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RISK ASSESSMENT SCENARIO

Laboratories and laboratory networks consist of independent laboratories and laboratory departments. This scenario describes a laboratory with several independent departments that have varying hazards and risks. Each group will represent a laboratory department, and will be expected to identify the hazards and analyze the risks. Subsequently, all groups will identify similarities and differences in risk and will begin to understand how hazard identification and risk assessment can be done collectively by an institution with distinct departments and by laboratory networks.

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Scenario Description and Instructions

The Central Veterinary Laboratory represents a laboratory with independently functioning departments. The concepts used to identify hazards, analyze risk, and establish a standardize process to conduct risk assessment can also be applied to laboratory networks.

The objectives of this exercise are as follows:

1. Enable participants to identify laboratory hazards and consider the impact that they may have on laboratory staff and their families, the community, the surrounding animal population, and the environment

2. Enable participants to consider these hazards, characterize as safety and security risks, and evaluate the potential likelihood and consequences of each adverse effect

3. Enable participants to begin to consider standardization of the risk analysis process across departments and laboratory networks

The Central Veterinary Laboratory

The Central Veterinary Laboratory (CVL) is in the country's capital and is responsible for the diagnosis and characterization of animal diseases. In recent years, the country has suffered from multiple outbreaks of foot and mouth disease (FMD), avian influenza, and Pestes des Petits Ruminants (PPR).

The CVL consists of several departments that are responsible for the diagnosis of infectious and non-infectious diseases of animals. The departments are as follows: 1) Bacteriology; 2) Virology; 3) Parasitology; 4) Hematology and Biochemistry; 5) Necropsy; 6) Molecular Biology/PCR; 7) and Sample Receiving. The laboratory is in a country that currently has a problem with Foot and Mouth Disease (FMD) caused by strains A, O, and Asia 1, Brucellosis, anthrax, Pestes des Petits Ruminants, New Castle Disease, avian influenza, infectious bursal disease, rabies, diarrheal diseases of ruminants, bovine abortions, Rift Valley Fever, and respiratory disease of ruminants including contagious caprine pneumonia. Recently, a unique strain of foot and mouth disease virus was identified along the southern border. Additionally, many cases of brucellosis have been identified in humans in the capital; therefore, the Ministry of Agriculture initiated a brucellosis control program that requires extensive laboratory services.

The laboratory receives samples from farmers, private and public-sector veterinarians, and in cases of a severe outbreak, the laboratory sends staff members to the site of the outbreak to collect samples. The samples enter the laboratory through Sample Receiving. The samples are distributed to individual departments by staff in Sample Receiving.

Each laboratory department functions independently. The departments occasionally exchanged or refer samples to other departments when a challenging case is encountered. In addition, laboratory departments also refer samples to OIE reference laboratories when am emerging disease is suspected or when they believe the disease-causing agent is too dangerous to handle. These samples are processed for shipment through Sample Receiving.

The laboratory is in the center of the city, in a region with an increased threat of terrorism. In addition, the CVL also provides oversight of ten provincial laboratories that can conduct routine tests for enteric and blood parasites, basic hematology, basic veterinary care, and sample collection and processing. The laboratory is surrounded by a large fence. The entrance is locked outside of business hours, and there are two guards at the laboratory entrance during the day. The staff are not required to wear badges.

Bacteriology

Bacteriology is responsible for the diagnosis and characterization of disease causing bacteria in animals. The laboratory uses isolation and culture of pathogens as one of many methods to diagnose bacterial diseases including salmonellosis, colibacillosis, *Pasteurella* and *Mannheimia* pneumonia, anthrax, and contagious caprine pneumonia. In some cases, the laboratory conducts antimicrobial sensitivity testing using the Kirby-Bauer method. In addition, Bacteriology staff will occasionally conduct isolation and culture on suspected Brucellosis cases when there are outbreaks of abortion in ruminants. All work with *B. anthracis*, *B. mallei*, and *Brucella sp*. is done in the Class II biosafety cabinet.

The laboratory also evaluates specimen smears using microscopy from tissues and abscesses. Bacteriology also conducts milk ring tests for Brucellosis diagnosis. The laboratory is working with the molecular biology section to establish PCR based assays for *Brucella sp*. and *Bacillus anthracis* to minimize staff exposures, but currently there are no PCR based assays in the laboratory. Most of the testing protocols used in Bacteriology require isolation and culture of pathogens.

Currently samples are transferred to Bacteriology from Sample Receiving, and in some cases, Necropsy. Sample Receiving does not open the packages and distributes the specimens based on the clinical history provided by the farmer and/or referring veterinarian. Bacteriology staff open the sample in the Class II biosafety cabinet located in the laboratory. The staff typically use personal protective equipment to open the samples and begin the testing protocols.

The laboratory disposes of needles, blades and microscope slides in a plastic container labeled with a black marker. The sharps are then placed in the incinerator and burned along with tissue and other biological waste.

