.1. | Framework for Healthcare-Associated Infection Outbreak Notifications: Immediate and Expanded Notifications

STEP 1: IMMEDIATE NOTIFICATION

Patients who may be at risk for future exposure (or their designated healthcare proxies if appropriate) including the following:

a. Patients undergoing a procedure or admitted to a ward or area in a healthcare setting experiencing an outbreak
b. Immunocompromised and frail elderly patients

How to Notify *(one or more of the following, as appropriate)*	**When to Notify**	**What to Notify** *(public health agency to be involved on an ongoing basis to ensure accuracy)*	**Justification** *(one or more of the following)*
Verbally in person or by phone call, or written posting. A written descriptive statement and FAQ responses should also be given or sent where possible. If unable to reach patients in person or by phone, a written communication should be sent. Postings (e.g., in the lobby, patient units, handwashing stations, restrooms, and admission packets). Depending on the situation, consider establishing a hotline or other opportunity for questions. With guidance from your legal team, consider establishing a central location such as an easily accessible 508 compliant web page that provides the same vetted information communicated in other correspondence, with FAQs and links to additional resources.	Notify before the potential exposure.	Applicable counseling and information about potential risk of transmission, infection, clinical illness, testing, post-exposure prophylaxis, alternate options for elective procedures, treatment, and additional care measures may need to be communicated and implemented (e.g., isolation, PPE, cohorting, screening, and/or changes in antibiotics administered).	To prevent and control transmission and assist with outbreak investigation activities. To fully inform patients about the event and implications for their health. To allow patients to seek appropriate treatment.

Patient's Primary Healthcare Provider(s) (as appropriate)

How to Notify *(one or more of the following, as appropriate)*	**When to Notify**	**What to Notify** *(public health agency to be involved on an ongoing basis to ensure accuracy)*	**Justification** *(one or more of the following)*
By confidential institutional email or by phone; public health agencies may consider sending a health alert.	As soon as possible.	The patient's risk or exposure.	To assist with questions from patients, for follow up and support. To assist with contacting patients who are difficult to reach.

Table 8.1. | Framework for Healthcare-Associated Infection Outbreak Notifications: Immediate and Expanded Notifications

STEP 1: IMMEDIATE NOTIFICATION			
Healthcare Personnel (HCP) including the following: a. HCP who need to make behavioral changes at the location(s) of the outbreak b. HCP who have underlying illnesses that place them at risk for complications if infected or colonized c. Other HCP who are employed by the healthcare setting but are not directly affected by the incident, including HCP who provide care to at-risk patients			
How to Notify *(one or more of the following, as appropriate)*	**When to Notify**	**What to Notify** *(public health agency to be involved on an ongoing basis to ensure accuracy)*	**Justification** *(one or more of the following)*
Verbally in person or during team huddles/meetings/rounds, and written postings (e.g., on patient units, at handwashing stations, and in breakrooms). Involve Employee Health Services to communicate with staff and offer testing or treatment if necessary.	As soon as possible.	Applicable counseling and information about potential risk of transmission, infection, clinical illness, testing, treatment, modification of personal behaviors associated with risk for infections, and additional care measures may need to be communicated and implemented to prevent and control transmission (e.g., isolation, PPE, cohorting, screening, enhanced surveillance, more frequent cleaning/ disinfection of surfaces, and/or environmental testing). HCP may alert internal team and public health agency if they work in multiple healthcare settings. Healthcare setting may refer HCP to Employee Health Services (especially those persons who may be at risk due to health complications and underlying illness).	To prevent and control transmission and assist with outbreak investigation activities. To engage Employee Health Services to support HCP. To fully inform and support HCP about the event and implications for their health. To allow HCP to seek appropriate treatment. To inform or alert all HCP about the event so that they are prepared to share accurate information and adequately respond to or direct questions to the appropriate parties.

Table 8.1. | Framework for Healthcare-Associated Infection Outbreak Notifications: Immediate and Expanded Notifications

STEP 1: IMMEDIATE NOTIFICATION			
Visitors including the following: a. Visitors who may have been exposed or need to make behavioral changes when present at the location(s) of the outbreak. b. Visitors who have underlying illness(es) placing them at increased risk from a potential exposure.			
How to Notify *(one or more of the following, as appropriate)*	**When to Notify**	**What to Notify** *(public health agency to be involved on an ongoing basis to ensure accuracy)*	**Justification** *(one or more of the following)*
Written postings displayed in areas in the proximity of the outbreak and common areas such as the lobby, nurse desk/station, patient units, restrooms, and handwashing stations. Direct notification through the patient visited. Public notification. With guidance from your legal team, consider establishing a central location such as an easily accessible 508 compliant web page that provides the same vetted information communicated in other correspondence, with FAQs and links to additional resources. Healthcare settings may offer education and demonstrations on safety precautions visitors should take when visiting infected or colonized patients.	As soon as possible in common areas and where appropriate. Upon entry to the unit/ location(s) of the outbreak (e.g., the NICU).	Applicable information about potential risk of transmission, testing, additional care measures, or modification of personal behaviors associated with risk for infections may need to be communicated and implemented to prevent and control transmission (e.g., handwashing, PPE, and testing).	To prevent and control transmission and assist with outbreak investigation activities. To prevent the spread of inaccurate information. To fully inform visitors about their healthcare risk.

Table 8.1. | Framework for Healthcare-Associated Infection Outbreak Notifications: Immediate and Expanded Notifications

STEP 1: IMMEDIATE NOTIFICATION			
Other Healthcare Settings Involved in the Care of Exposed Patients			
How to Notify *(one or more of the following, as appropriate)*	**When to Notify**	**What to Notify** *(public health agency to be involved on an ongoing basis to ensure accuracy)*	**Justification** *(one or more of the following)*
Patient status should be verbally communicated to appropriate HCP at the other healthcare setting and documented and flagged in patient transfer documents (e.g., a symbol or label prominently placed on the medical chart), especially when there is risk for pathogen transmission. Encourage documentation in electronic health records about the presence of a transmissible agent. Public health agencies may consider sending a health alert.	In preparation for and at the time of transfer.	Applicable information about additional care measures may need to be communicated and implemented to prevent and control transmission (e.g., isolation, surveillance, PPE, cohorting, and/or handwashing).	To alert healthcare settings to prevent and control transmission as well as to assist with outbreak investigation activities.

Table 8.1. | Framework for Healthcare-Associated Infection Outbreak Notifications: Immediate and Expanded Notifications

STEP 2: EXPANDED NOTIFICATION			
Case patients who have been infected but have not yet been notified (or their designated healthcare proxies and, if patients are deceased, the closest family member), including Patients who have been infected and identified as a result of additional case-finding activity			
How to Notify *(one or more of the following, as appropriate)*	**When to Notify**	**What to Notify** *(public health agency to be involved on an ongoing basis to ensure accuracy)*	**Justification** *(one or more of the following)*
Verbally, in person or by phone calls if the patient has already been discharged; provide the opportunity to ask questions. A written descriptive statement and FAQ responses should also be given or sent. If unable to reach patients in person or by phone, a written communication should be sent. Depending on the situation, consider establishing a hotline or other opportunity for questions. With guidance from your legal team, consider establishing a central location such as an easily accessible 508 compliant web page that provides the same vetted information communicated in other correspondence, with FAQs and links to additional resources.	Initiate the process within 24 hours after the risk is identified; for example, during the outbreak investigation, when updated laboratory results indicate the presence of infection on another floor or unit (e.g., in the case of a respiratory pathogen).	Applicable counseling and information about potential risk of transmission, infection, clinical illness, testing, treatment, and additional care measures may need to be communicated and implemented (e.g., isolation, PPE, cohorting, screening, and/or changes in antibiotics administered).	To prevent and control transmission, limit any further spread, and assist with outbreak investigation activities. To fully inform patients about the event and implications for their health. To allow patients to seek appropriate treatment.

Table 8.1. | Framework for Healthcare-Associated Infection Outbreak Notifications: Immediate and Expanded Notifications

STEP 2: EXPANDED NOTIFICATION			
Patients who have been exposed or potentially exposed but are not known to be infected (or patients' designated healthcare proxies if appropriate)			
How to Notify *(one or more of the following, as appropriate)*	**When to Notify**	**What to Notify** *(public health agency to be involved on an ongoing basis to ensure accuracy)*	**Justification** *(one or more of the following)*
Verbally, in person or by phone calls if the patient has already been discharged; provide the opportunity to ask questions. A written descriptive statement and FAQ responses should also be given or sent. If unable to reach patients in person or by phone, a written communication should be sent. Depending on the situation, consider establishing a hotline or other opportunity for questions. With guidance from your legal team, consider establishing a central location such as an easily accessible 508 compliant web page that provides the same vetted information communicated in other correspondence, with FAQs and links to additional resources.	Initiate the process within 24 hours once the risk is identified; for example, during the outbreak investigation, when updated laboratory results indicate the presence of infection on another floor or unit (e.g., in the case of a respiratory pathogen). Priority should be given to those who are still in the risk period for exposure.	Applicable counseling and information about potential risk of transmission, infection, clinical illness, testing, post-exposure prophylaxis, alternate options for elective procedures, treatment, and additional care measures may need to be communicated and implemented (e.g., isolation, PPE, cohorting, screening, and/or changes in antibiotics administered).	To prevent and control transmission, limit any further spread, and assist with outbreak investigation activities. To fully inform patients about the event and implications for their health. To allow patients to seek appropriate treatment.

