Orientation Guide for New Laboratory Employees

An Employee On-boarding Tool

MARCH 2021

APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES

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Sections highlighted in red denote interactive sections.

INTRODUCTION

ABOUT APHL

The Association of Public Health Laboratories (APHL) protects the public's health by strengthening governmental health laboratory systems in the US and globally. Its member institutions, known as "public health laboratories," detect health hazards and generate scientific data to inform public health action.

A global leader in laboratory science, practice and policy, APHL supports member laboratories and public health partners with laboratory guidance, high-quality training, national policymaking, leadership development, crisis response and development of laboratory information management systems, among other services. Its expert staff represent diverse disciplines, from infectious disease, environmental health and food safety to newborn screening and public health preparedness.

Founded more than 60 years ago, APHL served initially as a forum for directors of state health laboratories to collaborate and exchange information. Over time, the Association expanded its membership to include other governmental laboratories working in public health: local health laboratories and state environmental, agricultural and food safety laboratories. APHL membership now exceeds 800 institutions and individuals, including core laboratory members, federal officials, corporate partners, students and other interested parties.

A 501(c)3 nonprofit organization, APHL is funded through agreements with the US Centers for Disease Control and Prevention and other federal agencies, as well as member dues, sponsorships and revenue from products and services.

Mission

Shape national and global health outcomes by promoting the value and contributions of public health laboratories and continuously improving the public health laboratory system and practice.

Vision

A healthier world through quality laboratory systems.

TRAINING AND LEADERSHIP DEVELOPMENT

APHL offers high quality continuing education programs for public health and clinical laboratory scientists; prepares emerging leaders for senior management positions through its National Center for Public Health Laboratory Leadership; manages fellowship and traineeship programs and promotes careers in public health laboratory science and practice. The Association also convenes national conferences and webinars on critical issues in laboratory science.

SERIES DESCRIPTION

Welcome to the APHL New Employees Orientation Guide! Through its programs, APHL is fulfilling its priority to assure a pool of technically qualified public health scientists. As a participant in one of our programs, this is your opportunity to learn about some of the most critical competencies required for a successful public health laboratory career.

In this workbook, you will have the opportunity to learn more about some of the competency domains seen as integral to work in the public health laboratory environment. The activities will also help you prepare for a meeting with your supervisor following each section to assess your learning.

The sections in this guide are:

- Management and Leadership
- Communication
- General Laboratory Practice
- Research
- Surveillance
- Ethics
- Safety, Emergency Management and Response
- Quality Management Systems

YOUR FIRST SUPERVISOR MEETING

Use this space to describe notes from your first supervisor meeting:

SECTION 1: **MANAGEMENT AND LEADERSHIP**

ABOUT THE MANAGEMENT AND LEADERSHIP SECTION

This section begins with some general information about public health laboratories, then focuses on management and leadership. This section looks at how you can demonstrate awareness of laboratory organization and operations. It also describes the impact of internal and external policies, how to exercise effective communication and teamwork and how to model overall effective leadership behavior at a public health laboratory.

LEARNING OBJECTIVES

Once you have completed all of the materials in this section and met with your supervisor, you should be able to:

- Outline the organizational structure and core functions of your public health laboratory.
- Describe the importance of mission, vision and value statements, as well as selected internal and external policies to public health laboratories.
- Describe the characteristics of an effective public health laboratory leader.

REFLECTION

Describe how these objectives can help you in your position:

ANALYST PROFILE: HARUMI

Harumi is an Infectious Diseases analyst hosted by a public health laboratory in Florida.

Harumi joined the laboratory after completing her MS degree in biology. Recent stories in the media about bioterrorism and pathogens such as Ebola and Zika sparked an interest in applied research and public health while Harumi was a student. The position will allow Harumi to explore opportunities in public health laboratory science.

As Harumi begins her orientation, she will explore the different functions of her laboratory under the guidance of a supervisor. She will have the opportunity to work with a team of microbiologists and chemists working toward a common goal—the identification of disease agents of public health importance.

NOTE: The analyst profiles in this publication are fictitious. Any resemblance to real persons, living or dead, is purely coincidental.

YOUR STORY

How does your own experience align with or differ from Harumi's profile?

PUBLIC HEALTH LABORATORY GENERAL INFORMATION

Public health laboratories serve major cities, counties and states. Federal public health laboratories include the US Centers for Disease Control and Prevention (CDC). These laboratories vary widely in structure and function.

A local public health laboratory is part of a larger board of health that addresses everything from epidemiology to tattoos and food safety. It is said that once you have seen one public health laboratory, you have seen ONE public health laboratory!

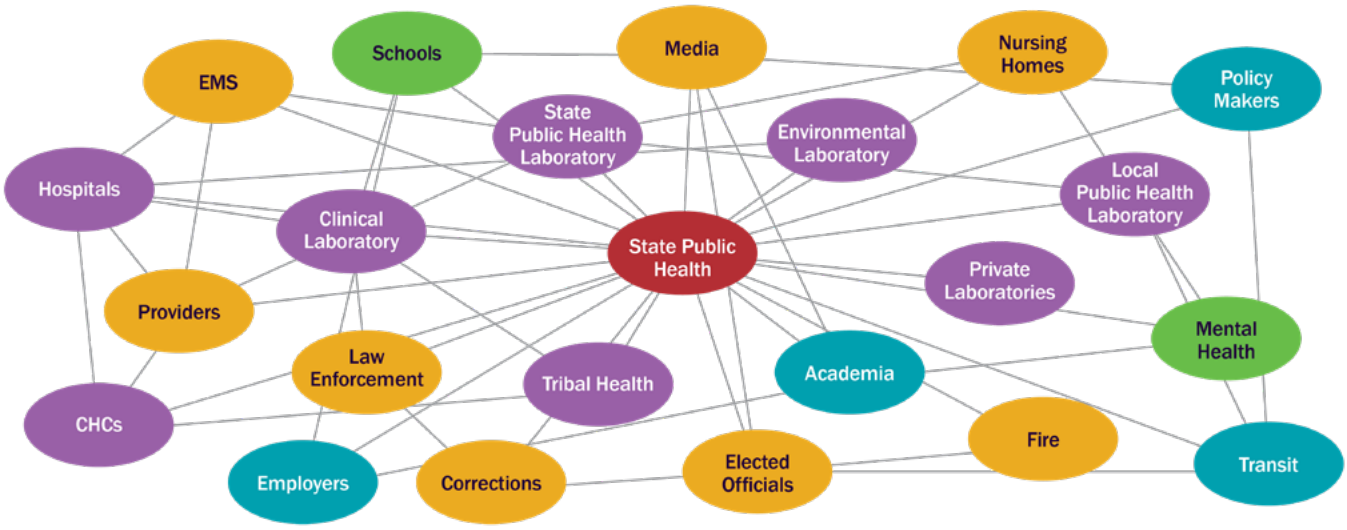
The Public Health Laboratory System

Public health laboratories often work collaboratively with other entities like emergency medical services and law enforcement organizations, the media and school systems to serve the public by providing diagnostic and reference testing, disease surveillance, emergency response support and training for laboratory personnel.

The actual structure and function of your public health laboratory will vary on the basis of available resources, needs and governance in your particular jurisdiction.

Public Health Laboratory Organization Hierarchy

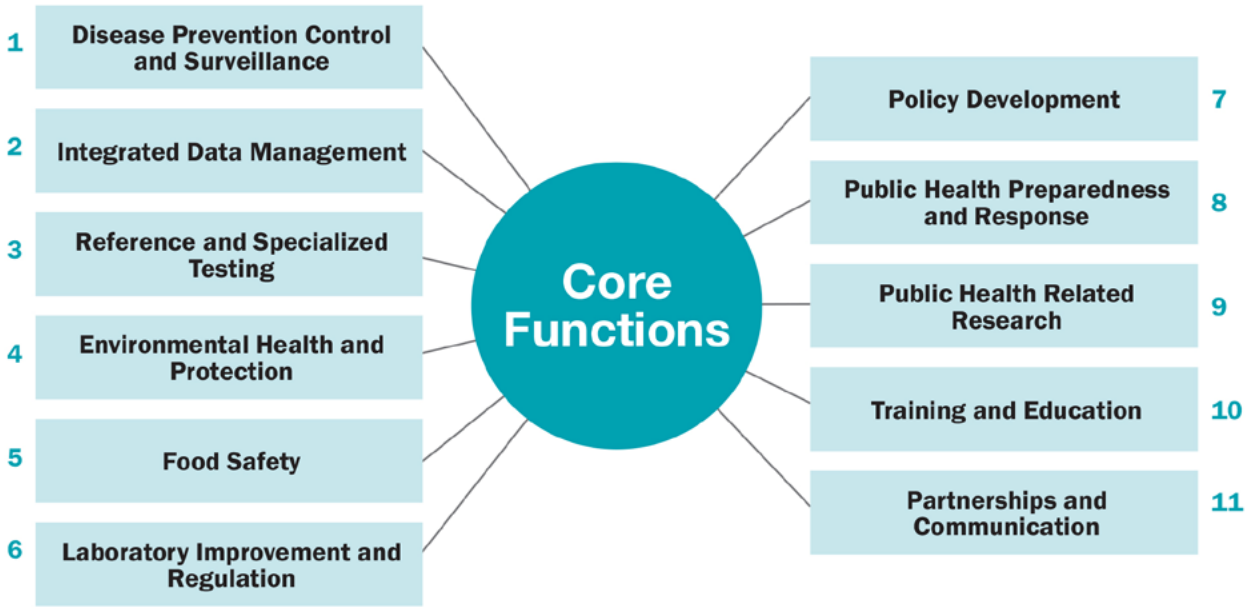
Public health laboratories are part of a network that make up the public's first line of defense against infectious diseases and other health hazards. They work to protect and improve public health by testing specimens to support identification and confirmation of illnesses during outbreaks, providing the expertise required to conduct research for future responses to public health situations and communicating information that can be used to generate policies and procedures related to public health.



How does your laboratory function within the larger public health system?

CORE FUNCTIONS OF PUBLIC HEALTH LABORATORIES

The operations of the public health laboratory can be categorized into eleven core functions. Each of these functions is described in detail below.



1. Disease Prevention, Control And Surveillance

Provides accurate and precise analytical data in a timely manner in support of the:

- Prevention and control of infectious, communicable, genetic and chronic diseases and environmental exposure. This may include testing for emerging and re-emerging microbial agents, immune status, antibiotic resistance, inherited neonatal metabolic disorders, environmental toxins and heavy metals like blood lead.
- Recognition of outbreaks and other significant public health events, by identifying and characterizing the causative agents of disease and their origin.
- Population-based surveillance for conditions of public health importance and to guide programmatic decisions.
- Early detection of congenital disorders in newborns leading to timely diagnosis and treatment.
- Monitoring of low incidence and/or high risk diseases, such as antibiotic-resistant tuberculosis, influenza, botulism and rabies.
- Investigation and control of communicable or environmental diseases, when testing is not available in the private sector.

2. Integrated Data Management

Serve as the conduit for scientific data and information in support of public health programs through the:

- Capturing of laboratory data essential for public health analysis and decision making, including detecting trends and sentinel events.
- Use of standardized data formats.
- Influencing public health policy.
- Participation in statewide disease reporting networks.
- Linkage with CDC and other national and international surveillance databases.
- Collaboration with state and national laboratory systems.
- Continuous improvement of laboratory data systems.

3. Reference And Specialized Testing

Serve as centers of excellence using their expertise, reference and resources in the areas of biological, chemical and radiologic issues of public health importance to:

- Support the diagnosis of and surveillance for unusual and emerging pathogens.
- Confirm atypical laboratory test results.
- Verify results of other laboratories' tests.
- Provide reference services to laboratories that may not have the capability to fully identify disease agents of public health importance.
- Provide diagnostic testing for diseases of public health importance directly to providers when testing is not readily available.
- Test for diseases of public health importance that are too rare and unusual for other laboratories to maintain capacity.

4. Environmental Health And Protection

Collaborate with partners to coordinate and ensure scientific analysis of environmental and human samples to identify, quantify and monitor potential threats to health by:

- Testing for toxic chemical, radiological and microbiological contaminants in air, water, soil and hazardous waste.
- Conducting biomonitoring of human specimens in the assessment of toxic chemical exposure.
- Testing of environmental samples in support of federal and state regulations, aiding in compliance with those regulations.
- Industrial hygiene/occupational health testing to assist in efforts to protect indoor air quality and worker health, such as routine analysis of asbestos, lead, pesticides and radon.
- Participating in the Chemical Laboratory Response Network (LRN-C) and the Environmental Response Laboratory Network (ERLN).

5. Food Safety

Collaborate in the detection, monitoring and response to food safety issues by:

- Testing samples from persons, food and beverages implicated in food-borne illness outbreaks to detect and identify potential food-borne pathogens.
- Characterizing isolates and participating in national strain characterization databases, such as PulseNet, to inform epidemiological investigations.
- Analyzing food specimens to detect, identify and quantify toxic contaminants such as pesticide residues, heavy metals and volatile organic compounds.
- Monitoring for radioactive contamination.
- Participating in the Food Emergency Response Network (FERN).

6. Laboratory Improvement And Regulation

Provide leadership for laboratory improvement in areas of public health importance by:

- Promoting quality improvement programs for partner laboratories through activities such as training, consultation and proficiency testing.
- Developing and overseeing statewide laboratory improvement programs to ensure the reliability of laboratory data used for environmental monitoring and communicable disease surveillance and control.
- Promoting safe laboratory practice through education, training and consultation.
- Assessing and improving the State Public Health Laboratory System by implementing the Laboratory System Improvement Program (L-SIP).
- Guiding the creation of and supporting enforcement of regulations and laws that contribute to laboratory improvement.

