NATIONAL OPEN UNIVERSITY OF NIGERIA

FACULTY OF HEALTH SCIENCES

DEPARTMENT OF ENVIRONMENTAL HEALTH SCIENCES

COURSE CODE: EHS 505

COURSE TITLE: ENVIRONMENTAL EPIDEMIOLOGY

COURSE GUIDE

EHS 505 - ENVIRONMENTAL EPIDEMIOLOGY

Course Team

Course Developers/Writers: Dr. (Mrs.) I.C. Ugwu
University of Nigeria Nsukka

And

Dr. C. C. Ugwu
Federal University of Technology, Owerri

Course Editor: Professor D.A. Dakul
University of Jos, Jos, Plateau State.

Course Coordinator: Professor Grace C. Okoli-Nnabuenyi
HOD, Dept. of Environmental Health Science
Faculty of Health Sciences
National Open University of Nigeria

Programme Coordinator: Professor Grace C. Okoli-Nnabuenyi
Dean, Faculty of Health Sciences
National Open University of Nigeria

National Open University of Nigeria
Headquarters
91 Cadastral Zone
Nnamdi Azikiwe Expressway,
Jabi Abuja
Nigeria

Abuja Annex
245Samuel AdesujoAdemulegunStreet
Central Business
District Opposite
Arewa Suites Abuja
E-mail:centralinfo@nou.edu.ng

URL: www.nou.edu.ng

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Headquarters

91 Cadastral Zone

University Village

Nnamdi Azikiwe Express Way

Jabi, Abuja

e-mail:

centrainfo@nou.edu.ngur/:

www.nou.edu.ng

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INTRODUCTION

EHS 505 Environmental Epidemiology is a three (3) unit course with three (3) modules which contains nine (9) units. This course provides an excellent background in the knowledge of environmental epidemiology which includes the effect of physical, biologic, and chemical factors in the external environment on human health. The course seeks to clarify the relationship between physical, biologic or chemical factors and human health. Modernity and industrialisation have brought about increasing volume of wastes which has created unprecedented concern over the potential consequences for public health and the environment of exposure to these wastes that are deemed to be hazardous. Methods of investigation, data generation, analysis, interpretation and implication will be discussed. This course will be useful for anyone considering a career in environmental science especially as it impacts on human and animal health considering the concept of "one health".

WHAT YOU WILL LEARN IN THIS COURSE

In this course, you will be given the course units and a course guide. The course guide will tell you what the course is all about. It is a general overview of the course materials you will be using and how to use those materials. It also helps you to allocate the appropriate time to each unit so that you can successfully complete the course within the stipulated time limit. The course guide also helps you to know how to go about your Tutor Marked Assignment (TMA) which will form part of your overall assessment at the end of the course. Also, there will be regular tutorial classes that are related to this course, where you can interact with your facilitator and other students. Please, I encourage and request you to attend these tutorial classes.

Course Aim

The overall aim of this course is to introduce you to *Environmental Epidemiology*, which is an important branch of environmental science.
Study the details and check your progress as you read.

Course Objectives

It is expected that at the end of this course, you should be able to:

A. Define Environmental Epidemiology and describe their concepts.
B. Understand the principles of exposure assessment and descriptive analysis
C. Describe methods of epidemiological investigation of the environment
D. Understand the methods of risk assessment and management of pollution of air, water and soil
E. Understand the effects of ionizing and de-ionizing radiation on environment
F. Understand methods of investigation of disease clusters
G. Describe recent advances in environmental epidemiology and know the different statistical tools used in analysing environmental data.

Working through this Course

The organization of this course takes cognizance of the fact that this might be the first time the student is being exposed to this specialized area. The subject is therefore simplified and aided with many illustrations to enable the student understand the important concept and terminologies in the course. Efforts have been made to avoid

unnecessary details, especially those meant for medical professionals who have been grounded in clinical sciences in order not to confuse the students. The distinct contents of the course would help deliver the knowledge and skills needed by the student to function effectively either in individual tasks or as a member of a public health team during meat inspection and abattoir management activities.

Although the course has been designed to support independent study, attending tutorial sessions and participating in the practical activities included in this course will greatly enhance understanding of concepts discussed, as it will avail the student the opportunity to seek clarifications on poorly understood sections. Studying the course resources and attending tutorial sessions and practical are therefore vital to enhancing not only student's grade but also their understanding and usability of the knowledge garnered from the course.

COURSE MATERIALS

The course materials are as listed below:

- The Study Guide
- Study Units
- References / Further Reading
- Assignments
- Presentation Schedule

STUDY UNITS

The study units in this course are outlined below:

MODULE 1 INTRODUCTION TO ENVIRONMENTAL EPIDERMIOLOGY

Unit1: Definitions, concepts and general introduction to epidemiology and environmental epidemiology

Unit 2: Exposure assessment and descriptive analysis

Unit 3: Methods of investigation including the use of time and trend; and spatial pattern analysis, Poisson regression and surveillance.

MODULE 2: RISK ASSESSMENT, POLLUSION AND INTERPRETATION OF SCIENTIFIC DATA

Unit 1: Risk assessment and management of pollution of air, water and soil

Unit 2: Ionizing and de-ionizing radiation

Unit 3: Investigation of disease clusters

MODULE 3: RECENT ADVANCES

Unit 1: Recent advances in environmental epidemiology

Unit 2: Critical interpretation of scientific evidence relating to potential environmental hazards to health

Unit 3: Use of statistical packages (SPSS, EPI-INFO, epi data and other vital statistics)

There are activities related to the lecture in each unit which will help your progress and comprehension of the unit. You are required to work on these exercises together with the TMAs to enable you achieve the objectives of each unit.

ASSIGNMENT FILE

There are two types of assessments in this course. First are the Tutor- Marked Assessments (TMAs); second is the written examination. In solving the questions in the assignments, you are expected to apply the information, knowledge and experience acquired during the course. The assignments must be submitted to your facilitator for formal assessment in accordance with prescribed deadlines stated in the assignment file.

The work you submit to your facilitator for assessment accounts for 30 percent of your total course mark. At the end of the course, you will be required to sit for a final examination of 1½ hours duration at your study center. This final examination will account for 70 % of your total course mark.

PRESENTATION SCHEDULE

There is a time-table prepared for the early and timely completion and submissions of your TMAs as well as attending the tutorial classes. You are required to submit all your assignments by the stipulated time and date. Avoid falling behind the schedule time.

ASSESSMENT

There are three aspects to the assessment of this course. The first one is the self-assessment exercises. The second is the tutor marked assignments and the third is the written examination or the examination to be taken at the end of the course. Do the exercises or activities in the unit by applying the information and knowledge you acquired during the course. The tutor-marked assignments must be submitted to your facilitator for formal assessment in accordance with the deadlines stated in the presentation schedule and the assignment file. The work submitted to your tutor for assessment will count for 30% of your total course work. At the end of this course, you have to sit for a final or end of course examination of about a three-hour duration which will count for 70% of your total course mark.

TUTOR-MARKED ASSIGNMENTS

This is the continuous assessment component of this course and it accounts for 30% of the total score. You will be given four (4) TMAs by your facilitator to answer. Three of which must be answered before you are allowed to sit for the end of course examination.

These answered assignments will be returned to your facilitator. You're expected to complete the assignments by using the information and material in your reading's references and study units. Reading and researching into your references will give you a wider view point and give you a deeper understanding of the subject.

1. Make sure that each assignment reaches your facilitator on or before the deadline given in the presentation schedule and assignment file. If for any reason you are not

able to complete your assignment, make sure you contact your facilitator before the assignment is due to discuss the possibility of an extension. Request for extension will not be granted after the due date unless there in exceptional circumstances.

2. Make sure you revise the whole course content before sitting for the examination. The self-assessment activities and TMAs will be useful for this purpose and if you have any comment please do so before the examination. The end of course examination covers information from all parts of the course.

COURSE MARKING SCHEME

Assignments	Marks
Assignments 1 - 4	Four assignments, best three marks of the four count at 10% each = 30% of course marks
End of course examination	70% of overall course marks
Total	**100% of course materials**

Table 2: Course Organization

Unit	Title of Work	Weeks Activity	Assessment (End of Unit)
	Course Guide	Week	
1	Definitions, concepts and general introduction to epidemiology and environmental epidemiology	Week 1	Assignment 1
2	Exposure assessment and descriptive analysis	Week 2	Assignment 2
3	Methods of investigation including the use of time and trend; and spatial pattern analysis, Poisson regression and surveillance.	Week 3	Assignment 3
4	Risk assessment and management of pollution of air, water and soil	Week 4	Assignment 4
5	Ionizing and de-ionizing radiation	Week 5	Assignment 5
6	Investigation of disease clusters	Week 6	Assignment 6
7	Recent advances in environmental epidemiology	Week 7	Assignment 7
8	Critical interpretation of scientific evidence relating to potential environmental hazards to health	Week 8	Assignment 8
9	Use of statistical packages (SPSS, EPI-INFO, epi data and other vital statistics)	Week 9	Assignment 9

HOW TO GET THE MOST OUT OF THIS COURSE

In distance learning, the study units replace the university lecturer. This is one of the huge advantages of distance learning mode; you can read and work through specially designed study materials at your own pace and at a time and place that suit you best.

Think of it as reading from the teacher, the study guide tells you what to read, when to read and the relevant texts to consult. You are provided exercises at appropriate points, just as a lecturer might give you an in-class exercise.

Each of the study units follows a common format. The first item is an introduction to the subject matter of the unit and how a particular unit is integrated with the other units and the course as a whole. Next to this is a set of learning objectives. These learning objectives are meant to guide your studies. The moment a unit is finished, you must go back and check whether you have achieved the objectives. If this is made a habit, then you will significantly improve your chances of passing the course.

The main body of the units also guides you through the required readings from other sources. This will usually be either from a set book or from other sources.

Self-assessment exercises are provided throughout the unit, to aid personal studies and answers are provided at the end of the unit. Working through these self-tests will help you to achieve the objectives of the unit and also prepare you for tutor marked assignments and examinations. You should attempt each self-test as you encounter them in the units.

The following are practical strategies for working through this course

1. Read the Course Guide thoroughly.

2. Organize a study schedule. Refer to the course overview for more details. Note the time you are expected to spend on each unit and how the assignment relates to the units. Important details, e.g. details of your tutorials and the date of the first day of the semester are available. You need to gather together all this information in one place such as a diary, a wall chart calendar or an organizer. Whatever method you choose, you should decide on and write in your own dates for working on each unit.

3. Once you have created your own study schedule, do everything you can to stick to it. The major reason that students fail is that they get behind with their course works. If you get into difficulties with your schedule, please let your tutor know before it is too late for help.

4. Turn to Unit 1 and read the introduction and the objectives for the unit.

5. Assemble the study materials. Information about what you need for a unit is given in the table of contents at the beginning of each unit. You will almost always need both the study unit you are working on and one of the materials recommended for further readings, on your desk at the same time.

6. Work through the unit, the content of the unit itself has been arranged to provide a sequence for you to follow. As you work through the unit, you will be encouraged to read from your set books.

7. Keep in mind that you will learn a lot by doing all your assignments carefully. They have been designed to help you meet the objectives of the course and will help you pass the examination.

8. Review the objectives of each study unit to confirm that you have achieved them. If you are not certain about any of the objectives, review the study material and consult your tutor.

9. When you are confident that you have achieved a unit's objectives, you can start on the next unit. Proceed unit by unit through the course and try to pace your study so that you can keep yourself on schedule.

10. When you have submitted an assignment to your tutor for marking, do not wait for its return before starting on the next unit. Keep to your schedule. When the assignment is returned, pay particular attention to your tutor's comments, both on the tutor-marked assignment form and also that written on the assignment. Consult you tutor as soon as possible if you have questions or problems.

11. After completing the last unit, review the course and prepare yourself for the final examination. Check that you have achieved the unit objectives (listed at the beginning of each unit) and the course objectives (listed in this course guide).

FACILITATORS/TUTORS AND TUTORIALS

Sixteen (16) hours are provided for tutorials for this course. You will be notified of the dates, times and location for these tutorial classes. As soon as you are allocated a tutorial group, the name and phone number of your facilitator will be given to you.

These are the duties of your facilitator: He or she will mark and comment on your assignment. He will monitor your progress and provide any necessary assistance you need. He or she will mark your TMAs and return to you as soon as possible. You are expected to mail your tutored assignment to your facilitator at least two days before the scheduled date.

Do not delay to contact your facilitator by telephone or e-mail for necessary assistance if you do not understand any part of the study in the course material. You have difficulty with the self-assessment activities. You have a problem or question with an assignment or with the grading of the assignment.

It is important and necessary you acted the tutorial classes because this is the only chance to have face to face content with your facilitator and to ask questions which will be answered instantly. It is also period where you can say any problem encountered in the course of your study.

FINAL EXAMINATION AND GRADING

The final examination for EHS 505: General Epidemiology will be of 1½ hours duration. This accounts for 70 % of the total course grade. The examination will consist of questions which reflect the practice, exercises and the tutor-marked

assignments you have already attempted in the past. Note that all areas of the course will be assessed. To revise the entire course, you must start from the first unit to the ninth unit in order to get prepared for the examination. It may be useful to go over your TMAs and probably discuss with your course mates or group if need be. This will make you to be more prepared, since the examination covers information from all aspects of the course.

SUMMARY

Environmental epidemiology is the study of the effect on human health of physical, biologic, and chemical factors in the external environment, broadly conceived. By examining specific populations or communities exposed to different ambient environments, it seeks to clarify the relationship between physical, biologic or chemical factors and human health. In this course we will discuss all aspects of environmental epidemiology. From essential term definitions to understanding the domain concept of environmental epidemiology. We explore the different aspects of exposure assessment and descriptive analysis, time-trend investigation and risk assessment methodologies. We will discuss the environmental impacts of air, soil and water pollution, ionizing and non-ionizing radiation and disease cluster investigation. The field of environmental epidemiology has evolved over the years and has advanced tremendously in recent years by expanding into areas that are in collaboration with numerous scientific fields including public health. Methods of interpreting results from environmental research and surveys will also be discussed in the course including different statistical packages available for epidemiological studies.

MODULE 1 INTRODUCTION TO ENVIRONMENTAL EPIDERMIOLOGY

Unit1: Definitions, concepts and general introduction to epidemiology and environmental epidemiology

Unit 2: Exposure assessment and descriptive analysis

Unit 3: Methods of investigation including the use of time and trend; and spatial pattern analysis, Poisson regression and surveillance.

Unit 1 DEFINITIONS, CONCEPTS AND GENERAL INTRODUCTION TO EPIDEMIOLOGY AND ENVIRONMENTAL EPIDEMIOLOGY

Content

1.1 Introduction

In this unit, epidemiology and its speciality area of environmental epidemiology will be defined. The concept of the study area will also be explained to enable students understand what they are all about. While epidemiology is the study of the relationship of community with its environment; environmental epidemiology tries to understand demographic relationship between the exposure to environmental factors and public health. Numerous terms used in epidemiological studies will also be defined.

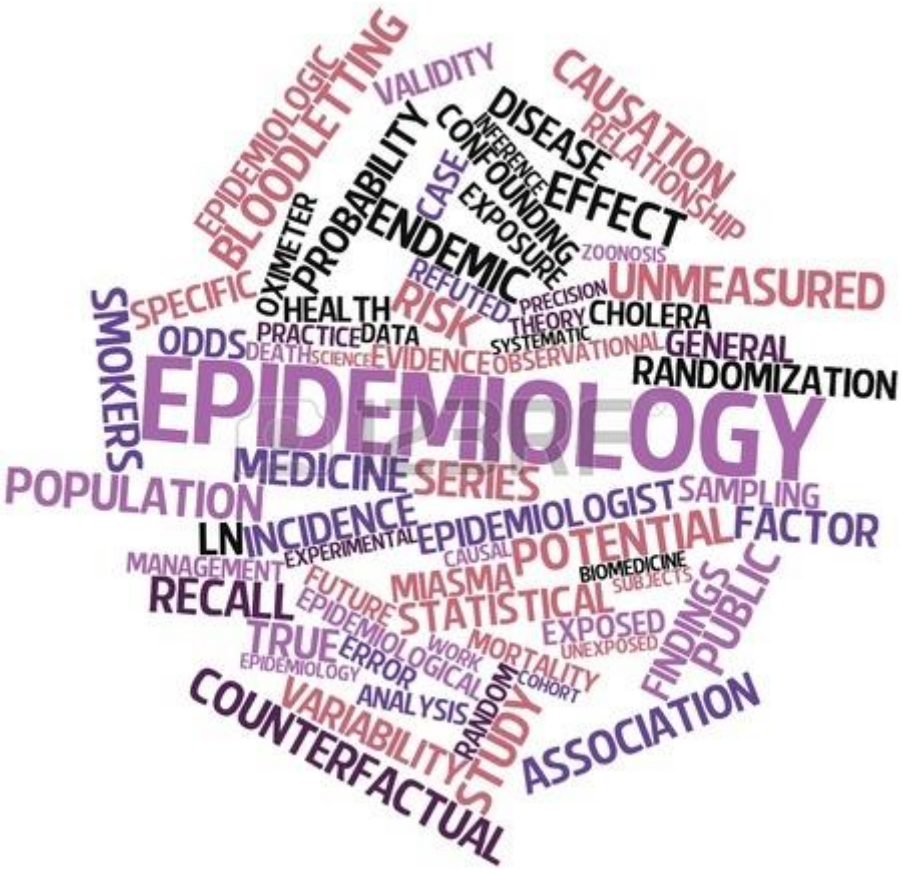

Fig. 1.1: General figurative concept of Environmental Epidemiology

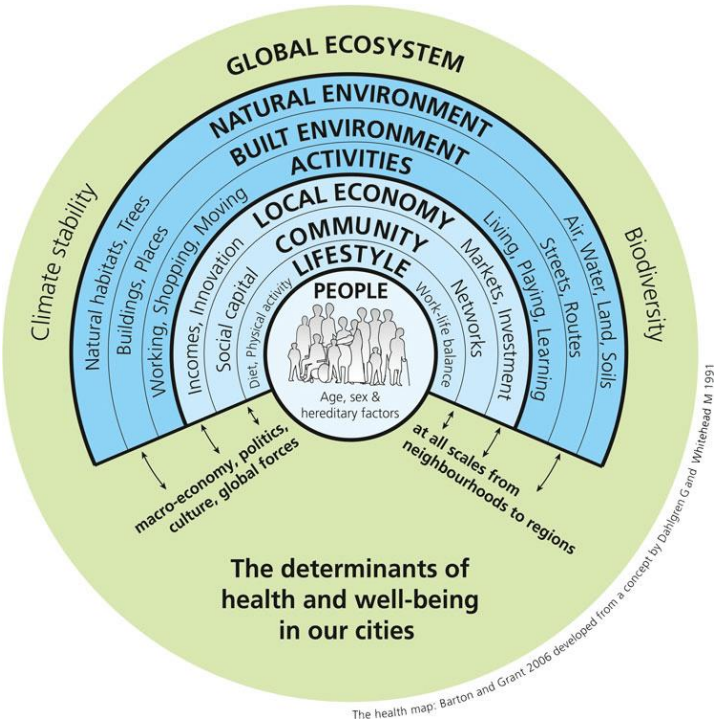

Fig. 1.2: Interrelationship between environment and public health

1.2 OBJECTIVES

By the end of this unit, you will be able to define some epidemiological terminologies and you will also understand the domain concept of epidemiology and environmental epidemiology.

1.3: DEFINITIONS OF TERMS USED IN EPIDEMIOLOGIC STUDIES

- Agent: A causative factor, such as a biological or chemical agent that must be present (or absent) in the environment for disease occurrence in a susceptible host.
- Analytic epidemiologic studies: Study designs that examine groups of individuals in order to make comparisons and associations and to determine causal relationships; also known as cohort, cross-sectional, and case-control studies.
- Attack rate: The number of cases of disease in a specific population divided by the total population at risk for a limited time period, usually expressed as a percentage.
- Attributable risk percentage: A statistical measure that estimates the number of cases of a disease attributable to the exposure of interest.
- Bias: An error in the study design caused by the tendency of researchers to expect certain conclusions on the basis of their own personal beliefs that results in incorrect conclusions regarding the association between potential risk factors and disease occurrence.
- Case fatality rate: Refers to deaths from a specific disease.
- Case reports: Client (case) history studies used in epidemiologic descriptive studies.
- Case series: A compilation of case reports.
- Case-control study: An analytic epidemiologic study design that assembles study groups after a disease has occurred; also called a retrospective study.
- Cause-specific death rate: Number of deaths from a specific cause; expressed as a number per 100,000 population.
- Chemical agents: Includes poisons and allergens.
- Cohort study: An analytic epidemiologic study design that assembles study groups before disease occurrence to observe and compare the rates of a health outcome over time; also called a prospective study.
- Co-relational study: A descriptive epidemiologic study design used to compare aggregate populations for potential exposures of disease.
- Cross- sectional survey: A descriptive epidemiologic study design that uses a representative sample of the population to collect information on current health status, personal characteristics, and potential risk factors or exposures at one point in time.
- Demography: The statistical science or study of populations, related to age-specific categories, birth and death rates, marital status, and ethnicity.
- Descriptive epidemiologic studies: Epidemiologic study designs that contribute to the description of a disease or condition by examining the essential features of person, place, and time.

- Disease frequency: Occurrence of disease as measured by various rates such as morbidity rate.
- Ecology: The study of relations and interactions among all organisms within the total environment; in community health, the individual's interaction with his or her social, cultural, and physical environments.
- Environment: Internal and external factors that constitute the context for agent-host interactions; the aspect of existence perceived outside the self; this perception changes with alterations in awareness and expansion of consciousness; one of the concepts of nursing metaparadigm.
- Epidemic: A number of cases of an infectious agent or disease (outbreak) clearly in excess of the normally expected frequency of that disease in that population.
- Eidemiology: An applied science that studies the distribution and determinants of health-related states or events in populations.
- False-negative test: A screening test result that is negative when the individual actually has the disease of interest.
- False-positive test: A screening test result that is positive when the individual does not have the disease of interest.
- Host: A person or living species capable of being infected.
- Incidence rate: The rate of new cases of a condition or disease in a population in a specified time period; provides an estimate of the condition/disease risk in that population.
- Infectious agents: Bacteria, fungi, viruses and protozoa.
- Intervention study: Epidemiologic study design that is experimental in nature and used to test a hypothesis about a cause-and-effect relationship.
- Levels of prevention: A three-level model of intervention (primary, secondary, tertiary) used in the epidemiologic approach, designed to prevent or to halt or reverse the process of pathological change as early as possible in order to prevent damage.
- Maternal mortality rate: Deaths of mothers at time of birth, expressed as a number per 100,000 live births.
- Measures of association: Statistical analysis methods used to investigate the relationship between two or more variables or events.
- Morbidity rate: A disease rate, specifically prevalence and incidence rates of diseases in a population in a specified time period.
- Mortality rate: The number of deaths from all causes divided by the total population at a particular time and place.
- Natural history of a disease: The course that a disease would take from onset to resolution without intervention by humans.
- Nutritive elements: Substances such as vitamins or proteins that, if excessive or deficient, act as an agent of disease.
- Observational studies: Non-experimental studies that describe, compare, and explain disease occurrence.
- Odds ratio: A statistical measure of association reflecting the ratio of two odds reflecting the relative risk (RR) when the specific risk of disease of both the exposed and the unexposed groups is low. Calculated when incidence rates are unavailable.

