EPIDEMIOLOGY AND RISK ANALYSIS

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Module Overview

At the end of this session, students are expected to understand the role of epidemiology in understanding events and the importance of the risk assessment process.

Module Competencies

Competencies#1	Learning Objectives to Develop Competencies
Be able to identify the role of epidemiology and risk analysis in a One Health setting.	a) Defining epidemiology/ epizootiology/ population health b) Listing the three components of the epidemiologic triad c) Listing and describing the different modes of transmission of communicable disease in a population d) Describing the elements of a case definition and explain the effect of changing any of the elements e) Listing the key features and uses of descriptive, analytic epidemiology f) Listing and describing primary applications of epidemiology in human and veterinary public health practice

A. INTRODUCTION TO EPIDEMIOLOGY

Epidemiology, epizootiology and population health are all terms describing the study of health and disease in populations, as distinct from individuals. Risk analysis is a systematic approach to evaluating both the likelihood of occurrence and the magnitude of impact if a particular adverse event occurs, and taking steps to mitigate that risk and communicate with relevant stakeholders and populations. Epidemiology and risk analysis are both important to the practice of the One Health approach, and professional health science programs incorporate these topics to some degree in their curricula. Recognizing that a One Health approach is broad and includes many disciplines distinct from health sciences (such as economics, social sciences, law and policy and many others), this module is designed to introduce those with little or no background in epidemiology to the history, concepts, theories, terminology and practice of epidemiology, to improve their ability to collaborate with epidemiologists.

The word epidemiology comes from the Greek words epi , meaning “on or upon,” demos, meaning “people,” and logos , meaning “the study of.” A more usual definition, however, is the scientific study of disease patterns among populations in time and space. Epidemiologists analyze how health-related events are distributed in specific human populations—who gets sick with what illnesses, when, and where. By comparing groups with different illness rates and looking at demographic, genetic, environmental, and other differences among these groups, epidemiologists seek to determine how and why certain groups get sick.

> “*Epidemiology is the* ***study*** *of the* ***distribution*** *and* ***determinants*** *of* ***health-related states or events*** *in* ***specified populations*** *, and the* ***application*** *of this study to the control of health problems.*” Last JM, ed. Dictionary of Epidemiology, Second edition. New York: Oxford U. Press, 1988:42. (17)

Key terms in this definition reflect some of the important principles of epidemiology.

Study

Epidemiology is a scientific discipline, sometimes called “the basic science of public health.” It has, at its foundation, sound methods of scientific inquiry:

Distribution

Epidemiology is concerned with the frequency and pattern of health events in a population. Frequency refers not only the number of such events in a population, but also the rate or risk of disease in the population. The rate (number of events divided by size of the population) is critical to epidemiologists because it allows valid comparisons across different populations.

Pattern refers to the occurrence of health-related events by time, place, and personal characteristics.

- Time characteristics include annual occurrence, seasonal occurrence, and daily or even hourly occurrence during an epidemic.
- Place characteristics include geographic variation, urban-rural differences, and location of worksites or schools.
- Personal characteristics include demographic factors such as age, race, sex, marital status, and socioeconomic status, as well as behaviors and environmental exposures.

Determinants:

Epidemiology is also used to search for causes and other factors that influence the occurrence of health-related events.

Health-related states or events

Originally, epidemiology was concerned with epidemics of communicable diseases. Then epidemiology was extended to endemic communicable diseases and noncommunicable infectious diseases. More recently, epidemiologic methods have been applied to chronic diseases, injuries, birth defects, maternal-child health, occupational health, and environmental health. Now, even behaviors related to health and well-being (amount of exercise, seat-belt use, etc.) are recognized as valid subjects for applying epidemiologic methods. In these lessons we use the term "disease" to refer to the range of health-related states or events."

Specified population

This pertains to affected populations. It should be noted that clinicians are concerned with the health of an individual; whereas epidemiologists are concerned with the collective health of the people in a community or other area. Their work is at different levels.

Application

Application pertains to the fact that epidemiology is intended to provide direction to health decisions. There are two main types of epidemiological studies and combinations thereof namely:

1. **Descriptive**

   In descriptive epidemiology, we organize and summarize data according to time, place, and person. These three characteristics are sometimes called the epidemiologic variables.