7. Policy Development

Play role in the development of state and federal health policy by:

- Generating scientific evidence that informs public health practice and law.
- Monitoring the impact of public health laboratory practice on health outcomes.
- Serving as centers of expertise, reference and resources in the areas of biological, chemical and radiologic issues of public health importance.
- Participating in the development and evaluation of standards related to the operation and performance of laboratories involved in public health testing.
- Advocating for the use of sound reasoning in the application of laboratory science and system infrastructure sustainment.
- Engaging in strategic planning at local, state and national levels.

8. Public Health Preparedness And Response

Fulfill a key partnership role in local, state and national disaster preparedness and response by:

- Functioning as a Laboratory Response Network (LRN) Reference Laboratory for biological agents and as an LRN Chemical Laboratory at a level designated by CDC.
- Assuring the triaging of environmental samples for the rapid identification of threat agents (chemical, biological, radiological, and nuclear — CBRN) and food samples as a part of the Food Emergency Response Network (FERN).
- Planning for and ensuring that surge capacity is available in a public health emergency.
- Having a Continuity of Operations Plan in the event of a disruption of laboratory services.
- Participating in the Environmental Response Laboratory Network (ERLN).

9. Public Health Related Research

Engage in research to improve and expand the scientific and policy basis of public health laboratory practice and assure their optimal application in support of the public health system by:

- Developing, evaluating and implementing new technologies and methodologies.
- Partnering with other public health disciplines.
- Collaborating with academic institutions to carry out clinical and translational science research.
- Conducting public health systems and service research.
- Working with the private sector to foster scientific innovation.

10. Training And Education

Facilitate access to training and education by:

- Sponsoring training opportunities to improve scientific and technical skills within the public health laboratory system.
- Supporting management and leadership development opportunities.
- Participating in the training of both domestic and international scientists.
- Partnering with academia to provide experiential learning opportunities.
- Providing continuing education in the area of laboratory practice.

11. Partnerships And Communication

Support their respective state public health laboratory systems by:

- Highlighting the importance of laboratory contributions to support public health.
- Maintaining a strong communication plan that links all system partners.
- Utilizing information technology for robust connectivity.
- Engaging traditional and non-traditional partners.
- Coordinating activities through the use of a laboratory program advisor (i.e., laboratory system coordinator).
- Linking the State Public Health Laboratory System to appropriate national surveillance networks.

YOUR LABORATORY'S CORE FUNCTIONS

Identify the core functions of your laboratory and contacts operating within each function that can help you gain a better understanding of your laboratory. If you need help, work with your supervisor.

MANAGEMENT AND LEADERSHIP

Management and leadership are not always the same thing but they are necessarily linked and complementary.

Public health laboratory leaders are usually required to be both good managers and good leaders. They must empower staff to perform to their maximum potential. Building positive relationships with staff and partners is also fundamental to successful leadership, as it is often necessary to not only manage and inspire, but to also resolve conflict and facilitate change while promoting the laboratory's mission, vision and values.

In addition to inspiring and motivating staff, effective public health laboratory leaders model other leadership behaviors. They are strategic thinkers, able to see ahead clearly and manage both conflict and change. They are also able to solve problems with a mixture of logical analysis and wisdom.

Effective public health leaders also have organizational awareness. They have to have the ability to explain how the organizational structure of the laboratory meets operational objectives and supports its mission, vision and values.

They are also able to describe the public health significance of internal and external policies on laboratory operations.

Effective public health leaders are effective communicators with a particular ability to resolve conflicts in a fair and equitable manner. Effective communicators are able to deliver messages through written, verbal and digital means clearly and succinctly across a variety of settings and styles.

YOUR LEADERSHIP SKILLS

Which of the leadership skills described in this section are natural strengths for you?

Which of these leadership skills do you need to develop further during your career?

MISSION, VISION AND VALUES

The mission, vision and values statements communicates the purpose of the laboratory to stakeholders, informs strategy development and serves as a set of goals by which success of the organization's strategy can be measured.

- The mission statement is a declaration of the organization's reason for being or view of itself. It answers the question "What do we do?"
- The vision statement communicates how the organization aspires to serve the community. It answers the question "Why are we here?"
- The values statement describes, as the name suggests, the most important beliefs of the organization. It answers the question "Who are we?"

INTERNAL AND EXTERNAL POLICIES

Internal policies are statements of prescribed acceptable methods or behaviors for staff and can provide guidance for everything from human resources issues to laboratory best practices and guidelines for meeting safety regulations. Some internal policies are in direct response to government regulation.

External laboratory policies outline the position of the governing entity behind the laboratory. These policies advise and communicate to the public a laboratory's position on particular issues related to disease prevention and health promotion. External policies range from recommendations for preventing injuries or maintaining fitness to statements that help shape the development of legislative, regulatory and media advocacy activities.

IDENTIFY YOUR LABORATORY'S STRUCTURE

Use this space to sketch out the organizational structure for your laboratory. If necessary, ask your supervisor for assistance.

IDENTIFY YOUR LABORATORY'S MISSION, VISION AND VALUES

Mission

Vision

Values

FIND YOUR POLICIES

Internal Policies

Identify several key internal policies at your laboratory.

Categorize them as human resources, best laboratory practices, safety or other.

Identify the consequences of violating each policy.

External Policies

Identify several key external policies that impact practice at your laboratory.

Categorize them as health recommendations, public policy issues or other.

Identify the consequences of violating each policy.

CASE STUDY: A VIOLATION OF LABORATORY POLICIES

The senior director of one state public health laboratory was faced with a dilemma. While conducting testing in response to a recent industrial accident involving biohazardous waste, a number of laboratory personnel violated processes and procedures in order to decrease turnaround time and report test results as quickly as possible.

The incident was picked up by the local news media. It was clear that the personnel in question took action with the best of intentions—timely reporting of test results—but it was reported that personnel safety was potentially put at risk in the laboratory and the reliability of the test results have been called into question. The situation has exposed the laboratory to public controversy in the media.

The laboratory supervisor is in favor of taking action against the laboratory personnel involved. It is up to the director to manage the conflict within the lab, gather all the facts and communicate with the public, as needed.

WHAT ACTION WOULD YOU TAKE?

Just as laboratories differ in the way they are organized, structured and what tests are performed, so too, do they differ in how information is shared with the public. This is highly regulated by each jurisdiction. It may be the Lab Director, the Public Information Officer or the State Health Official, to name a few. For this case study we will assume the Lab Director has authority to convey to the public.

Your first task is to manage conflict. If you were the Laboratory Director, who within the laboratory would you engage in discussion? Would you speak to both the personnel who violated the policy and the supervisor? Why?

Which stakeholders outside the laboratory where the incident occurred would you approach to gather more information?

How would you address the issue with the media and general public?

Case Study Resolved

1. The director should speak to each individual separately and then meet everyone involved as a group. It is important to get all sides of the story to be able to answer who, what, when, where and why questions. In the group meeting, discuss the facts of the situation and the outcomes - both positive and negative, to make sure that the supervisor and the employees see where the process and communications broke down.

2. The director should talk to the supervisor of the facility where the accident occurred, to fully understand the situation. Again, it is important to get all the facts.

3. The director should give the media the facts of the situation and the issues involved. However, he should not go too deep into specifics about internal issues but let the public know that the results obtained were not affected and an internal investigation is being conducted.

NEXT STEPS: SUPERVISOR MEETING

Be able to discuss:

- The larger organizational structure within which your laboratory fits
- Which core functions your laboratory performs. Does it perform any additional functions?
- Your laboratory's mission, vision and values statements
- Some internal policies at your laboratory
- External policies that impact laboratory practice
- Characteristics of an effective leader

SECTION 2: **COMMUNICATION**

ABOUT THE COMMUNICATION SECTION

In this section, we will focus on communication in public health laboratories. Effective internal and external communication is necessary for the optimal operation of a public health laboratory.

Internal communication between staff is essential to satisfy the organization's goals and quality management system. External communication is necessary to disseminate public health information and to highlight the importance of laboratory contributions in support of public health, thus ensuring continued interest and support of the public health laboratory system.

LEARNING OBJECTIVES

Once you have completed all of the materials in this section and met with your supervisor, you should be able to:

- Describe principles of clear, accurate, written communication in a public health setting.
- Describe principles of effective oral presentations.
- Articulate the importance of effective communications on work in a public health laboratory.

REFLECTION

Describe how these objectives can help you in your position:

WHAT IS EFFECTIVE COMMUNICATION?

Public health laboratory scientists are frequently called upon to communicate highly sensitive technical information to a variety of audiences over a range of situations. In addition to emergency response, communication can include reports for colleagues or many different types of interactions with the public.

Whether speaking or writing, especially about complex subjects, an effective communicator is someone who makes every effort to understand their audience and tailor content accordingly.

Training participants will be communicating with peers, as well as a wider audience, so be sure to consider the differences. With peers, it may be okay to assume a certain level of background knowledge about many subjects. Wider audiences have more complex needs.

Your audience may also be a mix of backgrounds. In this case, it is particularly important for you to provide a way for your audience to ask questions and get more information.

Finally, cultural differences are an important consideration, particularly with diverse audiences or audiences with backgrounds significantly different from your own.

An effective communicator is also careful with technical jargon and speaks in plain language whenever possible. It is best to be brief, with a logical structure that is to the point and targeted wherever possible. Make sure your audience understands your intended key messages. Use formatting tools like headings, tables and charts, graphs and visuals to emphasize and clarify those key messages.

Effective communication is a skill that can be improved through practice and continued training. Many resources are available in the Resource Library that will help you develop your communication skills.

THE IMPORTANCE OF CLEAR COMMUNICATION

Public Information Officer Profile: Paul

Paul acts as the public information officer for Kyle's laboratory. The laboratory has been tasked with testing drinking water, as there is concern among the population affected by a storm that local tap water is unsafe to drink. The media has contacted the laboratory for comment.

As Paul works in a hurricane-prone region, his laboratory has a relevant crisis communication plan in place, in addition to the laboratory's normal media relations protocols. Paul implements a plan that will minimize the potential for misinterpretation of the laboratory's actions.

Follow Protocol

Even though the pressure to release information immediately may be intense, Paul understands that the appropriate managers, as identified in the crisis communication plan, must approve all information before being released to the media.

Understand Audience Needs

Paul must tailor his message not only to the media but to public utility officials, as well as local and state government officials.

Be Clear

Paul's first goal is to allay public anxiety with clear statements to the media about the situation and exactly what actions the laboratory is taking to determine the condition of the local water supply. He details, in easily understood terms, what tests the laboratory will perform and how soon results can be expected.

Consider Target Audience

Paul prepares briefings for local and state government that outline potential public health risks and what actions the laboratory is taking. Paul continues to work closely with laboratory management to release the right information at the right time until testing confirms that drinking water is safe.

Analyst Profile: Kyle

Kyle has just begun working in a public health laboratory.

He has been tasked with assisting in an investigation of two local high school students who have tested positive for tuberculosis.

Other students may have been exposed. Local media has picked up the story and a reporter called Kyle's laboratory for more information.

As a laboratory analyst, Kyle understood it is not his role to speak to the media under any circumstances but he was not aware of the details of the laboratory's protocols. As a result, Kyle answered the telephone and stated, "I'm not the person who comments on active investigations of tuberculosis outbreaks."

Kyle clearly did not intend to imply that there was a major tuberculosis outbreak in progress. He was simply attempting to explain that he was not allowed to discuss specific cases with the media. However, Kyle's comment left room for interpretation. When the story about a "tuberculosis outbreak" at the school was reported, panicked parents began to call the school and laboratory.

The public information officer was forced into an unnecessary crisis management situation by Kyle's off-the-cuff comment.

KNOWLEDGE CHECK

What should Kyle have done when he received the phone call?

Where are the policies and protocols at your laboratory kept and which ones are relevant to communicating with the media?

Clear Communication

It would have been best for Kyle to not make any comments at all and respectfully refer the reporter to the public information officer or forward the call to his supervisor.

Scenario Summary

What differences did you notice between Kyle and Paul? Although Kyle said very little, he failed to fully understand the importance of the laboratory's media protocols when dealing with a volatile situation. Failure to understand effective communication can do more harm than good, as any off-the-cuff comment can easily be misinterpreted.

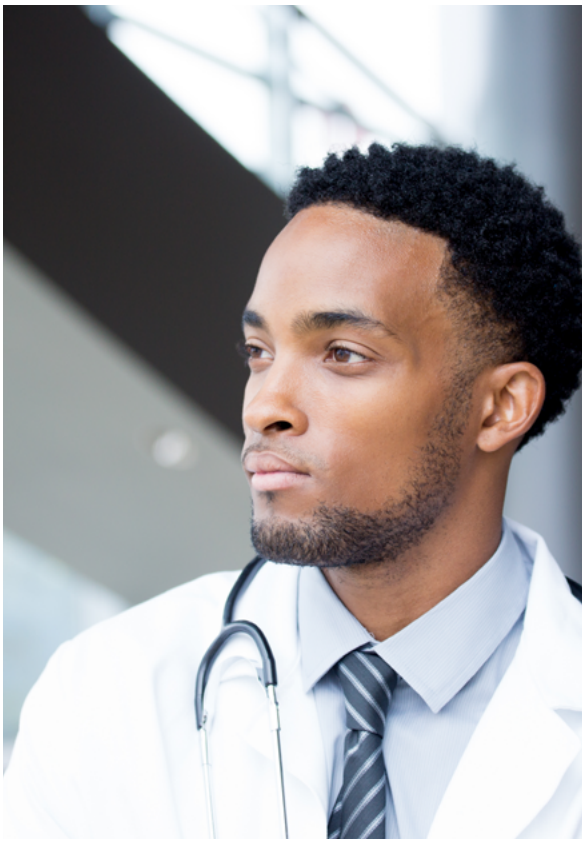
Kyle would have been better prepared to handle the situation if he had been more familiar with the laboratory's own media protocols and the outcome of the situation would have likely been quite different if Kyle did not have any contact with the media until he understood
those protocols.

Paul had a plan, understood his laboratory's protocols and understood his diverse audiences. He made sure he met the needs of each audience by directly addressing their concerns in a clear and consistent manner. Working with other agencies, Paul made sure each target audience was getting the right information at the right time. We will learn more about crisis communication in another module.