- Physical agents: Agents of disease that must be present or absent for a problem to occur. Examples include radiation, excessive sun exposure, and mechanical agents.
- Point prevalence: The total number of persons with a disease at a specific point of time.
- PRECEDE-PROCEED model: A health–promotion planning framework useful in applying the epidemiologic approach to community health planning.
- Prevalence rate: A proportion or percentage of a disease or condition in a population at any given time.
- Prevention trials: An epidemiologic intervention study design used to compare measures or interventions aimed at the prevention of disease.
- Prospective study: An epidemiologic study design that assembles study groups before disease occurrence.
- Relative risk: An epidemiologic measure of association that indicates the likelihood that an exposed group will develop a disease or condition relative to those not exposed.
- Retrospective study: An epidemiologic study design that assembles study groups after disease occurrence.
- Risk: The probability that an event, outcome, disease, or condition will develop in a specified time period.
- Sensitivity: The probability that an individual who has the disease of interest will have a positive screening test result.
- Specificity: The probability that an individual who does not have the disease of interest will have a negative screening test result.
- Surveillance: The systematic collection and evaluation of all aspects of disease occurrence and spread, resulting in information that may be useful in the control of the disease.
- Therapeutic trials: An epidemiologic intervention study design used to compare measures or interventions aimed at therapeutic benefits.
- Vital statistics: Systematically tabulated data on vital events such as births, deaths, marriages, divorces, adoptions, annulments, separations, and health events that are based on registration of these events.

1.4 Epidemiology

Epidemiology is the method used to find the causes of health outcomes and diseases in populations. In epidemiology, the patient is the community and individuals are viewed collectively. By definition, epidemiology is the study (scientific, systematic, and data-driven) of the distribution (frequency, pattern) and determinants (causes, risk factors) of health-related states and events (not just diseases) in specified populations (neighborhood, school, city, state, country, global). It is also the application of this study to the control of health problems

Epidemiologic study could include the following

Environmental exposures	• Lead and heavy metals • Air pollutants and other asthma triggers • Cold weather or extreme heat
Infectious diseases	• Foodborne illness • Influenza and pneumonia
Injuries	• Road accidents • Occupational or domestic accidents
Non-infectious diseases	• Localized or widespread rise in a particular type of cancer • Increase in a major birth defect
Natural disasters	• Hurricanes Katrina and Rita (2005) • Haiti earthquake (2010)
Terrorism	• World Trade Center (2001) • Anthrax release (2001)

1.5 Environmental epidemiology

This could be defined as the study of diseases and health conditions occurring in a population that are linked to environmental factors. The general concept of epidemiology can be seen in Fig. 1.1 while its relationship to public health is shown in Fig. 1.2. Environmental epidemiology is the study of the effect on human health of physical, biologic, and chemical factors in the external environment, broadly conceived. By examining specific populations or communities exposed to different ambient environments, it seeks to clarify the relationship between physical, biologic or chemical factors and human health. This could be difficult due to real world constraints which impede the ability to estimate health effects associated with exposures to hazardous-wastes. Combination of evidence from different sources may be required to reach conclusions in estimating health effects associated with hazardous-wastes. Knowledge of potential exposures is derived from studies that characterize the substances found at hazardous-waste sites. Knowledge of health risks to humans from potential exposures can be obtained from a variety of sources. For some chemicals, such knowledge will be available from published studies of occupational risks, usually involving higher exposures than those in the general environment. For others, especially for airborne and waterborne exposures, knowledge of health risks will come from studies of the general effects of the pollutants and from clinical reports, case-comparison studies, and animal studies; and it can be extended to circumstances where such pollutants are emitted from hazardous-waste sites. Knowledge of symptomatology or disease occurrence has in some instances been derived from studies of populations exposed to hazardous-waste sites. In some cases, these knowledges could not describe exposures accurately or identify specifically the causal factor. Nevertheless, with the knowledge that is available about exposure elsewhere, and from the knowledge that some of these exposures can result in the

observed symptomatology or diseases found in excess in those exposed to hazardous waste sites, sufficient indirect evidence of causality can sometimes be inferred. Epidemiology, like that of any human science, seldom permits elegant inferences to be drawn about causation. The object domain of epidemiology consists of numerous uncontrollable aspects, with considerable variations. To make a reasonable inference of causation in environmental epidemiology, six basic characteristics of the findings should be considered:

- the strength, specificity, and consistency of the association,
- the period of exposure,
- the relationship between the dose and the response,
- the effects of the removal of the suggested cause,
- the biologic plausibility of the association and
- the overall coherence of the findings.

The advent of meta-analysis as a technique that pools related studies offers an important opportunity to strengthen the inferences that can be drawn from epidemiologic research. Potentially misleading conclusions can be drawn from single studies because of insufficient sample size, inadequacies of exposure determination, or publication and other biases. Meta-analysis reduces these problems and can lessen the danger of misinterpretation because it allows for combining relevant studies. Meta-analysis is limited by lack of routine publication of negative findings, and interpretation must be tempered by the awareness that reporting and publication biases can distort the sample of studies available for pooling.

1.6 SUMMARY

Epidemiology is the study (scientific, systematic, and data-driven) of the distribution (frequency, pattern) and determinants (causes, risk factors) of health-related states and events (not just diseases) in specified populations (neighbourhood, school, city, state, country, global). Environmental epidemiology which is a branch of environmental science, uses epidemiologic principles to study the effect on human health of physical, biologic, and chemical factors in the external environment.

1.7 TMA

1. Define 5 terms used in epidemiology
2. Define epidemiology
3. Define environmental epidemiology

1.8 REFERENCES/FURTHER READING

Bonita R., Beaglehole R., and Kjellström T. (2006). Basic epidemiology. 2nd edition. WHO Library Cataloguing-in-Publication Data.

Unit 2: **EXPOSURE ASSESSMENT AND DESCRIPTIVE ANALYSIS**

Content

Fig. 2.1: Water pollution and human-environment interplay

2.1 **INTRODUCTION**

In this unit you will learn about exposure assessment in environmental epidemiology. This is an attempt by environmental epidemiologist to assess the level of exposure of pollutants to the environment and its impact on public health.

2.2 **OBJECTIVES**

At the end of this unit you will understand the principles and methods of carrying out exposure assessment and descriptive epidemiologic studies.

3.3 **EXPOSURE ASSESSMENT**

Exposures to chemical and physical agents in the environment can produce a wide range of adverse health consequences. Environmental epidemiology attempts to determine whether a

hazard exists—that is, whether there is a causal relation between exposure to certain chemical or physical agents and adverse health effects—and to measure

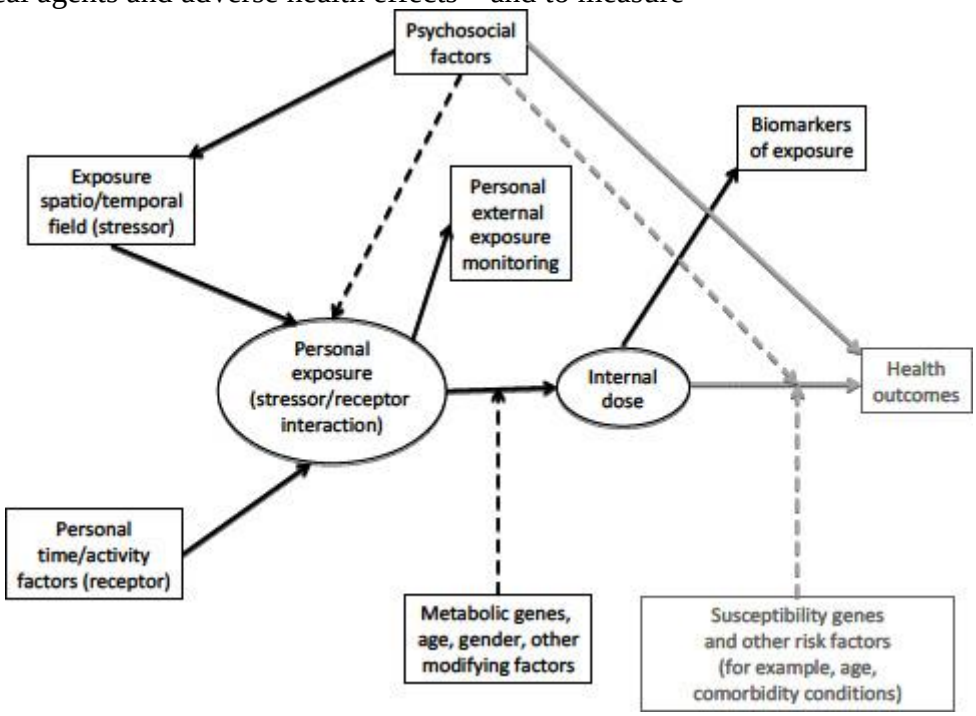

Fig. 2.2: Relationship between exposure to contaminants, exposure biomarkers and human demography/genomic changes

and characterize any causal relations (to assess the exposure-response relationship) Fig. 2.2. Typically, a continuum between level of exposure and the size or probability of health effects is assumed. Emphasis is placed on characterizing the associations across the continuum, and quantitatively defining the relation is a central feature of the epidemiologic investigation. Assessment of exposure is then a crucial component of environmental epidemiology research. The estimation of exposure in relation to health effects is frequently difficult, and it has generally received inadequate attention. However, a field of exposure assessment is emerging. Exposure assessment for purposes of environmental epidemiology may differ from exposure assessment for site remediation, mitigation, control, and risk assessment. The differences are sometimes subtle but may have substantial impact on the conduct of studies and associated allocation of resources. Investigations for the purpose of risk assessment, for example, generally include information on the source and identity of chemical agents, the concentration of each toxicant in various media, and the toxicity of identified toxicants as defined in experimental studies. Mathematical modelling may be used to define breakdown, transport, and ultimate location as well as the potential health risk. Environmental epidemiology, on the other hand, is more often hypothesis-based research that seeks to examine specific populations or communities to clarify the relation between health and physical, biologic, and chemical factors. Some limitations and problems in the quantitative estimation of exposure may exist especially when the focus of a study is possible adverse consequences of chemical exposure from hazardous-waste sites. Some aspects of exposure assessment or analysis in environmental epidemiology are very important and could illustrate the central role of exposure assessment. The overall goal of exposure assessment is to obtain periodic and systematic measurements of the exposure of certain population to multiple chemicals and generate data on important environmental media, pathways, and routes, so that accurate current status and trends are determined; and use it to predict possible future directions for exposures to hazardous chemicals. There are set objectives in carrying out exposure assessment surveys:

1. To document the occurrence, distribution, and determinants of exposures to hazardous environmental agents, including geographic and temporal trends
2. To understand the determinants of exposure for potentially at-risk population subgroups, as a key element in the development of cost-effective strategies to prevent or reduce exposures (risks) deemed to be unacceptable; and
3. To provide data and methods for linking information on exposures, doses, and health outcomes that will improve environmental health surveillance, enhance epidemiologic investigations, promote development of predictive models, and ultimately lead to better decisions.

2.3.1 PRINCIPAL CONCEPTS THAT UNDERLIE THE CONTENT OF THIS UNIT

The effective application of exposure assessment methods may improve the results of any epidemiologic investigation. As in any line of epidemiologic investigation, an improvement in exposure assessment can reduce bias and improve statistical power to detect adverse effects associated with exposure to environmental contaminants. However, important findings may derive from environmental-epidemiologic investigation even when the exposure assessment uses only simple and crude tools to characterize the exposure of a given population. Over reliance on sampling of exposure of individuals may not be cost effective and may limit the size of the study, with little improvement over the findings based on indirect methods.

2.3.2 CONCEPTS AND METHODS IN EXPOSURE ASSESSMENT

Epidemiologic research uses various exposure metrics. The choice of a specific metric will depend on the type of study in question, the resources available to the investigator, the conceptual framework behind the investigation, and above all, biologic considerations. In deciding which exposure metric is best in a particular study, one must be clear about basic concepts of exposure analysis. Exposure assessment for use in environmental epidemiology must attend to 5 primary issues:

1. The definition and characterization of the potentially exposed population;
2. The collection of quantitative information on population exposure, temporal characteristics, and dose-response relations;
3. The medium and the microenvironment of principal concern in terms of exposure;
4. The use of information collected in one population in assessing potential risk to others; and 5.
5. The biologic plausibility of any hypotheses based on mechanistic considerations that can assist and help guide the exposure assessment.

EXPOSURE can be defined as “an event that occurs when there is contact at a boundary between a human being and the environment with a contaminant of a specific concentration for an interval of time; the units of exposure are concentration multiplied by time.” For purposes of exposure assessment, some terminologies for determination of level and type of exposure have been developed and defined. These includes **potential dose, applied dose, internal dose**, and **biologically effective dose**.

Potential dose is the amount of the chemical ingested, inhaled, or in material applied to the skin.

Applied dose is the amount of a chemical that is absorbed or deposited in the body of an exposed organism.

Internal dose is the amount of a chemical that is absorbed into the body and available for interaction with biologically significant molecular targets.

Biologically effective dose is the amount of a chemical that has interacted with a target site over a given period so as to alter a physiologic function. A concept important to any type of

study is that of total exposure. Assessment of total exposure has received considerable attention in recent years. Total-exposure assessment consists of estimating possible exposure from all media (soil, water, air, and food) and all routes of entry (inhalation, ingestion, and dermal absorption). Total-exposure assessment has particular relevance in environmental epidemiology insofar as it facilitates identification of the principal medium or microenvironment of concern and provides information on potentially confounding exposures.

Different measurement and estimation techniques used in exposure assessment. Measurements are categorized to include direct measurement of exposure (personal monitoring, biologic monitoring, and biomarkers); indirect measures (microenvironmental monitoring coupled with exposure models, where microenvironmental monitoring is defined as the monitoring of contaminant concentrations in locations or media in which exposure occurs); that include mathematical modelling, questionnaire/diaries, or spatial factors, e.g., residence in a country or region or distance from a source of chemical contamination. When direct measurement of exposure is possible, it generally provides more-accurate information than indirect assessment of a particular individual's contact with a specific contaminant over time. The trade-off is often between accurately measuring exposures over short periods, often outside the period of disease aetiology, and indirect methods of assessing exposure over lengthier, more-relevant intervals. Personal monitoring has been widely used in workplace settings and can provide a measure of exposure across a range of microenvironments where individuals reside or work, though it is generally limited to a single chemical compound. However, personal sampling is often expensive, may demand extensive analytic capability and methodologies, and requires care in selecting study subjects. Biologic monitoring provides direct measures that integrate all routes of exposure to contaminants. Biologic monitoring may also provide more-precise estimates of target-organ dose, if appropriate toxicokinetic and metabolic information is available. Indirect sampling uses exposure data available for defined areas or other microenvironments, generally from monitoring with time-activity information. Exposures in each microenvironment are weighted for the average time spent there and added to assess total personal exposure. Validation of the specific applicability of indirect monitoring is an important requirement for the successful use of this method. Some important epidemiologic studies have emphasized indirect measures of exposure as the primary linkage to health outcome.

2.3.3 EXPOSURE-DATA NEEDS FOR EPIDEMIOLOGY STUDIES

The type of exposure assessment and the acceptable level of uncertainty in the data vary according to whether the assessment is designed to generate or test hypotheses about exposure, test instruments, make risk assessment decisions, or make regulatory decisions. It is pertinent to find out what kind of exposure data do epidemiologists need. It will depend on the development of a well-defined research question. It has been points out that the definition of dose-response relations is usually critical to establishing causality. It is expected that, when it is possible to examine ordered categories of exposure, higher doses will have greater effects so that the dose-response relationship is monotonic. Therefore, when assessment departs from monotonicity, it raises questions about causality. Therefore, a key purpose of exposure assessment is often to support evaluation of dose-response relations.

2.3.4 RISK ASSESSMENT AND ENVIRONMENTAL EPIDEMIOLOGY

Better measures of exposure are clearly desirable in epidemiology. Exposure data exist on a continuum ranging from measures of emission, to measures of ambient concentration, to microenvironmental measures weighted by time spent in each environment, to personal monitoring, to measures of internal dose and biomarkers. Pirkle *et al.* (1995) provide a summary with examples of 6 different uses of biomarker data: to identify priority exposures,

to evaluate effectiveness of risk-mitigation strategies, to identify at-risk subpopulations, to recognize trends, to establish reference ranges, and to provide integrated dose measurements. Several of these measures may be available to evaluate a given exposure. Activity patterns may also allow extrapolation from microenvironmental data to aggregate risk, though with some additional error. While time-activity studies can often model the mean dose delivered to a population with reasonable accuracy, it is more difficult to predict accurately the distribution, or even the variance, about that mean. Epidemiologic studies that associate the ambient pollutant directly with the outcome inherently incorporate the distribution of population activity patterns. More-accurate exposure assessment can increase the power of an environmental-epidemiology study to find an association. However, increased precision is likely to be more costly, and better information for each subject may reduce the number of subjects who can be studied. This trade-off between sample size and precision per subject means that statistical power will not necessarily increase monotonically with improvements in the accuracy of the exposure assessment. Spending additional resources to obtain better measurements of risk factors other than the pollutant of interest may also increase the power of the study by reducing misclassification of co-founders and modifiers, but the additional costs are another set of trade-offs. For any given budget, the optimal trade-off is usually not knowable in advance, though studies of multifactorial outcomes and low relative risks almost always require large sample sizes. This need for a large sample puts a premium on using inexpensive methods, such as questionnaire data on activity patterns and other exposure modifying behavior, rather than expensive but more-accurate methods.

2.3.5 MEASUREMENT ERROR

The term measurement error is different from exposure misclassification because the former implies a continuous variable, while the latter suggests a dichotomous one. Exposure to environmental toxicants is a continuous variable in the real world, and one of the most important improvements in exposure assessment is for studies to move from dichotomizing exposure into continuous, or at least multilevel, measurements. For example, consider a study relating air pollution to respiratory illness. The outdoor ambient-air pollution concentration is available from community monitoring. The analysis of these data will seek to correlate variations in air pollution with variations in respiratory outcome. Variations in recorded levels of air pollution may be thought of as having the following components: measurement error associated with the monitoring instrument, variation in the amount of time individuals spent outdoors, geographic variation in the outdoor concentration of the pollutant in the vicinity of the monitor, variations in the indoor/outdoor ratio, and individual variations in delivered dose. Critical issues include the size of each error component and the cost of reducing each component.

2.3.6 MISCLASSIFICATION

One of the most important advantages of improved exposure assessment derives from its impact on misclassification. Small errors in exposure assignment may have dramatic results on estimation of effect. Because of the limited scope of exposure assessments in most environmental epidemiology, misclassification is likely to be a substantial problem. In general, the internal validity of an epidemiologic investigation can be reduced by misclassification of study subjects. Bias from misclassification could be a function of the sensitivity and specificity of the classification procedure, the disease frequency, and exposure frequency. And in all case-control studies the bias depends on whether misclassification is the same or different in cases and controls, that is, nondifferential or differential in cases and controls. In general, nondifferential misclassification causes measures of effect to be biased toward the null value. Such misclassification produces an underestimate of the effect, whereas differential misclassification can result in bias either toward or away from the null value. Classification errors cannot be ignored and investigators should attempt to estimate the

magnitude of the errors. The predominant view that nondifferential misclassification of exposure can only bias an estimate of a true positive odds ratio downward and not away from or beyond the null value may sometimes be wrong. This problem is not common, but caution is needed in interpreting results in the presence of nondifferential misclassification.

2.3.7 THE NEED FOR IMPROVEMENT IN EXPOSURE ASSESSMENTS

Better measures of exposure can improve the ability of a study to assess adverse effects from environmental agents. Such improvements lead to an increase in the power of the study and reduction in bias, but also to increased cost. The health outcomes and exposure analysis must be considered together to arrive at a balanced prioritization of study requirements. A wide array of exposure-assessment tools is available to the epidemiologic investigator, ranging from personal monitoring to the use of diaries or other indirect means. All the tools have potential value when used logically and reasonably. Collaboration is necessary between scientists whose emphasis is on exposure assessment and epidemiologic investigators. In this regard, there is a need for continued dialogue to focus on critical questions that will reduce ambiguity in terminology and conceptual design and improve the experimental design of both health and exposure studies. The average concentration of arsenic in well water was a poor indicator of individual exposure because some of the persons studied had supplemented their consumption or changed completely to drinking bottled water. When estimates of bottled water consumption were incorporated into individual exposure assessment, the dose-effect relationship was strengthened. In a cross-sectional study of pulp and paper workers exposed to chlorine gas, no differences were found compared with workers in other industries but when those pulp and paper workers who had an acute gas exposure were considered, symptom and Forced-Expiratory Volume (FEV1 and FEV25-75) differences were found. It was now concluded that accidental chlorine or chlorine dioxide exposures in pulp mills are associated with increased respiratory symptoms and airflow obstruction, particularly among non-smokers and former smokers. Teachers and pupils at a kindergarten near a factory with emissions of tetrachloroethane were studied and found that the levels of tetrachloroethane in the air exhaled by teachers and school-children were significantly greater than in a control group. The study demonstrated the applicability of biologic monitoring, where the exposure derives from the environment instead of the workplace. Monitoring of air at a hazardous-waste remedial site revealed that when workers remained in fixed job locations, occupational inhalation exposure monitoring must consider contaminants generated upwind of the job location. The selection of individual monitoring versus area or population monitoring of exposure is a matter of continuing concern. In particular, overreliance on “central-site monitoring” for assessment of exposure to air pollutants may be undesirable because of the possibility that personal exposures may differ from those estimated by central-site monitoring. Unrecognized variation among individuals in true air-pollution exposure contributes to variability among individuals in estimated slopes. While important findings have derived from air-pollution studies that make use of ambient-air monitoring data, investigations of more-precise questions such as determinants of variations in response may be improved through the use of personal monitors that are now becoming available. The improved accuracy of personal monitoring of exposure generally comes at the expense of a substantial increase in cost and may therefore have its greatest value in the validation of other, less-expensive models of exposure.