Table 8.1. | Framework for Healthcare-Associated Infection Outbreak Notifications: Immediate and Expanded Notifications

STEP 2: EXPANDED NOTIFICATION

Patients who may be at risk for future exposure (or their designated healthcare proxies if appropriate), including the following:

a. Patients undergoing a procedure or admitted to a ward or area in a healthcare setting that is experiencing an outbreak
b. Immunocompromised and frail elderly patients

As the outbreak is contained, this group will become smaller.

How to Notify *(one or more of the following, as appropriate)*	**When to Notify**	**What to Notify** *(public health agency to be involved on an ongoing basis to ensure accuracy)*	**Justification** *(one or more of the following)*
Verbally, in person or by phone call. A written descriptive statement and FAQ responses should also be given or sent. If unable to reach patients in person or by phone, a written communication should be sent. Postings (e.g., in the lobby, patient units, handwashing stations, restrooms, and admission packets.) Depending on the situation, consider establishing a hotline or other opportunity for questions. With guidance from your legal team, consider establishing a central location such as an easily accessible 508 compliant web page that provides the same vetted information communicated in other correspondence, with FAQs and links to additional resources.	Notify before the potential exposure.	Applicable information about potential risk of transmission, alternate options for elective procedures, post-exposure prophylaxis, additional care measures, or modification of behaviors may need to be communicated and implemented (e.g., isolation, PPE, cohorting, and/or screening).	To fully inform patients about the event and implications for their health; patients may need testing or treatment. To prevent and control transmission, limit any further spread, and assist with outbreak investigation activities. To allow patients to seek appropriate treatment.

Patient's Primary Healthcare Provider(s) (as appropriate)

How to Notify *(one or more of the following, as appropriate)*	**When to Notify**	**What to Notify** *(public health agency to be involved on an ongoing basis to ensure accuracy)*	**Justification** *(one or more of the following)*
By confidential institutional email or by phone. Public health agencies may consider sending a health alert.	As soon as possible.	The patient's risk of exposure. Applicable information about potential risk of transmission, alternate options for elective procedures.	To assist with questions from patients, follow up, and support. To assist with contacting patients who are difficult to reach.

Table 8.1. | Framework for Healthcare-Associated Infection Outbreak Notifications: Immediate and Expanded Notifications

STEP 2: EXPANDED NOTIFICATION			
Other Healthcare Personnel (HCP) including the following: a. HCP who need to make behavioral changes at the location(s) of the outbreak (e.g., specific PPE and handwashing) b. HCP who have underlying illnesses that place them at risk for complications if infected or colonized; involve Employee Health Services as needed c. Other HCP who are employed by the healthcare setting but are not directly affected by incident, including HCP providing care to at-risk patients			
How to Notify *(one or more of the following, as appropriate)*	**When to Notify**	**What to Notify** *(public health agency to be involved on an ongoing basis to ensure accuracy)*	**Justification** *(one or more of the following)*
Verbal announcement, mass email, notices in break/locker room. Involve Employee Health Services to communicate with staff and offer testing or treatment if necessary.	As soon as possible. Consider actions already taken. Urgency is greater if an action can be taken.	Applicable counseling and information about potential risk of transmission, infection, clinical illness, testing, treatment, modification of personal behaviors associated with risk for infections, and additional care measures may need to be communicated and implemented to prevent and control transmission (e.g., isolation, PPE, cohorting, screening, enhanced surveillance, more frequent cleaning/ disinfection of surfaces, and/or environmental testing). HCP may alert internal team and public health agency if they work in multiple healthcare settings. Healthcare setting may refer HCP to Employee Health Services (especially those persons who may be at risk due to health complications and underlying illness).	To prevent and control transmission and assist with outbreak investigation activities. To engage Employee Health Services to support HCP. To support HCP and fully inform them about their healthcare risk. To allow HCP to seek appropriate treatment. To inform or alert all HCP about the event so that they are prepared to share accurate information and adequately respond to or direct questions to the appropriate parties.

Table 8.1. | Framework for Healthcare-Associated Infection Outbreak Notifications: Immediate and Expanded Notifications

STEP 2: EXPANDED NOTIFICATION			
Visitors including the following: a. Visitors who may have been exposed or need to make behavioral changes when present at the location(s) of the outbreak b. Visitors who have underlying illness(es) placing them at increased risk from a potential exposure			
How to Notify *(one or more of the following, as appropriate)*	**When to Notify**	**What to Notify** *(public health agency to be involved on an ongoing basis to ensure accuracy)*	**Justification** *(one or more of the following)*
Written postings displayed in areas in the proximity of the outbreak and common areas such as the lobby, nurse desk/station, patient units, and handwashing stations. Healthcare settings may offer education and demonstrations on safety precautions visitors should take when visiting infected or colonized patients. Direct notification through the patient visited. Public notification. With guidance from your legal team, consider establishing a central location such as an easily accessible 508 compliant web page that provides the same vetted information communicated in other correspondence, with FAQs and links to additional resources.	As soon as possible in common areas and where appropriate. Upon entry to the unit/ location(s) of the outbreak (e.g., NICU). Consider actions already taken. Urgency is greater if an action can be taken.	Applicable information about potential risk of transmission, testing, additional care measures, or modification of personal behaviors associated with risk for infections may need to be communicated and implemented to prevent and control transmission (e.g., handwashing, PPE, and/or testing).	To prevent and control transmission and assist with outbreak investigation activities. To prevent the spread of inaccurate information. To fully inform visitors about the event and implications for their health.

Table 8.1. | Framework for Healthcare-Associated Infection Outbreak Notifications: Immediate and Expanded Notifications

STEP 2: EXPANDED NOTIFICATION			
Other Healthcare Settings Involved in the Care of Exposed Patients			
How to Notify *(one or more of the following, as appropriate)*	**When to Notify**	**What to Notify** *(public health agency to be involved on an ongoing basis to ensure accuracy)*	**Justification** *(one or more of the following)*
Patient status should be verbally communicated to appropriate HCP at the other healthcare setting and documented and flagged in patient transfer documents (e.g., symbol or label, prominently placed on the medical chart), especially when there is risk for pathogen transmission. Encourage documentation in electronic health records about the presence of a transmissible agent. Public health agency may consider sending a health alert.	In preparation for and at the time of transfer.	Applicable information about additional care measures may need to be communicated and implemented to prevent and control transmission (e.g., isolation, surveillance, PPE, cohorting, and/or handwashing).	To alert healthcare settings to prevent and control transmission, and to assist with outbreak investigation activities.

Box 8.3 | Example of Patient Notification: *Legionella* Outbreak in a General Medicine Ward

An example of notification is presented below illustrating a *Legionella* outbreak in a hospital setting. This example can be used as a model for other conditions and settings, bearing in mind how the investigation may proceed, the characteristics of the pathogen and method of transmission, and the specifics of the setting of the outbreak. For infection control breaches, immediate notification may include all groups listed in the table below, except for affected patients; in infection control breach investigations, there are often no infected or colonized patients thus far identified (for more information see CORHA Principles and Practices, Supplement B).

The situation: The infection preventionist in a large hospital identified two patients who met the case definition for hospital-acquired legionellosis within the same month. He calls the epidemiologist at the local public health agency to report a concern that the hospital may have a *Legionella* outbreak. Patient 1 was found positive for *L. pneumophilia* 1 (Lp1) by a urine antigen test 21 days after admission. Patient 2 was found positive for Lp1 9 days after admission. Both patients had stayed in the same single-occupancy hospital room 7 days apart from each other.