Understanding Your Audience and Context

Whether speaking or writing, especially about complex subjects, context will be a primary consideration. By context we mean answers to the "who, what, where" questions.

- Will communication be internal or external?
- Will your internal communication be with peers and colleagues or leadership?
- What about external communication? Who will be your audience?
- Will communication be in written form or verbal?
- Is there a specific format such as a standard procedure, presentation, a resume or CV?



PLANNING YOUR COMMUNICATION

Laboratory staff will be communicating with peers, as well as a wider audience, so be sure to consider the differences. With peers, it may be okay to assume a certain level of background knowledge about several subjects.

- Wider audiences have more complex needs. How do you determine those needs?
- Where possible, interact with your target audience.
- Ask questions. Try and discover who they are and what they know.
- Consider what terms and concepts may need to be explained and be sure that you are responding accordingly.

Consider what type of communication will most effectively meet the needs of your audience.

- Will written communication, with many terms and concepts defined, be more helpful?
- Would a presentation that provides many opportunities to ask and answer questions work best?

Tailoring how you provide information to your audience means finding ways to send the right message in the right way to the right people.

COMMUNICATING CLEARLY

As stated earlier, an effective communicator is careful with technical jargon, acronyms and using too much data.

Using specific and technical information may be best when discussing work with colleagues, but the background of the audience should be considered when communicating with others. Be brief, with a logical structure that is to the point and targeted wherever possible. Make sure your audience understands your intended key messages.

If it is necessary to share technical information to emphasize and clarify your key messages, be sure to use tools such as:

- Headings
- Tables and charts
- Graphs and visuals
- Video

Keep it as simple as possible, as an overly complicated graph or table can be just as confusing as a bunch of technical jargon!

GROWING YOUR COMMUNICATION SKILLS

You may not have realized that an essential part of your job would be to effectively communicate with colleagues at the laboratory, external partners and the public. The importance of practice and continued training cannot be emphasized enough.

Be sure to check your Resource Library for additional information and training aids.

COMMUNICATION WITH YOUR COLLEAGUES

Here are a few general tips for communicating effectively with colleagues:

Listen

Effective communication is as much about listening as speaking.

- Actively listen when communicating with colleagues.
- Engage your audience through asking questions and checking for understanding. Not only will this enable you to better strengthen your understanding of your audience, it will also make a better impression and increase the effectiveness of your message.

Be Aware of Your Tone

Sometimes clarity and linguistic aptitude are not enough. When tone is perceived incorrectly, it impedes effective communication as your audience becomes more concerned with how you are saying something and less concerned with what you are saying.

- Body language, levels of eye contact and the pace of your speech can also communicate a specific tone. There are also cultural differences in the use and expectations of these non-verbal communication elements.
- The intended tone is difficult to communicate in writing. In such cases, consider how you are delivering your message. Sometimes meeting in person or making a phone call is the most effective way to communicate on sensitive subjects where tone is especially important.

Use Email Wisely

Effective email communication can be a subject unto itself.

- Never write when you are frustrated or angry. It is usually best to return to the task later.
- Use “reply all” only when necessary, especially with large groups of recipients. Effective communicators specifically target their audience while limiting their content to what is most relevant.

Be Brief

Use subject lines effectively and avoid text presented as a “wall of words.” Instead, use:

- White space,
- Bold text,
- Bullet points and
- Paragraph headings.

Highlight Key Information

Any important questions or action items should be in the first few lines of your content. Email is not an effective medium for large pieces of detailed content. Large segments will likely go unread and unanswered. Consider a face-to-face meeting instead.

MEETINGS

Meetings can be an effective form of communication, as they allow for a great deal of interactivity. Here are some tips:

Have an Agenda

Meetings are more organized and time efficient if there is a clearly stated purpose, along with a list of topics to be discussed. Agendas in themselves are effective communication tools, as they can also serve as a framework for note-taking and questions.

Have a Set End Time

Having a definite end time helps ensure that participants stay on task, maintain focus and accomplish what is set out in the agenda.

End With Next Steps

Spending the last few minutes discussing next steps serves as an effective summary and enables participants to have a clear understanding of deadlines and the specific tasks they need to accomplish.

COMMUNICATING WITH LEADERSHIP

Communicating with laboratory leaders can be quite different from communicating with peers. As always, it is important to tailor your content to your audience. What is your leader's background? What information will they need from a person in your position? What are their priorities?

The key term to keep in mind when communicating with laboratory managers and directors is **focus**.

Focus on Impact, Not Process

Effective communicators focus on what is important to their audience. Leaders are most interested in information that will help them make decisions. With certain exceptions, leaders are less interested in the process you used to arrive at your conclusions. Developing and finding ways to repeat a concise message that communicates what is important will aid in maintaining focus.

Focus on the Future

Unless your leadership is asking you to justify a particular action, they are most likely interested in information that will help them make decisions about the future.

Focus on the Facts

Leaders may require specific supporting data behind your conclusions in order to make sound decisions but will be less interested in long explanations.

Focus on a Compelling Message

Although facts are important, storytelling can be an effective communication method for educating leaders about public health laboratory science.

For example, a story about a child being saved due to timely newborn screening or how testing prevented a foodborne illness from spreading can provide a powerful backdrop to illustrating the importance of and uses for public health laboratory science.

CASE STUDY: WEST NILE VIRUS OUTBREAK

George is the director of a regional public health laboratory.

There has been a recent outbreak of West Nile Virus and he has been asked to share some general preventative information with some local community groups.

In addition to presenting some facts, he is planning to create a handout for the audience.

WHAT ACTION WOULD YOU TAKE?

Keep in mind that your actions will impact both the personnel in question as well as the local community. Be prepared to discuss this case with your supervisor.

What questions should George ask about his audience or the context before he begins planning his communication?

What are some other things he should think about before he begins?

Case Study Resolved

1. Should George focus on sharing information or data? With a community group, information would probably be more useful than a mass of data.

2. What information would be most useful? Perhaps information about what West Nile Virus is, where it comes from, how it is spread and how to take precautions against contracting the disease.

3. How should this information be shared? Perhaps a mixed approach with a short presentation, some handouts that the audience can take with them, as well as a question and answer period.

4. George could also provide ways the audience could get more information on the virus.

PUBLIC COMMUNICATION

Public communication is an essential part of the operation of a public health laboratory. Given the right kind of specialized training, there are many opportunities to work in roles such as public affairs or public information officers, tasked with addressing the media and the public, in general.

Many of the same rules of written communication apply to spoken communication:

- Tailor content to the intended audience.
- Communicate concisely and without unnecessary technical jargon.
- Improve your skills through practice and continued training.

The first rule is vital and bears repeating. Consider your audience! Your laboratory will likely communicate with a diverse audience including government officials, community groups, etc.

Those who communicate with the public must constantly resist the tendency to slip into jargon and technical terms, particularly when talking about research findings or other scientific topics.

Visuals are particularly useful in public communication. It is better to keep graphs and charts to a minimum with a non-technical audience but other images and illustrations can be a very effective way to engage the audience. It is also helpful to try and create a "mental picture" for the audience through examples, analogies and relevant stories.

Check your Resource Library for additional information and training aids.

PRESENTATION SOFTWARE

When George gives his talk to the group, he will most likely include a PowerPoint presentation. Many of you may have heard the phrase "death by PowerPoint." A classic presentation by Don McMillan sums up what the term means and outlines all the pitfalls that George should avoid.

You can also find the link to this video in the Resource Library.

WHAT ACTION WOULD YOU TAKE?

What are some of the pitfalls mentioned in the video that should be avoided?

Activity Response: What Action Would You Take?

George has decided to begin with preparing the handout first.

- He begins with "Who is the audience?" He quickly realizes that a wide variety of people need this information.
- George examines internal memos and reports on the topic and quickly sees that the information will be difficult for non-technical people to understand. He will need to be careful about using jargon and will need to define or explain any required technical terms.
- George consults his lab's style guide for ideas on how to lay out his handout. He outlines the information he wants to present and uses a document template provided by the lab. As he begins to write, George looks for ways he can break up the text using titles, bullet points, white space and relevant images to hold the reader's interest and avoid projecting a "wall of words."
- He uses relevant images, charts and tables. George is particularly careful about designing charts that are clear and easy to understand.
- Tone is another consideration. George tries to make the written content as conversational and "user friendly" as possible and avoids dry technical language. He is especially careful not to sound condescending in his writing.
- Instead of simple black and white text and tables, George uses "friendlier" color and illustrations to better communicate important information.

PRESENTATION

Using the outline that he had already prepared, George begins to put together his presentation.

Please take a moment to watch the video, "Giving a Scientific Presentation - Hints and Tips" by Dr. James Clark of King's College London, which can be found in the Resource Library.

In our case study, once George has completed putting together his presentation, he returns to his handout. He compares the content of the presentation to his handout and makes sure it includes everything he needs to support his presentation. He then circulates a draft of his materials for feedback from other leaders at the laboratory.

Finally, George incorporates his feedback, finds out how much time he has for his talk, makes adjustments accordingly and practices, practices, practices!

NEXT STEPS: SUPERVISOR MEETING

For this module, you will present and discuss:

- A sample of written work tailored to a particular audience that you may encounter in the public health field.
- A brief presentation on any subject relevant to your laboratory. Be sure to prepare a brief explanation of how you decided to present your material.

SECTION 3: **GENERAL LABORATORY PRACTICE**

ABOUT THE GENERAL LABORATORY PRACTICE SECTION

This section on general laboratory practice addresses the knowledge, skills and abilities needed to fulfill basic responsibilities for performing analyses of specimens across the wide spectrum of scientific and technical activities found in public health laboratories.

The broad practices we will discuss here will apply to most laboratory staff, regardless of their specific area of scientific or technical expertise.

In this section, we focus on three aspects of good laboratory practice:

- Rules and regulations
- Results
- Quality assurance

Laboratory testing is heavily regulated so it is essential that specific protocols and standard procedures are followed to ensure accurate test results. Regulation also applies to how those results are reported and stored. Quality assurance practices play a key role in guaranteeing both the accuracy of testing procedures and, ultimately, test results.

LEARNING OBJECTIVES

Once you have completed the materials in this section and met with your supervisor, you should be able to:

- Locate regulations applicable to testing specimens in a public health laboratory.
- Identify and describe the standard steps necessary to complete the pre-analytical, testing and post-analytical phases of specimen testing in a public health laboratory.
- Describe the relationship between quality assurance practices and accurate test results.

REFLECTION

Describe how these objectives can help you in your position:

ANALYST PROFILE: KATE

Kate is a new analyst at a public health laboratory tasked with molecular testing. Her laboratory has been notified of a recent outbreak of norovirus at two nursing homes in the area. Kate will be part of the team working to determine if specimens from both locations indicate infection by the same virus strain.

Before testing can begin, Kate will first register the request and order the test within her facility's laboratory information management system (LIMS). The laboratory receives stool specimens from the hospital, labels each one and delivers them to Kate in the microbiology laboratory.

Steps Kate will take to test the samples:

- Identifies the instruments and other equipment she will require and reviews the operating procedure for each instrument, as provided by the equipment manufacturer.
- Gathers and reviews the laboratory's own standard operating procedures (SOP) and policies that address each task she will perform. She makes sure that any required maintenance, cleaning and calibration of the equipment, as outlined in these procedures, has been completed.
- Performs quality checks using control specimens and confirms that the equipment will complete the test accurately.
- Performs the required tests and confirms that the same strain of norovirus is present in specimens from both nursing homes.
- Reports her results to her supervisor who reviews her results. Her laboratory will report the results to the health department and healthcare providers.

CLIA: CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

Public health laboratories like Kate's are subject to many important regulations and this depends on a number of variables, including the type of testing performed.

Public health laboratories must be certified or accredited by one or more appropriate regulatory bodies. Laboratory accreditation serves to determine the technical competence of laboratories to perform specific types of testing, measurement and calibration and not all laboratories are certified to conduct all kinds of testing. Laboratory accreditation and certification will be specific to the work performed at the facility and must be maintained through regular inspections and audits. As Kate's laboratory is called upon to test human specimens and report results to healthcare providers, her laboratory is regulated and accredited under the Clinical Laboratory Improvement Amendments of 1998, or CLIA.

CLIA is a set of regulatory standards that apply to all clinical laboratory testing performed on humans in the United States. The objective of the CLIA program is to ensure quality laboratory testing. All US facilities or sites that test human specimens for health assessment or diagnose, prevent or treat disease fall under CLIA regulation. Each laboratory must have a CLIA Certificate of Compliance that specifies a list of laboratory specialties the laboratory is allowed to perform. Requests can be made for waiver of CLIA regulations in certain circumstances.

It is important to note that CLIA does not necessarily apply to specimen testing conducted for clinical trials or basic research. Epidemiological surveillance testing, where no patient specific results are reported, is also not subject to CLIA.

Three federal agencies are responsible for CLIA: the US Food and Drug Administration (FDA), Centers for Medicare and Medicaid Services (CMS) and Centers for Disease Control and Prevention (CDC). Each agency has a unique role in assuring quality laboratory testing.

FDA

- Categorizes tests based on complexity
- Reviews requests for Waiver by Application (see above)
- Develops rules/guidance for CLIA complexity categorization

CMS

- Issues laboratory certificates
- Collects user fees
- Conducts inspections and enforces regulatory compliance
- Approves private accreditation organizations for performing inspections and approves state exemptions
- Monitors laboratory performance on Proficiency Testing (PT) and approves PT programs
- Publishes CLIA rules and regulations

CDC

- Provides analysis, research and technical assistance
- Develops technical standards and laboratory practice guidelines, including standards and guidelines for cytology
- Conducts laboratory quality improvement studies
- Monitors proficiency testing practices
- Develops and distributes professional information and educational resources

Additional information about CLIA is available in the Resource Library.

YOUR LABORATORY'S CERTIFICATIONS AND ACCREDITATIONS

Take a few minutes to locate the CLIA Certificate of Compliance for your laboratory. It will specify the tests your lab is permitted to perform. What are three tests that your lab can perform?