2.3.8 EXPOSURE ASSESSMENT AT HAZARDOUS-WASTE SITES

Potentially dangerous substances can be found at many hazardous-waste sites and could constitute future risks to public health. Exposure assessment is necessary to understand the associations among contaminants, exposures, and adverse health consequences. One of the problems in epidemiologic studies of hazardous-waste sites has been the limited nature of the

exposure assessments. Most studies have dichotomized subjects into exposed and unexposed categories or used surrogates of exposure, such as distance from a site or residence in a defined geographic area. Few assessments estimate quantitative exposure of groups and individual exposure measurements are seldom used. Accuracy of exposure data is a problem. There can be serious errors in making the assumption that the exposure level assigned to a geographic subunit applies to everyone in that unit. Investigations of hazardous-waste sites have generally focused on which chemicals are present at or under the site, especially the possible contamination of groundwater, and have given little attention to evaluating chemical movement from the site. So, information on exposure to the population in homes or businesses near the site is usually scanty or not available. The routine monitoring of groundwater for purposes of site remediation and problem mitigation entails significant costs (e.g., hydrogeologic characterization, boring of wells, and soil and water sampling). Government agencies have rarely assessed population exposure to chemicals from these sites.

2.3.9 ASSESSMENT OF PAST EXPOSURE

In environmental epidemiology, information on past exposures is usually not available, and current exposure may not fairly represent the past because of technologic developments, public or government awareness of a possible problem, or other changes. Because recall bias or other types of information bias may be important in these studies, documented information on past exposure is particularly useful. In some studies, water-consumption records have been used to estimate past exposures. Mathematical modelling, toxicokinetic models, and biomarkers may improve our ability to estimate past exposures, especially where the body burden of xenobiotic chemicals is related to toxic insult. In occupational epidemiology, it is sometimes possible to reconstruct an industrial environment for exposure estimation; exposure-monitoring records of workers may be available, and even employment records by job category may be of value. Since direct approaches like simulating past exposures are often infeasible, indirect approaches for evaluating the effects of exposure and confounder misclassifications are preferable.

2.3.10 COMPLEX MIXTURES

It is probable that waste sites may expose persons to multiple chemicals. Three important issues arise in studying exposures to complex mixtures in epidemiologic investigations:

1. Quantification of exposure,
2. Characterization of potential combined or interactive effects associated with exposure to multiple chemicals, and
3. Identification of subpopulations that are especially sensitive to exposure from certain complex mixtures.

These problems are multiplied where the mixture may vary from one site or time to another or when the mixture is not well characterized. Both problems are common in waste sites. Workplace studies often focus on exposure to a single chemical agent, e.g., lead in battery manufacturing or silica in a foundry. However, for the most part, epidemiologic studies of the environment must address the issue of complex mixtures. One approach to assessing the health impact of complex mixtures involves characterization of complex mixtures by toxicologic investigation. Toxicological characterization of complex mixtures has received inadequate attention as a complement to environmental investigation. Toxicologic studies are needed to characterize both mechanisms and interactive effects and to quantitate the exposure-effect relations of complex mixtures. Studies of exposure to the complex mixtures found in indoor air have implications for other aspects of environmental epidemiology. occupational epidemiology and characterized dose surrogates by exposure intensity, exposure duration, and cumulative exposure.

2.3.11 SUBJECTIVE SYMPTOMS AND EXPOSURE ASSESSMENT

An important issue in epidemiologic studies of hazardous-waste sites is the relation between positive findings as evidenced by increased subjective symptoms in a defined population and the general lack of exposure assessment that would link the findings to specific exposures. Some authors have suggested that the increased prevalence of subjective symptoms may derive from recall bias or psychogenic factors, whereas others have argued that symptoms may result from exposures of particularly susceptible members of a population. In volume 1, it was suggested that longitudinal studies of symptoms in response to changes in exposure could help to resolve this problem, if subjects have no knowledge of their level of exposure that could bias reporting. Several studies have found that subjective symptoms are associated with exposures from hazardous-waste sites. Issues of cumulative versus peak exposure appear to be relevant in these studies. In general, investigation of the averaging time of exposure indexes should be a priority in environmental epidemiology. Unfortunately, when environmental epidemiology is driven by citizen generated concern, the data available to the investigator may be so limited that precise questions cannot be addressed. The actual chemicals to which a community population is exposed are often poorly or inadequately identified, complex mixtures may be the rule rather than the exception, and exposure routes are not well defined, so the ability to address such complex issues as dose rate is seriously compromised A study at the Casmalia hazardous-waste site in California indicated that respiratory effects were associated with airborne releases of odorous materials from the site.

2.3.12 USE OF BIOLOGIC MARKERS OF EXPOSURE

Three types of biologic markers may be used to provide information on exposure. These are markers of internal dose, such as blood lead; markers of biologically effective dose, such as blood DNA and protein adducts; and markers of biologic effects, such as chromosomal micronuclei. The central, critical issue in the use of biologic markers of exposure is criteria for their validation. A major limitation of using biological markers for exposure assessments stems from the fact that most are in a developmental stage and not fully validated or field-tested. Ambiguity of many markers, the variability of markers, and the difficulty of establishing links between exposure and effect are issues associated with use of markers.

2.3.13 DESIGNING AND CONDUCTING A STUDY WITH BIOLOGIC MARKERS

When environmental-monitoring data are available for classifying individuals, it may not be necessary to perform biologic monitoring. Biologic monitoring of a sample of subjects can be used to validate environmental-monitoring variables. If there is a close correspondence between exposure and the biologic marker, then further use of the more-costly biologic monitoring may not be needed and the exposure classification scheme may be considered validated. If the correspondence is not close, it may be that exposure from diverse sources or by various rates is not covered by environmental monitoring. For example, classification of residents by distance from an arsenic smelter may not adequately reflect the arsenic concentrations in their diets, and environmental monitoring may not provide good estimates of total arsenic exposure. Biologic markers are often assumed to be good indicators of exposure because they represent the integrated exposure from various sources and through various routes. However, to assess this assumption requires correlation of the marker with the potentially less-adequate environmental measure. There is no “gold standard.” Perfect correspondence between the marker and the exposure could mean that neither is better than the other or that there are no other routes, sources, or host factors that intervene. On the other hand, it may mean that the marker is not an accurate reflection of these other intervening factors. It is important to determine whether the marker shows an exposure-response relation, whether all potential routes are accounted for, and whether susceptibility or host factors are addressed. Host factors, including behavioural factors and genetic characteristics, may

influence the amount of a toxic agent that interacts with critical macromolecules in cells and tissues. This is the "biologically effective dose." The biologically effective dose assesses exposure from all routes and sources as well as some aspects of effect modification, possibly including host characteristics for uptake, metabolism, absorption, and excretion. However, the marker may not necessarily encompass all these factors. Thus, even when biomarkers are useful, the best appraisal of exposure may still include ambient and environmental measurements as well as biologic measurements. Numerous biomarker-related issues may arise during the conduct of studies, including questions of specimen collection, transport, storage, and assay; measurement error of technical variables in the assay; biologic variability; and assay interpretation and communication of results. In cohort studies, biologic markers may be measured in subsets of populations, such as in a nested case-control or case-cohort approach, to assess etiologic questions and mechanisms and to identify high-risk subpopulations. In these situations, biologic markers of exposure may be useful to (1) distinguish exposure subgroups, (2) determine whether there is a relation between exposure and dose, or (3) evaluate the relation between exogenous exposure and internal or biologically effective dose. Biologic markers may also be useful to identify the effect of an intervention. For example, does reduction of environmental emissions result in a reduction in the level of DNA adducts? Research studies to assess interventions need to include assessment of baseline levels of biomarkers in order to interpret the effect of the interventions.

2.3.14 INTERPRETATION AND GENERALIZATION OF STUDY RESULTS

Biologic markers of exposure can be of use after a study has been completed. For example, if researchers wish to see how well the results of a completed study might apply to a broad population, they may sample the population for the distribution of a particular marker to determine whether exposures are constant over a wide range of geographic conditions, demographic descriptors, and occupations. Even if the original study did not measure such factors, biologic markers may clarify what exposures such target groups may have experienced. It may also be possible to perform individual risk assessments using biologic measures of exposure. A classic example of individual risk assessment is the use of serum-cholesterol measurement to predict disease risk. With more-recent technology, one might attempt precise individual risk assessment by studying an individual's specific spectrum of gene mutations from specific exposures to a carcinogen.

2.3.15 TRAINING IN ENVIRONMENTAL-EXPOSURE ASSESSMENT

Human exposure assessment is inadequately addressed in most environmental-epidemiology studies, and one of the roots of this problem is the lack of training at the graduate level. There is a major need, for the development of training programs in exposure assessment. Exposure assessment is addressed in courses on environmental risk assessment, but even there the context is more focused on risk assessment and site remediation than on epidemiologic investigation of public-health hazards. Training in exposure assessment must be multidisciplinary, with a multimedia approach, and should address all the major uses of exposure information—including risk assessment, epidemiology, environmental control, and exposure assessment—and industrial hygiene, toxicology, pollution prevention, and standard-setting. It would be useful to examine the relations among needs for training in these areas to define a new curriculum that would better address current and future needs. Given the costs, resource requirements, and political sensitivity of many environmental-epidemiologic studies, the failure to provide training for environmental assessment will need to be addressed by policymakers and educators if we are to have substantial improvement in environmental epidemiology and risk assessment.

2.4 DESCRIPTIVE EPIDEMIOLOGIC STUDIES

Descriptive epidemiology is the study of the amount and distribution of disease or other health-related characteristics in human populations by person, place and time. Descriptive epidemiology identifies non-random variation in the distribution of disease, injury or health. Descriptive epidemiology provides a way of organizing and analysing these data in order to understand variations in disease frequency geographically and over time, and how disease (or health) varies among people based on a host of personal characteristics (person, place, and time). Exposure data for descriptive epidemiologic studies must fairly apply to the population from which the disease is arising. This requires estimation of the whole probability distribution of exposure, not just means, with special attention to accurate estimation of the upper end of exposures. This is especially important if many or most persons are thought to be exposed at levels below some "threshold" where effects first appear. This is best achieved by random sampling, and sampling theory will dictate the nature and size of the sample, as well as any repetitions over time or circumstance, from which exposure will be assessed. Unless exposure information over time is already available or obtainable, data from an investigation that measures exposure "now" must be used to infer exposure levels at earlier times, e.g., the times when cases of the disease were induced. If the distribution of induction times is not known, the use of current exposures may be highly uncertain. In some instances, disease rates in an exposed population are compared with disease rates in unexposed population units, but inferences are stronger if the investigator classifies risk by some population gradation of exposure. Sometimes, if exposure is measured in only a few areas, analysis may have to be limited to simple "exposed-control" comparisons. Sometimes, as may often happen in studies of pollutants in air or diet, there are no unexposed population units, and low- (or lower-) exposure groups fulfil the role of a "baseline" group. The sophistication of the exposure information collected will in general depend on resources. Environmental modelling may be necessary to deal with area and temporal variation.

2.4.1 ANALYTIC EPIDEMIOLOGIC STUDIES

Some exposure requirements are considered in carrying out epidemiologic studies. In case-control studies, the past exposures of cases and controls will have to be estimated, using historical records, if available, or current exposure measurements extrapolated back in time. Quantitative measures of exposure can reduce misclassification and allow the development of a dose-response curve. Cohort Studies Requirements for historical cohort studies are similar to those for case control studies. For prospective cohort studies, there may be a need to estimate the extent of continuing exposure. In view of the large numbers required for cohort studies, resource constraints may make it impossible to do more than measure current or recent exposure. The identification of potentially hazardous exposures in a group often results in cessation of exposure. This does not remove the need for characterization of past exposures. Nested Case-control and Case-cohort Studies Sometimes in a cohort study it is possible to collect specimens that could characterize exposure (e.g., biologic markers), where the expense largely resides in the analysis rather than specimen collection. When stored specimens are available, for a discussion of quality assurance associated with specimen archives, and can be analysed after those subjects have been followed long enough to classify them as cases or controls, precision almost as great as in the full cohort study may be obtained. The case-cohort design can allow similar efficiency in exposure assessment, often at far less cost than a full-scale cohort study.

2.5 SUMMARY

Exposure assessment is an emerging area in environmental epidemiology that determines if hazard exists in an environment and the causal effects on public health. We were able to

discuss concepts of exposure assessment, methods, data, errors, miscalculation, need for improvement in assessment of exposure, hazardous sites assessment, past exposure, complex mixtures, relationship in subjective symptoms, use of biologic markers and their limitations and interpretation of results of assessment; and training of exposure assessors. We also discussed descriptive and analytical epidemiologic studies.

2.6 TUTOR-MARKED ASSIGNMENT

1. Define exposure assessment
2. Describe the use of biologic marker in exposure assessment
3. Describe methods of descriptive epidemiologic analysis

2.7 REFERENCES/FURTHER READING

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Unit 3: METHODS OF INVESTIGATION INCLUDING THE USE OF TIME AND TREND; AND SPATIAL PATTERN ANALYSIS, POISSON REGRESSION AND SURVEILLANCE.

CONTENTS

3.1 INTRODUCTION

Time-trend designs are a form of longitudinal ecological study, and can provide a dynamic view of a population's health status. Data are collected from a population over time to look for trends and changes.

3.2 Objectives

At the end of this unit you will understand the meaning of time and trend analysis and how to use it to conduct environmental investigation. You will also learn spatial pattern analysis, Poisson regression and surveillance as they apply to environmental epidemiology.

3.3 WHAT IS TREND ANALYSIS?

Trend analysis is a technique used in technical analysis that attempts to predict the future environmental occurrences based on recently observed trend data. Trend analysis is based on the idea that what has happened in the past gives environmental epidemiologists an idea of what will happen in the future. Time-trend designs are a form of longitudinal ecological study, and can provide a dynamic view of a population’s health status. Data are collected from a population over time to look for trends and changes. Like other ecological studies, the data are collected at a population level and can be used to generate hypotheses for further research, rather than demonstrating causality.

Ecological studies are described elsewhere in these notes, but there are four principal reasons for carrying out between-group studies:

- To investigate differences between populations
- To study group-specific effects, for example of a public health intervention aimed at a group
- Where only group-level data are available, such as healthcare utilisation
- They are relatively cheap and quick to conduct if routine data are available

In a time-trend analysis, comparisons are made between groups to help draw conclusions about the effect of an exposure on different populations. Observations are recorded for each group at equal time intervals, for example monthly. Examples of measurements, typically expressed as numbers, proportions or rates, include prevalence of disease, levels of pollution, or mean temperature in a region.

3.3.1 Uses of time-trend analysis

Trends in factors such as rates of disease and death, as well as behaviours such as smoking, are often used by public health professionals to assist in healthcare needs assessments, service planning, and policy development. Examining data over time also makes it possible to predict future frequencies and rates of occurrence.

Studies of time trends may focus on any of the following:

- Patterns of change in an indicator over time – for example whether usage of a service has increased or decreased over time, and if it has, how quickly or slowly the increase or decrease has occurred
- Comparing one time period to another time period – for example, evaluating the impact of a smoking cessation programme by comparing smoking rates before and after the event. This is known as an *interrupted* time series design.
- Comparing one geographical area or population to another – for example, comparing changes in rates of cardiovascular deaths between the UK and India.
- Making future projections – for example to aid the planning of healthcare services by estimating likely resource requirements

3.3.2 Analysis of time-trend studies

The most obvious first step in assessing a trend is to plot the observations of interest by year (or some other time period deemed appropriate). The observations can also be examined in tabular form. These steps form the basis of subsequent analysis and provide an overview of the general shape of the trend, help identify any outliers in the data, and allow the researcher to become familiar with the rates being studied.

Statistical methods used in analysis could include:

- Regression analysis (if the trend can be assumed to be linear)
- Mann-Kendall test (a non-parametric method which can be used for non-linear trends)

3.3.3 Time series analysis

Time series analysis refers to a particular collection of specialised regression methods that illustrate trends in the data. It involves a complex process that incorporates information from past observations and past errors in those observations into the estimation of predicted values. Briefly, there are three types of modelling used to analyse time series data: AutoRegressive (AR) models, Integrated (I) models and Moving Average (MA) models.

Autoregression is based on the premise that past observations have an effect on the current, and the number of previous observations that contribute to the current observation can be varied in the model. For example, in a first-order autoregressive model – AR(1) – the current observation is only predicted by the immediately preceding value, and in a second-order model – AR(2) – the current observation is predicted by the previous two observations, etc. Moving average models are slightly different. Here, instead of using past *observed* values as predictors, we instead use the *errors* of previous forecasts. Again, the number of previous forecasts used in the model can be set, so an MA (1) model only uses the error of the previous forecast. The AR and MA models can be combined to produce autoregressive moving average (ARMA) models. An assumption in ARMA models is that the time series is *stationary* (i.e. that the mean and variance is constant over time). However, this isn't always the case, such as with global temperatures over time. Addition of an integrated (I) term helps account for any underlying trends (i.e. it makes non-stationary data appear stationary) – such models are known as autoregressive integrated moving average (ARIMA) models.

3.3.4 Presentation of trend data

Presentations of time-trend data should usually include the following:

- Graphical plots displaying the observed data over time
- Comment on any statistical methods used to transform the data
- Report average percent change
- An interpretation of the trends seen

Moving averages (or rolling averages) provide a useful way of presenting time series data. (Note that "moving averages" is not the same as a "moving average model", described above!) The calculation and plotting of moving averages highlights long-term trends whilst smoothing out any short-term fluctuations. An example is the calculation of the average annual rainfall in Nigeria shown in Table 3.1 and 3.2 below.

Table 3.1: **Six-year average annual rainfall in Nigeria**

Year	Average annual rainfall (mm)
2010	1135
2011	1150
2012	1235
2013	1200

2014	1225
2015	1205

We can calculate a three-year moving average for each year by taking the average of the value of each given year and the values either side of it. For 2010 this can't be done as we don't have the data from the preceding year. For 2011, the moving average value would be the average annual rainfall of the 2010, 2011 and 2012 [(1135+1150+1235)/3 = 1173.3]. This could be repeated for 2012, 2013 and 2014. (We can't calculate the moving average value for 2015 as we don't have the 2016 data.) This would give us the following:

Table 3.2: **Calculation of moving average for smoothing data**

Year	Average annual rainfall (mm)	Moving average
2010	1135	-
2011	1150	(1135+1150+1235)/3 = 11173.3
2012	1235	(1150+1235+1200)/3 = 1195
2013	1200	(1235+1200+1225)/3 = 1220
2014	1225	(1200+1225+1205)/3 = 1216.7
2015	1205	-

When using moving averages to smooth data, be careful not to average too many years' worth of data for each calculation (e.g. using 10-year moving averages), as you risk over-smoothing the line and losing potentially important trends.

3.3.5 Interpretation of trend data

The results of time-series designs should be interpreted with caution:

Data on exposure and outcome may be collected in different ways for different populations

Migration of populations between any groups during the study period may dilute any difference between the groups

Even within a single population, there may be underlying changes, such as in age structure, which affect the outcome

Seasonal variation can result in fluctuations which affect the outcome trend (although this can be accounted for during analysis)

Such studies usually rely on routine data sources, which may have been collected for other purposes

Ecological studies do not allow us to answer questions about individual risks

3.4 Spatial pattern analysis

Place or area of occurrence has long been recognized as an essential component in epidemiological science. Over the past 20 years, interest in place has experienced resurgence, facilitated by improved accessibility of computer-based geographic information systems (GIS). Personal computing, improvements in processing speed, and user-friendly applications have placed spatial analysis within reach of a large number of researchers. Recent advances in spatial statistics and geographic information systems provide innovative platforms for diagnosing environmental health problems and for developing interventions. Many health outcomes are shaped by multiple and interacting factors, including social, environmental, and host-factor influences. The key to spatial analysis is that most data contain a geographic component that can be tied to a specific location, such as a state, county, zip code, census block, or single address, as well as to more ecologically oriented geographic features, such as a watershed, airshed, floodplain, and riparian zone. Geographic analysis enables users to explore and overlay data by location, revealing hidden trends that are not readily apparent in traditional spreadsheet and statistical packages. GIS allows for the construction of space (and space-time) data architectures that can then be analysed with either spatial or aspatial statistics. Analytical results can then be displayed in GIS, to enhance ease of interpretation. Additionally, GIS contains advanced capabilities to generate clear and accessible maps and data reports that can serve as powerful tools for research, outreach, and policy design.

3.4.1 Geographical Information System (GIS)

A Geographic Information System (GIS) is a system designed to capture, store, manipulate, analyse, manage, and present spatial or geographic data. GIS applications are tools that allow users to create interactive queries (user-created searches), analyse spatial information, edit data in maps, and present the results of all these operations. GIS (more commonly GIScience) sometimes refers to geographic information science (GIScience), the science underlying geographic concepts, applications, and systems. Since the mid-1980s, geographic information systems have become valuable tool used to support a variety of city and regional planning functions.

GIS can refer to a number of different technologies, processes, techniques and methods. It is attached to many operations and has many applications related to engineering, planning, management, transport/logistics, insurance, telecommunications, and business. For that reason, GIS and location intelligence applications can be the foundation for many location-enabled services that rely on analysis and visualization.

GIS could be applied in the spatial analysis research on ambient levels of the 6 criteria air pollutants: carbon monoxide, lead, nitrogen dioxide, particulate matter, ozone, and sulphur dioxide and collect data which are then used to prevent public exposure that could have harmful effect on health. Because GIS maps serve as a powerful communication tool, GIS and spatial analysis are especially helpful for directing community outreach activities and reaching communities at risk especially as both help in targeting exposure control interventions.