   Compiling and analyzing data by time (season, month, day of week and time of day etc.), place (place of residence, birthplace, place of employment, school district, hospital unit etc.) , and person (age, sex, Ethnic and racial groups etc.) is desirable for several reasons.

   First, the investigator becomes intimately familiar with the data and with the extent of the public health problem being investigated. Second, this provides a detailed description of the health of a population that is easily communicated. Third, such analysis identifies the populations that are at greatest risk of acquiring a particular disease. This information provides important clues to the causes of the disease, and these clues can be turned into testable hypotheses.

2. **Analytic**

   This analysis is carried out by comparing groups with different rates of disease occurrence and with differences in demographic characteristics, genetic or immunologic make-up, behaviors, environmental exposures, and other so-called potential risk factors. As such you compare your case (or affected) group with a healthy comparator. These comparison groups, which provide baseline data, are a key feature of analytic epidemiology. When persons with a particular characteristic are more likely than those without the characteristic to develop a certain disease, then the characteristic is said to be associated with the disease. The characteristic may be a demographic factor such as age, race, or sex; a constitutional factor such as blood group or immune status; a behavior or act…"Epidemiology is the study of the distribution and determinants of health-related states or events in specified populations, and the application of this study to the control of health problems." Last JM, ed. Dictionary of Epidemiology, Second edition. New York: Oxford U. Press, 1988:42.

EXERCISE

Discussion

✓ Identify the potential uses of epidemiological studies.

Notes:

B. EPIDEMIOLOGICAL APPROACH

The practice of epidemiology relies on a systematic approach. In very simple terms, the epidemiologist:

- **Counts** cases or health events, and describes them in terms of time, place, and person;
- **Divides** the number of cases by an appropriate denominator to calculate rates; and
- **Compares** these rates over time or for different groups of people.

Before counting cases, however, the epidemiologist must decide what a case is. This is done by developing a case definition. Then, using this case definition, the epidemiologist finds and collects information about the case-patients. The epidemiologist then performs descriptive epidemiology by characterizing the cases collectively according to time, place, and person. To calculate the disease rate, the epidemiologist divides the number of cases by the size of the population. Finally, to determine whether this rate is greater than what one would normally expect, and if so to identify factors contributing to this increase, the epidemiologist compares the rate from this population to the rate in an appropriate comparison group, using analytic epidemiology techniques.

Defining a case

Before counting cases, the epidemiologist must decide what to count, that is, what to call a case. For that, the epidemiologist uses a case definition. A case definition is a set of standard criteria for classifying whether a person has a particular disease, syndrome, or other health condition. By using a standard case definition, every case is diagnosed in the same way and every case is equivalent, regardless of when or where it occurred, or who identified it. Furthermore, the number of cases or rate of disease identified in one time or place can be compared with the number or rate from another time or place. With a standard case definition, when we find a difference in disease occurrence, we know it is likely to be a real difference rather than the result of difference in how case were diagnosed.

A case definition consists of clinical criteria and, sometimes, limitations on time, place, and person. The clinical criteria usually include confirmatory laboratory tests, if available, or combinations of symptoms, signs, and other findings. A case definition may have several sets of criteria, depending on how certain the diagnosis is. For example, during an outbreak of measles, we might classify a person with a fever and rash as having a suspect, probable or confirmed case of measles, depending on what additional evidence of measles is present. In other situations, we temporarily classify a case as suspect or probable until laboratory results are available. When we receive the lab report, we then reclassify the case as either confirmed or "not a case", depending on the lab culture result. In the midst of a large outbreak of a disease caused by a known agent, we may permanently classify some cases as suspect or probable because it is unnecessary and wasteful to run laboratory tests on every patient with a consistent clinical picture and a history of exposure (e.g., chickenpox). However, case definitions should not rely on lab culture results alone, since organisms are sometimes present without causing disease.