Bacteriology stores isolates in a -80-degree Celsius freezer located inside Bacteriology. Bacteriology does not have an inventory system nor are there any security measures in place in the laboratory.

- What are the hazards in Bacteriology?
    - Consider the categories of hazards discussed in Hazard Identification?
- Characterize the identified hazards.
    - What tests are done?
    - Are they hazardous?
    - What can go wrong? (Safety and Security)
    - Is the hazard present outside of the laboratory?
    - Does prophylaxis exist?
    - Is there is an efficacious therapy
- Assess Risk
    - What is the impact of a release on the animal and human populations?
    - What are the likelihood and consequences of a release?
    - Use the flow chart from the OIE Terrestrial Manual Chapter 1.1.4. to work through risk assessment?
    - Are there existing mitigation measures?

Virology

Virology is responsible for the diagnosis and characterization of viral diseases of animals. The virology section uses serology, ELISAs and lateral flow assays to diagnose viral diseases of animals. The most common diseases include FMD, PPR, sheep and goat pox, avian influenza, infectious bursal disease, and Newcastle Disease. Serology is used to conduct FMD and PPR sero-surveillance. Detection of active viral infections is done using ELISAs and lateral flow assays; these assays provide rapid and accurate results. PCR assays have been developed and standardized and are used to detect and characterize foot and mouth disease virus and avian influenza viruses since identification of serotypes and strains is important. Virology does not conduct any assays that require virus isolation.

Currently samples are transferred to Virology from Sample Receiving, and in some cases, Necropsy. Sample Receiving does not open the packages and distributes the specimens based on the clinical history provided by the farmer and/or referring veterinarian. Virology staff open samples in the Class II biosafety cabinet located in the laboratory. The staff typically use personal protective equipment to open the samples and begin the testing protocols.

The laboratory disposes of needles, blades and microscope slides in a plastic container labeled with a black marker. The sharps are then placed in the incinerator and burned along with tissue and other biological waste.

Virology stores select clinical specimens in a -80-degree Celsius freezer located inside Virology. Most of the samples saved are those containing foot and mouth disease virus and avian influenza virus. Virology does not have an inventory system nor are there any security measures in place in the laboratory. The samples are simply labeled using a marking pen.

- What are the hazards in Virology?
    - Consider the categories of hazards discussed in Hazard Identification?
- Characterize the identified hazards.
    - What tests are done?
    - Are they hazardous?
    - What can go wrong? (safety and Security)
    - Is the hazard present outside of the laboratory?
    - Does prophylaxis exist?
    - Is there is an efficacious therapy
- Assess Risk
    - What is the impact of a release on the animal and human populations?
    - What are the likelihood and consequences of a release?
    - Use the flow chart from the OIE Terrestrial Manual Chapter 1.1.4. to work through risk assessment?
    - Are there existing mitigation measures?

Parasitology

Parasitology is responsible for the diagnosis and characterization of diseases caused by parasites. Parasitology uses sucrose flotation to diagnose intestinal parasites, microscopy to diagnose ectoparasites, and blood smear evaluation to detect blood parasites. Parasitology mostly encounters gastrointestinal parasites including Haemonchus, Trichuris, and Ostertagia in sheep and goats. In addition, Babesiosis and Anaplasmosis are often encountered in blood smears.

There has been an increase in Cryptosporidium cases in dairy calves. The laboratory has recently developed a staining assay to diagnose Cryptosporidium. The laboratory staff wear gloves when handling samples suspected of containing Cryptosporidium because it is infectious to humans.

Currently samples are transferred to Parasitology from Sample Receiving, and in some cases, Necropsy. Sample Receiving does not open the packages and distributes the specimens based on the clinical history provided by the farmer and/or referring veterinarian. Parasitology staff open samples on the laboratory bench. The staff typically wear gloves when opening the samples because often time the fecal samples have leaked.

The laboratory disposes of needles, blades and microscope slides in a plastic container labeled with a black marker. The sharps are then placed in the incinerator and burned along with tissue and other biological waste.

Parasitology does not store any samples. Fecal samples are simply thrown in the garbage, while blood samples are disposed of with other biological waste.

- What are the hazards in Parasitology?
    - Consider the categories of hazards discussed in Hazard Identification?
- Characterize the identified hazards.
    - What tests are done?
    - Are they hazardous?
    - What can go wrong? (Safety and Security)
    - Is the hazard present outside of the laboratory?
    - Does prophylaxis exist?
    - Is there is an efficacious therapy
- Assess Risk
    - What is the impact of a release on the animal and human populations?
    - What are the likelihood and consequences of a release?
    - Use the flow chart from the OIE Terrestrial Manual Chapter 1.1.4. to work through risk assessment?
    - Are there existing mitigation measures?