1.

2.

3.

Ask your laboratory supervisor and colleagues for more information about the certifications and accreditations your laboratory holds. For example, does your facility also test environmental samples? If so, what regulatory body applies?

PROTOCOLS AND PROCEDURES

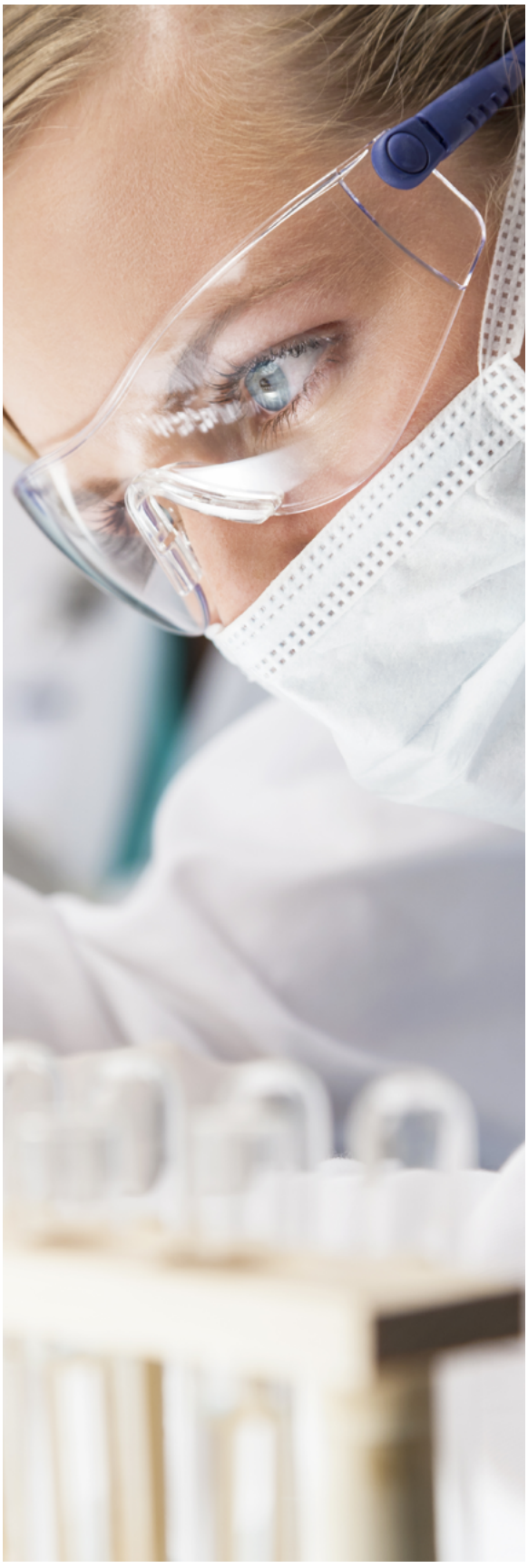
Regulations require that written procedures are made available for every step of the specimens testing process. CLIA Standard 493.1251, for example, specifies provision of a manual for all tests, assays and examinations performed by the laboratory.

These manuals include items such as:

- Procedures for patient preparation, specimen collection, labeling, storage and preservation
- Step-by-step performance of the test procedure, including test calculations and interpretations of results
- Preparation of materials such as solutions, controls, reagents and other materials, as required
- Calibration and calibration verification procedures
- Corrective action to take when calibration or control results fail to meet criteria for acceptability

Manufacturer's test system instructions may be used, but if any items specified by CLIA are not included they must be provided by the laboratory.

CLIA also designates requirements to ensure that testing personnel are appropriately educated, trained, and deemed competent to perform specific procedures.



SPECIMEN TESTING

Specimen testing is considered one of the core functions of public health laboratories. Laboratories are tasked with monitoring and detecting health threats in the human population, as well as the environment. This can range from foodborne outbreaks and communicable diseases to man-made and natural disasters.

While policies and procedures vary along with the mission of a particular laboratory, specimen testing can generally be described as a three-phase process:

- Pre-analytic
- Analytic
- Post-analytic

PRE-ANALYTIC TESTING PHASE

Pre-analytic Testing Phase Part 1

The pre-analytical phase encompasses the time from when the test is ordered until the sample is ready for analysis. Specimen testing can require extensive preparation, so there are many steps in the pre-analytical phase of the testing process.

Regulation requires every laboratory to have policies and standard operating procedures (SOPs) in place for tasks like equipment maintenance, operation and cleaning of equipment, quality control and of course, testing procedures.

In most cases, this step of the process will also involve interaction with a laboratory information management system, as specimens must be tracked and tests ordered. A laboratory information management system (LIMS) is computer software that processes, stores and manages data from all stages of medical processes and tests.

The actual pre-analytical testing process varies widely depending on the test being performed. Some tests require specialized equipment with specific standard operating procedures (SOPs) provided by the equipment manufacturer. Other tests have been developed by the individual laboratories themselves and they will have their own SOPs and protocols.

Proper sample collection and handling by the submitting facility, such as a hospital or environmental sampling team, is also part of the pre-analytical phase. While the laboratory cannot control this variable, written protocols and regular communication with the submitters will help ensure quality samples are provided for analysis.

Some examples of errors include:

- Improper collection of specimen or an inadequate specimen
- Delay in transporting specimen to the lab
- Storing specimen at wrong temperature

ACCESS TO YOUR LIMS AND STANDARD OPERATING PROCEDURES

Confirm you can identify and access your laboratory information management system (LIMS). If you have not received a login password, contact your system administrator.

Identify and access a standard operating procedure for specimens testing. Standard operating procedures at your laboratory may be stored on a compliance management system, such as Medialab or iPassport. Obtain your login information from your laboratory supervisor.

Do you have access? ☐ Yes ☐ No

Where is your CLIA competency, documentation of competence, and/or other testing personnel training and record keeping policy kept?

Pre-analytic Testing Phase Part 2

Once the required tests have been ordered and the specimens collected and processed in the information system, the pre-analytical phase continues with preparations for the test:

- All required equipment must be checked and calibrations verified.
- Instruments and equipment may need to be cleaned or maintained, as specified.
- All safety considerations, including Personal Protective Equipment (PPE)
- All solutions, reagents and other materials must be checked.
    - Are they in date?
    - Have they been stored correctly?
    - Are they available in sufficient quantities?

Quality control tests should be performed to ensure that all results are accurate and reliable. Incorrect quality control test results alert the user to potential problems.

Pre-analytical variables can account for up to 75% of laboratory errors, so it is essential that correct procedures are followed, particularly quality control checks.

Some examples of errors include:

- Incorrect sample labeling
- Standard Operating Procedure (SOP) is not up to date
- Equipment calibration or quality control is not performed

ANALYTIC PHASE

The analytic phase includes what is usually considered the "actual" laboratory testing or the diagnostic procedures, processes and products that ultimately provide results.

This phase will vary widely depending on the exact test performed and it is important to be aware of the variety of steps, materials and equipment needed for each one. Some considerations include:

- The analyst scheduled to perform the test is competent for the specific procedure.
- Calculation formulas provided and checked
- The specific sample and test requirements must be met:
    - Time limitations and specimen stability
    - Sources of error or test interference accounted for
    - Parameters for centrifuge speed, pipette volumes, etc. provided and checked

Procedures for handling instruments and other equipment that may be shared with others during testing are also very important.

As with the pre-analytic phase, it is imperative to follow procedures that specify how every step of the testing process should be documented.

Improper or missing documentation can affect the future handling of the sample, causing more mis-takes throughout the process. This can create a situation, such as the improper identification of a biological organism, which can cause further harm to a patient or population by hampering effective treatment or containment procedures.

Quality assurance and personal safety protocols should always be followed carefully. Maintaining safety protocols is important while conducting any testing but it is particularly important to follow procedures that apply to the handling of biohazard waste and sharps containers. A checklist or worksheet may help ensure each step is adhered to and properly documented.

Some examples of errors include:

- Temperature, hold times, or other test parameters were not adhered to
- Calculations not documented
- Out of date reagents or supplies were used.

POST-ANALYTIC PHASE

Once testing procedures have been completed, we move to the post-analytic phase. The primary task in this phase is reporting of results. The person responsible for reporting results must be able to recognize erroneous or questionable results, which may require re-testing or follow up to resolve discrepancies. Results should not be reported to the submitter until they have received the appropriate level of review, which often entails second review by a trained analyst or supervisor.

Common errors in this phase can impact traceability of the result to the specimen, which may include:

- Sample misidentification
- Transcription errors
- Inability to identify interference or questionable test results for re-testing

In our norovirus example, Kate confirmed that a number of specimens she tested contained the same virus strain and this was an indication of a possible outbreak. In such a case, the results would be reported back to the submitting facility, which would coordinate with the healthcare facility to contact the patients for treatment purposes.

Since these results also indicate a possible outbreak, they should be reported to the appropriate HAI (Healthcare-Associated Infections) program coordinator or epidemiologist, and in some cases, the county or state health department as per regulatory requirements.

CASE STUDY: JAIME

Jaime is a new analyst at a state laboratory tasked with molecular testing. His laboratory is responding to new reported cases of Zika virus. Jaime will be conducting tests to confirm the presence of the virus in samples collected by an area hospital. He has completed training and is competent to perform the procedure.

- What questions should Jaime ask before he begins?
- What are the steps that Jaime should take to test the specimens?
- Test results will be reported to the hospital. What regulations will apply?

Case Study Resolved

1. In this situation, Jaime should first make sure that he is familiar with regulations, procedures and policies pertaining to the specimen testing and his laboratory.

2. Jaime should also make sure that he has access to the laboratory's information system and equipment SOPs.

3. As part of the pre-analytic phase, Jaime should make sure the appropriate tests have been ordered and equipment has been maintained and is ready to use. He should also identify control specimens for verifying the results of the testing process.

4. When Jaime is ready to begin the analytic phase or testing the specimens, he should use proper procedures for documenting and testing specimens to prevent errors.

5. When all specimens have been appropriately processed according to the relevant procedures, Jaime will need to accurately report the results of the testing in the post-analytic phase.

NEXT STEPS: SUPERVISOR MEETING

Meet with your supervisor and discuss:

- Types of specimen testing done at your laboratory
- Plans for testing a specimen. Identify all of the necessary regulations and protocols that apply to your test.

Discuss other considerations, such as:

- Is the test for clinical, surveillance or research purposes?
- What regulations apply to your test? What is the impact of those regulations?
- What happens to the test results? Where are they reported?
- What process is used to deem analysts competent to perform testing in your facility?

SECTION 4: **RESEARCH**

ABOUT THE RESEARCH SECTION

Public health related research is one of the core functions of many public health laboratories. We will define "research" as a systematic investigation designed to develop or contribute to generalizable knowledge. Public health laboratory research includes development of new methods and products used to solve new or existing problems, to reaffirm results of previous work and to support or develop new hypotheses.

Research is critical to public health, as communities are continually challenged with new and recurring diseases and unknown environmental public health threats.

Public health research is conducted in many different settings:

- Public health laboratories
- Academic medical centers
- Private sector laboratories

LEARNING OBJECTIVES

Once you have completed all of the materials in this section and met with your supervisor, you should be able to:

- Describe scientific and technical concepts relevant to research in public health laboratories.
- Identify strategies for pilot testing, method validation and performance validation relevant to public health laboratories.
- Describe methods used for collecting, managing, analyzing and interpreting public health research project data.

REFLECTION

Describe how these objectives can help you in your position:

ANALYST PROFILE: KARA

Kara is a new analyst at a state public health laboratory and hopes to pursue a career in research. Knowing her interest, her supervisor has asked her to assist with a new project.

We'll be following along with Kara as she performs tasks that she has been assigned.

AN APPLIED RESEARCH PROJECT

A new pathogen that causes acute illness has been reported. The laboratory has not been able to determine why this illness is occurring exclusively in one geographic area but has developed a hypothesis. The laboratory has not had the resources to conduct the research required until now.

The first stage of the project plan is to develop a new blood test for the pathogen, as no such test currently exists. Kara has been assigned the project. Kara's job will be to conduct the planned experiments, report the results and in consultation with her laboratory, plan further research.

APPLIED VS. BASIC RESEARCH

Most of the research performed in a public health laboratory is "applied research." Unlike basic researchers, whose primary objective is to expand knowledge, applied researchers in a public health laboratory try to find solutions to current or imminent public health threats.

This is an important distinction because in many cases, the research needs to happen immediately or within a short time frame, taking environmental factors and population proximity in consideration when investigating the situation.

A good example would be during an outbreak of Legionnaire's disease, where it is necessary to find out what pathogen is causing illness, its source, treatment options and steps to stop transmission.

In most cases, basic research happens within a private sector or academic laboratory setting, removed from the immediate location of the problem.

Kara's research goal is not primarily to learn more about an unknown pathogen. Per the mission of public health laboratories, her goal is to solve an immediate problem by developing a new test for a known pathogen, which will hopefully lead to better diagnostics, surveillance and outbreak response.

RESEARCH ETHICS

Ethics are very important when it comes to research. Ethics in research prevents the falsifying of results or creation of fake data. It also encourages an environment of trust and accountability between researchers, which is necessary to make agreements regarding data sharing, co-authorship and copyright issues.

Ethics are also needed to assure the public that appropriate guidelines are being followed in areas like animal welfare, safety, health standards and conflicts of interest.

ETHICS OF HUMAN SUBJECT RESEARCH

Much of the research that public health laboratories conduct involves human subject research, or HSR.

There are many rules and safeguards in place to protect research study participants such as:

The Institutional Review Board (IRB)

The IRB is a panel of people who:

- Ensure the safety of the human subject
- Assist to make sure the subject's rights are not violated
- Review the methodology in grant proposals make sure ethical practices are included in study design.
- Protect institutions and researchers against potential legal issues.