STEP 1: IMMEDIATE NOTIFICATION	
Affected patients	Patients 1 and 2 should be notified immediately of their diagnosis of *L. pneumophila* infection and the suspicion that there may be a common source for their infections, indicating a possible outbreak. They should be notified that an investigation will occur and what steps will be taken, including a review and testing of water systems, beginning with the patient room. Ideally, notification will be given by the treating provider in person or over the phone if the patient has already been discharged. Affected patients should be kept informed of major investigation findings, including the final results of the investigation and the mitigation measures put into place.
Exposed and potentially exposed patients	All patients who shared the same room within a specific period of time should be notified as soon as possible and given information about *Legionella,* patients' risk of infection, and symptoms to watch out for. The time period may depend on the information known. If construction was undertaken on the water system supplying the room 2 months ago, for example, the initial notification may involve patients who stayed in the room over the last 2 months since the construction commenced. Notification of potentially exposed patients will also help with additional case finding, and, when notified, patients should be asked about any symptoms they may have experienced. Patients may be past the incubation period, but it is possible that they could have developed the infection previously and recovered. Even patients who are exposed but no longer at risk should be notified for the sake of transparency. Ideally, notification of exposed patients will be made by the treating provider in person or over the phone if the patient has already been discharged. If the water supply to the entire unit may be of concern for *Legionella*, patients on the same ward should also be notified using the same method of notification. They should be told that a possible outbreak occurred and there is an ongoing investigation; they should be kept informed of major investigation findings, including the final results of the investigation, similar to affected patients.
Patients who may face future risk	Patients who will be admitted to the area of concern (e.g., a ward if the water supply is shared) should be notified of the investigation and possible outbreak. They should be informed of their risk. Mitigation of this risk, such as closing the ward affected, should be considered; if this is done, there may be no patients at future risk. Patients should be kept informed of major investigation findings, including the final results of the investigation.

Box 8.3 | Example of Patient Notification: *Legionella* Outbreak in a General Medicine Ward

STEP 1: IMMEDIATE NOTIFICATION	
Patients' healthcare providers	Healthcare providers who provide care to affected patients in the affected area should be notified that multiple patients were identified with hospital-acquired legionellosis, leading to suspicion of an outbreak. Information communicated should include where the patients were located, what has been determined so far, initial mitigation measures, and what the facility is doing to investigate. Healthcare providers who provide care to potentially exposed patients should also be notified and given the same information. Healthcare providers can be informed during rounds and via larger communication, such as by an email. Providers should be given information about legionellosis, including what they should do when such a diagnosis is suspected (e.g., diagnostic testing available at the facility and reporting to infection control).
Healthcare personnel	If the water supply affects multiple locations or it is unclear whether additional exposed patients in the facility may be found in other areas, healthcare providers at all potentially affected locations in the facility should be notified. Providers should be given information about legionellosis, including what they should do when the diagnosis is suspected (e.g., diagnostic testing available at the facility and reporting to infection control). Healthcare providers and staff who need to make behavioral changes at locations of the outbreak should be notified because some patient rooms may be closed, sinks or drinking water fountains may be tested or closed off, or other changes may be made. Decisions may be made to install filters on faucets, and other control measures may be implemented about which healthcare providers should be made aware. Healthcare providers and staff who could themselves be at risk, such as those with underlying illnesses that place them at risk for complications (persons who are smokers or have chronic lung disease, cancer, diabetes, etc.) should be notified to allow them to modify their behavior to keep themselves safe, if applicable. Healthcare providers should be notified as soon as possible and can be informed during rounds and via larger communication, such as by an email. Keep in mind that healthcare providers and staff may themselves develop the condition under investigation, and messaging should include any case findings for affected providers and staff.

Box 8.3 | Example of Patient Notification: *Legionella* Outbreak in a General Medicine Ward

STEP 1: IMMEDIATE NOTIFICATION	
Visitors	Visitors and others who enter the hospital could be at risk until water system control measures are in place. Visitors should be notified as soon as possible, considering the following circumstances: • When visitors need to make behavioral changes when present at locations of the outbreak. • When visitors need to be aware of room closures, closed drinking fountains, closed ice machines, or other changes resulting in changes to their behavior. • When visitors may have an increased risk of becoming sick with the condition under investigation, which for legionellosis would be due to some visitors' health-related conditions such as smoking, lung disease, cancer, diabetes, etc. Visitors can be informed via information sheets posted in key locations or provided to each visitor. Written posting in the lobby and at the check-in desk can help notify visitors on entry into the facility. In some circumstances, consideration could be given to notifying visitors ahead of a visit, when it is logistically feasible to do so. Messages should include what visitors should do to keep themselves as safe as possible. Visiting families may also need to be informed if patients have requested that their health information be shared. Family members may need to know the same information as their ill, exposed, or at-risk family member patient, as well as information provided to visitors.
Other healthcare facilities	When patients who have been exposed or are at risk are transferred to another facility, the transferring affected facility should communicate with the receiving facility directly about the outbreak. Healthcare personnel at receiving facilities need to know that legionellosis should be listed in the differential diagnosis if the patient remains within the incubation period to develop disease and could develop signs and symptoms of legionellosis while in their care. Ideally, this communication is done at each individual patient transfer by the transferring affected facility during regular reporting.

STEP 2: EXPANDED NOTIFICATION	
Patients	During the investigation, it is critical to identify additional cases of hospital-acquired legionellosis. See Chapter 5 for more information about case detection as part of an outbreak investigation. As cases are identified, patients should immediately be notified using the same information and methods outlined in Step 1, Immediate Notification.
Exposed and potentially exposed patients	Additional exposed and potentially exposed patients are likely to be identified over the course of the investigation. For example, a review of building water systems and water sample testing may indicate that other units on the same floor as well as floors above and below where case patients 1 and 2 stayed also share the risk for *Legionella* exposure. When additional exposed patients have been identified, they should be immediately notified using the same methods and information outlined during Step 1, Immediate Notification.

Box 8.3 | Example of Patient Notification: *Legionella* Outbreak in a General Medicine Ward

STEP 2: EXPANDED NOTIFICATION	
Patients who may face future risk	As additional locations are identified that may have *Legionella* in their water supply, patients newly admitted to those locations should also be notified and informed of their risk. They should be kept informed of major investigation findings, including the final results of the investigation as per Step 1, Immediate Notification.
Patients' healthcare providers	As additional patients, exposed patients, and at-risk patients are identified, their healthcare providers should also be notified as per Step 1, Immediate Notification. Although the providers may have already received notification during Step 1, it is important to ensure that no healthcare provider caring for additional patients has not been notified and updated if appropriate.
Healthcare personnel	As additional locations that may place patients, staff, and providers at risk are identified, additional healthcare providers and staff will need to be notified. Information provided and methods for notification can be the same as those outlined in Step 1. However, if the locations identified are numerous or widespread, consideration should be given to notifying providers and staff facility-wide; in some situations this may be simpler because there may be confusion among providers and staff over what areas are affected and who may be at risk. Continue to keep in mind that healthcare providers and staff may also be at risk in any newly affected areas that are identified, and messaging these groups as per Step 1 should continue as new locations are identified. Being clear about who is at risk as well as who is not at risk can help alleviate concerns.
Visitors	As additional locations at risk for legionellosis are identified, visitors to those areas should be informed in the same manner as described in Step 1.
Other healthcare facilities	As additional patients at risk are identified during the investigation, additional information will need to be communicated upon those patients' transfer to other facilities. It is important to make sure the transferring affected facility is communicating with receiving facilities for these patients as well as those initially identified in Step 1.

Box 8.4 | Example of Patient Notification: New Delhi Metallo-Beta-Lactamase–Producing Carbapenem-Resistant *Enterobacteriaceae* (NDM-CRE) In A Long-Term Care Facility

An example of notification is presented for an outbreak of NDM-CRE in a long-term care facility setting.

The situation: The epidemiologist at a local public health agency identified three patients with CRE in the same long-term care facility. All CRE were found to harbor NDM. The epidemiologist calls the director of nursing to notify the facility as well as to obtain more information. All three patients are in the same unit of the facility, and all have wounds for which they are receiving wound care.

STEP 1: IMMEDIATE NOTIFICATION	
Affected residents (patients)	All affected residents (in long-term care settings patients are called residents) or their healthcare proxies should be notified immediately about the positive culture for NDM-CRE. Residents/proxies should be notified that an investigation will occur and what steps will be taken, including determining commonalities among patients and an evaluation of infection control practices. Ideally, notification will be done by the treating provider in person or over the phone if the resident has already been discharged to home or transferred to another facility. Affected residents or their healthcare proxies should be kept informed of major investigation findings, including the final results of the investigation and what mitigation measures have been put into place.
Exposed and potentially exposed residents	Depending on information shared by the Director of Nursing, in some situations it may be possible to quickly identify initially exposed residents. If it is not possible to identify that population initially, which is more likely, exposed and potentially exposed persons should be notified immediately after they have been identified. If an outbreak is suspected based on initial information, consideration should be given to notifying all residents or their healthcare proxies in the unit or in the facility that there may be an outbreak and that the investigation is ongoing. Under most circumstances for an NDM-CRE outbreak, the entire facility should be considered to be potentially exposed since this pathogen is primarily transmitted via contact. Even those who are exposed but no longer at risk should be notified for the sake of transparency; this may include former residents of the facility. Ideally, notification of exposed residents would be done by the treating provider or a representative of the facility in person or over the phone if the resident has already been discharged from the facility. Exposed and potentially exposed residents should be notified about a possible outbreak and an ongoing investigation, and kept informed of major investigation findings, including the final results of the investigation, similar to affected residents.
Residents who may face future risk	Residents who will be admitted to the area of concern (e.g., an affected unit or a facility) or their healthcare proxies should be notified of the possible outbreak and investigation, as well as informed of the risk to the resident. These residents should also be kept informed of major investigation findings, including the final results of the investigation.