Necropsy

Necropsy receives living and dead animals for gross pathologic examination to determine the cause of a given illness or death. Necropsy receives many different types of cases including both communicable and non-communicable diseases. In recent years, Necropsy has received cases of anthrax, brucellosis, foot and mouth disease, Rift Valley fever, avian influenza, rabies, and PPR. Post-mortem evaluation requires staff to open the animal with knives and saws. In many cases, the animals are heavy and the facility does not have hoist or pully system to move the animals. Farmers primarily bring dead or sick animals to necropsy. The provide Laboratory Receiving a summary of the illness. Dead animals are admitted through a large door in Necropsy. The Necropsy staff have a cart that the animal is pulled onto and then pushed into the building where the Necropsy is performed.

Necropsy staff wear coveralls, a plastic apron, and rubber boots. If they suspect a zoonotic disease, they wear a surgical mask and protective eyewear. Samples are collected from the dead animals and sent to other laboratory departments based on the pathological findings for confirmatory diagnoses.

When live animals arrive, Necropsy staff must administer euthanasia solution to each animal so that the necropsy can be done.

Carcasses are disposed of using the laboratory incinerator. Unfortunately, the cost of fuel is very high and the incinerator is only used one to two times per week.

- What are the hazards in Necropsy?
    - Consider the categories of hazards discussed in Hazard Identification?
- Characterize the identified hazards.
    - What tests are done?
    - Are they hazardous?
    - What can go wrong? (Safety and Security)
    - Is the hazard present outside of the laboratory?
    - Does prophylaxis exist?
    - Is there is an efficacious therapy
- Assess Risk
    - What is the impact of a release on the animal and human populations?
    - What are the likelihood and consequences of a release?
    - Use the flow chart from the OIE Terrestrial Manual Chapter 1.1.4. to work through risk assessment?
    - Are there existing mitigation measures?

Molecular Biology/PCR

Molecular Biology is a new laboratory department, and the staff are in the process of establishing new assays that can provide sensitive and specific diagnostics infectious diseases of livestock. The laboratory staff has developed assays to target dangerous pathogens so that they can detect the agent without conducting dangerous diagnostic such as isolation and culture. The diagnostic samples still require processing; however, the sample is inactivated for molecular biology shortly after it is opened and labeled. Molecular biology based assays minimize laboratory staff's handling and storage of dangerous agents; therefore, assay development is a priority.

Standardized assays have been established for: Avian Influenza Viruses, Foot and Mouth Disease Virus, *Brucella melitensis*, *Brucella abortus*, and *Bacillus anthracis*.

Currently samples are transferred to Molecular Biology from Sample Receiving, and in some cases, Necropsy. Sample Receiving does not open the packages and distributes the specimens based on the clinical history provided by the farmer and/or referring veterinarian. Molecular Biology staff open samples on the laboratory bench. The staff typically open the samples in the Class II biosafety cabinet.

Molecular Biology stores all samples if they need to be sent to a referral laboratory for further evaluation.

- What are the hazards in Molecular Biology?
    - Consider the categories of hazards discussed in Hazard Identification?
- Characterize the identified hazards.
    - What tests are done?
    - Are they hazardous?
    - What can go wrong? (Safety and Security)
    - Is the hazard present outside of the laboratory?
    - Does prophylaxis exist?
    - Is there is an efficacious therapy
- Assess Risk
    - What is the impact of a release on the animal and human populations?
    - What are the likelihood and consequences of a release?
    - Use the flow chart from the OIE Terrestrial Manual Chapter 1.1.4. to work through risk assessment?
    - Are there existing mitigation measures?

Sample Receiving

All samples are submitted through Sample Receiving. The samples are submitted by farmers and referring veterinarians. In some cases, laboratory staff must respond to an outbreak, and will bring samples back to the laboratory for analysis.

Samples are often dropped off after hours and left in a small refrigerator just outside of the office. The individual submitting the sample is required to fill out a standard form that requests the name and address of the submitting party as well as the signalment and history of the presenting case.

Sample Receiving establishes records for all submissions. The samples are then transported to the most appropriate laboratory for analysis. Sample Receiving staff do not open the samples.

Sample Receiving staff are expected to wear laboratory coats and gloves when handling the packaged samples.

- What are the hazards in Sample Receiving?
    - Consider the categories of hazards discussed in Hazard Identification?
- Characterize the identified hazards.
    - What tests are done?
    - Are they hazardous?
    - What can go wrong? (Safety and Security)
    - Is the hazard present outside of the laboratory?
    - Does prophylaxis exist?
    - Is there is an efficacious therapy
- Assess Risk
    - What is the impact of a release on the animal and human populations?
    - What are the likelihood and consequences of a release?
    - Use the flow chart from the OIE Terrestrial Manual Chapter 1.1.4. to work through risk assessment?
    - Are there existing mitigation measures?

GAP Analysis

Although the above departments function somewhat independently, they are all part of the Central Veterinary Laboratory. In many cases, the individual departments handle dangerous pathogens and have similar practices.

- What steps can the CVL take to improve its overall risk analysis process?
- How can this process be standardized so that all the departments analyze the risks similarly?
- Can the Departments create a standard process?
- How can the departments work together to create a standard process?
- How are policies established and formalized at the level of individual laboratories?
- How are polices established and formalized at the level of a laboratory network?