Informed Consent

Informed consent principles are followed to guarantee that human subjects have been fully informed regarding procedures and potential risks while participating in the study.

Human Subjects Training

As a researcher, you may be required to take human subject research training such as that offered by the Collaborative Institutional Training Initiative, or CITI Program.

KNOWLEDGE CHECK

What kinds of applied research studies does your laboratory currently have in progress?

What are some potential consequences if good research and ethical practices are not followed during these (or any) research projects?

Activity Responses: Knowledge Check

Every public health laboratory will engage in different types of research. Poor research practices can:

- Provide the public with incorrect information, causing potential risk to the public and undermining confidence.
- Damage chances of gaining additional research funding.
- Put laboratory personnel at risk through exposure.
- Create additional risks to the public, such as mutating a virus strain.

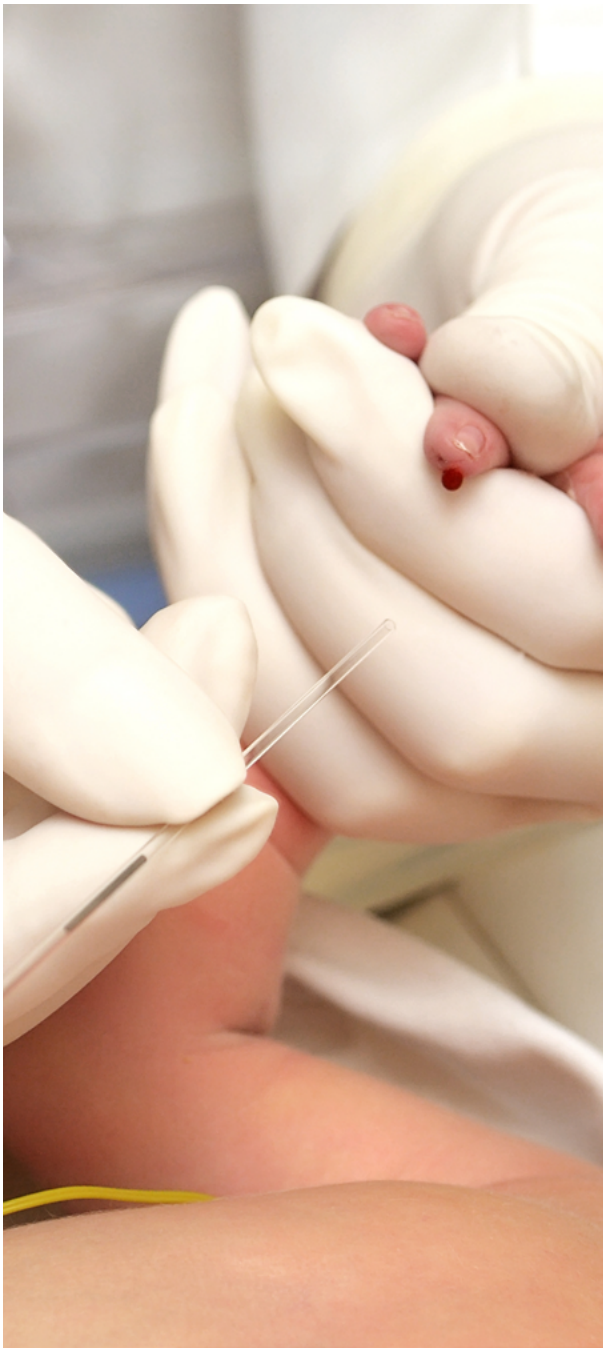
PUBLIC HEALTH RESEARCH

Once the need for research has been identified, there are several things that Kara can work on before a research project can be initiated.

Typically, a protocol or research plan should outline the various components of the research study.

Protocols include:

- An **abstract**, which explains the main purpose of the study, how the study will be conducted and what the expected outcomes will be.
- A **study description**, which explains the study in greater detail. The description should answer the following questions:
    - Why? Why is this research being conducted, what is the topic of the research and what is the relevant background information needed?
    - How? What is the study design and what is the rationale behind choosing that design?
    - Who? Who is the study population and what sample size is needed?
    - What? What variables are to be measured, what instruments will be needed and what outcomes will be analyzed?
    - So what? What is the significance of the results?
- Protocols also include a **justification** for the study, a **budget** and a list of the **investigators** and their roles in the study. Other components are a timeline and risk assessments.



PILOT TESTING

Pilot tests are designed to:

- Assess the safety and effectiveness of treatments, instruments or sampling procedures and interventions.
- Assess study recruitment potential.
- Assess the feasibility of collaboration or coordination for multi-center trials.
- Increase laboratory research experience with the study medication or intervention.

Pilot tests are also the best way to assess feasibility of a large, expensive full-scale study. Conducting a pilot prior to the main study can enhance the likelihood of success of the main study. Pilot testing is more common in epidemiology and health departments than in public health laboratories.

The results of the pilot are used to improve the program or procedure being piloted before it is used on a larger scale.

METHOD VALIDATION

Method validation is the process used to confirm that the analytical procedure used for a specific test works as expected and achieves the intended results.

Results from method validation can be used to judge the quality, reliability and consistency of analytical results; it includes determination of performance characteristics and it is an integral part of any good analytical practice.

PERFORMANCE VERIFICATION

Performance verification is the ongoing process that confirms specified requirements are fulfilled.

Verification is needed when, for example, the laboratory replaces a test system or instrument, adds a new test or changes the manufacturer of a test kit.

The laboratory must verify that the manufacturer's performance specifications are confirmed.

KNOWLEDGE CHECK

Identify a research project conducted in your lab and describe how the three-step process of pilot testing, method validation and performance verification was completed. Please note that you need to use this research project for another exercise later in the section.

RESEARCH PRACTICES

Data collection is the process whereby information pertaining to a targeted area of interest is gathered and measured in an established and systematic manner. The collected data will allow the researcher to answer specific research questions, test hypotheses and evaluate outcomes.

There are two broad types of data — qualitative and quantitative. Each type has unique uses, depending on how you wish to use the data within your study. It is also possible to use a combination of these methods.

Qualitative

Non-numerical, descriptive information

- Answers to open-ended questions, focus groups or unstructured interviews.
- Can be harder to analyze than quantitative data.

Quantitative

Information about quantities, which includes anything that can be captured as a number or measurement: height, weight, duration, etc.

RESEARCH DATA

During a research project, there are four steps dealing with data: Collecting, Managing, Analyzing and Presenting.

Collecting Data

Data collection is an important part of any research study. Inaccurate data collection can cause incorrect results and invalidate your entire study.

Depending on the type of data that you are looking for (qualitative or quantitative), there are different types of data collection that can be used.

Qualitative data uses:

- Random sampling
- Unstructured interviews
- Observation
- Document reviews

Quantitative data is collected through:

- Questionnaires
- Interviews with structured, closed-ended questions
- Scales

The choice of appropriate data collection methods should be based on the research questions, design, sample and the possible data sources.

Managing Data

Data management is important because it will:

- Expedite the scientific process, saving time and resources.
- Ensure the accuracy, completeness, security and integrity of the data.
- Meet funding agency requirements and protect their investment.
- Allow others to use the data, preventing duplication of effort and ensuring compliance with industry standards.

Analyzing Data

The purpose of analyzing data is to obtain usable and useful information. The analysis, regardless of whether the data is qualitative or quantitative, may:

- Describe and summarize the data
- Identify relationships between variables
- Compare and identify the difference between variables
- Forecast outcomes

Presenting Data

After collecting, managing and analyzing data, it needs to be shared it in a way that is understandable and useful.

Here are some tips:

- Whenever appropriate, make your findings visual. Too much text and people won't want to read it.
- Keep things focused and as simple as possible. Don't try to cram everything on one slide, in one table, etc. This also applies with the actual information that you want to share. Don't waste your time sharing a lot of information that doesn't add value to what people need to know.
- Consider your audience. Don't use a lot of scientific jargon, acronyms or statistics if it isn't going to mean anything to the people with whom you're sharing your information.
- Make sure you choose the format that fits the data best. Again, keep it simple and easy for people to read and understand.

KNOWLEDGE CHECK

Using the research project that you identified for the previous activity, describe how data was collected, managed and interpreted. How would you present the data?

You will be discussing this with your supervisor at the end of the section.

CASE STUDY: KARA

After her training, Kara is now a researcher with a public health laboratory that works closely with a university. She has identified the need for additional study on the effects that prolonged exposure to pesticides may have on migrant workers.

- Is this basic or applied research and why?
- What ethical concerns should Kara consider when approaching this project?
- Should Kara gather qualitative or quantitative data and why?
- What are some effective ways for her to present the data?

Case Study Resolved

1. The type of project is considered basic research, as it deals with gathering additional information, rather than solving a specific problem.

2. Kara will be working with human subjects and will need to gain their informed consent before beginning her study. She will also need to protect their privacy and be sure protocols are in place to make the data anonymous.

3. The data gathered can be either quantitative or qualitative. Quantitative information could be number of subjects per age group or the number of times workers were unable to work due to illness. Qualitative information could be a list of symptoms displayed by the subjects.

4. Graphs and charts, tables and narrative would all be acceptable forms of presentation. Studies will contain a combination of most forms of data presentation.

NEXT STEPS: SUPERVISOR MEETING

Meet with your supervisor to:

- Describe scientific and technical concepts relevant to research in public health laboratories.
- Using the research project that you identified for the exercises in this section, identify the strategies for pilot testing, method validation and performance validation.
- Using the research project you identified for the exercises, describe the methods used for collecting, managing, analyzing and presenting the data.
- Discuss the case study and your answers.

SECTION 5: **SURVEILLANCE**

ABOUT THE SURVEILLANCE SECTION

In this section, we will look at surveillance — the continuous and systematic collection, analysis and interpretation of health-related data needed for the planning, implementation and evaluation of public health practice. In a surveillance project, the spread of disease is monitored to establish patterns of progression to predict, observe and minimize the harm caused by the disease.

Surveillance is a continuous information loop between health care providers, public health agencies and the public. When cases of disease occur, health care providers, and sometimes members of the general public, report those cases to public health agencies, who in turn continue the cycle.

Well-developed surveillance capacity is the foundation on which health departments detect, evaluate and design effective responses to public health threats.

LEARNING OBJECTIVES

Once you have completed the materials in this section and met with your supervisor, you should be able to:

- Describe the importance of public health laboratory surveillance
- Identify and describe methods and procedures used to conduct and evaluate testing methods in public health laboratory surveillance
- Explain how surveillance test results are managed, interpreted and reported

REFLECTION

Describe how these objectives can help you in your position:

ANALYST PROFILE: JACOB

It is Jacob's first week in a public health laboratory. Although his background is not specifically in epidemiology, he has a developed an interest in laboratory surveillance.

Over the course of his research into the topic, he came across a particularly notable story about the development of a national surveillance network called PulseNet.

A link to the story can also be found in the Resource Library.

AN OUTBREAK

- In 1993, 600+ people fell ill with *E. coli*, a then-obscure bacteria.
- 4 children died from the infection and many others suffered from long-term illness.
- 39 days passed before it could be determined that an outbreak was in progress.
- One alert physician notified the Washington State Health Department of a sudden uptick in children ill with this infection.
- State epidemiologists alerted emergency rooms to look for symptoms of infection; patients were interviewed regarding recent eating habits.
- Within one week, epidemiologists had pinpointed undercooked hamburgers served at a fast food restaurant as the source of the outbreak.
- It is estimated this discovery and prompt action prevented an additional 800 *E. coli* cases and an unknown number of deaths.
- The state was the first to make the disease "reportable," meaning doctors were required to report *E. coli* infections to the health department.
- This outbreak played a major role in development of what would become PulseNet, a national network that brings together public health and food regulatory agency laboratories around the US.
- Through PulseNet, laboratories share test results, which act as fingerprints to distinguish strains of organisms and may identify foodborne disease outbreaks.

SURVEILLANCE

Jacob learned that laboratory based surveillance saves lives by monitoring trends and patterns in disease occurrence from the standpoint of both the public health impact of disease and treatment of individuals.

Public health surveillance asks questions like:

- What health problems exist in the population?
- Who is experiencing these conditions?
- Where are these people located?

Surveillance was initially used as part of the process to control communicable disease. Today, surveillance methods have been applied to:

- Non-communicable diseases and conditions as varied as occupational hazards and highway crashes.
- Evaluation of current disease prevention and control programs.
- Understanding the effectiveness of vaccines or whether disease prevention messages are reaching all intended groups.
- Initiation of public health research, by raising unanswered questions that identify where more information is needed to identify or treat disease.

ACTIVE, PASSIVE AND HYBRID SURVEILLANCE

There are several types of public health surveillance activities: active, passive and hybrid.

Active Surveillance

- Is proactive and planned out.
- Aggressively looks for cases, perhaps by calling or visiting health care providers on a regular basis or collecting samples.
- Is not always triggered by a pivotal event like a disease outbreak.
- Can originate from a perceived trend in one type of disease over a longer time period that requires very specific resources and monitoring programs.
- Can originate from outbreaks in other regions that call for monitoring over time.

Passive Surveillance

- Is reactive and unplanned.
- Is usually initiated by health care providers, clinical laboratories and others. Although it originated from an active surveillance program, PulseNet is currently considered a component of passive surveillance.
- Can quickly become an active program if an outbreak is reported.

Sentinel Surveillance

A third, or hybrid type of surveillance is sentinel surveillance. These programs seek out particular health events.

KNOWLEDGE CHECK

Identify the surveillance projects that currently involve your laboratory. Is your laboratory actively or passively participating?

SURVEILLANCE PROCESS

Surveillance is a three-step process of planning, implementation and evaluation. An analyst could be involved in one or all three phases of a surveillance project.

Planning

Public health departments will usually have crisis response protocols in place that act as a framework for planning a surveillance project.

In the planning stage, epidemiologist and public health officials will look at:

- The pathogen or other possible cause of disease
- The population at risk
- Available infrastructure

Public health officials must determine how to conduct surveillance at the necessary scale in the most cost effective manner possible.