3.5 **POISSON REGRESSION AND SURVEILLANCE**

The Poisson regression model is a technique used to describe count data as a function of a set of predictor variables. In the last two decades it has been extensively used both in human and in veterinary Epidemiology to investigate the incidence and mortality of chronic diseases. Among its numerous applications, Poisson regression has been mainly applied to compare exposed and unexposed cohorts and to evaluate the clinical course of ill subjects. Poisson regression analysis is a technique which allows to model dependent variables that describe count data. It is often applied to study the occurrence of small number of counts or events as a function of a set of predictor variables, in experimental and observational study in many disciplines, including Economy, Demography, Psychology, Biology and Medicine. In particular, in the last twenty years, Poisson regression model has been extensively applied in many contexts in biomedical studies, including Epidemiology, to investigate the occurrence of selected diseases in exposed and unexposed subjects in observational prospective studies, or to evaluate the clinical course of patients in experimental and observational investigations in human clinical setting. The Poisson regression model may be used as an alternative to the Cox model for survival analysis, when hazard rates are approximately constant during the observation period and the risk of the event under study is small (e.g., incidence of rare diseases). For example, in ecological investigations, where data are available only in an aggregated form (typically as a count), Poisson regression model usually replaces Cox model, which cannot be easily applied to aggregated data. Furthermore, using rates from an external population selected as a referent, Poisson regression model has often been applied to estimate standardized mortality and incidence ratios in cohort studies and in ecological investigations. Some variants of the Poisson regression model have been proposed to take into account the extra-variability (overdispersion) observed in actual data, mainly due to the presence of spatial clusters or other sources of autocorrelation. Besides medical studies, the Poisson regression model has been used in different fields of veterinary research, ranging from herd management assessment to animal health in domestic and wild animals and control of infectious diseases in different animal species. The Poisson model has been applied also to data analysis in a multidisciplinary study on cancer incidence in veterinary and other workers of veterinary industry compared to that of other part of active population in Sweden. The most recent applications of the Poisson model and of its variations (e.g., negative binomial model, Poisson random effect model, Poisson model with autocorrelation terms, etc.) in veterinary medicine are aimed to evaluate: the effect of anthelmintic treatment with eprinomectin at calving on milk production in dairy herds with limited outdoor exposure; the periparturient climatic, animal, and management factors influencing the incidence of milk fever in grazing systems in cows; the effects, both positive and negative, of widespread badger culling programs on Mycobacterium bovis tuberculosis in cattle in Britain; the seasonality of equine gastrointestinal colic. In spite of its recent wide application, Poisson regression model remains partly poor known, especially if compared with other regression techniques, like linear, logistic and Cox regression models.

3.6 SUMMARY

Trend analysis is a technique used in technical analysis that attempts to predict the future environmental occurrences based on recently observed trend data. This is applicable for investigation of pattern of disease, comparing different time periods, comparing geographical areas or populations and in making future predictions relating to diseases or health conditions associated with environmental exposure. Spatial pattern analysis is the study of how place or area plays a role in the epidemiology of disease. This is particularly useful because proximity to some environmental hazards could play a role on incidences if certain health conditions. Poisson regression model is a technique used to describe count data as a function of a set of predictor variables.

3.7 TUTOR-MARKED ASSIGNMENT

1. Discuss the use of time trend in environmental studies
2. State factors necessary for time trend data interpretation
3. What id GIS and how does it apply in environmental epidemiology research
4. Discuss Poisson regression

3.8 REFERENCES/FURTHER READING

Carneiro I, Howard N. Introduction to Epidemiology. Open University Press, 2011.

MODULE 2: RISK ASSESSMENT AND POLLUTION OF AIR, SOIL AND WATER

Unit 4: Risk assessment and management of pollution of air, water and soil

CONTENTS

4.1 INTRODUCTION

In this unit risk assessment as it applies to environmental epidemiology; air, water and soil pollution will be discussed. Processes of risk assessment, causes and management measures of air, water, and soil pollution; and how they impact on environmental health will be given attention. Pollution may be defined as an undesirable change in the physical, chemical and biological characteristics of air, water and soil which affect human life, lives of other useful living plants and animals, industrial progress, living conditions and cultural assets. A pollutant is something which adversely interfere with health, comfort, property or environment of the people. Generally, most pollutants are introduced in the environment by sewage, waste, accidental discharge or else they are by-products or residues from the production of something useful. Due to this our precious natural resources like air, water and soil are getting polluted.

4.2 OBJECTIVES

At the end of this unit, students will have understood the meaning of risk assessment and how it applies to environmental epidemiology. They will also understand what constitutes pollution of air, water and soil and how they cause problems for the environment, animal, aquatic and public health.

4.3 RISK ASSESSMENT

Risk assessment provides a systematic procedure for predicting potential risks to human health or the environment. The aim of a chemical risk assessment is to investigate if a chemical is being used or can be used as intended without causing detrimental effects to human health or the environment. Risk assessment is a systematic process for identifying and describing health hazards and for determining the extent of human exposure. The result is an assessment of the extent and likelihood of health risks and of those exposed to them. Since risk assessment is used to support risk management and decision-making, the assessment process must be scientific and based on research data.

The general principles for assessing environmental health risks are described below.

Risk assessment determines whether a health hazard poses an actual health risk at the identified level of exposure, the nature of the said health risk, and the risk management measures that should be taken.

The risk assessment process has four stages

Emphasis here is on exposure agent that constitute factors hazardous to human health:

1. Hazard characterisation, i.e. identifying the hazard

- What adverse health effects does the exposure agent cause?
- What is the so-called critical effect, i.e. the adverse effect caused at the lowest level of exposure?
- Determining the exposure-response relationship for the critical effect

2. Exposure assessment

- What are the environmental sources of exposures?
- Through which medium does exposure take place?
- What is the extent of exposure?
- Who are exposed, and are there vulnerable groups that are highly sensitive to the exposure agent?

3. Health risk characterisation

- Comparison of adverse effects and exposure
- Is the hazardous level of exposure exceeded, and what is the safety margin?
- Does a health risk exist, what is it like, and who is at risk?

4. Risk management

- If a health risk exists, can it be managed, for example, by preventing exposure to it?

Risk assessment is concerned with making quantitative assessments of the risk associated with a certain level of exposure to a substance or factor in the population. The traditional demarcations are those between hazard assessment, i.e., establishing that a substance or factor can possibly damage health because of its intrinsic properties; exposure response or dose–response assessment, i.e., establishing at what level of expo-sure (in epidemiology) or at what dose level (in toxicology) a certain adverse effect on health occurs in which frequency and/or severity; exposure assessment, i.e., establishing the distribution of exposure within the population, and risk characterization, the final quantitative assessment of which proportion of an exposed population will experience an adverse effect of a certain severity. Epidemiology has a role to play in each of these.

4.3.1 Hazard identification

An example of how epidemiological studies identified a possible hazard is the two case control studies carried out to find out the association between plastic surface materials in the home and asthma. In the first study, 251 children with asthma were compared to 251 children without, and 72 of the asthma cases were found to live in homes with PVC floor materials as opposed to 5 of the control children. These studies were preceded by occupational studies suggesting that materials used in plastic production may be related to asthma and by some toxicological work exploring exposure pathways and mechanisms. After the initial studies in children and in homes, further work has been done to explore this issue.

4.3.2 Exposure assessment and risk assessment

Whereas exposure assessment in itself is not epidemiology, the approaches and tools to assess population exposures for the purpose of risk assessment and for the purpose of epidemiology studies are similar. For the purpose of risk assessment and epidemiology, exposures need to be measured or estimated for the specific population of interest, that is the population for which one wishes to quantify the risk. For the purpose of epidemiology studies, exposures need to be measured or estimated for the subjects of the population which is being studied. In so far as the populations are the same, the exposure assessments can be similar. Regardless of the purpose, the tools to assess exposures in populations are the same. The validity of studies in the field of environmental epidemiology depends both on the assessment of exposure and of the effects on health. Each of these aspects can present difficulties and uncertainties. Thus, it is important that everyone involved in the design, conduct and interpretation of investigations has a clear understanding of the problems. Exposure assessment in environmental epidemiology therefore has a different, and more limited aim than assessment of human exposure to environmental agents in general. Other aims of exposure assessment can be the development of effective control strategies, or control of compliance to environmental quality standards. In environmental epidemiology, exposure assessment must primarily fulfil the needs of the epidemiologist. The epidemiologist, who studies the effect of exposure to environmental agents on health

and disease, needs measures of exposure that are accurate and precise, so that the effect of exposure on disease can be estimated with minimal bias and maximum efficiency. Accuracy is how close a measurement is to the truth. Each measurement method or instrument needs to be calibrated against a standard that is (often by convention!) the 'truth'. As an example, a mercury thermometer can be approximately calibrated to degrees centigrade by first immersing it in ice water to define the 0◦ mark, then to immerse it in boiling water at sea level to define the 100◦ mark. Now, if the tube containing the mercury would shift for some reason relative to the marks on the background, measurements with it would no longer be accurate. To establish the accuracy of a measurement is often difficult, as it is not always obvious what the 'truth' is, or how the 'truth' itself can be reliably established. Precision is how well a measurement can be repeated, given that all measurements have some degree of inherent variability. As an example, a series of ten measurements of benzene in a parking garage will not all produce the same number, but numbers that are more or less different from each other. If the numbers follow a so-called normal, bell-shaped distribution, the variation can easily be captured by calculating the relative standard deviation, also described as the 'coefficient of variation', of the measurement. In thinking about precision, it is very important to realize that precision has several components. To begin with, any laboratory determination has a certain analytical error. Then, sampling in the field has a sampling error that needs to be taken into account. Then, if the variable to be measured is not uniform in space and/or time, there will also be an error related to temporal and/or spatial variability. To establish the precision of a measurement is often easy, because all it takes is to perform replicate measurements. The combination of accuracy and precision are often defined as the validity of the measurement. To asses validity of exposure measurements, investigators should perform so called validation studies aimed at measuring accuracy, precision or both. If an exposure variable used in epidemiology study is not completely accurate or precise, then the result is that the estimated relationship between exposure and disease becomes attenuated, or in other words, appears less strong than it actually is. The improvement of accuracy and precision of exposure assessment in epidemiology has very important benefits. Working with poor surrogates reduces the statistical power to detect a relationship between exposure and disease even when it exists; all too often, it is being assumed then that there is no relationship, and this may endanger public health. Also, even when a relationship is established using poor surrogates, the inevitable underestimation of relative risks leads to underestimation of the public health burden associated with exposure. The two major classes of methods for exposure assessment are:

1. Measurement which implies the use of some instrument to measure the value of an exposure variable and
2. Modelling of exposure which is the use of mathematical models to predict the value of an exposure variable.

The models are based on knowledge of factors which determine or influence the exposure variable, and of the quantitative relationship between these factors and exposure. Exposure to environmental agents has been defined as any contact between a potentially harmful agent present in an environmental medium and a surface of the human body. Interpreted in this narrow sense, exposure can only be properly assessed by measuring or modelling actual contact between the agent and the body surface. It is

rarely feasible, however, to obtain this information for a sufficient number of free-living individuals in epidemiologic studies. Exposure variables used in practice in environmental epidemiology usually have to be regarded as approximations to the 'true' exposure of the subjects who are being studied. The accuracy and precision with which 'true' exposure is being approximated may vary widely from one 'surrogate' exposure variable to the next.

4.4 AIR POLLUTION

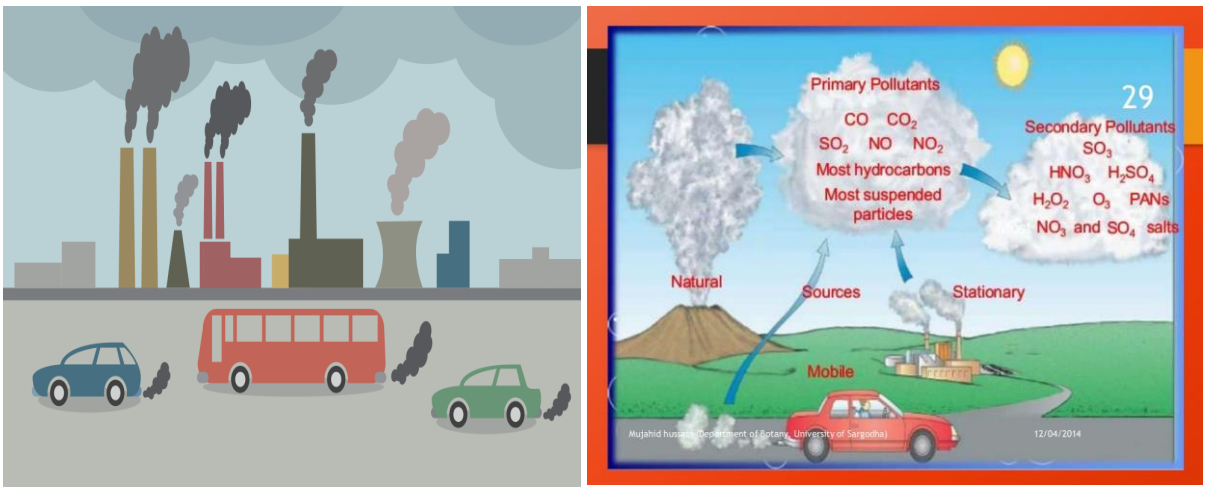

Fig: 3.2: Showing various sources of air pollution

4.4.1 What is air pollution?

Air pollution is a mix of particles and gases that can reach harmful concentrations both outside and indoors. Its effects can range from higher disease risks to rising temperatures. Soot, smoke, mold, pollen, methane, and carbon dioxide are a just few examples of common pollutants. In the U.S., one measure of outdoor air pollution is the Air Quality Index, or AQI which rates air conditions across the country based on concentrations of five major pollutants: ground-level ozone, particle pollution (or particulate matter), carbon monoxide, sulphur dioxide, and nitrogen dioxide. Some of those also contribute to indoor air pollution, along with radon, cigarette smoke, volatile organic compounds (VOCs), formaldehyde, asbestos, and other substances.

4.4.2 A global health hazard

Poor air quality kills people. Worldwide, bad outdoor air caused an estimated 4.2 million premature deaths in 2016, about 90 percent of them in low- and middle-income countries, according to the World Health Organization. Indoor smoke is an ongoing health threat to the 3 billion people who cook and heat their homes by burning biomass, kerosene, and coal. Air pollution has been linked to higher rates of cancer, heart disease, stroke, and respiratory diseases such as asthma. In the U.S. nearly 134 million people—over 40 percent of the population—are at risk of disease and premature death because of air pollution, according to American Lung Association estimates. Despite decades of progress, the air quality in the United States has started to decline over the past few years, according to data provided in summer 2019 by the Environmental Protection Agency. The agency recorded 15 percent more days with unhealthy air in the country in 2018 and 2017 compared to the average from 2013 to 2016. The reasons for the recent decline in air quality remain unclear, says the agency, but may be related to high numbers of wildfires, a warming climate, and increasing human consumption patterns driven by population growth and a strong economy. The long-term outlook also remains unclear, even as politicians debate air pollution standards. While those effects emerge from long-term exposure, air pollution can also cause short-term problems such as sneezing and coughing, eye irritation, headaches, and dizziness. Particulate matter smaller than 10 micrometres (classified as PM_{10} and the even smaller $PM_{2.5}$) pose higher health risks because they can be breathed deeply into the lungs and may cross into the bloodstream. Air pollutants cause less-direct health effects when they contribute to climate change. Heat waves, extreme weather, food supply disruptions, and other effects related to increased greenhouse gases can have negative impacts on human health. The U.S. Fourth National Climate Assessment released in 2018 noted, for example, that a changing climate "could expose more people in North America to ticks that carry Lyme disease and mosquitoes that transmit viruses such as West Nile, chikungunya, dengue, and Zika."

4.4.3 Environmental impacts

Though many living things emit carbon dioxide when they breathe, the gas is widely considered to be a pollutant when associated with cars, planes, power plants, and other human activities that involve the burning of fossil fuels such as gasoline and natural gas. That's because carbon dioxide is the most common of the greenhouse gases, which trap heat in the atmosphere and contribute to climate change. Humans have pumped enough carbon dioxide into the atmosphere over the past 150 years to raise its levels higher than they have been for hundreds of thousands of years. Other greenhouse gases include methane —which

comes from such sources as landfills, the natural gas industry, and gas emitted by livestock—and chlorofluorocarbons (CFCs), which were used in refrigerants and aerosol propellants until they were banned in the late 1980s because of their deteriorating effect on Earth's ozone layer.
Another pollutant associated with climate change is sulphur dioxide, a component of smog. Sulphur dioxide and closely related chemicals are known primarily as a cause of acid rain. But they also reflect light when released in the atmosphere, which keeps sunlight out and creates a cooling effect. Volcanic eruptions can spew massive amounts of sulphur dioxide into the atmosphere, sometimes causing cooling that lasts for years. In fact, volcanoes used to be the main source of atmospheric sulphur dioxide; today, people are. Airborne particles, depending on their chemical makeup, can also have direct effects separate from climate change. They can change or deplete nutrients in soil and waterways, harm forests and crops, and damage cultural icons such as monuments and statues.

4.4.4 Management of air pollution

Countries around the world are tackling various forms of air pollution. China, for example, is making strides in cleaning up smog-choked skies from years of rapid industrial expansion, partly by closing or cancelling coal-fired power plants. In the U.S., California has been a leader in setting emissions standards aimed at improving air quality, especially in places like famously hazy Los Angeles. And a variety of efforts aim to bring cleaner cooking options to places where hazardous cookstoves are prevalent. In any home, people can safeguard against indoor air pollution by increasing ventilation, testing for radon gas, using air purifiers, running kitchen and bathroom exhaust fans, and avoiding smoking. When working on home projects, look for paint and other products low in volatile organic compounds. To curb global warming, a variety of measures need to be taken, such as adding more renewable energy and replacing gasoline-fuelled cars with zero-emissions vehicles such as electric ones. On a larger scale, governments at all levels are making commitments to limit emissions of carbon dioxide and other greenhouse gases. The Paris Agreement, ratified on November 4, 2016, is one effort to combat climate change on a global scale. And the Kigali Amendment seeks to further the progress made by the Montreal Protocol, banning heat-trapping hydrofluorocarbons (HFCs) in addition to CFCs.

4.4.5 Air-pollution studies and exposure assessment

For more than 4 decades, researchers have studied the impact of air pollution, most notably respirable particles and other priority pollutants, on human health. Carefully designed studies have provided a wealth of important information about relations between ambient exposures and adverse health consequences. There are several benefits of ambient-air monitoring in epidemiologic characterization of health-related effects of air pollution. Rather than relying on the mean concentration of ambient air

pollutants only, evaluation of the numbers of hours that ambient air pollutants exceeded thresholds could be more helpful. In a large-scale analysis of ambient daily air pollution and mortality, there was a strong relation between air-pollution levels and daily mortality over the period 1958-1972 in London, England. Inclusion of terms for changes in temperature and humidity increased the strength of the relation between particles and mortality. The inclusion of weather data in the analysis illustrated how indirect measures of exposure can strengthen existing associations. Individuals in the study groups should be encouraged to keep health diaries because information derived from daily health diaries can be particularly important. For example, diaries can capture variability in the occurrence of symptoms, which can be related to variation in air-pollutant concentrations. Diary should record the health status of each study participant repeatedly over time and can define the impact of short-term changes in the environment on human health. In an analysis of data from Six Cities Study of Air Pollution and Health and from a nurses' diary study in Los Angeles, exposure information was obtained from air-monitoring stations as well as from data on the type of cooking stove and history of parental and roommate smoking. A statistically significant relation between air pollution and reported symptoms remained after the effects of autocorrelation and heterogeneity were addressed. The Health Interview Survey (HIS) of a sample of thousands of US residents was used to assess the relation between acute respiratory morbidity and air pollution. The large number of subjects in this study aided in the identification of statistically significant associations.

4.5 SOIL POLLUTION

Environment pollution is a burning topic of the day. Air, water and soil are being polluted alike. Soil being a "universal sink" bears the greatest burden of environmental pollution. It is getting polluted in a number of ways. There is urgency in controlling the soil pollution in order to preserve the soil fertility and increase the productivity.

The basis of agriculture is Soil. All crops for human food and animal feed depend upon it. We are losing this important natural resource by the accelerated erosion 10 some extent. In addition to this the enormous quantities of man-made waste products, sludge and other product" from new waste treatment plants even polluted water are also causing or leading to soil pollution. In order to preserve the fertility and the productivity of the soil, control measures are to be taken in a herculean manner, thereby improving the health of all living beings.

Assessing the ecological risk of contaminated soil, pesticide application, sewage sludge amendment, and other human activities leading to exposure of the terrestrial environment to hazardous substances is a complicated task with numerous associated problems. Not only is terrestrial ecological risk assessment a relatively new field of science that has developed rapidly only since the mid-1980s, but it is also complicated by the fact that soil, in contrast to most aquatic environments, is very often on private lands and traded as real estate. Professional and economic divergence between the interests of scientists, stakeholders, authorities, engineers, managers, lawyers, nongovernment organizations (NGOs) and regulators is therefore not unusual. Even neglecting those aspects, a number of unresolved problems exist in the way we currently assess risk and manage the impact of anthropogenic substances in the terrestrial environment.

Soil pollution is defined as the build-up in soils of persistent toxic compounds, chemicals, salts, radioactive materials, or disease-causing agents, which have adverse effects on plant growth and animal health. Soil is the thin layer of organic and inorganic materials that covers the Earth's rocky surface. The organic portion, which is derived from the decayed remains of plants and animal, is concentrated in the dark uppermost topsoil. The inorganic portion made up of rock fragments, was formed over thousands of years by physical and chemical weathering of bedrock. Productive soils are necessary for agriculture to supply the world with sufficient food.
There are many different ways that soil can become polluted, such as:

- Seepage from a landfill
- Discharge of industrial waste into the soil
- Percolation of contaminated water into the soil
- Rupture of underground storage tanks
- Excess application of pesticides, herbicides or fertilizer
- Solid waste seepage

The most common chemicals involved in causing soil pollution are:

- Petroleum hydrocarbons
- Heavy metals
- Pesticides
- Solvents

4.5.1 Inorganic toxic compounds

Inorganic residues in industrial waste cause serious problems as regards their disposal. They contain metals which have high potential for toxicity. Industrial activity also emits large amounts of arsenic fluorides and sulphur dioxide (so_2). Fluorides are found in the atmosphere from superphosphate, phosphoric acid, aluminium, steel and ceramic industries. Sulphur dioxide emitted by factories and thermal plants may make soils very acidic. These metals cause leaf injury and destroy vegetation.
Copper, mercury, cadmium, lead, nickel, arsenic are the elements which can accumulate in the soil, if they get entry either through sewage, industrial waste or mine washings. Some of the fungicides containing copper and mercury also add to soil pollution. Smokes from automobiles contain lead which gets adsorbed by soil particles and is toxic to plants. The toxicity can be minimized by building up soil organic matter, adding lime to soils and keeping the soil alkaline.

4.5.2 Organic wastes

Organic wastes of various types cause pollution hazards. Domestic garbage, municipal sewage and industrial wastes when left in heaps or improperly disposed seriously affect health of human beings, plants and animals. Organic wastes contain borates, phosphates, detergents in large amounts. If untreated they will affect the vegetative growth of plants. The main organic contaminants are phenols and coal.
Asbestos, combustible materials, gases like methane, carbon dioxide, hydrogen sulphide, carbon monoxide, sulphur dioxide, petrol are also contaminants. The radioactive materials like uranium, thorium, strontium etc. also cause dangerous soil

pollution. Fallout of strontium mostly remains on the soil and is concentrated in the sediments. Decontamination procedures may include continuous cropping and use of chelate amendments. Other liquid wastes like sewage, sewage sludge, etc. are also important sources of soil problems.