Box 8.4 | Example of Patient Notification: New Delhi Metallo-Beta-Lactamase–Producing Carbapenem-Resistant *Enterobacteriaceae* (NDM-CRE) In A Long-Term Care Facility

STEP 1: IMMEDIATE NOTIFICATION	
Residents' healthcare providers	Healthcare providers who provide care to affected residents in the affected area should be notified that there are multiple residents with NDM-CRE, leading to the suspicion of an outbreak. Information communicated should include where the residents are located, what has been determined so far, what are the initial mitigation measures, and what the facility is doing to investigate. Any affected residents should immediately be treated using transmission-based precautions (specifically, contact precautions), and healthcare providers should be notified as to their role in adhering to these precautions, with education provided on the rationale for PPE and how to use it appropriately. Healthcare providers who provide care to potentially exposed patients should also be notified and given the same information; this can include providers in the unit and those within the entire facility. Healthcare providers can be informed via larger communication, such as by an email, as well as by in-person communication when providers enter the facility. Providers should be given information about NDM-CRE, including information on infection versus colonization and what the provider should do when a culture returns the result of NDM-CRE (e.g., reporting the finding to infection control).
Healthcare personnel	For a suspected outbreak of NDM-CRE in a long-term care setting, all providers offering care in the facility should be notified and given the same information as providers treating affected and exposed residents.
Visitors	Visitors and others who enter the facility and interact with affected residents, including family members, should understand their role in transmission-based precautions. All visitors should be aware that there is a suspected outbreak and should be informed of any precautions they need to take, such as washing their hands.
Other healthcare facilities	When initiating the transfer of an affected, exposed, or at-risk resident, which for this type of outbreak could include any resident in the entire facility, the affected long-term care facility should communicate with the receiving facility directly about the outbreak and state whether the resident being transferred has an infection or colonization with NDM-CRE. Receiving facilities need to know that transmission-based precautions should be continued.

Box 8.4 | Example of Patient Notification: New Delhi Metallo-Beta-Lactamase–Producing Carbapenem-Resistant *Enterobacteriaceae* (NDM-CRE) In A Long-Term Care Facility

STEP 2: EXPANDED NOTIFICATION	
Affected residents (patients)	During the investigation, additional cases of NDM-CRE may be identified. See Chapter 5 for more information about case detection as part of an outbreak investigation. As cases are identified, residents should immediately be notified using the same information and methods specified in Step 1, Immediate Notification.
Exposed and potentially exposed residents	Additional exposed and potentially exposed residents may be identified over the course of the investigation. When additional exposed residents have been identified, they should be immediately notified using the same methods and information outlined during Step 1, Immediate Notification.
Residents who may face future risk	If additional residents are admitted to the facility, they may also be at risk and should be notified using the same methods as those used for exposed and potentially exposed residents.
Residents' healthcare providers	As additional affected, exposed, and at-risk residents become identified, their healthcare providers should also be notified as per Step 1, Immediate Notification. Although these providers may already have been notified during Step 1, it is important to ensure that no healthcare provider caring for additional patients has not been notified and updated if appropriate.
Healthcare personnel	As additional healthcare providers are notified, other healthcare personnel should also be notified.
Visitors	Visitors should continue to be notified in the same way specified in Step 1, Immediate Notification.
Other healthcare facilities	Until the outbreak is considered to be resolved, the affected long-term care facility should continue to notify receiving facilities when affected, exposed, or at-risk residents are being transferred, including providing information directly about the outbreak and whether the resident being transferred has an infection or colonization with NDM-CRE. Receiving facilities need to know that transmission-based precautions should be continued.

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SUPPLEMENT A

Medical Product Investigations

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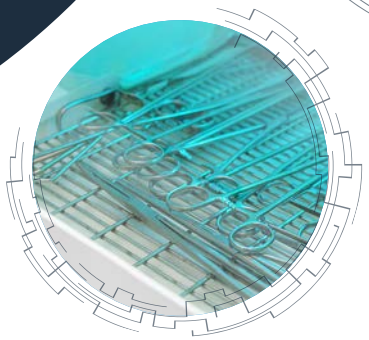
SUPPLEMENT A

Medical Product Investigations



A.0 Introduction

Healthcare-associated infections (HAIs) and outbreaks can be caused by the use of contaminated medical products. These medical products include devices (also known as instruments or equipment) and drugs (also known as medications), as well as biological products, nutrition products, and patient care items.

The general principles outlined in the *CORHA Principles and Practices* can be employed when responding to events related to medical product contamination. These investigations often involve infection control assessments and require the active coordination of investigation partners across multiple jurisdictions. Readers are encouraged to familiarize themselves with the full *Principles and Practices* text, as details addressed in other chapters or supplements are not repeated here.

Supplement A addresses some unique challenges associated with medical product contamination events. One challenge is difficulty with identifying connections between one or more patient infections and specific medical products. Often, patient records lack documentation of medical product use. In addition, there are limitations to investigators' ability to identify or obtain potentially contaminated products, such as when suspected items have been used and replaced by new item lots or product types. Moreover, the source of contamination—whether user error or a manufacturing deficit—can be difficult to distinguish, even when there is a clear association with medical product use; this is particularly evident at early stages of an outbreak response. As a result, this type of investigation is often marked by tensions and a sense of urgency, as investigators seek to determine whether the outbreak is localized and contained, or represents a product safety issue with broad potential for harm.

A.1 Background: Intrinsic and Extrinsic Contamination

Contamination of medical products can result from errors that occur during their production, manufacturing, or packaging, as well as during their transportation or storage. Contamination can also occur during the preparation and use of medical products at the point of patient care, and may even result from intentional misuse or tampering.

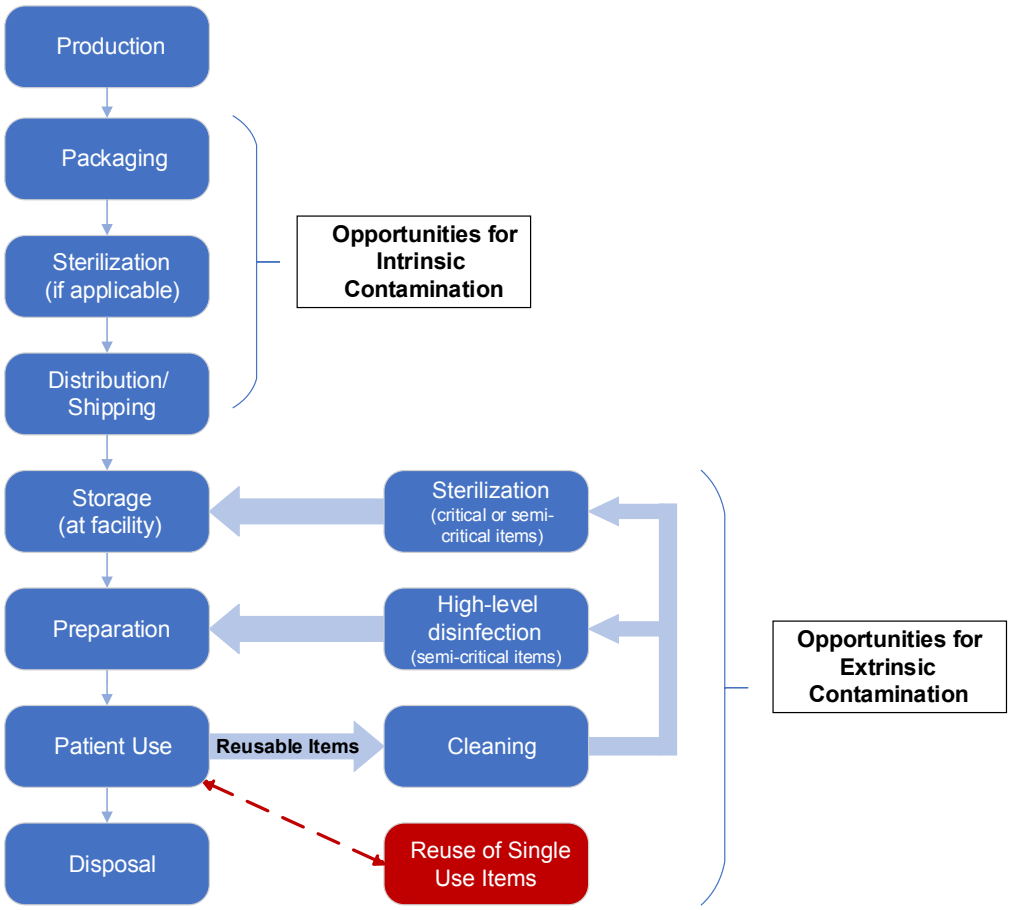
Investigators find it helpful to distinguish two broad categories of medical product contamination. **Intrinsic contamination** occurs before the product arrives at its point of use in a healthcare facility. In addition to traditional manufactured products, compounded

pharmaceuticals are also included in this category when produced outside (upstream) of the receiving healthcare facility. **Extrinsic contamination**, on the other hand, results from errors made during the product's storage, preparation, and use in a healthcare facility. This can include inappropriate reuse of single-use items and deficiencies in reprocessing of reusable items. As summarized in Figure A.1, there are many points at which a medical product could become contaminated; assessments related to root cause analysis should consider the possibilities of both intrinsic and extrinsic contamination events.