There are additional infrastructure considerations for conducting surveillance, such as being able to ensure that specimens can efficiently be transported from patients to the testing laboratory.

Implementation

Effective surveillance is about scale. Many surveillance projects will be implemented by more than one laboratory. Communication between the laboratories is essential, as it will be necessary to develop and maintain standardized testing methods and protocols, as well as identify ongoing needs for training, support and required infrastructure.

Larger projects involving several laboratories are implemented in a phased roll out. This is necessary, as scaling up is dependent upon getting additional equipment and personnel into the laboratories.

Evaluation

Surveillance projects must be measured or evaluated to ensure they are generating meaningful, useful data in a cost-effective manner.

As surveillance projects are considered research projects and do not focus on individuals, regulations such as Clinical Laboratory Improvement Amendments, or CLIA, do not apply. However, most laboratories try to operate in compliance with CLIA as this set of federal regulations include valuable quality assurance methods.

We will discuss CLIA regulation and Quality Management Systems in different modules.

SURVEILLANCE METHODS AND PROCEDURES

For public health departments to respond to health threats, surveillance test results must be effectively managed, interpreted and reported.

Management

Surveillance projects involve large-scale testing that can generate masses of data. It is necessary to engineer systems that can efficiently manage data as it is interpreted and reported. A quality management system (QMS) plays a key role in the development of such systems. As mentioned, we will discuss QMS in greater detail in another section.

Interpretation

For a surveillance project to be successful, management systems must be in place that facilitate data interpretation and reporting. As this data is managed, it must be interpreted, or translated, from data into meaningful information that can lead to action by public health departments.

The data obtained from large numbers of surveillance test results alone will not be sufficient. Test results must be integrated with many other pieces of information.

Interpretation of data calls for multidisciplinary teams of laboratory scientists, clinicians and epidemiologists that can bring needed perspectives to the data.

Reporting

For meaningful information to be actionable, it must be communicated effectively. Government officials, the media and other non-technical audiences must have reports that are clearly written and accessible to make use of the information. We discussed effective communication in section 2.

All patient or test subject identifiers must be carefully controlled, as privacy is an important consideration.

CASE STUDY: DANA

Dana is an analyst with a background in epidemiology. She has been asked by her laboratory to assist in responding to an outbreak of illness among workers at a chemical plant. Workers have been successfully treated for the symptoms of this illness but the cause is unknown. This is the third time this type of outbreak has occurred at this plant, which manufactures many different chemicals. Dana learns that the raw materials for the chemicals are received by ship. Dana's task is to plan the laboratory's effort to determine the cause of this illness.

- Would this be an active or passive surveillance project?
- What are four factors you would try to identify when planning this project? Describe the details of each factor.
- What must be developed to implement this project?
- What role do quality assurance protocols play in assessing the project?

Case Study Resolved

1. The laboratory is responding to an unforeseen outbreak. Therefore, this would be considered a passive project.

2. The planning stages of this surveillance project are:
   - **Cause:** Dana must investigate both the environment and the affected workers themselves to determine if the cause was a pathogen or was due to environmental factors. For example, what were the workers doing when they fell ill? Was a chemical being manufactured when the workers became sick? Was a ship docked at that time? If so, where did the ship come from?
   - **Population:** Dana attempted to create a profile of the workers who fell ill. She determined that the workers performed similar jobs in the same location and shared a similar set of physical characteristics.
   - **Available infrastructure:** Dana's team devised a set of tests to detect the presence of a chemical in the affected workers' bloodstreams. Dana's task was to determine if the laboratory had the equipment, personnel and other infrastructure to collect specimens and conduct the tests.
   - **Actionable data:** Dana and her team were required to determine what of the collected information was useful for not only determining the cause of the illness but also determining how the illness could be prevented in the future.

3. To be developed:
   - Protocols for the tests they devised, including safety instructions and risk assessment.
   - Protocols to effectively communicate how the tests should be conducted in other locations that may face an outbreak of the same illness.
   - Equipment and other infrastructure required to successfully conduct the tests.

4. Quality assurance protocols to ensure that the tests conducted as part of the surveillance project are valid, accurate and reliable.

NEXT STEPS: SUPERVISOR MEETING

Be able to discuss:

- A surveillance project conducted by your laboratory.
- Was your laboratory's participation part of a larger project involving many laboratories?
- Was it in response to an outbreak or was it an actively planned project?
- Is it ongoing or has it concluded?
- What have been the findings to date?
- What action has your public health department taken in response to the issue being studied?

SECTION 6: **ETHICS**

ABOUT THE ETHICS SECTION

Ethics are principles or a set of values held by a person or group. These principles and rules include characteristics such as personal accountability, maintaining confidentiality and, in a public health context, ensuring the accuracy of testing results.

In this section, we will discuss how ethical, professional and scientific behaviors help ensure scientific integrity and sustain effective relationships with stakeholders and the public.

LEARNING OBJECTIVES

Once you have completed all of the materials in this section and met with your supervisor, you should be able to:

- Describe the principles of scientific conduct at it applies to your workplace.
- Locate resources that provide details regarding professional and scientific codes of conduct.

REFLECTION

Describe how these objectives can help you in your position:

ANALYST PROFILE: SANJAY

Sanjay is a new analyst at a state public health laboratory. Sanjay has spent time working on undergraduate biological research in a university setting and understands the ethical considerations involved with his work there. He realizes that plagiarism, falsifying data and not giving proper credit are all unethical.

Now that he is in a public health laboratory with a much broader scope than his university laboratory, he realizes he has just scratched the surface of ethical concerns.

Let's look at some of the areas of ethical responsibility that Sanjay will have to deal with daily as he moves forward in his public health laboratory career.

PRINCIPLES OF ETHICAL PROFESSIONAL CONDUCT

Ethics is the method, perspective or procedure that can help an individual analyze complex issues and even decide how to act in certain situations. An ethical concern is concern with values and principles.

Ethical standards are particularly important for the conduct of scientific research. Government agencies that support scientific research have adopted specific rules and policies related to research ethics.

Examples include:

- National Institutes of Health (NIH)
- Food and Drug Administration (FDA)
- Environmental Protection Agency (EPA)
- US Department of Agriculture (USDA)

You can find out more about these principles by visiting the Resource Library.

ETHICAL CONSIDERATIONS

The functions of the public health laboratory serve to protect the public from disease through identification of pathogens and research on issues of public health concern. Ethical considerations must be at the forefront of any scientists' action in the laboratory.

For example, research must be published in a socially responsible manner. This social responsibility includes the concept of dual-use as scientific discovery can frequently be used for both good and evil.

For an overview of the considerations regarding dual-use, visit the Resource Library and watch the short video, "**Dual-Use Research — A Dialogue"** (https://youtu.be/0yS1ur24j40) presented by the NIH.

ETHICS DILEMMA IN PUBLIC HEALTH

In 2012 the scientific community faced a dual-use dilemma. Two researchers developed a genetically engineered strain of the H5N1 avian influenza virus, commonly known as the "bird flu." Results of the research potentially contributed to understanding of how the virus could be transmitted between humans. Controversy soon erupted surrounding the dual-use dilemma and publication of the results of the research.

The concern was that publication could lead to a pandemic as a potentially lethal pathogen was released into the human population either:

- By means of a laboratory accident as scientists attempted to duplicate the research, or
- Through criminal activity that could lead to the unleashing of a terrorist weapon.

Researchers, public health and government officials questioned whether the benefits gained by publication of the research outweighed the risks of the potential release of a pandemic. The results of the research were eventually published but the controversy continues.

If you would like to read more about this event, here is a link to the manuscript **H5N1 Avian Flu Research and the Ethics of Knowledge** (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3953619/), written by David Resnick, in your Resource Library.

In addition to dual-use research, ethical considerations also apply to:

- Research and human subjects
- Patient privacy
- Animal welfare

HUMAN SUBJECTS PROTECTION

Research on human subjects brings up many ethical concerns and is tightly regulated by government and academic institutions.

Three basic ethical principles from the **Belmont Report**, created by the Office for Human Research Protections, form the basis for these policies and regulations:

Respect for Persons

Individuals should be treated as autonomous agents and persons with diminished autonomy should be protected. A basic example is protection of personal information. This means an individual's opinions and choices must not be restricted. It also means that researchers must protect children, as well as the ill and mentally disabled.

Beneficence

Researchers are obligated to maximize possible benefits and minimize possible harms to both research subjects and society at large. An example would be research on childhood illness that presents risks without immediate benefits to the children involved.

Justice

Injustice occurs when an individual is unfairly denied a benefit or when a burden is unfairly imposed. For example, historically the burdens of serving as research subjects fell largely on the poor while the benefits of improved medical care flowed to wealthier patients.

To read the **Belmont Report** or find out more about the Office of Human Research Protections, visit the Resource Library.

INFORMED CONSENT

Informed consent is one of the main tenets upon which human subject research is based. Without it, the research cannot be considered to be ethical.

All participants in a research study must understand the purpose, the procedures, the potential risks and benefits of their involvement and their alternatives to participation.

For additional information about the requirements of informed consent, visit the Resource Library.

PATIENT PRIVACY

HIPAA or Health Insurance Portability and Accountability Act of 1996 is United States legislation that provides data privacy and security provisions for safeguarding medical information.

The HIPAA Privacy Rule establishes national standards to protect individuals' medical records and other personal health information and is applicable to institutions that conduct research.

Laboratories are permitted to use or disclose for research purpose health information which has been de-identified, in accordance with specific parameters.

The Privacy Rule protects the privacy of individually identifiable health information, while at the same time ensuring that researchers continue to have access to medical information necessary to conduct vital research.

ANIMAL WELFARE

The issue of using animals in scientific research is controversial. The position of the federal government on the issue is:

"The use of animals is instrumental in certain research and education for advancing knowledge of cures and treatment for diseases and injuries which afflict both humans and animals."

The Animal Welfare Act is the only federal law in the US that regulates the treatment of animals in research. The law was later amended with the addition of the Improved Standards for Laboratory Animals Act. This amendment created new minimum standards for the handling, housing, sanitation, feeding and other care practices of animals used in laboratory research. The psychological well-being of animals was also taken into consideration.

Each research facility is to establish an Institutional Animal Care committee to oversee research proposals and provide oversight for animal experimentation.

The Public Health Service Policy on Humane Care and Use of Laboratory Animals is applicable to all public health service conducted or supported activities involving animals.

The policy does not affect applicable state or local laws or regulations that impose more stringent standards for the care and use of laboratory animals.

For guidance on the use of laboratory animals consult the *"Guide for the Care and Use of Laboratory Animals"* and the Animal Research Advisory Committee Guidelines in the Resource Library.

KNOWLEDGE CHECK

Earlier in this section we discussed the principles of ethical professional conduct and four agencies were mentioned:

- National Institutes of Health (NIH)
- Food and Drug Administration (FDA)
- Environmental Protection Agency (EPA)
- US Department of Agriculture (USDA)

Select one of these agencies and locate their ethics policies on their website. Write down the agency that you have selected and 3 facts that you have learned from their policies.

CASE STUDY: HENRIETTA LACKS

Let's consider a real-life ethics case, described in the book *The Immortal Life of Henrietta Lacks*, by author Rebecca Skloot.

In 1950, Henrietta Lacks, a poor African-American woman in her early 30s, was admitted to Johns Hopkins Hospital for treatment of cervical cancer. During surgery, Henrietta's cells were harvested without her consent or knowledge and were cultured and grown for further research, becoming the HeLa cell line, the first immortal cell line.

Because of the unique nature of her cells, they ended up being used by research facilities for countless studies around the world, generating a multimillion dollar industry around the production and use of the HeLa line, continuing on to this day.

Research involving HeLa has led to medical and scientific breakthroughs. It has also lead to new and evolving policies concerning patient and research subject rights.

Based on what you know of Henrietta Lacks' story, what considerations were ignored during her care and what negative effects might this bring about?

Case Study Resolved

1. No informed consent was given: Mrs. Lacks did not give permission for her cells to be harvested and in fact, was not even asked.
2. Lack of beneficence and justice: There was no benefit for Mrs. Lacks to provide her cells and her family also received nothing, despite the untold number of medical and scientific breakthroughs and the money made from the discoveries. A year later, Mrs. Lacks died due to her illness and her family continued to struggle living in poverty.
3. Loss of privacy: Mrs. Lacks name was used during the research and due to the publication of the article, her family lost all anonymity.
4. Ethical dilemma: Did the merits of scientific and medical discovery outweigh the lack of benefit and privacy to Mrs. Lacks' family?

NEXT STEPS: SUPERVISOR MEETING

Meet with your supervisor to discuss:

- Principles of scientific conduct as it applies to your laboratory
- Your answers to the Henrietta Lacks case study

SECTION 7:
SAFETY, EMERGENCY MANAGEMENT AND RESPONSE

ABOUT THE SAFETY, EMERGENCY MANAGEMENT AND RESPONSE SECTION

Safety focuses on the occupational and personal safety of staff members and the environments in which they work.

A safety culture is fundamental to ensuring the protection of the laboratory facility, its staff and the surrounding environment from hazards and risks related to laboratory operations and services. Safety is the background against which all staff members must perform all aspects of their job. A culture of safety recognizes that to err is human and establishes procedures and processes to minimize errors and avoid harm.
To be effective, all staff members are expected to be part of the culture of safety.

Emergency management and response addresses the need to mitigate, prepare for, respond to and recover from laboratory-specific emergency events and situations.

LEARNING OBJECTIVES

Once you have completed all of the materials in this section and met with your supervisor, you should be able to:

- Identify and describe policies, practices and procedures required to mitigate safety hazards in a public health laboratory.
- Describe public health laboratory emergency response protocols.
- Describe public health laboratory incidence response plan and any other necessary emergency preparedness activities.

REFLECTION

Describe how these objectives can help you in your position:

ANALYST PROFILE: SHERRY

Sherry has been working in her public health laboratory for a few months.

During her time there, there have been no safety incidents and she has gotten comfortable working with the various samples, even though many of them can be potentially dangerous.