4.5.3 Sewage and sewage sludge

Soil pollution is often caused by the uncontrolled disposal of sewage and other liquid wastes resulting from domestic uses of water, industrial wastes containing a variety of pollutants, agricultural effluents from animal husbandry and drainage of irrigation water and urban runoff. Irrigation with sewage water causes profound changes in the irrigated soils. Amongst various changes that are brought about in the soil as an outlet of sewage irrigation include physical changes like leaching, changes in humus content, and porosity etc., chemical changes like soil reaction, base exchange status, salinity, quantity and availability of nutrients like nitrogen, potash, phosphorus, etc. Sewage sludges pollute the soil by accumulating the metals like lead, nickel, zinc, cadmium, etc. This may lead to the phytoxicity of plants.

4.5.4 Heavy metal pollutants

Heavy metals are elements having a density greater than five in their elemental form. They mostly find specific absorption sites in the soil where they are retained very strongly either on the inorganic or organic colloids. They are widely distributed in the environment, soils, plants, animals and in their tissues. These are essential for plants and animals in trace amounts. Mainly urban and industrial aerosols, combustion of fuels, liquid and solid from animals and human beings, mining wastes, industrial and agricultural chemicals etc. are contributing heavy metal pollution. Heavy metals are present in all uncontaminated soils as the result of weathering from their parent materials. Concentration of heavy metals in soils and plants is given in Table 1.

Table 4.1. Heavy metal concentration in the lithosphere, soils and plants (Ug/gm dry matter)

S/No	Heavy metal	Lithosphere	Soil range	Plants
1	Cadmium (Cd)	0.2	0.01-0.7	0.2-0.8
2	Cobalt (Co)	40	1-40	0.05-0.5
3	Chromium (Cr)	200	5-3000	0.2-1.0
4	Copper (Cu)	70	2-100	4-15
5	Iron (Fe)	50,000	7000-5,50,000	140
6	Mercury (Hg)	0.5	0.01-0.3	0.015
7	Manganese (Mn)	1000	100-4000	15-100
8	Molybdenum (Mo)	2.3	0.2-5	1-10
9	Nickel (Ni)	100	10-1000	1
10	Lead (Pb)	16	2-200	0.1-10
11	Tin (Sn)	40	2-100	0.3
12	Zinc (Zn)	80	10-300	8-100

In agricultural soils, however, the concentration of one or more of these elements may be significantly increased in several ways, like through applications of chemicals, sewage sludge, farm slurries, etc. Increased doses of fertilizers, pesticides or agricultural chemicals, over a period, add heavy metals to soils which may contaminate them. Certain phosphatic fertilizers frequently contain trace amounts of cadmium which may accumulate in these soils. Likewise, some fertilizers when applied to soils, they add certain heavy metals which are given in Table 2.

Table 4.2: Heavy metal content of fertilizers (ug/gm)

S/No	Fertilizer	Co	Cr	Cu	Mn	Mo	Ni	Pb	Zn
1	Nitrochalk	-	-	22	24	-	2	-	15
2	Calcium	0.1	Traces	Traces	Traces	-	-	-	1
3	Nitrate	-	-	To 10	To 5	-	-	-	-
4	Ammonium sulphate	<5	<5	0.800	0.80	<0.05 to 0.22	<5	Traces to 200	0.800

5	Super phosphate	0.02-13	0-1000	Traces to 1000	Traces to 2842	Traces to 35	Traces to 32	Traces to 92	70-3000
6	Potassium chloride	001	-	0-10	Traces -8	<0.05	<1	<1	0-3
7	Potassium sulphate	<5	<5	0-300 to 80	Traces to .33	0.09	<5	<50	<50

The range of heavy metal contents in sludges is given in Table 3.

Table 4.3: Heavy metal contents in sludges (ppm)

S/No	Heavy metal	Range (ppm)
1	Cadmium	< 60-1500
2	Cobalt	2-260
3	Chromium	40-8800
4	Copper	200-8000
5	Iron	6000-62,000
6	Manganese	150-2500
7	Molybdenum	2-30
8	Nickel	20-5300
9	Lead	120-3000
10	Zinc	700-49,000

The fate of heavy metals in soil is controlled by physical and biological processes acting within the soil. Metal ions enter the soil solution from these various forms of combination at different rates. They may either remain in solution or pass into the drainage water or be taken up by plants growing on the soil or retained by the soil in sparingly soluble or insoluble forms. The organic matter of these soil has a high affinity to heavy metals cations that form stable complexes, thereby leading to reduced nutrient content.

4.5.5 Organic pesticides

Pesticides are quite frequently used to -control several types of pests now-a-days. Pesticides may exert harmful effects to micro-organisms, as a result of which plant growth may be affected. Pesticides which are not rapidly decomposed may create such problems. Accumulation is residues of pesticides in higher concentrations are toxic. Pesticides persistence in soil and movement into water streams may also lead to their entry into foods and create health hazards. Pesticides particularly aromatic organic compounds are not degraded rapidly and therefore, have a long persistence time which can be seen in Table 4.

Table 4.4 Persistence time for some selected pesticides

S/No	Pesticide	Persistence time
1	BHC	11 yrs
2	DDT	10 yrs
3	2,4-D	2-8 weeks
4	Aldrin	9 yrs
5	Diuron	16 months
6	Atrazine	18 months
7	Siwazine	17 months
8	Chlordane	12 yrs
9	2,3 6-Trichlorobenzene (TBA)	2-5 yrs

Mercury, cadmium and arsenic are common constituents of pesticides and all these heavy metals are toxic. At present DDT and a number of organochlorine compounds used as pesticides have been declared harmful and banned in U.S.A. and England. It is due to the persistence of their residues in soils for considerable time without losing their toxicity. This has led to higher concentration of these pesticides in vegetation, in animal flesh and milk. Eventually man has been affected. In view of their demerits, organochlorines have been replaced by organophosphate pesticides which are more toxic, but do not leave any residue. They do not pollute the soil. The rodenticides too add to soil pollution. A major method of checking this pesticidal pollution is to increase the organic matter content of the sol and choose such pesticides which are non-persistent and leave no harmful residue.

4.5.6 Types of soil pollution

Agricultural Soil Pollution

- pollution of surface soil
- pollution of underground soil

Soil pollution by industrial effluents and solid wastes

- pollution of surface soil
- disturbances in soil profile

Pollution due to urban activities

- pollution of surface soil
- pollution of underground soil

4.5.7 Sources of soil pollution

The sources which pollute the soil are twofold: Agricultural sources and non-agricultural sources. Figure 1 below shows the different sources for the soil pollution.

Agricultural sources

Soil pollution comes from different sources including agriculture and animal husbandry. Some of the agricultural practices lead to soil pollution. They are animal wastes, use of long-lived pesticides, herbicides, fungicides, nematocides, etc. fertilizers and some agricultural practices.

Non-agricultural sources

Soil pollution by non-agricultural sources is usually the direct result of urban sprawl caused by rapidly increasing population and a rapidly per capita output of waste related to our modem way of life. Its materials that find their entry into the soil system have long persistence and accumulate in toxic concentration and thus become sources of pollution. Some of those most important soil pollutants are inorganic toxic compounds.

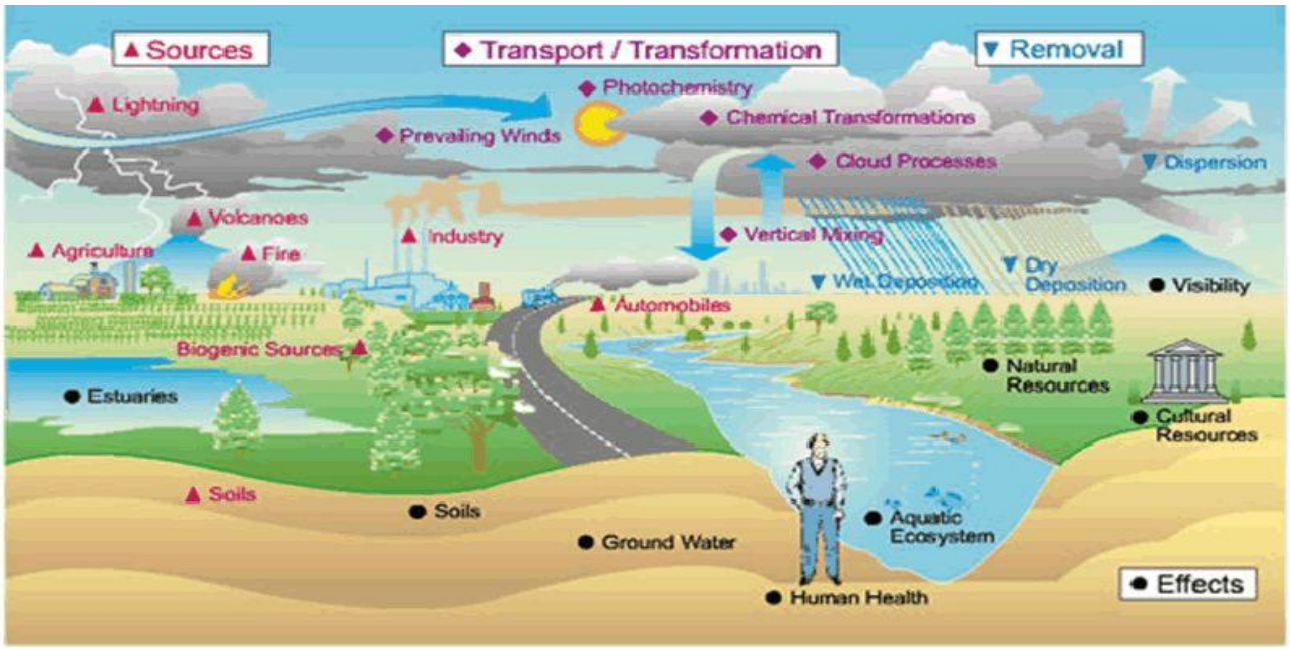

Figure 4.1: Sources of Soil Pollution

4.5.8 Causes of soil pollution

Soil pollution is caused by the presence of man-made chemicals or other alteration in the natural soil environment. This type of contamination typically arises from the rupture of underground storage links, application of pesticides, and percolation of contaminated surface water to subsurface strata, oil and fuel dumping, leaching of wastes from landfills or direct discharge of industrial wastes to the soil. The most common chemicals involved are petroleum hydrocarbons, solvents, pesticides, lead and other heavy metals. This occurrence of this phenomenon is correlated with the degree of industrialization and intensities of chemical usage. A soil pollutant is any factor which deteriorates the quality, texture and mineral content of the soil or which disturbs the biological balance of the organisms in the soil. Pollution in soil has adverse effect on plant growth.

Pollution in soil is associated with, indiscriminate use of fertilizers, indiscriminate use of pesticides, insecticides and herbicides, dumping of large quantities of solid waste, deforestation and soil erosion

4.5.9 Indiscriminate use of fertilizers

Oxygen from air and water but other necessary nutrients like nitrogen, phosphorus, potassium, calcium, magnesium, sulphur and more must be obtained from the soil. Farmers generally use fertilizers to correct soil deficiencies. Fertilizers contaminate the soil with impurities, which come from the raw materials used for their

manufacture. Mixed fertilizers often contain ammonium nitrate (NH_4No_3), phosphorus as P_2O_5 , and potassium as K_2O . For instance, As , Pb and Cd present in traces in rock phosphate mineral get transferred to super phosphate fertilizer. Since the metals are not degradable, their accumulation in the soil above their toxic levels due to excessive use of phosphate fertilizers becomes an indestructible poison for crops. The over use of NPK fertilizers reduce quantity of vegetables and crops grown on soil over the years. It also reduces the protein content of wheat, maize, grams, etc., grown on that soil. The carbohydrate quality of such crops also gets degraded. Excess potassium content in soil decreases Vitamin C and carotene content in vegetables and fruits. The vegetables and fruits grown on over fertilized soil are more prone to attacks by insects and disease.

4.5.10 Indiscriminate use of pesticides, insecticides and herbicides

Plants on which we depend for food are under attack from insects, fungi, bacteria, viruses, rodents and other animals, and must compete with weeds for nutrients. To kill unwanted populations living in or on their crops, farmers use pesticides. The first widespread insecticide use began at the end of World War II and included DDT (dichlorodiphenyltrichloroethane) and gammaxene. Insects soon became resistant to DDT and as the chemical did not decompose readily, it persisted in the environment. Since it was soluble in fat rather than water, it biomagnified up the food chain and disrupted calcium metabolism in birds, causing eggshells to be thin and fragile. As a result, large birds of prey such as the brown pelican, ospreys, falcons and eagles became endangered. DDT has been now been banned in most western countries. Ironically many of them including USA, still produce DDT for export to other developing nations whose needs outweigh the problems caused by it.

4.5.11 Dumping of solid wastes

In general, solid waste includes garbage, domestic refuse and discarded solid materials such as those from commercial, industrial and agricultural operations. They contain increasing amounts of paper, cardboards, plastics, glass, old construction material, packaging material and toxic or otherwise hazardous substances. Since a significant amount of urban solid waste tends to be paper and food waste, the majority is recyclable or biodegradable in landfills. Similarly, most agricultural waste is recycled and mining waste is left on site. The portion of solid waste that is hazardous such as oils, battery metals, heavy metals from smelting industries and organic solvents are the ones we have to pay particular attention to. These can in the long run, get deposited to the soils of the surrounding area and pollute them by altering their chemical and biological properties.

4.5.12 Deforestation

Soil Erosion occurs when the weathered soil particles are dislodged and carried away by wind or water. Deforestation, agricultural development, temperature extremes, precipitation including acid rain, and human activities contribute to this erosion. Humans speed up this process by construction, mining, cutting of timber, over cropping and overgrazing. It results in floods and cause soil erosion. Forests and grasslands are an excellent binding material that keeps the soil intact and healthy.

They support many habitats and ecosystems, which provide innumerable feeding pathways or food chains to all species. Their loss would threaten food chains and the survival of many species. During the past few years quite a lot of vast green land has been converted into deserts. The precious rain forest habitats of South America, tropical Asia and Africa are coming under pressure of population growth and development (especially timber, construction and agriculture). Many scientists believe that a wealth of medicinal substances including a cure for cancer and aids, lie in these forests. Deforestation is slowly destroying the most productive flora and fauna areas in the world, which also form vast tracts of a very valuable sink for CO_2.

4.5.13 Pollution due to urbanization

Pollution of surface soils materials (like vegetables, animal wastes, papers, wooden pieces, carcasses, plant twigs, leaves, cloth wastes as well as sweepings) and many non-biodegradable materials (such as plastic bags, plastic bottles, plastic wastes, glass bottles, glass pieces, stone / cement pieces). On a rough estimate Lagos State is producing solid city wastes to the tune of about 15,000 metric tons every day. If left uncollected and decomposed, they are a cause of several problems such as;
Clogging of drains: Causing serious drainage problems including the burst / leakage of drainage lines leading to health problems.
Barrier to movement of water: Solid wastes have seriously damaged the normal movement of water thus creating problem of inundation, damage to foundation of buildings as well as public health hazards.

Foul smell: Generated by dumping the wastes at a place.
Increased microbial activities: Microbial decomposition of organic wastes generate large quantities of methane besides many chemicals to pollute the soil and water flowing on its surface.
When such solid wastes are hospital wastes, they create many health problems: As they may have dangerous pathogen within them besides dangerous medicines, injections.

Pollution of underground soil

Underground soil in cities is likely to be polluted by Chemicals released by industrial wastes.
Decomposed and partially decomposed materials of sanitary wastes
Many dangerous chemicals like cadmium, chromium, lead, arsenic, selenium products are likely to be deposited in underground soil. Similarly, underground soils polluted by sanitary wastes generate many harmful chemicals. These can damage the normal activities and ecological balance in the underground soil.

4.5.14 Effects of soil pollution

Agricultural

- Reduced soil fertility
- Reduced nitrogen fixation
- Increased erodibility
- Larger loss of soil and nutrients
- Deposition of silt in tanks and reservoirs
- Reduced crop yield

- Imbalance in soil fauna and flora

Industrial

- Dangerous chemicals entering underground water
- Ecological imbalance
- Release of pollutant gases
- Release of radioactive rays causing health problems
- Increased salinity
- Reduced vegetation

Urban

- Clogging of drains
- Inundation of areas
- Public health problems
- Pollution of drinking water sources
- Foul smell and release of gases
- Waste management problems
- Environmental
- Soil becomes unavailable to grow food

If contaminated soil is used to grow food, the land will usually produce lower yields
Can cause even more harm because a lack of plants on the soil will cause more erosion. The pollutants will change the makeup of the soil and the types of microorganisms that will live in it. Thus, it's possible for soil pollution to change whole ecosystems

4.5.15 Control of soil pollution

The following steps have been suggested to control soil pollution. To help prevent soil erosion, we can limit construction in sensitive area. In general, we would need less fertilizer and fewer pesticides if we could all adopt the three R's: Reduce, Reuse, and Recycle. This would give us less solid waste.

Extraction and separation techniques

In solvent extraction, the contaminated & oil is mixed with an extracting agent in general (an aqueous solution but preferably an organic solvent). Potential applications include the removal of metals such as cadmium, copper, zinc, nickel, chromium, arsenic, antimony and lead using a mineral solution, zinc lead, organo-metallic compounds and some cyanides using sodium hydroxide solution. Hydrocarbons and halogenated hydrocarbons can also be removed. Contamination is often preferentially present in the finer or coarser fraction of the soil or the organic components (ex. humus), contamination can therefore, be removed in some cases using a process which separates the soil into fractions on the basis of specific gravity or particle size or settling velocity.

Thermal methods

In thermal methods, there are two ways of heat treatment; removal of contaminants by evaporation either by direct heat transfer from heated air or an open flame or by indirect heat transfer, and destruction of the contaminants directly or indirectly at an appropriate temperature. The gas leaving the heating appliance must be treated to destroy or remove any contaminants or unwanted products of combustion. A related

process is stream stripping in which steam is injected into soil to aid evaporation of relatively volatile contaminants which may be water soluble or insoluble.

Chemical methods
Treatment of the soil in suspension in a suitable liquid and without sludging is the two possible methods. In these, intimate, contact between soil and chemical is essential and should be frequently done so that the process of detoxification is complete.

Microbial treatment methods
The microbial treatment methods appear to be more promising which can deal with whole range of organic contaminants including phenol, polychlorinated hydrocarbons, oil and oil products, dioxins, etc. There are two different ways of approaching the problems. A community of microbes already existing on the site is collected and cultured in the laboratory. Strains of microbes are developed in the laboratory that is capable of metabolizing particular chemicals. Excavation of the soil prior to treatment offers the greatest scope for creating optimum conditions. The excavated soil can be placed on thin layers to various depth using standard earth moving techniques and microbes and nutrients applied using standard agricultural techniques such as fertilizing, ploughing, harrowing, etc.

Reducing chemical fertilizer and pesticide use
Applying bio-fertilizers and manures can reduce chemical fertilizer and pesticide use. Biological methods of pest control can also reduce the use of pesticides and thereby minimize soil pollution.

Reusing of materials
Materials such as glass containers, plastic bags, paper, cloth etc. can be reused at domestic levels rather than being disposed, reducing solid waste pollution.
Recycling and recovery of materials
This is a reasonable solution for reducing soil pollution. Materials such as paper, some kinds of plastics and glass can and are being recycled. This decreases the volume of refuse and helps in the conservation of natural resources. For example, recovery of one tonne of paper can save 17 trees.

Reforesting
Control of land loss and soil erosion can be attempted through restoring forest and grass cover to check wastelands, soil erosion and floods. Crop rotation or mixed cropping can improve the fertility of the land.

Solid waste treatment
Proper methods should be adopted for management of solid waste disposal. Industrial wastes can be treated physically, chemically and biologically until they are less hazardous. Acidic and alkaline wastes should be first neutralized; the insoluble material if biodegradable should be allowed to degrade under controlled conditions before being disposed. As a last resort, new areas for storage of hazardous waste should be investigated such as deep well injection and more secure landfills. Burying

the waste in locations situated away from residential areas is the simplest and most widely used technique of solid waste management.

4.6 WATER POLLUTION

Fig. 3: Water and Soil pollutions constituting hazard to human inhabitants

4.6.1 Introduction

Industrialization, in any society, is a major initiator of development and urbanization. Although the merits of industrialization are innumerable, it has been identified as a major threat to the environment as it releases various toxic chemicals, gases, solid wastes as well as microbes of various kinds into our immediate environment—land, air, and water. Of particular interest is water pollution, which has become a global challenge, developing nations being highly affected due to their drive for development.

Pollution of our water bodies poses a great threat to humans and the aquatic ecosystem while marked population increase catalyzes climatic changes. For instance, various human activities as well as the release of greenhouse gases by industries greatly contributes to global warming, planet temperature enhancement, and lowering of atmospheric air quality.

The drive for sustainable development must bring along water pollution prevention techniques. Effective wastewater treatment before their eventual discharge is one way to driving water pollution prevention. Some remediate climate change mitigation measures against water pollution can also be explored.

This chapter is aimed at critically discussing water pollution effects viz-a-viz global challenges, threat, and climatic impacts while also focusing on various possible preventive measures.

4.6.2 Water pollution

Promoting environmental sustainability

Sustainable development in any society is an access to initiate a good standard of living for the populace. It aims at providing solutions to the economic, environmental, and societal challenges without posing a threat to human and environmental future development, that is, we must consider the future as we make present decisions. Also, these include social progress and equality, environmental protection, conservation of natural resources, and stable economic growth.

There are numerous instances where urbanization has destroyed the environment and threatened its survival chances. Sustainable development put into consideration how we survive in the natural world protecting it from destruction and damages. One of the major challenges of urbanization is sustainability, as most developed or developing society now revitalizes a lot of natural resources daily. Most of these resources meet the needs of man but they are also limited. Sustainable development tends to balance the competing needs of the society. In achieving this, many science bodies and institutions have seen the requisite of sustainable development and have set goals and targets to meet it. This also has pushed such institutions to have a role in measuring and monitoring the impact of these goals on the society. However, the contribution of scientist in sustainable development should not only focus on the environment. It should also take into consideration the health of the populace in ensuring that no area of life suffers.

While sustainable development may mean different things to different people, environmental sustainability is all encompassing. It is directly concerned with the future of humanity, and it defines how we should protect and handle the sustainability of resources, air quality, water quality, and ecosystems. It also helps to prevent the environment from impending damage from technological advancement. One way to achieving environmental sustainability is via effective wastewater treatment.