Case definitions may also vary according to the purpose for classifying the occurrences of a disease. For example, health official need to know as soon as possible if someone has symptoms of plague or foodborne botulism so that they can begin planning what action to take. For such rare but potentially severe communicable disease, in which it is important to identify every possible case, health officials use a sensitive, or "loose" case definition. On the other hand, investigator of the cause of a disease outbreak want to be certain that any person included in the investigation really had the disease. The investigator will prefer a specific, or "strict" case definition. For instance in an outbreak of *Salmonella agona*, the investigators would be more likely to identify the source of the infection if they included only persons who were confirmed to have been infected with that organism, rather than including everyone with acute diarrhea. The only disadvantage of a strict case definition is an underestimate of the total number of cases.

C. EPIDEMIOLGY IN PUBLIC HEALTH PRACTICE

Epidemiology is a tool that is essential for carrying out four fundamental functions: public health surveillance, disease investigation, analytic studies, and program evaluation.

Public Health Surveillance

Most health departments use simple surveillance systems. They monitor individual morbidity and mortality case reports, record a limited amount of information on each case, and look for patterns by time, place, and person. At the local level, the most common source of surveillance data is reports of disease cases received from health-care providers, who are required to report patients with certain "reportable" diseases, such as cholera or measles or syphilis. In addition, surveillance data may come from laboratory reports, surveys, disease registries, death certificates, and public health program data such as immunization coverage.

Disease Investigation

For some diseases, the objective of an investigation may be simply to learn more about the disease itself—its natural history, clinical spectrum, descriptive epidemiology, and risk factors whereas for others, the objective of an investigation may be to identify a source or vehicle of infection which can be controlled or eliminated.

Analytical

Surveillance and case investigation sometimes are sufficient to identify causes, modes of transmission, and appropriate control and prevention measures. Sometimes they provide clues or hypotheses which must be assessed with appropriate analytic techniques.

Program Evaluation

This component pertains to assessing the effectiveness and efficiency of programs.

Program Evaluation

Characteristic of Surveillance

These are amongst many the important characteristics of surveillance to be taken into consideration while setting the objectives of surveillance

- Timeliness, to implement effective control measures;
- Representation, to provide an accurate picture of the temporal trend of the disease
- Sensitivity, to allow identification of individual persons with disease to facilitate treatment; quarantine, or other appropriate control measures; and
- Specificity, to exclude persons not having disease.

D. RISK MANAGEMENT

Risk assessment is a systematic process for gathering, assessing and documenting information to assign a level of risk. It provides the basis for taking action to manage and reduce the negative consequences of acute public health risks. The risk management cycle includes:

- Risk assessment — hazard, exposure and context assessment and risk characterization in which the level of risk is assigned to the event
- Identification of potential control measures — ranked by priority, taking into account likelihood of success, feasibility of implementation and unintended consequences for the affected population and society more broadly
- Continuous monitoring and evaluation as the event unfolds
- Effective ongoing communication to ensure that risk managers, other stakeholders and affected communities understand and support the control measures that are implemented
- An evaluation of lessons learned at the end of the response.

D.1. Assembling the risk assessment team.

After confirming that a reported event is real and may be considered an immediate public health risk, its public health importance must be determined. Depending on the quality and completeness of the information available to assess the risk, a risk assessment team may be assembled. Deciding on the disciplines that should make up the risk assessment team is a critical step that is often overlooked. Additional expertise (e.g. in toxicology, animal health, food safety or radiation protection) can be brought in at any time but may be needed at the beginning of the risk assessment if: • the hazard is unknown • the event is unlikely to be caused by an infectious agent • an event is associated with disease or deaths in animals, and/or is otherwise identified as a suspected zoonosis • the event is related to a food or product recall, known chemical accident, or radionuclear incident with or without reports of human disease.

Operational communication and risk communication are integral parts of risk management. At a minimum, links should be established between the risk assessment team and communication specialists. If possible, a communication specialist should be included in the risk assessment team. Ensuring that there is good communication between decision-makers and the affected population from the start of the process will increase the likelihood of effective implementation of control measures, especially those requiring behavioral change.