Intrinsic contamination events can result in widespread outbreaks. They may affect patients in multiple states or regions of the US or may even be global in scope. Notable incidents of intrinsic medical product contamination have included the presence of *Exserohilum rostratum* in methylprednisolone acetate from a compounding pharmacy,[1] *Burkholderia cepacia* complex in oral docusate,[2] *Serratia marcescens* in prefilled heparin flushes,[3] and *Mycobacterium chimaera* in heater-cooler devices.[4] Depending on gaps in the manufacturing process, contaminated products may include parts of lots or entire lots. All known lots of the specific product may be contaminated or only lots produced in a certain facility during a certain time period or lots including certain raw materials.

Many examples of extrinsic contamination events are presented in *Chapter 2, table 2.2*. Notable incidents have stemmed from unsafe injection practices and inadequate reprocessing of endoscopes. Unsafe injection practices,

Figure A.1 | Opportunities for Intrinsic Contamination or Extrinsic Contamination, from Production through Patient Use and Reprocessing



including reuse of syringes or single-dose vials and preparation of parenteral medications in contaminated environments (e.g., near sinks) have caused numerous outbreaks of hepatitis B and hepatitis C viruses as well as outbreaks of bacterial and fungal pathogens. While extrinsic contamination often results from errors committed by healthcare personnel, it can also reflect problems with a product's design or instructions for use, which predispose the product to become contaminated at the point of use. For example, Carbapenem-resistant Enterobacterales (CRE) transmission has been associated with duodenoscopes that were reprocessed in accordance with approved instructions; in this instance, a protocols investigation revealed that the intricate design of the particular endoscope product made it very difficult to clean and disinfect.[5]

A.2 Detection and Reporting

Many different pathogens or medical products can be involved in medical product contamination events. Table A.1 illustrates examples of organ systems, products, and pathogens that can be encountered together in association with transmission events or outbreaks stemming from medical product contamination. The examples shown may span both intrinsic and extrinsic contamination events. In addition, pathogens introduced through a contaminated medical product to one organ system may be detected in another organ system due to subsequent spread. Nonetheless, this table may be a helpful aid in recognizing and evaluating possible causes of product-related transmission relative to clinical illness and other factors. Practitioners should maintain a high index of suspicion for medical product involvement and bear in mind that individuals who are immunocompromised or receive frequent medical procedures may be at greater risk for infection.

Healthcare facilities and providers should report infections and potential outbreaks suspected to be linked to medical products. Product concerns should be conveyed early. For example, a single patient infection may warrant notification to public health authorities if there is a severe outcome (e.g., hospitalization or death) and the infection type suggests a route of infection possibly related to a medical product (see Table A.1). Identifying and reporting associations between HAIs and medical products requires active efforts to identify relevant patient exposures. Reports can be directed to public health jurisdictions and regulatory agencies (including via the US Food and Drug Administration's [FDA's] MedWatch) as well as to manufacturers.

Public health authorities should consider the possible role of medical products when investigating healthcare-associated infections (HAIs), even if this concern has not been raised by the facility. Due to the potential for widespread harm, public health agencies should engage state, local, and federal partners early in investigations of outbreaks that could be related to intrinsically contaminated medical products.

Table A.1 | Groupings of Organ Systems and Infection Types with Contaminated Medical Products and Pathogens

ORGAN SYSTEM	CONTAMINATED MEDICAL PRODUCT	EXAMPLE PATHOGENS, BY SOURCE
Bloodstream Infections	• Medications or products administered intravenously • Intravenous lines, ports, or tubing • Wound care products or dressings	**Environmental** • Nontuberculous mycobacteria • *Serratia marcescens* • *Stenotrophomonas maltophilia* • *Burkholderia cenocepacia* **Skin flora** • *Staphylococcus species*

Supplement A Medical Product Investigations

Table A.1 | Groupings of Organ Systems and Infection Types with Contaminated Medical Products and Pathogens

ORGAN SYSTEM	CONTAMINATED MEDICAL PRODUCT	EXAMPLE PATHOGENS, BY SOURCE
Skin and Wound Infections	• Skin care cleaning products or dressings (e.g., alcohol prep pads and bandages) • Wound care products or dressings	**Skin flora** • *Staphylococcus species* **Environmental** • *Bacillus cereus* • *Aspergillus*
Gastrointestinal Infection/ Colonization	• Duodenoscopes, endoscopes, etc. • Ingested products (e.g., medications, infant formula, and other nutritional products) • Products administered through feeding tubes (e.g., nasogastric tubes or percutaneous endoscopic gastrostomy (PEG) tubes)	**Environmental (e.g., soil, water, and gastrointestinal flora)** • *Escherichia coli (E. coli)* • *Carbapenem- or vancomycin-resistant Enterobacterales (CRE or VRE)* • *Cronobacter* • *Listeria monocytogenes* • *Burkholderia cepacia*
Neurologic Infections	• Medications or products used during lumbar punctures • Medications or products administered through patches, ports, implants, or catheters with delivery into the central or peripheral nervous system • Medications or products administered ocularly (e.g., drops, implants, ophthalmic procedures, and drains)	**Environmental** • Fungal species • Nontuberculous mycobacteria
Respiratory Infections	• Ventilators, intubation sequence products • Aerosolization and nebulizer products	**Environmental (e.g., soil and water)** • *Pseudomonas aeruginosa* • *Stenotrophomonas maltophilia*
Genitourinary Infections	• Urinary catheters • Ureteroscopes or devices used for treatment or diagnosis of genitourinary conditions	**Environmental (e.g., soil, water, gastrointestinal flora)** • *Pseudomonas aeruginosa* • *E. coli* • CRE or VRE

A.3 Investigation

Investigations of healthcare-associated outbreaks due to medical product contamination can be approached using many of the principles described elsewhere in the *CORHA Principles and Practices.* The remainder of Supplement A focuses primarily on investigation procedures for outbreaks that potentially involve drugs and devices, with an emphasis on intrinsic product contamination. For resources specific to blood, organ, and tissue contamination, see Box A.1.

Multiple avenues of investigation may need to be pursued simultaneously. Early in an investigation, working hypotheses related to both extrinsic and intrinsic contamination may be in play; initial investigation activities may have to cover both possibilities. These activities could include a targeted assessment of relevant healthcare delivery practices and rapid correction of any identified gaps in infection control procedures. At the same time, it might also be helpful to sequester implicated products (both opened/unopened) and collect information such as photos, product or medical lot numbers or identifiers, manufacturer instructions for use (IFUs), facility protocols, purchase orders, and other records related to the implicated product(s). See Box A.2 for a list of assessment questions and considerations for information collection when organizing a medical product-related investigation.

As outlined in Table A.1, previously observed patterns and associations involving specific medical products, organ systems, pathogens, and infection types are useful to consider when initiating an investigation. To help distinguish intrinsic from extrinsic contamination, consider two hallmarks of intrinsic contamination. First, intrinsic contamination events are not readily explained by infection control practice deficiencies. Second, intrinsic contamination events are marked by the appearance of additional outbreak signals. Reporting product contamination concerns to the United States Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) can help "connect the dots." In some cases, reporting can be supplemented by organizing an active outreach process (e.g., via CDC/Epi-X or clinician listservs) to determine whether similar concerns have been identified elsewhere.

Entities with detailed knowledge of the possible modes of contamination of medical products at the production, distribution, storage, and use stages should be engaged early and can include the following:

- Manufacturers
- Distributers
- Licensure boards of pharmacy, medicine, nursing, etc.
- State and federal public health agencies (e.g., CDC and FDA)
- Laboratory partners
- Infection prevention personnel
- Healthcare organizations

Collaboration and communication, particularly among public health agencies, healthcare facilities, and regulatory agencies, serve to increase awareness, evaluate patterns and processes at a broader scale, and confirm widespread intrinsic contamination events as early as possible. Additional communication activities, including engaging impacted patients, can be performed using guidance outlined in *Chapter 8, Notification and Communication.*

Unique product testing considerations attend medical product investigations. For example, suspected products or devices should be sequestered (i.e., cease their use but do not discard them). As outlined in *Chapter 6, Laboratory Best Practices,* laboratories have differing capabilities; public health and regulatory partners can often facilitate product or environmental testing support in a manner that is consistent with requirements pertaining to documentation and chain of custody for sample transport.