Let's see what happens on this particular day.

LABORATORY ACCIDENT

When working with dangerous materials, safety is a major concern not only for the public but for the laboratory workers as well.

Sherry was using an autoclave to destroy *Mycobacterium tuberculosis* cultures after specimen testing was completed. She was using a biosafety containment unit and was wearing a lab coat and gloves. However, she was not wearing any respiratory protection. Gaskets on the autoclave failed and contaminated steam was released into the room, exposing Sherry and her co-workers to the TB pathogen.

Outcome

Investigation of both the incident and existing procedures determined that it was unclear who was responsible for maintaining the autoclave.

It was also determined that there was no personal protective equipment (PPE) requirement sufficient to protect an operator from exposure, should the autoclave fail.

Several of Sherry's co-workers noticed the gaskets needed replacement but did not report it to management. The equipment was left in disrepair until it failed. Subsequently, Sherry and her laboratory co-workers had to be tested for tuberculosis.

Corrective Action

Management instituted revised operating procedures for the autoclave. Procedures required operators to wear respiratory protection whenever operating an autoclave. They also required that operators must stop using an autoclave anytime there was a deviation in the condition of the gaskets and report the need for maintenance to a designated equipment manager.

Debrief

The cause of this incident was a deficiency or breakdown in the "psychology of safety" or as it's more commonly called, "safety culture".

Safety culture can be defined as the product of individual and group values, attitudes, perceptions, competencies and patterns of behavior that determine the commitment to, and the style and proficiency of, an organization's health and safety management.

Organizations with a positive safety culture are characterized by communications founded on mutual trust, by shared perceptions of the importance of safety and by confidence in the efficacy of preventive measures.

Organizations with a deficient safety culture can be characterized by complacency and an attitude that safety measures are only important when someone is watching or when an inspection is anticipated.

In the case of the autoclave, the operators knew the gaskets needed to be replaced but, as a "safety culture" was lacking, all of them failed to take responsibility for ensuring safety and report the problem.

This resulted in Sherry and her co-workers being exposed to a dangerous pathogen.

BIOLOGICAL SAFETY LEVELS

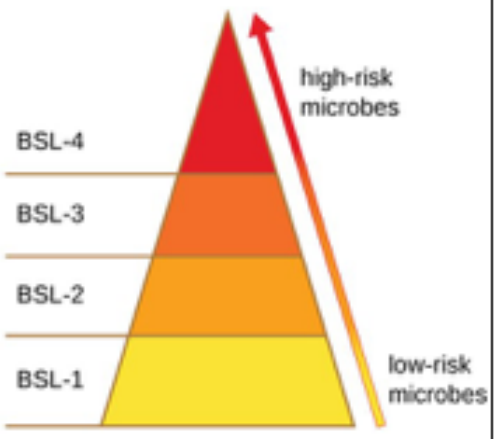
Biological safety (or biosafety) levels (BSL) are based on the types of organisms or agents being housed at a facility and range from Level 1 to 4.

The higher the level, the more risk posed to the public and danger involved in working with the organisms/agents housed there.

The laboratories that students use in high school and college are Level 1, while most public health laboratories are typically biosafety Level 2 or 3.

The US Centers for Disease Control and Prevention, which conducts research on life threatening illnesses such as smallpox, and the US Army Medical Command laboratories at Fort Detrick, Maryland, which studies potential bioterrorism agents, are examples of Level 4 laboratories.

Visit the Resource Library if you would like to learn more about the various biosafety levels.

Biosafety Levels			
Biological Safety Levels	**Description**	**Examples**	**CDC Classification**
BSL-4	Microbes are dangerous and exotic, posing a high risk of aerosol-transmitted infections, which are frequently fatal without treatment or vaccines. Few labs are at this level.	Ebola and Marburg viruses	
BSL-3	Microbes are indigenous or exotic and cause serious or potentially lethal diseases through respiratory transmission.	*Mycobacterium tuberculosis*	
BSL-2	Microbes are typically indigenous and are associated with diseases of varying severity. They pose moderate risk to workers and the environment.	*Staphylococcus aureus*	
BSL-1	Microbes are not known to cause disease in healthy hosts and pose minimal risk to workers and the environment.	Nonpathogenic strains of *Escherichia coli*	

HAZARD VS RISK

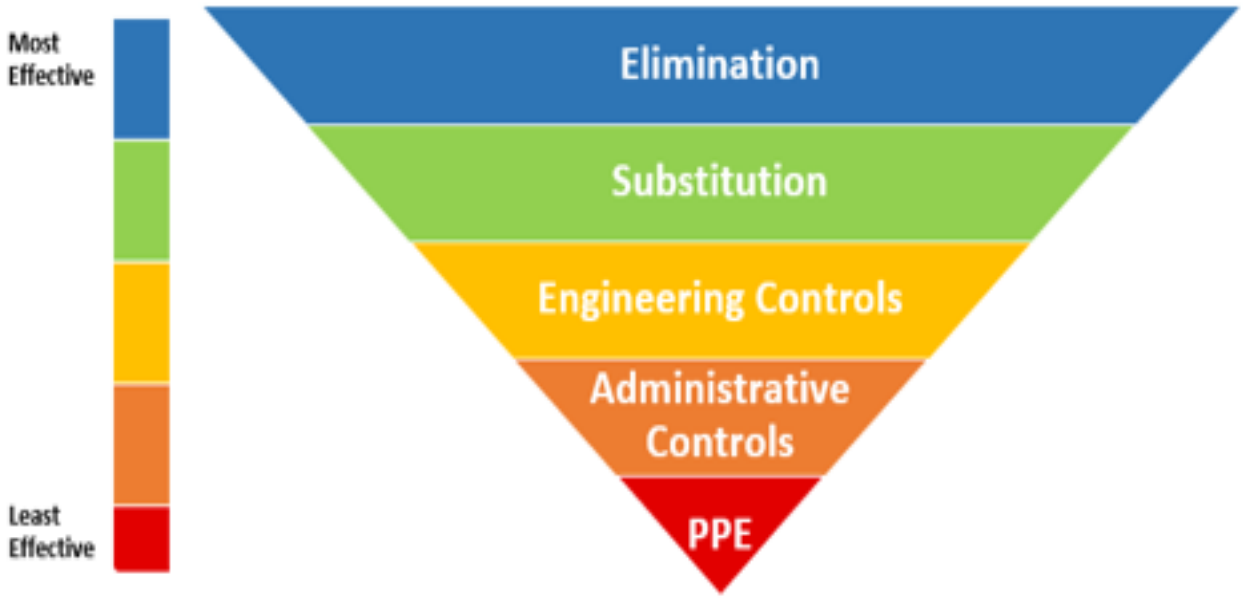
Key terms in an occupational safety context:

- **Hazard:** any source of potential damage, harm or adverse health effects. Exposure to a hazard will not necessarily always cause harm.
- **Risk:** the chance or probability that a person will be harmed if exposed to a hazard. Risk is the combination of the likelihood of the occurrence of harm and the severity of that harm.

Laboratory-related example: *Brucellosis* – a BSL 3 organism that is highly infectious. It is the hazard.

- If worked up in a biological cabinet, there is decreased risk.
- If worked up in a cabinet with gloves and lab coat, risk is decreased further.
- If worked up in a cabinet with respiratory protection, risk is decreased to low to moderate.

HIERARCHY OF HAZARD CONTROLS



The Hierarchy of Hazard Controls is a system of control methods used to minimize or eliminate exposure to hazards. Control methods at the top of the graphic are potentially more effective and protective than those at the bottom.

Following this hierarchy normally leads to the implementation of safer systems, where the risk of illness or injury has been substantially reduced.

Elimination and Substitution

Elimination and Substitution entails physically removing or replacing the hazard and are the most effective controls. This is not always possible in a public health laboratory context, as one purpose of the laboratory is to test dangerous pathogens. However, other hazards such as trip hazards, overloaded electrical plugs and malfunctioning equipment can be removed or replaced.

Engineering

Engineering precautions do not eliminate hazards but rather isolate people from them or provide tools to help them mitigate the effects. This includes solutions such as locked doors restricting access to the laboratory, eye wash and shower stations and specialized cabinets and ventilation systems.

Administrative Controls

Administrative controls are controls for or changes to the way people work. This can include standard operating procedures, equipment manuals, staff training and installation of signs and warning labels.

Personal Protective Equipment

Personal Protective Equipment (PPE) includes gloves, laboratory coats, safety glasses and respirators. These are considered the last line of defense because personal protective equipment may fail without warning. Gloves can be punctured or respirators can malfunction. A PPE program should be in place specifying how and what PPE should be worn.

To learn more about each level, visit the Resource Library.

ADMINISTRATIVE CONTROL EXAMPLE: SAFETY DATA SHEETS

Safety data sheets describe the properties and potential hazards of a hazardous material or product. It includes information on how to use the product or material, as well as instructions on storage, use, transportation and what to do in an emergency. Sheets can be created by manufacturers or government agencies.

Safety data sheets should be available for all chemicals, reagents, and bio organisms. Data sheet information should be updated every three years at minimum or immediately if there are any changes made to the product. Laboratory staff should consult this information about the materials in their own labs, before using them.

Please visit the Resource Library for specific examples of safety data sheets.

KNOWLEDGE CHECK

Identify one engineering control and one administrative control in place for a hazard at your lab.

Locate and read a safety data sheet for a chemical or reagent commonly used in your laboratory. What topic did your data sheet cover?

RISK MITIGATION

Risk mitigation are steps taken to reduce the likelihood and severity of harm. It is the final product of a risk assessment strategy.

Steps of Risk Assessment:

Hazard Identification: finding, listing and characterizing hazards such as biohazards, fire, physical hazards such as trip hazards or other potential injury, workplace violence and external hazards such as adverse weather, natural disaster, nearby industrial accidents or terrorism.

Risk Analysis: determine the likelihood and potential severity of harm of identified hazards. Identifying who may be at risk — staff, contractors, visitors, etc.

Risk Evaluation: estimating the likelihood and potential severity of harm posed by each hazard.

Hazard controls are then planned, implemented and periodically evaluated. At this stage risk is considered mitigated.

INFORMATION SECURITY

Information security is a hazard in a public health lab. Like safety culture, labs need to foster a "security culture", as laboratory information systems contain sensitive information.

Engineering controls include restricted access to computer systems as well as technological safeguards for the computer network.

Administrative controls include restricting access to certain areas to authorized personnel only, work practices such as restricting the use of USB flash drives and general security considerations, such as being aware of who is in the lab at all times.

Laboratory staff are prevented by law from examining individual patient information unless specifically necessary.

WORKPLACE VIOLENCE

The Occupational Safety and Health Administration (OSHA) defines workplace violence as "any physical assault, threatening behavior or verbal abuse occurring in the work setting" and it is a hazard.

Engineering controls such as building security, adequate parking lot lighting and restricted access can mitigate external risks posed.

However, internal risks can be encountered and can include bullying, verbal and emotional abuse and sexual harassment. Administrative controls should include zero-tolerance policies for employees and visitors who display
these behaviors.

Workers should also be responsible for their own safety and be aware of potential areas of risk, such as working alone after usual business hours or allowing unauthorized people into secured areas.

Public health care workers can also be exposed to violence while working in emergency conditions out in the community, especially in areas of political unrest or places that have suffered a catastrophe and people are panicked.

Please visit the Resource Library for more information.

SUSPICIOUS PACKAGE

You have discovered a duffel bag or suspicious package in a corridor.

How could this kind of hazard have been prevented?

What would you do?

What policies or procedures are in place at your laboratory that would deal with this situation?

Who could you ask to find out what to do?

Activity Response: Suspicious Package

1. Consider the security arrangements at your laboratory. What doors are locked? Is there a guard desk? What are your policies regarding visitors?
2. Move away. Notify your supervisor. Follow your local procedures for evacuating the building.
3. Ask your supervisor about your laboratory's procedures and familiarize yourself with them.
4. Speak with your supervisor about proper protocols for your laboratory.
   NOTE: You will be discussing this further when you meet with your supervisor.

ABOUT EMERGENCY MANAGEMENT AND RESPONSE

This portion of the section addresses the need to respond to and recover from laboratory-specific emergency events and situations.

Emergency management and response encompasses events such as natural disasters, public health emergencies and facility or operation failures. In addition, this pertains to the laboratory's responsibility to detect and respond to real or potential biological, chemical or radiological threats.

Emergency management and response is basically thinking of what dangerous situations could happen and writing procedures to prevent or deal with the situation. How can you keep your people safe and still have the laboratory function?

ANALYST PROFILE: BEV

Bev works in a state public health laboratory located in a largely rural area.

Each year, the laboratory must respond to hazards that occur due to seasonal flooding, caused by rain and melted snow runoff from the mountains.

Bev has been asked to help create an emergency response plan in answer to this situation.

Let's look at some of the situations that Bev may need to consider when putting an emergency plan together.

- The flooding causes water well contamination, as flood waters wash agricultural wastes into wells in remote areas and sampling must be done to test the safety of the local drinking water.
- Some water sampling is done by public health officials, who bring their samples with them back to the laboratory and some by land owners, who send the samples in via couriers.
- To conduct valid samples testing, water samples must be received at the laboratory within 30 hours of the time they were collected.

RESPONSES TO THE EMERGENCY

Some of the steps that Bev should advise the laboratory to create include:

- Specific water sample collection and transportation procedures and protocols.
- A training and communications program for all stakeholders, private landowners and laboratory staff who will be involved.
- Local emergency response coordinators and private couriers, such as FedEx and UPS, will also need to be made aware of the time sensitive nature of water sample delivery in this type of crisis.

As you can see, an effective response to this one emergency requires considerable planning, coordination with many outside entities and effective execution of training and communication strategies.

In other circumstances, laboratory staff may need to work closely with first responders, such as fire and police officers, as well as local, state and federal agencies, such as Homeland Security.

Bev sees that a clear communication plan and cross agency training are necessary for everyone to perform their jobs in an effective way.