The knowledge and expertise of the team greatly influence the risk assessment. Local knowledge about the environment in which the event is occurring is a critical component of risk assessment. The level of risk of an acute public health event depends on the social, economic, environmental and political conditions in the affected area and the effectiveness of local health services (e.g. curative and public health services). For some hazards, the effectiveness of links between health services and other responsible sectors and agencies (e.g. with the animal health sector for zoonotic diseases) may also affect the risk and must be assessed.

D.2. Formulating risk questions.

The risk assessment team should decide on the key questions to be answered. This helps to define the scope of the assessment and ensures that all the relevant information is collected. Clearly defined questions help identify priority activities to be conducted as part of the risk assessment. This may include literature reviews, epidemiological investigations, enhanced surveillance, consultation with disease experts, surveys and research.

A risk question is similar to a research question and typically focuses on:

- Who is likely to be affected
- The likely exposure to a hazard
- When, why and how a population might be adversely affected by exposure to a hazard.

The questions asked by the risk assessment team will be influenced by factors including:

- The population at risk
- The level at which the risk assessment is taking place – local, sub-national, national, international (e.g. cross-border), or global
- The technical and policy disciplines and agencies that are included in the risk assessment team and their collective experience with the type of event they are assessing (e.g. a wellcharacterized disease compared to a public health event of unknown cause (unknown etiology)
- The level of risk accepted by decision-makers, other stakeholders and society (i.e. the acceptable risk)
- The timing of the risk assessment during the course of the event
- The outcome of previous risk assessments carried out for the event and similar situations in the past
- The level of perceived external (e.g. international community) interest or awareness of the event.

The team should not try to answer all the possible risk questions at once. Instead, critical questions should be identified and ranked by priority for immediate response. Less time-critical questions can be addressed later or by other teams.

The main question asked during acute public health events is, 'what is the public health risk of the event' (i.e. what is the risk related to exposure to a particular hazard in a particular location, or to a particular population at a particular time)?

This question often leads to others, such as:

- What is the likelihood of exposure to the hazard if no action is taken?
- What are the consequences (type and magnitude) to public health if the event were to occur?

Risk questions may be framed as a series of scenarios, such as:

- What is the public health risk of the event in the current situation?
- What is the public health risk of spread to a major city?
- What is the public health risk of the event affecting more than one area (province/state, country)?

Based on the characteristics of the event, the risk assessment team should decide how frequently the risk assessment should be updated. The team should also agree on the priority questions and decide the time needed to complete each assessment. The time available between assessments may help to direct the number and scope of risk questions considered.

D.3. Undertaking the risk assessment.

The level of risk assigned to an event is based on the suspected (or known) hazard, the possible exposure to the hazard, and the context in which the event is occurring. Risk assessment includes three components — hazard, exposure, and context assessments. The outcome of these three assessments is used to characterize the overall level of risk.

Completing a risk assessment is not always a sequential process with hazard, exposure and context usually assessed at the same time. Although each is assessed separately, there is overlap in the information required to assess each domain.

D.4. Hazard assessment

Hazard assessment is the identification of a hazard (or number of potential hazards) causing the event and of the associated adverse health effects.

Public health hazards can include biological, chemical, physical and radionuclear hazards. Hazard assessment includes:

- Identifying the hazard(s) that could be causing the event
- Reviewing key information about the potential hazard(s) (i.e. characterizing the hazard)
- Ranking potential hazards when more than one is considered a possible cause of the event (equivalent to a differential diagnosis in clinical medicine).

When there is a laboratory confirmation of the causative agent or the event is easily characterized on clinical and epidemiological features, hazard identification can be straightforward. In such cases the hazard assessment would start with a known or strongly suspected hazard. However, in all other cases hazard assessment starts with listing possible causes based on the initial description of the event (e.g. the clinical and epidemiological features), known burden of disease in the affected community, and type and distribution of existing hazards (e.g. the number and location of chemical plants and the chemicals they use).

Medical practitioners, nurses, veterinarians and others working in clinical settings will be familiar with the importance of the differential diagnosis in the process of assessing a patient; hazard assessment is similar.

The less specific the information reported about an acute public health event, the broader the list of possible hazards becomes. However, as more information becomes available, the number of potential hazards is reduced and they can be ranked in order of the likelihood of being the cause.