Various conventional wastewater treatment methods are available; their characteristics vary from complexities of operations through sludge generations among other things to various inadequacies. Their economic disadvantages are widely related to expensive equipment, complexities of operations and skilful manpower requirement. Many industries avoid the conventional wastewater treatment methods due to their economic disadvantages, hence discharging untreated or fairly treated wastewater into the water bodies. A simple and cheap wastewater treatment method will therefore facilitate effective wastewater treatment and protect the water environment from pollution.

4.6.3 Effects and challenges

Water is an essential and general need of life with an undeniable effect directly or indirectly. All industrial, environmental, and metabolic processes are water dependent. In living organisms, water plays a number of roles such as solvent, temperature buffer, metabolite, living environment, and lubricants. Water, however, is said to be polluted when some of the water quality parameters have been hampered by unguided and irregularities from several anthropogenic activities, thus rendering water unfit for intended use.

Water pollution may pose serious threat to the environment as well as lives. Pollutant effects may vary depending on their types and source. For instance, while heavy

metals, dyes, and some other organic pollutants have been identified as carcinogens, hormones, pharmaceuticals, and cosmetics and personal care product wastes are known as endocrine disruptive chemicals. These pollutants, which enter into the water body through various channel but predominantly anthropogenic, have become a great concern to environmentalists due to various hazard they pose on the environment.

4.6.4 Heavy metal pollution

Heavy metals top the list of inorganic pollutant with wide range of negative effects on aquatic organisms, plants, and human. Heavy metals are released into the environment via different routes such as industries, mining activities, agricultural activities etc. Bioavailable metals present in the soil may be absorbed by plants resulting in serious plant metabolism dysfunction. High heavy metal ion concentrations are also known to damage the cell membrane, affect enzyme involved in chlorophyll production, thus reducing photosynthetic rate as well as affect plant reproduction via decrease in pollen and seed viability.

Humans and animals can be exposed to heavy metal toxicity through the food web, direct consumption of water containing metal or via inhalation. Heavy metals readily bioaccumulates in vegetables and enters into man and animal through food chain. Effects of heavy metal toxicity on human ranges from mild eye, nose and skin irritations through severe headache, stomach ache, diarrhoea, hematemesis, vomiting, dizziness to organ dysfunction such as cirrhosis, necrosis, low blood pressure, hypertension, and gastrointestinal distress. While some heavy metals also called essential elements (cobalt, copper, iron, manganese, vanadium, and zinc) are required in minute amount in the body for various biochemical processes; others such as lead, cadmium, arsenic, and mercury are of serious threat and considered foreign in the body. Looking at specifics, human ingestion of water polluted with arsenic can cause cancer of the lungs, liver, and bladder. Kidney and lungs damage as well as bone fragility may result when cadmium containing water is ingested. Exposure to lead can severely damage the brain and kidneys. In children, lead exposure even at very low concentration may hamper learning, cause memory loss, affect attention and response functions, and generally make children aggressive. In pregnant women, high levels of exposure to lead may cause miscarriage, whereas in men, it can damage the organs responsible for sperm production. Mercury is unique amidst other heavy metals; it has the capacity to travel a wide range of distance, thus have been classified as a global pollutant. The chemical form of mercury in the environment is also important in analysing their toxicity. The organic form of mercury, that is, methyl mercury $[CH_3Hg]^+$ and dimethyl mercury $(CH_3)_2 Hg$, is known to be more toxic than inorganic mercury. While inhaled mercury goes into the blood stream, their elimination from the body is either through the urine or faeces. Mercury has the ability to exist in the urine for about 2 months, hence their renal dysfunction characteristic.

Many physiological disorders may accompany crustaceans' exposure to metals, and instant metabolic activities' alterations. Exposure of crustaceans to heavy metals may also result in loss of appetite for food and subsequently body weight loss. Continuous exposure may reduce reproduction in adults as well as hamper the growth larvae.

4.6.5 Organic pollutants

Organic pollutants are very wide in variety with a huge range of toxicity. Among the list of organic pollutants that has been of great threat to aquatic organisms, plants, and humans are dyes, plant and animal pharmaceuticals, personal care products waste as well as petroleum organic pollutants. A group of chemicals referred to as Endocrine Disruptive Chemicals (EDCs) also belongs to the organic pollutants group, which are classed as emerging contaminants. EDCs are described as external agents that interfere with hormonal activities, thus affecting the normal homeostatic reproduction, development or behaviour.

Dyes are water soluble giant chemical that is greatly used in many industries viz; textile, leather and tanning, food, paper, etc. to impact color on products. Aquatic organisms, plants, and humans are greatly affected by dyes' presence in water. They impede sunlight penetration into water bodies and reduce dissolved oxygen, thus leading to death of photosynthetic organism and other lives within the aquatic environment. Humans may be exposed to dye toxicity via consumption of vegetables and fish which bioaccumulate dyes. The use of colored paper towels used in drying hands and in food preparation is another route of exposure to human. Dyes are considered as carcinogenic and mutagenic, thus their removal from wastewater before disposal is ultimately important.

Human and veterinary pharmaceuticals, which are members of EDCs, are chemicals used as curative or preventive of various diseases. Veterinary pharmaceutical may also serve the purpose of increasing efficiency of food production. Pharmaceuticals are used widely and unavoidably, thus they enter into the environment through indiscriminate disposal of hospital and household waste, landfill leaching, drainage water and sewage. Although pharmaceuticals have been found to exist in various environmental samples at the ng/l to μg/l levels, it is considered a great threat to both aquatic lives and humans. The presence of pharmaceuticals in water is known to pose both acute and chronic toxicity on aquatic organisms. EDCs as their name implies causes abnormal endocrine activities and increase cancer risk in human. Their effects on aquatic lives may range from endocrine system disruption through the reduction in eggs and sperm cells production to feminization of female aquatics.

4.6.6 Salvaging the aquatic environment: demands and expectations

Water is one important part of our day to day activities and their preservation can never be overemphasized. Three quarter of the fluid in man is made of water and it forms the essential medium in which the biochemical reactions take place in human body. Water moves blood from one place to the other in the body and helps in digestion; electrically charged ions, which generate nerve signals that make the human brain possible, are also held and transported by water. Water is a good solvent and it is usually referred to as universal solvent; all the major components in cells, that is, protein, deoxyribonucleic acid (DNA) and polysaccharides are all soluble in water. Pure water is tasteless, odourless, and transparent and thus provides a habitat for aquatic plants and organisms because sunlight can reach them within the water. Though clean water is a vital commodity for the well-being of human but unfortunately, the availability of fresh water is unevenly distributed and greatly threatened where available due to problems associated with climate change, inefficient water management and pollution. Recent report says very high percentage of the world population still lacks water for human well-being and ecosystem conservation.

The world is faced with the dilemma of achieving balance between economic development and sustainable natural environment.
Effective wastewater treatment has been earlier identified a way of protecting the water environment with detailed discussion on effective, cheap, and accessible method of wastewater treatment. Various other methods of water purification such as forward and/or reverse osmosis, precipitations, coagulation, filtrations, modular anaerobic system, microbial fuel cell, and advanced oxidation process with their attendant challenges have been reported in literature.
Various environmental policies stipulating discharge protocols exists. These policies are however not effectively executed as the industries consider them as damaging to business. The ability of industries to run with the various environmental discharge policies will sustain our natural environment.
Policy integration, that is, factoring environmental issues of concern into the core of economic development, is highly important to facilitate policy performance. The main actors in environmental issues, that is, the industries, agro firms, and populace, show very little understanding of the impact of their activities on the present and future environment. While organized periodical training concerning environmental sustainability should form part of environmental policy objectives, ensuring that these objectives are integrated into sectors plains and policies is important.

4.6.7 Microbial perspective of water pollution and remediation

Drinking water supplied to our communities is usually sourced from rivers, springs, and underground sources. Usually, some form of treatment is carried out to ensure the water is fit for drinking although some sources are somewhat free from contaminating microorganism and can be clean, for example deep well. In many developing countries, one source of water can serve many uses such as drinking, washing, swimming, bathing, etc. In the same vein, sewage can be channelled into water bodies. Sewage can be defined as used water draining out of homes and industries that contain a wide range of debris, chemicals, and microorganisms. Such water is regarded as potential health hazard to consumers or the users of other sort. A major kind of hazard is the presence of pathogenic organisms in such water. This is why water is usually treated in three phases.
The first is to separate large matter in the water source and the second stage focuses on removing more toxic substances and other matter. The tertiary phase involves total purification of water commonly by chemical disinfection. More recently, membrane bioreactors are being used and have been found to be very efficient in removing contaminants. These are combinations of communities and high-efficiency membranes that are much more effective at removing contaminants. The role of microbes is obvious in the second stage where microorganisms actively carry out biodegradation of organic matter in the aqueous portion produced after the first stage. Biodegradation of materials, such as paper and petroleum, are by bacteria, algae, and protozoa. When water is exposed to air, soil as well as effluents, it gains saprobic microorganisms; it can also pick up pathogens such as *Cryptosporium*, *shigella Campylobacter*, *Salmonella*, etc.
To monitor water for each of these pathogens may not be possible but detection of fecal contamination is an easier way of spotting contamination. In such case, when the fecal contamination is high, pathogens are believed to be present and the water is

unsafe for drinking. Hence, indicator organisms are used as tools to detect fecal contamination of water. They usually inhabit the intestine of mammals and birds and can be easily identified using common laboratory procedures. To achieve water protection, it will be almost impossible to search for the pathogens themselves. Hence, certain organisms with specified criteria are used as 'indicators' of the presence of enteric pathogens in a water sample. An indicator bacterium should be applicable for analysis of all types of water; it should be found anytime enteric pathogens are present and it should thrive in the wastewater longer than the toughest enteric pathogen. In addition, such organism should not reproduce in the contaminated water because this will give exaggerated values and it should not be harmful to human begins. Other criteria are that the level of contamination should be directly proportional to the level of fecal contamination; assay procedure for the indicator organism should be highly specific and the test procedure should be easily performed.

The following are commonly used as indicators of fecal contamination in water: total coliforms, Escherichia coli, fecal coliforms, fecal streptococci/enterococci, coliphage, and *Clostridium perfringens*. Coliforms are members of the family Enterobacteriaceae (they include *E. coli*). They are facultative anaerobic, Gram-negative, non-sporulating, rod-shaped bacteria that ferment lactose with gas formation within 48 hours at 35°C.

Microbial contamination of water can be detected by checking for certain organisms including heterotrophic bacteria, coliforms, and Escherichia coli in such samples.

Another biological treatment process of interest is the activated sludge. It is made up of an aeration basin where aeration equipment provides both oxygen and adequate mixing of wastewater to maintain a uniformly Mixed Liquor Suspended Solids (MLSS). The aeration basin is followed by a liquid–solid separation usually in a clarifier by gravity and finally the settled biomass is returned again to the activated sludge basin. Examples of aeration basin configurations are – plug-flow systems, single completely mixed basins, and basins in series. The Solid Retention Time (SRT) is important in this treatment process. The solid retention time is the average time biomass is maintained in a biological treatment process reaction. Generally, SRT control is temperature dependent and for a warmer climate (15–25°C), SRT should be between 4 and 9 days. The clarifier is very important in the performance of activated sludge processes. It ensures that efficient clarification and thickening of mixed liquor occurs. When the readily degradable soluble biochemical oxygen demand is high in wastewaters, growth of filamentous bacteria is encouraged leading to poor sludge settlement. The use of Powdered Activated Carbon (PAC) has been discovered to enhance the efficiency of activated sludge processes. The PAC functions by adsorbing inhibitory chemicals or adsorbing chemicals that buffer variable loads. The application between 10 and 50 mg/liter of wastewater has been proven to remove organic inhibitors of the process as well as improve nitrification since it absorbs organic compounds that can prevent this process (ammonia-nitrite/nitrate conversion) in autotrophic bacteria.

Apart from the aforementioned, anaerobic bioreactors are also beneficial for the industrial wastewater treatment. This is because it is cost effective and can be used for industrial wastewater with high strength. The processes in the anaerobic bioreactor lead to the production of mainly methane as well as other gases. However, there is a need to strike a balance between fermentation bacterial activity and methanogenic bacteria activity as the latter is slow growing. Advantages of anaerobic treatment

include low sludge formation, production of useful product, low nutrient requirement, and more importantly less energy requirements since aeration is not necessary. In addition to the energy production, advantages of anaerobic wastewater treatment, high organic matter removal efficiency, low excess sludge production, and stable operation are characteristics of this wastewater treatment technique.

A most recent advancement in the biological treatment of wastewater is the use of membranes in bioreactors. In such cases, the membrane can serve three major purposes. Firstly, membranes can be used as a surface for the attachment for growth of organisms and to permit oxygen to permeate into the biofilm. An example of this is the hollow-fiber gas-permeable membranes in wastewater treatment. Such membrane is produced from microporous, hydrophobic polypropylene and allows almost 100% oxygen transfer while ensuring high biomass density within the space. The second way membranes can be used as selective barriers. Such membranes permit organic compounds in wastewater to permeate but do not transport ions into the bioreactor. Thus, it allows for the selection of biodegradable organic compounds. An example of a material used for such membrane is silicone rubber. Finally, membranes can be for biomass separation. This third category requires that the membrane be used instead of a clarifier after activated sludge treatment. When such membranes are used, the effluent produced is of high quality and less sludge. In addition, automated processing can be easily employed. The disadvantage however is the financial enormity of the investment for initial start-up as well as maintenance.

4.6.8 Herbal disinfection of water

Several modern methods of water purification have been well embraced in our society today. However, some rural dwellers who may not be able to afford these modern treatment methods still have water pollution as a major challenge. Furthermore, the disinfection by-products which remain after treatment is another reason why herbal attempt in water treatment should be encouraged.

It is important to note that not many researchers apply their antimicrobial extract or fractions directly in water treatment. Many groups stop at establishing the antimicrobial potential of their study plant, whereas others go further to apply the extracts in water treatment. For instance, a reported work used alcoholic, aqueous, and fresh juice extracts of *Ocimum sanctum* (tulsi) and *Azadirachta indica* (neem) and applied them in vitro against salmonella, which was chosen as an indicator organism. The alcoholic extract gave the best result for well water, whereas the aqueous extract was best for lake water. Similarly, inspired by the fact that tulsi, neem, and amla are used to treat microbial infection without any side effect, another researcher compared the effectiveness of these three herbs in water purification, using percentage of E. coli removal to measure the effectiveness of each herb. A notable observation is the fact that a mixture of 1% concentration of each herb is not as efficient as the synergistic combination of the three.

An indirect application of herbs in water purification is their use in the synthesis of nanoparticles, which are afterwards applied to remove contaminants from water. These extracts influence the surface properties of the nanoparticles, thus dictating their unique properties Owing to the obvious advantages of natural disinfection, there is a need for more research into natural products for water purification. This will in no

small way help rural dwellers to cheaply assess cheap clean water and so live a healthier lifestyle.

4.6.9 Water pollution and impact on climate

All organisms, including man need water for their survival. Water resource managers had strongly depended on wastewater treatment in ensuring that the quality of water is sustained, preserved, and maintained for optimal use. By 2025, an estimated around 5 billion people out of a total population of around 8 billion will be living in areas of water stress. One of the major environmental issues affecting humanity is the increasing worldwide contamination of freshwater systems as a consequence of industrial and chemical compound materials being emptied into their pathways/runways, majorly in form of micro-pollutants. Most of these pollutants are present at low concentrations although many of them can raise significant toxicological concerns, more importantly when such compounds are present as constituents of composite blends. Numerous micro-pollutants had been identified in literatures, which are not vulnerable to current treatment and are subsequently transported to the aquatic environment. Some of these include steroid hormones, pesticides, industrial chemicals, pharmaceuticals, and many other emerging materials. This consequently endangers both the aquatic and human life. It is therefore not surprising that freshwater pollution is a strong public menace, which requires global concern. The next quotation properly situates the environmental risk humans are exposed to:

*"**It is in the interest of all the world that climatic changes are understood and that the risks of irreversible damage to natural systems, and the threats to the very survival of man, be evaluated and allayed with the greatest urgency**"*

The above quotation were the statements of the President of the Republic of the Maldives, His Excellency Maumoon Abdul, Gayoom, during the United Nations General Assembly held in 1987 in the United States of America, as adapted from the (World Health Organization Geneva Report). The meeting was centered on Issues of Environment and Development. Due to climate change effect, both the thermal and hydrological phases of rivers are expected to vary. Owning to these, it is necessary to briefly discuss what climate change is as climate change has the potential of imposing additional pressures in some regions of the world.

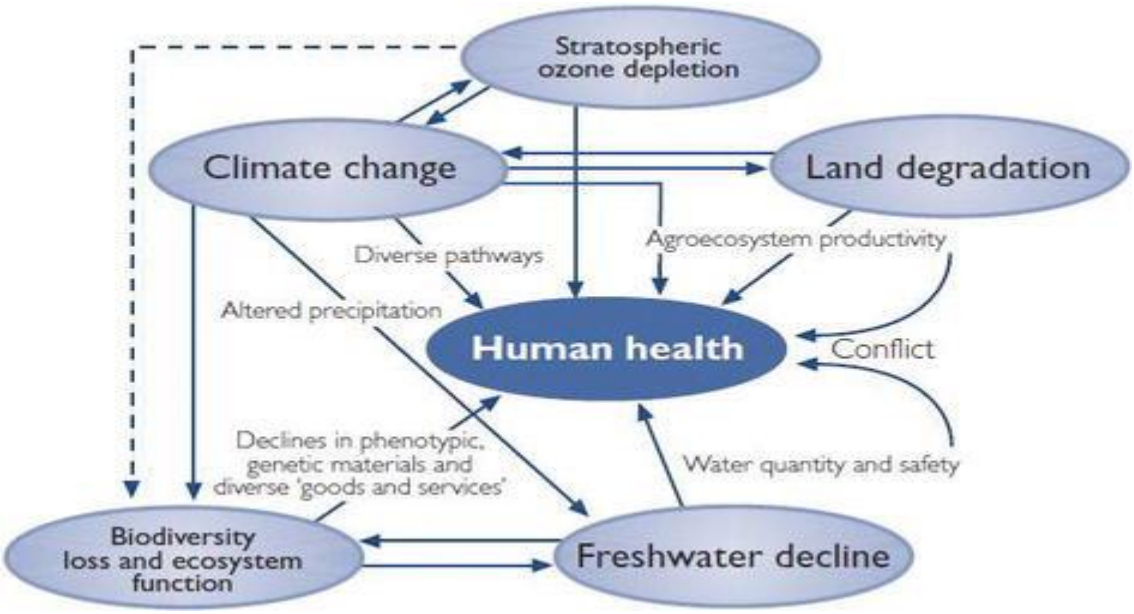

Figure 4.4: Inter-relationship between various kinds of environmental change. Adapted from WHO Geneva Report.

4.6.10 Probable link between water pollution and climatic impact

According to Intergovernmental Panel on Climate Change (IPCC), observational records and climate projections provide abundant evidence that freshwater resources are vulnerable and have the potential to be strongly impacted by climate change, with wide-ranging consequences for human societies and ecosystems. Human activity affects weather, climate, and the environment. While some of human activities are harmless, others damage the environment. While the environment can absorb some abuse without long-term effects, much harmful human activity exceeds the environment's capacity to recover. Water pollution is one of the inevitable human-induced climate change issues that called for urgent remedial measures. Water pollution will in no small measure affect or alter the basic water quality parameters comprising the micro-pollutants, physiochemical, and biological parameters. Probable and incessant changes in both rainfall and air temperature has the capacity to affect river flow thereby inducing chemical reaction kinetics as well as drop in the freshwater ecological quality. Associated with such process are dilution of contaminants and water sediment loads, which when ran into lakes will alter its natural features and affect its inhabitants. This form of water pollution or through man-made toxic chemical or/and by-products addition may therefore generate some toxic and greenhouse gases, which may subsequently contribute to global warming activities or more severe environmental threats.

The greenhouse gases are the gaseous constituents of the atmosphere (both natural and anthropogenic), which can absorb and emit radiation at certain wavelengths within the spectrum of thermal infrared radiation emitted by the earth's surface, the atmosphere itself, and the clouds. The primary greenhouse gases in the Earth's atmosphere include carbon dioxide (CO_2), nitrous oxide (N_2O), water vapor (H_2O), methane (CH_4), and ozone (O_3). The other ones identified from the Kyoto Protocol include hydrofluorocarbons (HFCs), perfluorocarbons (PFCs), and sulphur hexafluoride (SF_6

). Some of these environmental threats include earth's temperature enhancement (as earlier stated), lowering of atmospheric air quality, and killing of aquatic animals. Consequently, given the legacy of historic greenhouse gas emissions and the prospect of inevitable climate change, one cannot but commit significant financial and technical resources to remediating the effect through rigorous research efforts and sensitization activities, more importantly to water pollution and water-related issues. Thus, water resources managers are continuously and increasingly looking for information on the possible changes in hydrological regimes, which may arise in the next few decades for likeable adaptation measure plan.

An interesting challenge is that while incessant water pollution may bring about a change in climatic conditions through greenhouse effect and activities, the climate too will in turn take its toll effect on the water system and environment (hydrological cycles). This is because the higher temperature generated from the greenhouse effect will eventually turn some part of the snowfall into rainfall, causing an earlier snowmelt season. These effects will consequently alter the timing and volume of spring flood appreciably. The rise in sea level during this time will then cause saline water intrusion into groundwater aquifers close to the coast thereby reducing the available groundwater resources. This process will in no small measure affect humans as almost about 50% of the world population depends on groundwater for their various activities.

4.7 SUMMARY

Since water forms a core of the existence of human and other living things, its preservation and sustainable availability cannot be overemphasized. The availability of clean water is greatly threatened by various human activities and of interest is pollution which in turn affects the ecosystem and causes various climatic changes. While various wastewater treatment methods are being explored by industries and various treatment plants, untreated wastewater is still being discharged into the water bodies by some industries. Thus, effective environmental protection policies compliance drive will be of immense benefit to the environment and by extension to human. Factoring these environmental protection policies into the goals and objectives of various actors involved in environmental deterioration will help policies performance. This will serve as a step forward in the direction of ameliorating water pollution.

4.8 TUTOR-MARKED ASSIGNMENT

1. Describe how water pollution can affect climate change
2. What is soil pollution and how can it be managed?
3. What are the components of heavy metal pollution of the soil?
4. Define risk assessment and describe its components.