EMERGENCY PREPAREDNESS

External

Public health laboratories must be prepared to respond to emergencies both within the laboratory, as well as the community.

Examples of external emergencies include incidents such as:

- Natural disasters
- Industrial accidents
- Bioterrorism

An infectious disease outbreak can also be considered an emergency but, as this is related to the primary purpose of a public health laboratory, it is considered a separate issue.

Internal

Labs must also prepare for internal emergencies such as:

- Fire
- Bomb threats
- Suspicious packages
- Intruders / workplace violence
- Chemical spills
- Air contamination
- Flooding

Like external emergencies, these require careful risk assessment, planning and effective communication with the appropriate people both in and out of the laboratory environment.

KNOWLEDGE CHECK

Have there been any emergency incidents, internal or external, that your laboratory has been involved with?

How was the situation handled?

NOTE: You will be discussing this further when you meet with your supervisor.

EMERGENCY RESPONSE PLANS

In addition to having plans in place to deal with specific emergencies in the community, a laboratory must have contingencies in place to protect the integrity of the laboratory. It needs an emergency response plan.

An emergency response plan is a document outlining the actions laboratory leadership must take in response to an internal or external threat. These plans vary by laboratory but they are relatively brief and easily accessible.

Some of the things planners must consider are:

External Threats and Potential Emergencies

The physical location of the laboratory, as well as the surrounding environment, must also be included in the plan. Planners must look at what has happened in the past, as well as what could potentially happen.

Availability and Capabilities of Required Resources

For internal threats, personnel roles and responsibilities are created. For external threats, factors such as the availability and response times for fire, police and emergency medical services are incorporated into the plan.

Communications and Training

Written procedures alone are insufficient. External resources required to respond to an emergency can include the public and outside entities, such as couriers and other businesses. They must know what to do and how to do it. Training includes regular drills that facilitate practice for different emergencies. As plans are executed in practice, they are reviewed and revised as needed.

GENERAL PLANS

A general plan is a document outlining incidents that could possibly happen in and around the laboratory, as well as information that laboratory leadership can use for planning.

The general plan works along with safety and security plans and can include information about:

- Necessary training for staff
- Rescue procedures
- Needed security measures
- Specific emergency procedures for fire and gas leaks, power outage, alarms in the lab, suspicious packages, bomb threats, or workplace violence.

General plans contain basic information that is applicable across all laboratories but also specific information depending on a laboratory's biosafety level (BSL).

CASE STUDY: MANUFACTURING PLANT EMERGENCY RESPONSE PLAN

A paint manufacturing plant has begun construction in the same county as your laboratory.

While this is good news for the local economy, as with all industrial sites, it comes with challenges, including catastrophic events, such as a fire outbreak.

Industrial sites contain any number of dangerous combustibles, including metals, chemicals and possibly aerosols.

These all have the potential to affect not only the plant site but the surrounding community, especially if there is a major water source that flows out of the immediate area.

Your job is to assist with creating an emergency response plan in the event of a fire outbreak. What would you include in the plan?

Case Study Resolved

1. Make sure that your laboratory and its workers have the proper qualifications to assist. If not, you may need to work with another laboratory nearby.
2. Make sure your laboratory has appropriate internal resources (type and quantity) such as test kits and equipment.
3. Assign coordinator roles for each functional area within the laboratory (laboratory, analysis, quality assurance, monitoring and communication).
4. Work with local emergency officials and first responders to establish chain of command, as well as communication and training plans, including practice drills.
5. Coordinate with local health care providers to develop a plan for collecting, handling, testing and disposing of samples. A transfer of data also needs to be planned.

NEXT STEPS: SUPERVISOR MEETING

Meet with your supervisor and discuss the following situations:

1. You have discovered a duffel bag or suspicious package in a corridor.
    - How could this kind of hazard have been prevented? Think of possible engineering and administrative controls that could be useful in this situation.
    - What would you do?
    - What policies or procedures are in place at your lab?
    - Who could you ask to find out what to do?
2. Have there been any emergency incidents, internal or external, that your laboratory has been involved with? How was the situation handled?

SECTION 8: **QUALITY MANAGEMENT SYSTEMS**

ABOUT THE QUALITY MANAGEMENT SYSTEMS SECTION

The first responsibility of public health laboratories is to provide quality testing services to support the health of the public and meet the many needs of internal and external customers.

In this section, we will discuss how a quality management system (QMS) provides a systematic approach to all the business processes required to ensure the consistent quality of tests performed, products created and the data reported.

LEARNING OBJECTIVES

Once you have completed all of the materials in this section and met with your supervisor, you should be able to:

- Describe principles of a quality management system as they apply to research and laboratory operations.
- Illustrate the laboratory's relevant organizational structure and processes.
- Identify non-conforming events using given pre-analytical, analytical and post analytical indicators.
- Describes policies, processes and procedures related to the Continuous Quality Improvement (CQI) program.

REFLECTION

Describe how these objectives can help you in your position:

ANALYST PROFILE: RAYMOND

Raymond is concluding his first week as a new analyst at a state public health laboratory.

He has just been tasked with testing several specimens for the presence of a particular pathogen.

As Raymond examines the protocols and procedures he will need to follow to conduct the test, he is surprised to learn that the quality control procedures are extensive.

Coming from an academic background, Raymond is familiar with using control specimens in testing but he has discovered that quality management impacts just about every aspect of laboratory operations.

WHAT IS A QUALITY MANAGEMENT SYSTEM?

A quality management system, or QMS, can be viewed as a set of policies, processes and procedures that provide a comprehensive structure for both the planning and execution of the many complex operations that take place in a public health laboratory. It can also be a guiding philosophy that ensures laboratory processes are managed for quality.

A QMS has broad impact. It ensures that staff are properly trained, that equipment is monitored for performance and accuracy and it ensures that the complex processes surrounding the generating, interpreting and recording of data are executed consistently. When problems arise, a QMS ensures consistent mitigation of these issues.

Implementation of a QMS is an evolving state in many laboratories. Depending on the size and complexity of operations, a public health laboratory may have one or more managers dedicated to defining the processes and developing the documentation required to implement a quality framework.

The consequences of not developing a robust QMS are far-reaching. This can include:

- Inefficiencies, such as cost overruns and invalidated tests.
- Negative impact on individual patient treatment.
- Regulatory sanctions, such as loss of accreditation or certification.

There is currently no comprehensive quality management system that can be applied to all public health laboratories. Fortunately, APHL does provide a general framework and guidance on writing a laboratory quality manual.

For more information about the laboratory quality manual, visit the Resource Library.

QUALITY SYSTEM ESSENTIALS

The twelve quality system essentials, or QSEs, are a general framework that will be applied according to the needs of the individual laboratory. However, it will provide a good understanding of the different and overlapping aspects of a laboratory's operations a QMS may impact. These include:

Organization

The organizational structure of the laboratory, personnel roles and responsibilities, hiring and management policies, as well as policies for communication within the laboratory.

Personnel

Training processes, such as new employee orientation and continuing education, competency assessment, personnel qualification standards and policies on knowledge retention.

Equipment

How equipment is installed and operated. This can include validation or verification, maintenance procedures, calibration procedures, as well as decontaminating and decommissioning protocols.

Facilities and Safety

The laboratory's physical space. This can include building maintenance schedules and responsibilities, security policies and protocols, regulated hazardous waste disposal and building safety features.

Purchasing and Inventory

The laboratory's procurement processes such as contracts, vendor selection and ordering. Inventory processes include receiving, storing and managing reagents and supplies, as well as equipment.

Information Management

Information stored on both paper and electronic record keeping systems, information security issues such as computer access and use, records disposal, transmission of public health information and data integrity. This QSE can also address data backup procedures, laboratory information management system (or LIMS) operation and technical support.

Documents and Records

Document control and records management, record retention and disposal, archiving and management of standard operating procedures (SOPs). Document control is an important part of effective quality management, as many policies and procedures are constantly being updated and revised and versions must be tracked and individual revisions must be identified so as to keep all personnel apprised of changes.

Assessments

Protocols for internal or external monitoring to verify that practices continue to meet regulatory requirements or to determine how well a process or procedure is functioning as part of the overall quality management system. This includes a variety of audits, tests and reviews.

Process Improvements

A process for improving, assessing and monitoring the laboratory's operational protocols and procedures. This includes policies and procedures for determining and executing quality initiatives, management reviews and the setting of quality improvement goals.

Customer Service

Ensures the laboratory's internal and external customers receive data that is of high quality, is exactly what they need, is in the format that they need and is reliable. They identify who the customers are, identify their needs and measure customer satisfaction including processes for complaint identification and resolution.

Continued on the next page.

Process Management

How the laboratory develops, disseminates, controls and changes workflow processes specifically for the three phases of samples testing: pre-analytic, analytic and post- analytic. We discuss these three phases in greater detail in the section on general laboratory practice.

Non-conformance Management

A non-conformance or non-conforming event is defined as an unexpected outcome or result that is an indicator of a problem, such as a breakdown in quality, a process failure or a technical issue. The non-conformance management QSE describes the laboratory's policy around detecting, investigating, reporting and prevention of events that do not conform to existing processes and procedures. It includes root cause analysis and corrective action.

If you are interested in reading the Joint Commissions standards for QSE, please visit the Resource Library.

WHICH QSE WOULD APPLY? PART 1

Imagine you are Raymond and new to your laboratory. Determine which quality system essential (QSE) would apply.

The internal temperature of a refrigerator is too high.

A message has appeared while using the laboratory information management system (LIMS) indicating a software update is available.

The proper way to store reagents.

QSE Responses

1. That would be the equipment QSE. It covers maintenance and use of equipment.
2. We discussed laboratory information management systems (LIMS) in the information management QSE. In most cases, it will likely be best practice to consult your quality processes and procedures before automatically updating any software in the laboratory.
3. Reagents are a consumable and are typically kept in inventory. So the purchasing and inventory QSE would apply. Documentation will likely address keeping inventory, correct storage and dealing with expiration dates.

WHICH QSE WOULD APPLY? PART 2

Determine which QSE would apply:

You are about to receive several specimens for testing.

The results of your quality checks did not indicate expected results.

You believe you have found a more efficient way to complete a laboratory process.

QSE Responses

1. The answer is the process management QSE. This is the QSE that would address the pre-analytic phase of the samples testing process along with the analytic and post-analytic processes.
2. This result could be considered a non-conformance and call for a root cause analysis. The answer would be the non-conformance management QSE.
3. The process improvement QSE should specify a procedure for revising a process. The document and records QSE would likely apply as well, as this QSE specifies how SOPs and other similar documents are revised and updated.

QUALITY INDICATORS

Quality indicators are measures that make use of readily available data that can be indicative of a quality issue. They are indicators that can typically be measured numerically and make use of known correct parameters.

For example, let's consider quality indicators in the specimen testing process.

The process has three phases:

- Pre-analytical
- Analytical
- Post-analytical

A pre-analytical quality indicator could be metrics about the specimen itself, such as temperature or concentration. These indicators can be measured and there are known correct indicators.

An indicator during the analytical phase could be the operating parameters of an instrument. Any indication that testing has fallen outside known parameters could be a signal that something is wrong.

And finally, post-analytical indicators would involve analysis of the test results. This could include wildly erroneous results.

As you can see, these indicators are a signal that something needs the attention required to maintain quality.

CONTINUOUS QUALITY IMPROVEMENT

Continuous quality improvement, or CQI, is a management philosophy that recognizes that most work processes can be incrementally improved. It is the exact opposite of the old saying "If it ain't broke, don't fix it."

A CQI approach does not wait for something to go wrong. Instead, it empowers teams to constantly look for ways to refine what they are doing and improve work processes.

CQI focuses on work processes instead of individuals. It also recognizes and considers the needs of both internal and external customers.

To see an example of a CQI workbook dealing with newborn screening, visit the Resource Library.

RAYMOND AND CQI

For example, our new analyst Raymond has discovered a more efficient way to process specimens as they are delivered to his laboratory.

Instead of letting Raymond take shortcuts and follow his own new improved process, Raymond's supervisor would encourage him to follow procedures through experimentation and documentation of results.

If successful, Raymond's improved process could be adopted as an improved process by the entire team.

CASE STUDY: AN ACCIDENT AVOIDED

In another section, we discussed a laboratory accident.

While destroying cultures in an autoclave, the gaskets on the door failed and released contaminated steam into the laboratory. The person operating the autoclave was not wearing respiratory protection and was therefore exposed to a dangerous pathogen.

Subsequent investigations found that laboratory workers were aware that the gaskets on the autoclave were worn for some time.

Imagine you are performing the same task. You are about to place cultures in an autoclave when you notice the door gaskets are worn and could potentially fail.

How would application of a quality management approach prevent an accident from occurring?

Case Study Resolved

Two quality system essentials apply here:

Equipment

Having procedures and protocols in place that address equipment use and equipment maintenance could ensure that operators complete specific checks before using the autoclave. This approach could also ensure that a particular maintenance schedule was followed, thus preventing the use of the autoclave with worn gaskets.

Facilities and Safety

Having procedures and protocols that address use of PPE would ensure that the autoclave operator was wearing respiratory protection. Safety protocols could also ensure that an unsafe condition was reported and addressed. In this case, that condition would be the worn gaskets on the autoclave.

NEXT STEPS: SUPERVISOR MEETING

Meet with your supervisor to:

- Illustrate your laboratory's organizational structure relevant to QMS.
- Present an example of application of QMS at your laboratory.

CONCLUSION

Thank you for completing the APHL New Employees Orientation Guide series. These APHL activities will serve as the foundation for continued development of your knowledge and skills for some of the most critical competencies required for a successful public health laboratory career.

Association of Public Health Laboratories

The Association of Public Health Laboratories (APHL) works to strengthen laboratory systems serving the public's health in the US and globally. APHL's member laboratories protect the public's health by monitoring and detecting infectious and foodborne diseases, environmental contaminants, terrorist agents, genetic disorders in newborns and other diverse health threats.

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