A.4 Concluding a Medical Product Investigation

Chapter 5, Investigation and Control, describes important steps for concluding an investigation, which also apply to those involving medical product contamination. These include the following:

- Implementing control measures (e.g., infection control practices, product recall, and/or product removal)
- Ongoing surveillance and detection protocols depending on product/device distribution
- Monitoring until no additional cases are detected

In addition to the aforementioned steps, medical product contamination investigations may also involve some unique opportunities for implementing lessons learned. These can include process improvement and quality assurance efforts at the manufacturing, distribution, or facility level to detect and prevent future events. These collaborative processes can be important not just for stakeholders involved in a specific event but also for professional organizations and regulatory authorities at the national level, ultimately leading to improved patient safety and outcomes.

A.5 Summary

Medical products play crucial roles in medical diagnosis and treatment in health care settings. They also can present infection risks to patients. Early detection of medical product safety signals, combined with robust investigations, are needed to do the following:

- Evaluate and confirm the presence of a medical product infection risk
- Inform decision-making, e.g., whether to initiate product removal or regulatory action

Additional "Keys to Success" related to medical product investigations have been summarized in Box A.3. Working together, public health agencies, healthcare facilities, regulatory authorities, and other medical product investigation partners can support swift actions to identify causes of infection, contain threats, and prevent harm.

References

1. Ritter JM, Muehlenbachs A, Blau DM, et al. Exserohilum infections associated with contaminated steroid injections: a clinicopathologic review of 40 cases. *Am J Pathol*. 2013;183(3):881-892. doi: 10.1016/j.ajpath.2013.05.007
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3. West K, Janelle S, Schutz K, et al. Outbreak of Serratia marcescens bacteremia in pediatric patients epidemiologically linked to pre-filled heparin flushes. *Infect Control Hosp Epidemiol*. 2019;40(10):1201–1202. doi: 10.1017/ice.2019.196
4. Perkins KM, Lawsin A, Hasan NA, et al. Notes from the Field. Mycobacterium chimaera Contamination of Heater-Cooler Devices Used in Cardiac Surgery — United States. MMWR *Morb Mortal Wkly* Rep 2016;65:1117–1118. doi: http://dx.doi.org/10.15585/mmwr.mm6540a6
5. Humphries RM, Yang S, Kim S, Muthusamy VR, Russell D, Trout AM, Zaroda T, Cheng QJ, Aldrovandi G, Uslan DZ, Hemarajata P. Duodenoscope-related outbreak of a carbapenem-resistant Klebsiella pneumoniae identified using advanced molecular diagnostics. *Clin Infect Dis*. 2017 Oct 1;65(7):1159-66.

CORHA Keys to Success

Medical Product Investigations

1. Maintain a high index of suspicion for medical product contamination and report concerns to appropriate public health and regulatory agencies (including FDA MedWatch), as well as to manufacturers.
2. Consider both intrinsic and extrinsic contamination opportunities when formulating initial investigation steps and control actions.
3. Include individuals with specific product or device manufacturing expertise and engage state and federal support resources early in an investigation.
4. Communicate investigation findings to investigation partners, affected patients, and healthcare providers to support improved outcomes.
5. Leverage what lessons are learned to help detect and prevent future events (e.g., inform process improvement and quality assurance efforts at the manufacturing, distribution, or facility level).

Box A.1 | Resources for Investigations of Blood, Biologic, Tissue, and Organ Contamination

Centers for Disease Control and Prevention (CDC) — Blood Safety
https://www.cdc.gov/blood-safety/about/index.html

Centers for Disease Control and Prevention (CDC) — National Healthcare Safety Network — Biovigilance Component
https://www.cdc.gov/nhsn/biovigilance/index.html

Food and Drug Administration (FDA) — Biologics
https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics

Food and Drug Administration (FDA) — Tissue
https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/tissue-safety-availability

Centers for Disease Control and Prevention (CDC) — Clinical Guidance for Transplant Safety
https://www.cdc.gov/transplant-safety/hcp/clinical-guidance/index.html

Health Resources and Services Administration (HRSA) — Organ Procurement & Transplantation Network (OPTN)
https://optn.transplant.hrsa.gov/professionals/by-topic/patient-safety/

Box A.2 | CORHA Potential Medical Product–Related Outbreak: Assessment Questions

This tool is also available on the CORHA website (link)

High-level questions about the situation

- What types of adverse events have been identified? How was the situation detected and brought to light? To whom were the concerns reported and when?
- What patient harm has occurred, such as infections, serious complications/injuries, deaths?
- What are the specific product concerns? What is the potential for further patient harm at this facility or elsewhere?
- Which parties are currently involved in this investigation? How can we best organize ourselves to assess the situation and make sure that any necessary controls or actions get implemented?
- Who are the stakeholders in the investigation, including medical product, epidemiologic/public health perspective, laboratory, and healthcare facility/providers perspectives? What are their roles and responsibilities and immediate next steps and timelines? Are there any stakeholders missing, and if so what are the plans to engage them?
- Have the key stakeholders agreed upon the primary objectives and roles/responsibilities for collecting and sharing information? What are the immediate next steps and deliverables?
- What information is needed to support timely decision-making (e.g., whether to institute a product recall)?
- What are the most effective ways of gathering and sharing this information?
- What are the investigation objectives/goals? Are the goals clear?
- Have short-term and long-term goals been identified and placed in a timetable?
- What steps are needed to assure a timely and coordinated response moving forward? Is there a need for an Incident Command System (ICS) structure at the local, state, or federal level?

Key Questions – Descriptive Epidemiology

- What is/are the primary clinical outcome(s) or presentation(s) of concern?
- Have specific pathogens been identified; if so, from what specimen source(s)?
- What is the magnitude of impact as currently understood in terms of the numbers of patients currently affected and the number/location of facilities that are reporting adverse events?
- Describe the setting, the primary affected patient population; does this include children, pregnant women, the elderly or immunocompromised?
- Is there a working hypothesis for root cause(s)?
- What other possible source(s) of contamination and possible route(s) of transmission require evaluation?
- Has a case definition been established? Are there criteria available to classify cases as suspect, possible, or confirmed?
- Is there a need for additional case finding (consider person-place-time) and others with potential exposure?
- How should this be organized and who will implement and lead this?
- What information needs to be collected as part of case finding activities (e.g., patient characteristics, healthcare exposures, laboratory findings)? Has there been a call for cases at the local, state (e.g., Health Alert Network, known as HAN), or national (e.g., Epidemic Information Exchange, called Epi-X) level? If so, what was the message and how was it delivered?
- Based on currently available information, is there a need to implement enhanced infection control practices within affected facilities?
- Have public health partners taken steps to ensure that patient isolates will be saved? Has any testing been performed on patient or product samples? If so, what were the dates of the testing and what are the preliminary findings? What types of testing are still needed to inform decision-making?
- Are unopened product samples available to be collected?

Box A.2 | CORHA Potential Medical Product–Related Outbreak: Assessment Questions

Product-related questions

- Does patient-level documentation (e.g., medical record) indicate the exact product name, the product manufacturer, product code, lot number, and expiration date? If not, are there receipts or invoices from the time of the treatment or procedure to assist in identifying these data?
- What is the exact product name? Is there a product code?
- Who is the manufacturer?
- What is the lot number and expiration date?
- Can you provide pictures of the product, including how it is packaged and stored?
- Can you provide pictures or Internet links for product brochures, instructions for use (IFU), and other documentation?
- Can you describe how this product is used?
- Can you describe how this product is reprocessed?
- Can you describe how reprocessing information (such as biological indicators, chemical indicators, and physical parameters) is collected and monitored?
- If the product is reusable, has it been quarantined?
- Has a third-party service or repair organization been involved in the maintenance of the device?
- Has a MedWatch report been filed by the healthcare facility?

For devices,

- What is the intended function of the device? (What is it FDA-cleared for?) What was it being used for?
- Is the device still working properly? Has any malfunction or damage been identified?
- Can a Unique Device Identifier be located?
- Is the device part of a kit? Does the device have accessories? If so, what are the accessories? Are any of these components sterile, reprocessed or part of a kit?
- Is this a water-containing device or is water or ice used with the device? If so, is the water (or ice) sterile, filtered, or tap?
- Is the device intended to be sterile or non-sterile?
- Is this a single-use device?
- Does the device require reprocessing? If so, explain how, where, and by whom.
- Is there a facility document that describes how reprocessing should occur?
- Does the device require maintenance? If so, what is the schedule? When was maintenance last performed? By whom? Was any damage identified?
- When was the device acquired and first put into use? What is the vendor's role?
- What is the current status (e.g., still in use, removed from service) of the device?
- What steps have been taken to evaluate use of the device with regards to: Routine handling (including adherence with IFUs and any applicable infection control practices)? Reprocessing and/or maintenance?