The relative likelihood of a hazard can be determined by:

- The clinical features and natural history of the disease in humans or animals
- Timing of the event and the speed with which the event evolves
- Geographical area and settings affected
- The persons and populations affected.

D.5. Exposure assessment

Exposure assessment is the evaluation of the exposure of individuals and populations to likely hazards. The key output of the assessment is an estimate of the:

Number of people or group known or likely to have been exposed

Number of exposed people or groups who are likely to be susceptible (i.e capable of getting a disease because they not immune).

Information required to answer these questions includes:

- Modes of transmission (e.g. human-to-human transmission by droplet spread or direct contact transmission; animal-to-human transmission)
- Dose–response (e.g. some infectious agents, toxins, chemicals)
- Incubation period (known or suspected)
- Case fatality rate (CFR)
- Estimation of the potential for transmission (e.g. R0, the basic reproduction number)
- Vaccine status of the exposed population

For some hazards a dose–response relationship is an important determinant of the magnitude of exposure. Examples include the inhalation or ingestion of heavy metals such as lead, the number of salmonella bacteria ingested or the amount of a radionuclear isotope ingested or absorbed. For such hazards, in addition to assessing the exposure, the duration of exposure may also be important. With infectious diseases, differences in exposure can occur within households (e.g. measles), among close contacts (e.g. SARS) and other social networks (e.g. sexually transmitted diseases), in occupational risk groups (e.g. hepatitis B, Rift Valley fever, Q fever), and among travellers (e.g. malaria).

For vector-borne diseases (see Table 5) and other zoonoses, information about the vectors and their animal hosts is needed to assess exposure. This might include the species, distribution and density of vectors of disease, and the species, distribution and population density of animal hosts. The exposure assessment will provide an estimate of the likelihood that a particular area is vulnerable to the transmission of a zoonotic disease.

D.6. Context assessment

Context assessment is an evaluation of the environment in which the event is taking place. This may include the physical environment such as climate, vegetation, land use (e.g farming, industry) and water systems and sources as well as the health of the population (e.g. nutrition, disease burden and previous outbreaks), infrastructure (e.g. transport links, health care and public health infrastructure), cultural practices and beliefs.

Those who are trained in scientific disciplines, such as medicine, food safety and veterinary science, tend to approach risk assessment from a relatively narrow scientific perspective (e.g. of identifying the hazard) and may not consider other factors that affect risk.

Context assessment should consider all factors – social, technical and scientific, economic, environmental, ethical, and policy and political – that affect risk. These factors, summarized in the term STEEEP4 , can affect the level of risk by increasing or decreasing the likelihood of exposure or its consequences.

Information that helps to answer the following types of questions is a critical component of context assessment.

- What are the factors associated with the environment, health status, behaviours, social or cultural practices, health infrastructure and legal and policy frameworks that increase a population's vulnerability?
- Do any factors associated with the environment, health status, and social or cultural practices reduce the population's risk of exposure?
- What is the likelihood that all suspect cases can be identified?
- What is the availability and acceptability of effective preventive measures and of treatment or supportive therapies?

D.7. Risk characterization

Once the risk assessment team has carried out the hazard, exposure and context assessments, a level of risk should be assigned. This process is called risk characterization. If there is no mathematical output from a quantitative model or comparison with a guidance value (e.g. in food safety risk assessments), the process is based on the expert opinion of the team. A useful tool to assist the team is a risk matrix where estimates of the likelihood are combined with estimates of the consequences.

As the majority of acute public health event risk assessments are qualitative, the categories used in the matrix are not based on numerical values but on broad descriptive definitions of likelihood and consequences.

When applying the matrix, the definitions of likelihood and consequence can be refined to fit with the national or sub-national context in each country.

The choice of style of matrix depends on the team's preference; both styles serve as a visual tool to stimulate discussion and to help team members agree on a level of risk. During discussions, team members should consider all types of consequences in addition to the expected morbidity, mortality, and direct long-term health consequences of the event (e.g. disability). This includes consideration of the STEEEP consequences.

The risk matrix also helps to assess and document changes in risk before and after control measures are implemented. For some events, where information is limited and when the overall level of risk is obvious, the matrix may not be needed.