4.9 REFERENCES/FURTHER READING

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UNIT 5: IONIZING AND DE-IONIZING RADIATION

CONTENTS

5.1 INTRODUCTION

Ionizing radiation is a type of energy released by atoms in the form of electromagnetic waves or particles. People are exposed to natural sources of ionizing radiation, such as in soil, water, and vegetation, as well as in human-made sources, such as x-rays and medical devices. Ionizing radiation has many beneficial applications, including uses in medicine, industry, agriculture and research. As the use of ionizing radiation increases, so does the potential for health hazards if not properly used or contained. Acute health effects such as skin burns or acute radiation syndrome can occur when

doses of radiation exceed certain levels. Low doses of ionizing radiation can increase the risk of longer-term effects such as cancer. On the other hand, non-ionizing radiation are any form of electromagnetic radiation that does not have enough energy to ionise and atom. These types are much closer to people and although they are less harmful may still cause some negative health effects on long term exposure.

5.2 OBJECTIVES

It is expected that at the end of this unit you will be able to define ionizing and non-ionizing radiation and understand their sources, uses and negative effects on public health and the environment

5.3 IONIZING RADIATION

Ionizing radiation is a type of energy released by atoms that travels in the form of electromagnetic waves (gamma or X-rays) or particles (neutrons, beta or alpha). The spontaneous disintegration of atoms is called radioactivity, and the excess energy emitted is a form of ionizing radiation. Unstable elements which disintegrate and emit ionizing radiation are called radionuclides. Ionizing radiation (ionizing radiation) is radiation that carries sufficient energy to detach electrons from atoms or molecules, thereby ionizing them. Ionizing radiation is made up of energetic subatomic particles, ions or atoms moving at high speeds (usually greater than 1% of the speed of light), and electromagnetic waves on the high-energy end of the electromagnetic spectrum.

Gamma rays, X-rays, and the higher ultraviolet part of the electromagnetic spectrum are ionizing, whereas the lower ultraviolet part of the electromagnetic spectrum and all the spectrum below UV, including visible light (including nearly all types of laser light), infrared, microwaves, and radio waves are considered non-ionizing radiation. The boundary between ionizing and non-ionizing electromagnetic radiation that occurs in the ultraviolet is not sharply defined, since different molecules and atoms ionize at different energies. Conventional definition places the boundary at a photon energy between 10 eV and 33 eV in the ultraviolet (see definition boundary section below)

Typical ionizing subatomic particles found in radioactive decay include alpha particles, beta particles and neutrons. Almost all products of radioactive decay are ionizing because the energy of radioactive decay is typically far higher than that required to ionize. Other subatomic ionizing particles which occur naturally are muons, mesons, positrons, and other particles that constitute the secondary cosmic rays that are produced after primary cosmic rays interact with Earth's atmosphere. Cosmic rays are generated by stars and certain celestial events such as supernova explosions. Cosmic rays may also produce radioisotopes on Earth (for example, carbon-14), which in turn decay and produce ionizing radiation. Cosmic rays and the decay of radioactive isotopes are the primary sources of natural ionizing radiation on Earth referred to as background radiation. Ionizing radiation can also be

generated artificially by X-ray tubes, particle accelerators, and any of the various methods that produce radioisotopes artificially.

Ionizing radiation is not detectable by human senses, so radiation detection instruments such as Geiger counters must be used to indicate its presence and measure it. However, high intensities can cause emission of visible light upon interaction with matter, such as in Cherenkov radiation and radioluminescence. Ionizing radiation is used in a wide variety of fields such as medicine, nuclear power, research, manufacturing, construction, and many other areas, but presents a health hazard if proper measures against undesired exposure are not followed. Exposure to ionizing radiation causes damage to living tissue, and can result in radiation burns, cell damage, radiation sickness, cancer, and death.

All radionuclides are uniquely identified by the type of radiation they emit, the energy of the radiation, and their half-life.

The activity — used as a measure of the amount of a radionuclide present — is expressed in a unit called the becquerel (Bq): one becquerel is one disintegration per second. The half-life is the time required for the activity of a radionuclide to decrease by decay to half of its initial value. The half-life of a radioactive element is the time that it takes for one half of its atoms to disintegrate. This can range from a mere fraction of a second to millions of years (e.g. iodine-131 has a half-life of 8 days while carbon-14 has a half-life of 5730 years).

5.3.1 Radiation sources

People are exposed to natural radiation sources as well as human-made sources on a daily basis. Natural radiation comes from many sources including more than 60 naturally-occurring radioactive materials found in soil, water and air. Radon, a naturally-occurring gas, emanates from rock and soil and is the main source of natural radiation. Every day, people inhale and ingest radionuclides from air, food and water.

People are also exposed to natural radiation from cosmic rays, particularly at high altitude. On average, 80% of the annual dose of background radiation that a person receives is due to naturally occurring terrestrial and cosmic radiation sources. Background radiation levels vary geographically due to geological differences. Exposure in certain areas can be more than 200 times higher than the global average.

Human exposure to radiation also comes from human-made sources ranging from nuclear power generation to medical uses of radiation for diagnosis or treatment. Today, the most common human-made sources of ionizing radiation are medical devices, including X-ray machines.

5.3.2 Exposure to ionizing radiation

Radiation exposure may be internal or external, and can be acquired through various exposure pathways. Internal exposure to ionizing radiation occurs when a radionuclide is inhaled, ingested or otherwise enters into the bloodstream (for example, by injection or through wounds). Internal exposure stops when the radionuclide is eliminated from the body, either spontaneously (such as through excreta) or as a result of a treatment. External exposure may occur when airborne radioactive material (such as dust, liquid, or aerosols) is deposited on skin or clothes. This type of radioactive material can often be removed from the body by simply washing. Exposure to ionizing radiation can also result from irradiation from an external source, such as medical radiation exposure from X-rays. External irradiation stops when the radiation source is shielded or when the person moves outside the radiation field. People can be exposed to ionizing radiation under different circumstances, at home or in public places (public exposures), at their workplaces (occupational exposures), or in a medical setting (as are patients, caregivers, and volunteers). Exposure to ionizing radiation can be classified into 3 exposure situations. The first, planned exposure situations, result from the deliberate introduction and operation of radiation sources with specific purposes, as is the case with the medical use of radiation for diagnosis or treatment of patients, or the use of radiation in industry or research. The second type of situation, existing exposures, is where exposure to radiation already exists, and a decision on control must be taken – for example, exposure to radon in homes or workplaces or exposure to natural background radiation from the environment. The last type, emergency exposure situations, result from unexpected events requiring prompt response such as nuclear accidents or malicious acts. Medical use of radiation accounts for 98 % of the population dose contribution from all artificial sources, and represents 20% of the total population exposure. Annually worldwide, more than 3600 million diagnostic radiology examinations are performed, 37 million nuclear medicine procedures are carried out, and 7.5 million radiotherapy treatments are given.

5.3.3 Health effects of ionizing radiation

Radiation damage to tissue and/or organs depends on the dose of radiation received, or the absorbed dose which is expressed in a unit called the gray (Gy). The potential damage from an absorbed dose depends on the type of radiation and the sensitivity of different tissues and organs.

The *effective dose* is used to measure ionizing radiation in terms of the potential for causing harm. The Sievert (Sv) is the unit of effective dose that takes into account the

type of radiation and sensitivity of tissues and organs. It is a way to measure ionizing radiation in terms of the potential for causing harm. The Sv takes into account the type of radiation and sensitivity of tissues and organs.

The Sv is a very large unit so it is more practical to use smaller units such as millisieverts (mSv) or microsieverts (μSv). There are one thousand μSv in one mSv, and one thousand mSv in one Sv. In addition to the amount of radiation (dose), it is often useful to express the rate at which this dose is delivered (dose rate), such as microsieverts per hour (μSv/hour) or millisievert per year (mSv/year).

Beyond certain thresholds, radiation can impair the functioning of tissues and/or organs and can produce acute effects such as skin redness, hair loss, radiation burns, or acute radiation syndrome. These effects are more severe at higher doses and higher dose rates. For instance, the dose threshold for acute radiation syndrome is about 1 Sv (1000 mSv).

If the radiation dose is low and/or it is delivered over a long period of time (low dose rate), the risk is substantially lower because there is a greater likelihood of repairing the damage. There is still a risk of long-term effects such as cancer, however, that may appear years or even decades later. Effects of this type will not always occur, but their likelihood is proportional to the radiation dose. This risk is higher for children and adolescents, as they are significantly more sensitive to radiation exposure than adults.

Epidemiological studies on populations exposed to radiation, such as atomic bomb survivors or radiotherapy patients, showed a significant increase of cancer risk at doses above 100 mSv. More recently, some epidemiological studies in individuals exposed to medical exposures during childhood (paediatric CT) suggested that cancer risk may increase even at lower doses (between 50-100 mSv).

Prenatal exposure to ionizing radiation may induce brain damage in foetuses following an acute dose exceeding 100 mSv between weeks 8-15 of pregnancy and 200 mSv between weeks 16-25 of pregnancy. Before week 8 or after week 25 of pregnancy human studies have not shown radiation risk to fetal brain development. Epidemiological studies indicate that the cancer risk after fetal exposure to radiation is similar to the risk after exposure in early childhood.

5.4 NON-IONIZING RADIATION

Non-ionizing (non-ionising) radiation refers to any type of electromagnetic radiation that does not carry enough energy per quantum (photon energy) to ionize atoms or molecule – that is, complete removal of an electron from an atom or molecule. Instead of producing charged ions when passing through matter, non-ionizing electromagnetic radiation has sufficient energy only for excitation - the movement of an electron to a higher energy state. In contrast, ionizing radiation has a higher frequency and shorter wavelength than nonionizing radiation, and can be a serious health hazard; exposure to it can cause burns, radiation sickness, cancer, and genetic damage. Using ionizing radiation requires elaborate radiological protection measures, which in general are not required with nonionizing radiation. The region at which radiation becomes considered as "ionizing" is not well defined, since different molecules and atoms ionize at different energies. The usual definitions have suggested that radiation with particle or photon energies less than 10 electronvolts (eV) be considered non-ionizing. Another suggested threshold is 33 electronvolts, which is the energy needed to ionize water molecules. The light from the Sun that reaches the earth is largely composed of non-ionizing radiation, since the ionizing far-ultraviolet rays have been filtered out by the gases in the atmosphere, particularly oxygen. The remaining ultraviolet radiation from the Sun causes molecular damage (for example, sunburn) by photochemical and free-radical-producing means.

Different biological effects are observed for different types of non-ionizing radiation. The upper frequencies of non-ionizing radiation near these energies (much of the spectrum of UV light and some visible light) are capable of non-thermal biological damage, similar to ionizing radiation. Health debate therefore centers on the non-thermal effects of radiation of much lower frequencies (microwave, millimeter and radiowave radiation). The International Agency for Research on Cancer recently stated that there could be some risk from non-ionizing radiation to humans. But a subsequent study reported that the basis of the IARC evaluation was not consistent with observed incidence trends. This and other reports suggest that there is virtually no way that results on which the IARC based its conclusions are correct. The Bioinitiative Report 2012 makes the claim that there is significant health risk associated with low frequency non-ionizing electromagnetic radiation. This report claims that statistically significant increases in cancer among those exposed to even low power levels, low frequency, non-ionizing radiation. There is considerable debate on this matter. Currently regulatory bodies around the world have not seen the need to

5.4.1 Mechanisms of interaction with matter, including living tissue

Near ultraviolet, visible light, infrared, microwave, radio waves, and low-frequency radio frequency (longwave) are all examples of non-ionizing radiation. By contrast, far ultraviolet light, X-rays, gamma-rays, and all particle radiation from radioactive decay are ionizing. Visible and near ultraviolet electromagnetic radiation may induce photochemical reactions, or accelerate radical reactions, such as photochemical aging of varnishes or the breakdown of flavoring compounds in beer to produce the "lightstruck flavor" Near ultraviolet radiation, although technically non-ionizing, may still excite and cause photochemical reactions in some molecules. This happens because at ultraviolet photon energies, molecules may become electronically excited or promoted to free-radical form, even without ionization taking place. The

occurrence of ionization depends on the energy of the individual particles or waves, and not on their number. An intense flood of particles or waves will not cause ionization if these particles or waves do not carry enough energy to be ionizing, unless they raise the temperature of a body to a point high enough to ionize small fractions of atoms or molecules by the process of thermal-ionization. In such cases, even "non-ionizing radiation" is capable of causing thermal-ionization if it deposits enough heat to raise temperatures to ionization energies. These reactions occur at far higher energies than with ionizing radiation, which requires only a single particle to ionize. A familiar example of thermal ionization is the flame-ionization of a common fire, and the browning reactions in common food items induced by infrared radiation, during broiling-type cooking. The energy of particles of non-ionizing radiation is low, and instead of producing charged ions when passing through matter, non-ionizing electromagnetic radiation has only sufficient energy to change the rotational, vibrational or electronic valence configurations of molecules and atoms. This produces thermal effects. The possible non-thermal effects of non-ionizing forms of radiation on living tissue have only recently been studied. Much of the current debate is about relatively low levels of exposure to radio frequency (RF) radiation from mobile phones and base stations producing "non-thermal" effects. Some experiments have suggested that there may be biological effects at non-thermal exposure levels, but the evidence for production of health hazard is contradictory and unproven. The scientific community and international bodies acknowledge that further research is needed to improve our understanding in some areas. Meanwhile the consensus is that there is no consistent and convincing scientific evidence of adverse health effects caused by RF radiation at powers sufficiently low that no thermal health effects are produced.[2][4]

5.4.2 Non-ionizing radiation hazards

Non-ionizing radiation can produce non-mutagenic effects such as inciting thermal energy in biological tissue that can lead to burns. In 2011, the International Agency for Research on Cancer (IARC) from the World Health Organization (WHO) released a statement adding radiofrequency electromagnetic fields (including microwave and millimeter waves) to their list of things which are possibly carcinogenic to humans. In terms of potential biological effects, the non-ionizing portion of the spectrum can be subdivided into:

1. The optical radiation portion, where electron excitation can occur (visible light, infrared light)
2. The portion where the wavelength is smaller than the body. Heating via induced currents can occur. In addition, there are claims of other adverse biological effects. Such effects are not well understood and even largely denied. (MW and higher-frequency RF).
3. The portion where the wavelength is much larger than the body, and heating via induced currents seldom occurs (lower-frequency RF, power frequencies, static fields).

The above effects have only been shown to be due to heating effects. At low power levels where there is no heating affect, the risk of cancer is not significant.

Table 5.1: **Sources and properties of Non-ionizing Radiations**

Non-ionizing Radiation	Source	Wavelength	Frequency	Biological effects
UVA	Black light, Sunlight	318–400 nm	750–950 THz	Eye: photochemical cataract; skin: erythema, including pigmentation
Visible light	Sunlight, fire, LEDs, light bulbs, lasers	400–780 nm	385–750 THz	Eye: photochemical & thermal retinal injury; skin: photoaging
IR-A	Sunlight, thermal radiation, incandescent light bulbs, lasers, remote controls	780 nm – 1.4 µm	215–385 THz	Eye: thermal retinal injury, thermal cataract; skin: burn
IR-B	Sunlight, thermal radiation, incandescent light bulbs, lasers	1.4–3 µm	100–215 THz	Eye: corneal burn, cataract; skin: burn
IR-C	Sunlight, thermal radiation, incandescent light bulbs, far-infrared laser	3 µm – 1 mm	300 GHz – 100 THz	Eye: corneal burn, cataract; heating of body surface
Microwave	Mobile/cell phones, microwave ovens, cordless phones, millimeter waves, airport millimeter scanners, motion detectors, long-distance telecommunications, radar, Wi-Fi	1 mm – 33 cm	1–300 GHz	Heating of body tissue
Radio-frequency	Mobile/cell phones, television, FM, AM, shortwave, CB,	33 cm – 3 km	100 kHz – 1 GHz	Heating of body tissue, raised body temperature

radiation	cordless phones			
Low-frequency RF	Power lines	>3 km	<100 kHz	Cumulation of charge on body surface; disturbance of nerve & muscle responses[12]
Static field[2]	Strong magnets, MRI	Infinite	0 Hz (technically static fields are not "radiation")	Electric charge on body surface

5.4.3 Near ultraviolet radiation

Ultraviolet light can cause burns to skin[13] and cataracts to the eyes.[13] Ultraviolet is classified into near, medium and far UV according to energy, where near and medium ultraviolet are technically non-ionizing, but where all UV wavelengths can cause photochemical reactions that to some extent mimic ionization (including DNA damage and carcinogenesis). UV radiation above 10 eV (wavelength shorter than 125 nm) is considered ionizing. However, the rest of the UV spectrum from 3.1 eV (400 nm) to 10 eV, although technically non-ionizing, can produce photochemical reactions that are damaging to molecules by means other than simple heat. Since these reactions are often very similar to those caused by ionizing radiation, often the entire UV spectrum is considered to be equivalent to ionization radiation in its interaction with many systems (including biological systems).

For example, ultraviolet light, even in the non-ionizing range, can produce free radicals that induce cellular damage, and can be carcinogenic. Photochemistry such as pyrimidine dimer formation in DNA can happen through most of the UV band, including much of the band that is formally non-ionizing. Ultraviolet light induces melanin production from melanocyte cells to cause sun tanning of skin. Vitamin D is produced on the skin by a radical reaction initiated by UV radiation.

Plastic (polycarbonate) sunglasses generally absorb UV radiation. UV overexposure to the eyes causes snow blindness, common to areas with reflective surfaces, such as snow or water.

5.4.4 Visible light

Light, or visible light, is the very narrow range of electromagnetic radiation that is visible to the human eye (about 400–700 nm), or up to 380–750 nm.[4] More broadly, physicists refer to light as electromagnetic radiation of all wavelengths, whether visible or not.

High-energy visible light is blue-violet light with a higher damaging potential.

Infrared

Infrared (IR) light is electromagnetic radiation with a wavelength between 0.7 and 300 micrometers, which equates to a frequency range between approximately 1 and 430 THz. IR wavelengths are longer than that of visible light, but shorter than that of terahertz radiation microwaves. Bright sunlight provides an irradiance of just over 1 kilowatt per square meter at sea level. Of this energy, 527 watts is infrared radiation, 445 watts is visible light, and 32 watts is ultraviolet radiation.[4]

5.4.5 Microwave

Microwaves are electromagnetic waves with wavelengths ranging from as long as one meter to as short as one millimeter, or equivalently, with frequencies between 300 MHz (0.3 GHz) and 300 GHz. This broad definition includes both UHF and EHF (millimeter waves), and various sources use different boundaries.[4] In all cases, microwave includes the entire SHF band (3 to 30 GHz, or 10 to 1 cm) at minimum, with RF engineering often putting the lower boundary at 1 GHz (30 cm), and the upper around 100 GHz (3mm). Applications include cell phone (mobile) telephones, radars, airport scanners, microwave ovens, earth remote sensing satellites, and radio and satellite communications.

5.4.6 Radio waves

Radio waves are a type of electromagnetic radiation with wavelengths in the electromagnetic spectrum longer than infrared light. Like all other electromagnetic waves, they travel at the speed of light. Naturally occurring radio waves are made by lightning, or by astronomical objects. Artificially generated radio waves are used for fixed and mobile radio communication, broadcasting, radar and other navigation systems, satellite communication, computer networks and innumerable other applications. Different frequencies of radio waves have different propagation characteristics in the Earth's atmosphere; long waves may cover a part of the Earth very consistently, shorter waves can reflect off the ionosphere and travel around the world, and much shorter wavelengths bend or reflect very little and travel on a line of sight.

Very Low Frequency (VLF)

Very low frequency or VLF is the radio frequencies (RF) in the range of 3 to 30 kHz. Since there is not much bandwidth in this band of the radio spectrum, only the very simplest signals are used, such as for radio navigation. Also known as the myriameter band or myriameter wave as the wavelengths range from ten to one myriameter (an obsolete metric unit equal to 10 kilometers).

Extremely Low Frequency (ELF)

Extremely low frequency (ELF) is the range of radiation frequencies from 300 Hz to 3 kHz. In atmosphere science, an alternative definition is usually given, from 3 Hz to 3 kHz. In the related magnetosphere science, the lower frequency electromagnetic oscillations (pulsations occurring below ~3 Hz) are considered to be in the ULF range, which is thus also defined differently from the ITU Radio Bands.

5.4.7 Thermal radiation

Thermal radiation, a common synonym for infra-red when it occurs at temperatures commonly encountered on Earth, is the process by which the surface of an object radiates its thermal energy in the form of electromagnetic waves. Infrared radiation that one can feel emanating from a household heater, infra-red heat lamp, or kitchen oven are examples of thermal radiation, as is the IR and visible light emitted by a glowing incandescent light bulb (not hot enough to emit the blue high frequencies and therefore appearing yellowish; fluorescent lamps are not thermal and can appear bluer). Thermal radiation is generated when the energy from the movement of charged particles within molecules is converted to the radiant energy of electromagnetic waves. The emitted wave frequency of the thermal radiation is a probability distribution depending only on temperature, and for a black body is given by Planck's law of radiation. Wien's displacement law gives the most likely frequency of the emitted radiation, and the Stefan–Boltzmann law gives the heat intensity (power emitted per area).

Parts of the electromagnetic spectrum of thermal radiation may be ionizing, if the object emitting the radiation is hot enough (has a high enough temperature). A common example of such radiation is sunlight, which is thermal radiation from the Sun's photosphere and which contains enough ultraviolet light to cause ionization in many molecules and atoms. An extreme example is the flash from the detonation of a nuclear weapon, which emits a large number of ionizing X-rays purely as a product of heating the atmosphere around the bomb to extremely high temperatures.

As noted above, even low-frequency thermal radiation may cause temperature-ionization whenever it deposits sufficient thermal energy to raises temperatures to a high enough level. Common examples of this are the ionization (plasma) seen in common flames, and the molecular changes caused by the "browning" in food-cooking, which is a chemical process that begins with a large component of ionization.

5.4.8 Black-body radiation

Black body radiation is radiation from an idealized radiator that emits at any temperature the maximum possible amount of radiation at any given wavelength. A black body will also absorb the maximum possible incident radiation at any given wavelength. The radiation emitted covers the entire electromagnetic spectrum and the intensity (power/unit-area) at a given frequency is dictated by Planck's law of radiation. A black body at temperatures at or below room temperature would thus appear absolutely black as it would not reflect any light. Theoretically a black body emits electromagnetic radiation over the entire spectrum from very low frequency radio waves to X-rays. The frequency at which the black-body radiation is at maximum is given by Wien's displacement law.

5.5 SUMMARY

6.0 TUTOR-MARKED ASSIGNMENT

1. Define Ionizing and non-ionizing radiation
2. What are the health effects of non-ionizing radiation
3. Name 5 harmful effects of Ionizing radiation in humans
4. Name 5 sources each of ionizing and non-ionizing radiation

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UNIT 6: INVESTIGATION OF DISEASE CLUSTERS WITH EMPHASIS ON CRITICAL INTERPRETATION OF SCIENTIFIC EVIDENCE RELATING TO POTENTIAL ENVIRONMENTAL HAZARDS TO HEALTH

CONTENTS

6.1 INTRODUCTION

Following Cambridge dictionary, disease cluster could be defined as diseases occurring in a a place together over a short period. When this disease is as a result of exposure to environmental contaminant it then becomes an issue for environmental epidemiologist to investigate. In this unit we will discuss what cluster disease is all about and the various mechanisms required to classify a disease event as a cluster and the processed and stages of a cluster investigation.