For drugs,

- What is/are the clinical indications/applications? How is/are the drugs in question being administered and for what purpose?
- What is the drug FDA-approved for? What was it being used for?
- Are the drugs labeled as sterile or non-sterile?
- Were they supplied as part of a kit?
- In what form were the drugs supplied (e.g., vial, bag, syringe)?
- For manufactured drugs, provide the National Drug Code (NDC) and lot number, or, if applicable, the Investigational New Drug (IND) Application identifier.
- For drugs supplied by a compounder, provide pharmacy information.
- How were the drugs acquired (e.g., from a distributor, OTC, online)?
- How are the drugs stored prior to being administered? Under what conditions?
- How were the drugs manipulated between receipt at your facility and administration? Under what conditions? By whom?

Box A.2 | CORHA Potential Medical Product–Related Outbreak: Assessment Questions

- Did multiple patients receive drug from a single-use medication container or from a multi-dose medication container? Explain.
- If any of the drugs are controlled substances, how is security maintained? Is the drug delivered in a multi-dose vial or container? If so, are the opened date and expiration date clearly labeled?
- What is the current status (e.g., still in use, removed from service) of the drug(s)?
- Is there any remaining drug available to be saved or tested?
- Is this an unopened product (e.g., unaccessed vial) or has it been opened?
- Does the saved drug product have the same lot number and expiration date as what the patient received?
- What steps have been taken to evaluate use of the drug with regards to: Storage, handling, preparation and administration (including adherence with IFUs and applicable infection control practices or pharmacy standards)?
- Evaluation of potential for abuse, mishandling or tampering?

For the most up-to-date version please visit: https://www.corha.org/resources/corha-interim-potential-medical-product-related-infection-outbreak-assessment-questions/

Appendix A: Key Resources & Additional Reading

Medical Product Investigations – Key Resources

1. Dolan SA, Arias KM, Felizardo G, et al. APIC position paper: Safe injection, infusion, and medication vial practices in health care. *Am J Infect Control*. 2016;44(7):750–757. doi: 10.1016/j.ajic.2016.02.033.
2. U.S. Food and Drug Administration (FDA). MedWatch Online Voluntary Reporting Form. https://www.accessdata.fda.gov/scripts/medwatch/index.cfm
3. U.S. Food and Drug Administration (FDA). Sharing Non-Public Information. Published March 19, 2015. https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/UCM446165.pdf

Contaminated Medical Products – Selected Examples

Endoscopes

1. Botana-Rial M, Leiro-Fernández V, Núñez-Delgado M, et al. A pseudo-outbreak of Pseudomonas putida and Stenotrophomonas maltophilia in a bronchoscopy unit. *Respiration*. 2016;92(4):274–278. doi:10.1159/000449137
2. U.S. Food and Drug Administration (FDA). Infections Associated with Reprocessed Duodenoscopes. https://www.fda.gov/medical-devices/reprocessing-reusable-medical-devices/infections-associated-reprocessed-duodenoscopes
3. Guy M, Vanhems P, Dananché C, Perraud M, et al. Outbreak of pulmonary Pseudomonas aeruginosa and Stenotrophomonas maltophilia infections related to contaminated bronchoscope suction valves, Lyon, France, 2014. *Euro Surveill.* 2016;21(28). doi:10.2807/1560-7917.ES.2016.21.28.30286
4. Humphries RM, Yang S, Kim S, et al. Duodenoscope-related outbreak of a carbapenem-resistant Klebsiella pneumoniae identified using advanced molecular diagnostics. *Clin Infect Dis*. 2017;65(7):1159–1166. doi:10.1093/cid/cix527
5. Kumarage J, Khonyongwa K, Khan A, Desai N, Hoffman P, Taori SK. Transmission of multi-drug resistant Pseudomonas aeruginosa between two flexible ureteroscopes and an outbreak of urinary tract infection: the fragility of endoscope decontamination. *J Hosp Infect*. 2019;102(1):89–94. doi:10.1016/j.jhin.2019.02.015
6. Rahman MR, Perisetti A, Coman R, Bansal P, Chhabra R, Goyal H. Duodenoscope-associated infections: Update on an emerging problem. *Dig Dis Sci*. 2019;64(6):1409-1418. doi:10.1007/s10620-018-5431-7

Heater-Cooler Devices

1. Centers for Disease Control and Prevention (CDC). CDC Archive: Contaminated Heater-Cooler Devices. https://archive.cdc.gov/#/details?url=https://www.cdc.gov/hai/outbreaks/heater-cooler.html
2. Lyman MM, Grigg C, Kinsey CB, et al. Invasive nontuberculous mycobacterial infections among cardiothoracic surgical patients exposed to heater–cooler devices. *Emerg Infect Dis*. 2017; 23(5): 796–805. doi:10.3201/eid2305.161899
3. Perkins KM, Lawsin A, Hasan NA, et al. Notes from the Field. Mycobacterium chimaera contamination of heater-cooler devices used in cardiac surgery — United States. *MMWR Morb Mortal Wkly Rep*. 2016;65:1117–1118. doi:10.15585/mmwr.mm6540a6
4. van Ingen J, Kohl TA, Kranzer K, et al. Global outbreak of severe Mycobacterium chimaera disease after cardiac surgery: a molecular epidemiological study. *Lancet Infect Dis*. 2017;17(10):1033–1041. doi:10.1016/S1473-3099(17)30324-9

Appendix A: Key Resources & Additional Reading

Medication/Product

1. Dolan SA, Littlehorn C, Glodé MP, Det al. Association of Bacillus cereus infection with contaminated alcohol prep pads. *Infect Control Hosp Epidemiol*. 2012;33(7):666–671. doi:10.1086/666334
2. Kainer MA, Reagan DR, Nguyen DB, et al. Fungal infections associated with contaminated methylprednisolone in Tennessee. *N Engl J Med*. 2012;367(23): 2194–2203. doi:10.1056/NEJMoa1212972
3. West K, Janelle S, Schutz K, et al. Outbreak of *Serratia marcescens* bacteremia in pediatric patients epidemiologically linked to pre-filled heparin flushes. *Infect Control Hosp Epidemiol*. 2019;40(10):1201–1202. doi:10.1017/ice.2019.196
4. Hudson MJ, Park SC, Mathers A, et al. Outbreak of Burkholderia stabilis infections associated with contaminated nonsterile, multiuse ultrasound gel—10 states, May–September 2021. *MMWR Morb Mortal Wkly Rep*. 2022;71(48):1517–1521. doi:10.15585/mmwr.mm7148a3
5. Centers for Disease Control and Prevention (CDC). Outbreak of extensively drug-resistant *Pseudomonas aeruginosa* — Artificial Tears. https://www.cdc.gov/hai/outbreaks/crpa-artificial-tears.html
6. Schwartz NG, Hernandez-Romieu AC, Annambhotla P, et al. Nationwide tuberculosis outbreak in the USA linked to a bone graft product: an outbreak report. *The Lancet Infectious Diseases*. 22(11):1617–1625. doi:10.1016/S1473-3099(22)00425-X
7. Hartnett KP, Powell KM, Rankin D, et al. Investigation of bacterial infections among patients treated with umbilical cord blood–derived products marketed as stem cell therapies. *JAMA Network Open*. 2021;4(10):e2128615. doi:10.1001/jamanetworkopen.2021.28615

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Disclaimers: The findings and conclusions in this document are those of the authors and do not necessarily represent the official views of the CDC nor those of other CORHA member organizations.

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SUPPLEMENT B

Infection Control Breach Investigations

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SUPPLEMENT B

Infection Control Breach Investigations

B.0 Introduction

Outbreak investigation has been included within the scope of public health agencies' missions since their inception, and deficits in infection control are frequently identified during healthcare outbreaks. In contrast, the investigation of isolated reports of potentially serious infection control breaches, in the absence of known patient infections, represents relatively new territory. Increasingly, state and local public health program staff find themselves investigating infection control breaches to determine the risk of communicable disease transmission and to identify individuals who may have been exposed but have not yet developed or been diagnosed with infection or colonization.

A public health agency may receive an infection control breach report from healthcare providers or facilities, patients, or accrediting organizations. In recent years, the Centers for Medicare & Medicaid Service (CMS) has mandated reporting of infection control breaches discovered during accreditation or certification survey visits to public health agencies, increasing the ability of disease control epidemiologists to recognize and respond to infection control breaches. Examples of the types of breaches that are reported include the reuse of single-use devices and the failure to follow requirements for reprocessing reusable medical equipment. Public health authorities should be prepared to appropriately investigate such reports and to provide guidance and support to implicated health care providers or facilities so that follow-up actions can be implemented.

Investigation of serious infection control breaches often involves components and steps similar to those of outbreak investigation, and thus the principles discussed in *Chapter 5, Investigation and Control*, are applicable to the investigation of isolated infection control breach reports as well. A key aspect in the response to an infection control breach is consideration of patient notification (i.e., informing affected individuals about an outbreak or breach). Triggers for notifying patients include situations in which patients 1) have experienced harm, 2) may be able to provide information useful in the identification and or mitigation of a potential harm, or 3) may require an alteration in their healthcare. Patient notification in the context of infection control breaches typically involves Trigger 2, as described by Schaefer et al. (see section 1, reference 1, below). Additional information on patient notifications can also be found in *Chapter 8, Notification and Communication*.

The following three sections provide an overview of resources that public health agencies and healthcare partners can reference to assist in the investigation of infection control breaches.

Supplement B Infection Control Breach Investigations

B.1 Investigation of Infection Control Breaches

Below are some key resources that provide useful background, materials, and advice to assist in the investigation of and response to infection control breaches, including patient notification, as well as examples of publications in which infection control breach investigators described their specific findings and experiences.

1. Schaefer MK, Perkins KM, Link-Gelles R, Kallen AJ, Patel PR, Perz JF. Outbreaks and infection control breaches in health care settings: Considerations for patient notification. *Am J Infect Control.* 2020;48(6):718–724. doi: 10.1016/j.ajic.2020.02.013

   Schaefer and colleagues provide a useful framework for patient notification considerations, including a description of triggers for performing a notification when investigating an infection control breach and examples of commonly encountered scenarios.

2. Patel PR, Srinivasan A, Perz JF. Developing a broader approach to management of infection control breaches in healthcare settings. *Am J Infect Control.* 2008;36:685–690. doi: 10.1016/j.ajic.2008.04.255

   In this paper, Patel et al. introduce a number of useful concepts and suggested approaches for investigating infection control breaches, many of which were later revisited and expanded upon by Schaefer et al. in 2020 (reference 1 from this section).

3. Centers for Medicare and Medicaid Services (CMS). Infection control breaches which warrant referral to public health authorities. Published May 30, 2014. Revised October 28, 2016. https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-14-36.pdf

   Beginning in 2014, CMS required the reporting of infection control breaches discovered during accreditation or certification survey visits to public health agencies.

4. Braun BI, Chitavi SO, Perkins KM, et al. Referrals of infection control breaches to public health authorities: Ambulatory care settings experience, 2017. *Jt Comm J Qual Patient Saf.* 2020;46(9): 531–541. doi: 10.1016/j.jcjq.2020.05.005

   The authors characterize and summarize infection prevention and control (IPC) breaches that were identified by Joint Commission surveyors during the ambulatory health care and office-based surgery accreditation process and reported to state health departments in 2017.

5. Centers for Disease Control and Prevention (CDC). Injection Safety: Patient Notification Toolkit. https://www.cdc.gov/injectionsafety/pntoolkit/index.html

   This CDC toolkit provides step-wise guidance to assist public health agencies and healthcare facilities in the notification of patients following identification of an infection control breach. The toolkit is intended to be used after a decision has been made to notify patients and offers resources and template materials (such as sample notification letters) as well as some essential tips and strategies.

6. Schoonover H, Haydon K. Incident command structure using a daily management system and the Centers for Disease Control and Prevention's Patient Notification Toolkit drives effective response to an infection control breach. *J Healthc Risk Manag*. 2018;38(2):19–26. doi: 10.1002/jhrm.21323

   The authors describe how an incident command structure, information management system, and the CDC Patient Notification Toolkit were used to drive an effective response to an infection control breach—resulting in 92% of affected patients completing the recommended testing.

7. Arnold S, Melville SK, Morehead B, Vaughan G, Moorman A, Crist MB. Notes from the Field. Hepatitis C transmission from inappropriate reuse of saline flush syringes for multiple patients in an acute care general hospital — Texas, 2015. *MMWR Morb Mortal Wkly Rep*. 2017;66:258–260. doi: 10.15585/mmwr.mm6609a4

This report provides an example of an infection control breach investigation that uncovered hepatitis C virus transmission.

8. Rasmussen SA, Goodman RA (editors). The *CDC Field Epidemiology Manual*. Oxford University Press; 2018. https://www.cdc.gov/eis/field-epi-manual/index.html

This manual does not address infection control breaches specifically, but provides a comprehensive resource for responding to outbreaks, with many principles that can also be applied to infection control breach investigations. Particularly relevant chapters to healthcare infection control breach investigations include Chapter 3, Conducting a Field Investigation; Chapter 12, Communicating During an Outbreak or Public Health Investigation*; and* Chapter 18, Healthcare Settings.

B.2 Selected Infection Control Resources and References

Below are general resources for understanding the basic principles of infection control as well as some detailed resources relevant to a few more commonly reported infection control breaches.

1. Centers for Disease Control and Prevention (CDC). Infection Control. https://www.cdc.gov/infectioncontrol/index.html

The base directory for CDC infection control resources, this web page includes links to resources for standard and transmission-based precautions, infection control guidelines (see reference 2 in this section), training and education resources, and tools for specific healthcare settings.

2. Centers for Disease Control and Prevention (CDC). Infection Control: Guidelines and Guidance Library. https://www.cdc.gov/infection-control/hcp/guidance/index.html

This web page contains links to a variety of CDC infection control guidelines and documents including those developed under the auspices of the Healthcare Infection Control Practices Advisory Committee (HICPAC).

3. Association for Professionals in Infection Control and Epidemiology (APIC). The APIC Text. https://apic.org/resources/apic-text/

This comprehensive infection control resource, compiled by APIC, is organized by chapter. A subscription is required.

4. Centers for Disease Control and Prevention (CDC). Essential Elements of a Reprocessing Program for Flexible Endoscopes — Recommendations of the HICPAC. https://www.cdc.gov/hicpac/recommendations/flexible-endoscope-reprocessing.html.

Because many breaches involve medical device reprocessing techniques, this CDC resource can assist public health agencies in related investigations and can be a useful document with which to share and help educate facilities.

5. Centers for Disease Control and Prevention (CDC). Injection Safety: Safe Injection Practices and Your Health. https://www.cdc.gov/injectionsafety/index.html

This CDC webpage provides information about safe injection practices. Safe injection practices are part of standard precautions and are aimed at maintaining basic levels of patient safety and healthcare provider protections.

6. Centers for Disease Control and Prevention (CDC). Injection Safety: Considerations for Blood Glucose Monitoring and Insulin Administration. https://www.cdc.gov/injection-safety/hcp/infection-control/index.html

This CDC resource provides essential background for the investigation of infection control breaches associated with blood glucose monitoring (or other forms of point-of-care testing involving capillary blood samples) or insulin pens and other medication cartridges.

7. Dolan SA, Arias KM, Felizardo G, Barnes S, Kraska S, et al. APIC position paper: Safe injection, infusion, and medication vial practices in health care. *Am J Infect Control*. 2016;44(7):750–757. doi: 10.1016/j.ajic.2016.02.033

This position paper from the Association for Professionals in Infection Control and Epidemiology describes risks and outbreaks associated with unsafe injection practices and associated recommendations.

B.3 Investigation of a Drug Diversion Event

Broadly speaking, when prescription medicines are obtained or used illegally, the process is called "drug diversion." Healthcare providers who steal prescription medicines, such as opioids, for their own use place patients at risk for harm. This risk can include exposure to infectious diseases. For example, when a provider commits diversion by tampering with or otherwise misusing injection supplies, medications, or other equipment, these items may become contaminated with hepatitis B or C virus, human immunodeficiency virus (HIV), or bacteria. Drug diversion investigations involve assessments and actions that are akin to infection control breach investigations but include many special considerations. The resources listed below provide guidance and useful background for the investigation of healthcare drug diversion events.

1. Schaefer MK, Perz JF. Outbreaks of infections associated with drug diversion by US health care personnel. *Mayo Clin Proc*. 2014; 89(7):878–887. doi: 10.1016/j.mayocp.2014.04.007

This review article summarizes a variety of drug diversion–related outbreak investigations and includes a table describing key investigation steps.

2. Centers for Disease Control and Prevention (CDC). Injection Safety: Clinician Brief: Drug Diversion. https://www.cdc.gov/injection-safety/hcp/clinical-overview/index.html

This CDC website provides information on drug diversion including outbreaks associated with drug diversion, resources for clinicians, and additional resources.

3. Council of State and Territorial Epidemiologists (CSTE). Healthcare-Associated Infections (HAI) Drug Diversion Planning and Response Toolkit for State and Local Health Departments. Published June 2019. https://www.cste.org/page/Drug-Diversion-Toolkit

This Council of State and Territorial Epidemiologists (CSTE) toolkit provides information on best practices when responding to a drug diversion event and provides resources informed by past drug diversion investigations.

4. Clark J, Fera T, Fortier C, et al. ASHP Guidelines on Preventing Diversion of Controlled Substances. Am J Health Syst Pharm. 2022;79(24):2279-2306. doi: 10.1093/ajhp/zxac246

A framework from the American Society of Health-System Pharmacists, this guidance document describes controlled substance diversion prevention programs and provides a useful context for public health partners and others charged with investigating a drug diversion report.

Supplement B Infection Control Breach Investigations

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Disclaimers: The findings and conclusions in this document are those of the authors and do not necessarily represent the official views of the CDC nor those of other CORHA member organizations.

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The Council for Outbreak Response: Healthcare-Associated Infections and Antimicrobial-Resistant Pathogens