6.2 OBJECTIVES

At the end if this unit, you are expected to be able to define disease cluster and when it should be applied. You should also have a very good knowledge of different stages and steps at each stage involved in investigation of disease cluster.

6.3 INVESTIGATION OF DISEASE CLUSTERS

6.3.1 What is a Cluster?

The term “cluster” has been used to describe an aggregation of some relatively uncommon disease or event or occurrence of a greater than expected disease in a geographical area and or within a short period of time. In relation to environmental epidemiology, it is occurrence of an exposure related health event greater than expected in a geographical area and or within a short period of time. The initial characteristics of a cluster are:

1. There is a definable health event.
2. There are usually at least two cases of the health event.
3. There is a perceived closeness of the cases within a time period and/or area defined by the informant
4. A potential exposure is suspected, along with an alleged connection between the exposure and the health event
5. The situation is generally unusual or unexpected
6. The informant or the community requests some explanation of the health event.

6.3.2 Three categories of clusters

- Time clusters – when an unusual number of cases of a disease(s) occurs within a defined period of time
- Space clusters – when an unusual number of cases of a disease(s) occurs within a defined area.
- Time-space clusters – when an unusual number of cases of a disease(s) occurs within a defined time period and area.

6.3.3 Processes of disease cluster investigation

There are four distinct stages in the investigation of a cluster of non-communicable disease. These includes:

1. Preliminary Evaluation of a Report of an Alleged Cluster.
2. Verification of Index Case and Exposure Reports.
3. Full Case Ascertainment.
4. Surveillance or Epidemiological Study

Each successive stage involves collecting more specific, but a wider variety of data and greater verification of that data. The boundaries between these stages are flexible. Depending on local judgement, experience, and the available resources, a public health agency may choose to combine stages. At the end of each stage a decision must be made about whether to proceed further, and how to communicate the results of that decision to the public and other interested parties.

Stage 1 – Preliminary Evaluation of a Report of an Alleged Cluster

The first stage gives the procedure to follow when an alleged cluster is initially reported to a public health agency (Figure 2). If a cluster is suspected from monitoring or vital statistics, the procedure begins at Stage 2.

Step 1: Record the initial report

Alleged clusters can be identified by anyone, including members of the public, news media, health professionals, local, regional or national agencies, environmental or health monitoring systems and vital statistics. The public have a serious, quick and often adverse reaction to any thought of a cluster. They want the matter to be treated seriously and with concern by the public health authorities. Much of the success in managing public outrage depends on how the initial report is handled. Whoever receives the report should identify himself or herself to the informant and tell the informant what actions will be taken, how long these will take, and when a response can be expected. To avoid overlooking vital data, it is advisable to use a standardised form to collect this initial information. The informant's real concern may also only emerge in response to careful questioning. When an alleged cluster is initially reported, get as much information as possible about the informant and the index case(s). This can save time and resources later and also indicates that the report is being treated seriously.

Step 2: Form an initial case definition

The initial case definition is based on the following "what", "where", "when", and "who" questions.

- What is the specific disease, symptom or health event of concern?
- Where is the affected geographical area, population group or workplace?
- When did the specific disease, symptom or health event occur?
- Who are the age group, ethnic group or sex on whom the cases were first reported?
- What are the suspected specific exposures? If any

Step 3: Follow up with the informant

Many of the reports of an alleged cluster can often be resolved at this step, either by an explanatory letter or telephone call. The investigation of clusters should have a strong health education component and community involvement. Anxiety about a cluster can often be lessened when the informant is told that:

- A disease which the public perceives to be rare occurs quite often. For example, cancer is a relatively common disease and the risk increases with age; major birth defects occur in one to two percent of live births.
- The length of time cases live in the cluster area must be substantial to implicate a plausible environmental carcinogen, because there is a long latency for most known carcinogens.
- Cases that occurred among people who are now deceased may not be helpful in linking exposure to disease because of the lack of data on exposure and on possible confounding factors.
- The occurrence of clusters of specific diseases in a population is often due to chance.

There will rarely be a single explanation for the occurrence of a cluster. Many cluster investigations of non-communicable disease are initiated because one factor, often an easily identified environmental hazard, is suspected as the cause. However, most diseases have a number of possible causal factors, involving an interaction between genetic and environmental factors. For example, even though thalidomide is one of the most powerful teratogens, not all pregnant women who took it gave birth to an infant with birth defects.

Clusters with few cases are more readily explainable when the causal agent produces a five- to 10-fold excess rate (eg, diethylstilboestrol). Most types of cancer occur at a rate of about one per 100 000 person/years.

Step 4: Consult and review information: make a decision

The decision to further investigate the alleged cluster is made after reviewing the initial information and consulting with specialists in cluster investigations and in the disease(s) concerned. Let the informant know the outcome of the decision as soon as possible.

In general, further investigation is warranted if there is:

- An unusually high number of cases
- A biologically plausible exposure(s); or
- Intense community concern.

If it is decided that the alleged cluster demands further investigation, the informant could become an active participant in the data collection relating to the cluster. A member of the public may have easier access to some data that would be helpful to the investigation.

The following actions are recommended if a decision is made to end the investigation:

- Write a report with a summary and conclusion
- Obtain appropriate peer review
- Communicate the results to the public.

This could involve writing a letter to the informant, or a public announcement, complete with press releases and public meetings. A written response to the person or organisation who initially reported the cluster will reduce the possibility of any misunderstanding about what was done and when. Many reports of alleged clusters arise from genuine concerns of the public about either their current or future health. They want action, answers, and reassurance. All reports need to be treated seriously until there is evidence to the contrary. Public concerns can often be allayed by prompt action, keeping the public informed, and openly providing as much information as possible.

Stage 2 – Verification of Index Case and Exposure Reports

The next stage in the investigation is to verify the index case(s) and suspected exposure(s) that have been reported (Figure 3). In many instances the resources required to undertake an extensive verification are not available locally, and assistance from other specialists and agencies is needed.

Step 1: Establish who should do the verification

To verify the index case(s) it is advisable to consult with appropriate specialists (eg, a pathologist, neurologist, toxicologist) or specific agencies (eg, Occupational Safety and Health, Ministry of Health). An environmental health specialist or an occupational hygienist may be needed to verify the possibility of exposure. Often a perceived exposure is not verifiable. Measurements of exposure are usually not necessary at this point.

Step 2: Review the literature

The investigator also reviews the literature for evidence of any previously reported clusters of the disease, known exposure associations and other epidemiological and toxicological information. CD-ROM databases such as HAZARDTEXT or TOMES produced by MICROMEDEX may be useful when exposure to specific hazardous substances has occurred or is suspected.

Step 3: Identify the records that can be used for verification

Records that can be used to verify cases are death certificates, birth certificates, hospital discharge records and case notes, population-based cancer and birth defect registries, union or company employment records and doctors' records.

Exposure is relatively easy to determine in acute disease clusters and can be done by questionnaire. In most instances, exposure has been through personal contact or through food, drug or beverage consumption. In contrast, exposure through water, air or soil is poorly correlated with questionnaire responses. Potential exposure(s) can be verified from agency and company files about sites and facilities in the area of the cluster or where the index cases worked or lived, aerial photographs, records of water, soil and air quality from various monitoring agencies, and planning records about previous industrial sites and property uses. Availability and access to information may be constrained by Federal government laws on privacy. The informed consent of the index case(s) (or their next of kin if they are dead), may be necessary to access records.

Step 4: Review the appropriate records and verify cases and exposure

The easiest way to verify a disease is often by reviewing hospital records, in particular any diagnoses on pathology reports. Diseases can also be verified from doctors' records and disease registries. Cause of death can be confirmed using the death certificate and reviewing appropriate medical records. The case definition provides guidance in deciding what data are to be used. Verification of exposure is often more difficult because of the comparative lack of relevant data. It may be helpful to consult with epidemiologists and occupational and environmental health experts for information about the availability, access to, and use of data such as union or company

employment records, and residential histories. Early in the investigation of a cluster, there may be requests for new environmental data to be collected. Premature environmental measurements should be avoided, since they may be unfocused and uninterpretable.

Limitations of records

Much of the available data will have been collected for purposes other than for investigating a cluster. As a result, the recording of information may vary between sources and make the information difficult to interpret. For example, the hospital discharge form's diagnosis might be pneumonia with no indication that the condition may be the result of exposure to a toxic substance. An individual's cause of death also may not be identical to the reason for hospitalisation (eg, a subsequent pathology report could indicate a previously unreported tumour). Many studies have shown that the level of disease ascertainment is directly related to the number of records used in searching for cases. Studies using multiple sources have a higher validity and level of ascertainment than studies involving only a limited number of sources.

Step 5: Make a decision: Stop and Report or Investigate Further?

At this stage of the investigation it is helpful to summarise in writing and review the findings to date. This may stimulate new ideas about the disease or possible causes. Suicide clusters differ from other clusters, because the community's perception that a cluster exists may itself be an important risk factor for further suicides and attempted suicides. Action is required, regardless of the number of cases reported. A community response should be initiated to identify and refer individuals at high risk of suicide for assistance (O'Carroll and Mercy, 1990).

Reported clusters will fall into three categories:

1 No apparent cluster

The initial investigation will often find no apparent excess number of cases. In many instances the original disease and/or exposure allegations are not supported by the medical records and/or environmental inspection, or else the examination of records does not confirm the suspected environmental exposure. The possible effects of migration are also important. Some of the cases involved in the reported cluster may have developed the disease before moving into the area and encountering the possible exposure, and they should not have been included. The disease or exposures alleged in the reported cluster may be a number of different diseases or exposures. The term "birth defects" includes a wide range of specific defects which have different epidemiological characteristics and are likely to have different aetiologies. When the diagnoses of the reported cancer cases have been verified, they may be different types of cancer or not cancer. It is unlikely that unrelated cancers will constitute a cluster.

2 Explained apparent cluster

Many reports about clusters of cancer, spontaneous abortion, and birth defects result from the public not realising how common these conditions are. For example, after a clear explanation, the public are likely to understand that a few cases of lung cancer in a

retirement community with a high percentage of smokers and no unusual environmental exposure is not likely to constitute a cluster. A high number of Down syndrome births in a local population with a high proportion of older mothers is also not uncommon. The investigation can be stopped if either of the above options are found. A written report of the investigation to date and justification of the decision to stop should be made.

3 Unexplained apparent cluster

If the reported disease and/or exposure are confirmed, the investigator must decide to proceed to Stage 3 (full case ascertainment) or not. This decision depends on the type of disease(s) and exposure(s), the size of the apparent cluster, and the biological plausibility of a disease/exposure relationship. To avoid the possibility of misinformation or confusion it is preferable to let the original informant know the decision by both:

- A personal telephone call, which gives them the chance to ask questions
- A following letter, to document the information clearly.

Stage 3 – Full Case Ascertainment

This stage involves finding and verifying all additional unreported cases of the reported disease(s) in the time period and geographical area of interest.

Step 1: Establish a case-finding team

It is often helpful to form a case-finding team because of the complexity of the environmental and occupational health issues and the need for a variety of disciplines, perspectives, and skills to carry out and analyse the data. The team needs to include specialists in epidemiology, environmental epidemiologists (if exposure verification is needed), and public health at least. The roles and responsibilities of team members, the channels for communication between members, and the spokesperson to the press or public should be decided at the outset.

Step 2: Revise the case definition

It is crucial at this stage of the investigation to review and if necessary, revise the initial case definition. A complete case definition includes:

- A definition of the health events to be counted
- A time period during which diagnosis occurred
- A geographical area and/or population group of interest.

1. Health events

Only the specific disease or closely related diseases suspected of clustering are counted. For example, if squamous cell carcinoma of the lung is reported, all types of primary lung cancer would be counted because they might be caused by the same type of exposure. Other types of tumours would not be counted. For birth defects, both livebirths and stillbirths should be included and, if possible, other types of reproductive outcomes (eg, spontaneous abortions). If the investigation initially focused on spina bifida, all types of neural tube defects should be included. Many birth defects (eg, anencephalus) have a higher rate in stillbirths than in livebirths. Failure to collect stillbirth data will result in the investigation excluding an important number of cases. It is also important to decide on the follow up period in clusters of birth defects. A

number of birth defects (eg, heart defects) are not diagnosed until after the first year of life, and there may have to be an extended follow up period. A broader set of conditions should be counted if there is concern about general increases in diseases that might have resulted from exposure to a mixture of toxic chemicals, or if a number of unrelated diseases were reported. Cases which cannot be confirmed using medical records should be tabulated separately or not be counted.

2 Time period

The best time reference point for a chronic disease is the calendar year of diagnosis, but occasionally only the date of death is known. A time period of possible exposure needs to be defined, and all cases diagnosed during that period need to be identified. Clusters of cancer also need to consider an appropriate latency period. When investigating clusters of birth defects, focus on possible exposures at or before the time of conception, rather than at the time of birth. Exposures at the time of birth will not necessarily be the same or at the same level as at the time of conception. Most birth defects have a critical period when the defect can occur. For example, neural tube defects occur within the first 28 days after conception, so the occurrence of these defects will not be due to any potential exposure after that time.

3 Geographical area or population group

The community of interest (eg, suburb, city, health district or Territorial Local Authority (TLA)) is the basic areal unit for data collection and analysis involving possible community exposure(s). It is often more meaningful to disaggregate heavily populated areas into subareas. If the focus is on the occurrence of disease among a specific population subgroup (eg, a particular neighbourhood or all women over the age of 35 years) the smallest unit that includes the entire group and for which statistical data are available should be used as the denominator. This unit is also used for collecting information about membership in the subgroup. Alleged clusters are unlikely to respect the administrative boundaries that have determined reporting of population data or health statistics. If the focus of the investigation is potential exposure at the workplace, the work site itself is usually the basic unit of analysis. Specific occupations or subgroups working in high exposure areas may be defined, but counting cases in the entire workplace provides the basis for comparisons between subgroups. Whatever data are collected for the cases should also be collected for the comparison or unexposed population. The coding of data should also be consistent within and between these two groups.

Domicile data should relate to the place of usual residence. This may not be the domicile at the time of diagnosis. Data on the length of residence in a particular area are also important, especially for diseases such as cancers, in which exposure may have occurred 10 or more years previously. Without these additional data a person who has lived one year in an area is assumed to have a similar degree of exposure to a person who has lived in the same area for 10 or 20 years. In reality, the person with a short residency in an area, may have been exposed to a possible environmental hazard in another area, or have not been exposed to an environmental hazard in the current area. In clusters of birth defects, it is important to know the domicile of the mother at the time of conception, and if possible, during the year before the birth. For childhood

cancers, attempt to establish possible exposures from the time of gestation. In occupational clusters, the work history, not only the most recent occupation, is relevant. Occupation is recorded in the national mortality statistics as the occupation at the time of death. For example, in a cluster involving a pesticide-induced food illness, the case definition might include all individuals who experienced vomiting or diarrhoea within two hours of eating produce anywhere in a defined TLA. The initial case definition in a possible cancer cluster might include all cancers that occurred during the last five years in children aged less than 15, living in that geographical area before they were diagnosed.

Step 3: Develop and implement the case-finding

There are four phases in the process of finding the cases and collecting the data:

Phase 1: Decide what records need to be examined

All cases with the disease(s) that were diagnosed in the area or workplace and time period need to be identified. This usually involves finding and reviewing data from several sources, including:

- Hospital logs and hospital discharge records
- Death records
- Population-based registries (eg, for cancer)
- Hospital-based tumour registries
- Union or company employment records
- Birth certificates
- Records of specialists and researchers in the field.

Case finding could also involve laboratories, pharmacies, radiologists, and direct appeals to general practitioners and the public. Each data source has its own particular strengths and weaknesses. For example, hospital records are a good source of information, but may include unconfirmed cases, such as suspected diagnoses, and omit cases not diagnosed in the hospital or diagnosed in another hospital. Death records may have a vague non-specific diagnosis or may omit a diagnosis when it was not the underlying cause of death. Disease registries are a good source of cases for full case ascertainment. However, they may not be available in the area for the time period of interest. In the absence of a registry, full case ascertainment is more difficult and resource intensive.

Phase 2: Determine what data will be collected

Data availability depends on whether the source of information is registries, hospital or medical records, or interviews. In general, the following is the minimum data that is collected for each case:

- Name or another form of identification
- Date of birth
- Ethnicity
- Sex
- Age at time of diagnosis and/or death
- Residence at the time of diagnosis

- Diagnosis and basis of diagnosis.

If possible, also collect data on:

- Family history of the disease(s) in question
- Known exposures, such as smoking
- Length of residence at the current address
- History of past residence in the area of interest
- Other relevant exposure variables – for example, playing in contaminated fields, drinking contaminated water, eating contaminated foods, overseas travel.

If investigating a possible exposure in the workplace, detailed occupational history will be necessary. This includes:

- Occupation of the case or parent
- Employment history – job type, classifications, and duration at each position – as far back as possible.
- Known work exposures to toxic substances – for example, radiation exposure of the case or parent
- Identification of potential hazards at the work site.

Phase 3: Obtain ethical approval, if required, to carry out the data collection

Phase 4: Collect the data

The data collection methods chosen depend on the type of data needed to count all suspected cases. Much of the basic information can usually be obtained by reviewing existing data. It is important to indicate which source document is used to obtain the data so that data validity can be assessed. Data must be recorded and coded in a systematic and consistent manner. A questionnaire should be designed so that all the necessary data are obtained in a clear and unambiguous manner from one interview. Consultation with experts about the technical aspects of questionnaire design, pretesting, training of interviewers, and data coding and processing is advisable. It is important during data collection that confidentiality is adhered to.

Step 4: Count and analyse case data

Once every effort has been made to find all the cases in the cluster population that conform to the agreed case definition, the data are examined and any duplicate case reports are eliminated. Numerator data for calculating cluster and background disease rates can be obtained from the national health statistics – for example, mortality, hospitalisations, the National Cancer Registry, the mental health register, and special studies. Data specification (eg, by age groups and ethnicity) should be in the same format as for the denominator data. Rates are not routinely calculated for small areas such as a neighbourhood because the number of observed cases is usually too small for stable rates or meaningful analysis. Population data are necessary to calculate expected numbers of a disease based on published reference rates of disease. The expected number of cases can be compared to the actual number of cases observed in the study population to determine whether the community has experienced an excess rate of the disease. Cluster investigations usually require detailed population data (eg, by sex, ethnicity, and age groups) for very small geographical areas. Such data can be obtained every five years from national census data. Data for non-census years can be requested from Statistics New Zealand.

Using census data in a non-census year assumes that there has been no change in the demographic composition of the population. Denominator data can also be obtained from government agencies. In epidemiological terms, the number of cases in the study or cluster population is the number of observed cases. The number of expected cases of a disease is determined by multiplying a background or comparison rate of disease by the study population in the time period and geographical area that was used in counting the observed cases. Once a complete (or virtually complete) count of cases has been established, it must be decided whether the number of cases that has been observed is different from that expected. Usually cluster investigations are concerned with determining if there is an excess number of cases in a local population.
A finding of fewer than expected cases is, however, reassuring for the community. Often a cluster is thought to be "real" if there is a statistically significant excess of cases. The statistical tests used in the analysis calculate the probability that the disease rates observed in the cluster would occur by chance alone. This will usually involve comparing the observed rate in a known population with expected rates derived from larger population surveys or disease registries. As most diseases are not evenly distributed throughout a population, an observed excess (or deficit) of cases may, therefore, occur at random and the cluster not be aetiologically important.

There are many census areas and small towns in New Zealand, and hundreds of thousands of workplaces and social groups like clubs, and churches. All of these groupings are at risk of excess rates of a non-communicable disease, even if the distribution of the disease itself is random. The number of observed cases will rarely equal the number expected, even if there were no environmental cause. The pivotal question is "How far away from the expected number must the observed number be to make it a very unusual occurrence?" Standard statistical and epidemiological techniques for assessing excess risk can often be used to evaluate reported clusters, but statistical significance should not be used as the sole criterion for investigating a disease cluster. A small observed number of cases may be worth investigating if there is a biologically credible exposure present or there is intense public concern.

A useful first step is often to produce frequency tables of the disease and examine the related descriptive statistics. Mapping the data is also helpful. Diseases will occur at different rates in different age, ethnic and sex groups. The calculation of expected numbers should take into account the possible effect of these possibly confounding factors on the occurrence of the disease. If there are sufficient cases and population this can often be achieved using some form of standardisation, direct or indirect. If the number of health events is too small to show meaningful rates, pooling across geographical areas or time may be possible.

Other commonly used statistical approaches include chi-square tests of observed versus expected frequencies based on the Poisson distribution for low frequency data and Poisson regression used for comparison of rates. Confidence intervals may be calculated for point estimates. Evaluating a spatial cluster can be done by comparing the rate in the study area with that in adjacent census areas or changing the geographic

scale at which the analysis is carried out – for example, health district, TLA, region, New Zealand.

If a temporal cluster is being assessed, the occurrence in that time period can be evaluated in the context of previous or subsequent periods. When comparisons are made, the comparison population must be carefully chosen to ensure it has similar demographic or exposure characteristics. Analysis of cancer incidence data at a range of geographical scales gives information that can deal with public concerns, prevent expensive and unwarranted epidemiological studies driven by public and political pressure and target appropriate cases for further investigation. For example, although New Jersey was found to have an excess of childhood and young adult cancers when compared to other states, further examination showed that the clusters were not related to degree of urbanisation or county boundaries, and were made up of very few cases and in very few municipalities. Statistical verification of alleged clustering may be very difficult. For rare events the time frame selected from which to determine the expected incidence will influence whether the cluster is found to be statistically significant. Short time frames may be misleading. Definition of the geographical boundaries may have a similar effect.
Problems may arise from statistical techniques used to detect clusters. It is often difficult to distinguish between events of epidemiological and public health importance and those that occur as a result of chance. Some techniques may not be sensitive enough to detect true aggregations, while others may detect aggregations whose epidemiological and biological significance is difficult to interpret. False negative rates depended highly on the method used and the nature of the exposure pattern that was sought. True clusters are usually detected only if enough cases had been observed and if the method most sensitive to the type of exposure pattern had been used. The needs of public health authorities are not well met by the variety of statistical techniques available, and it is desirable to obtain statistical advice.

Many alleged clusters require only basic data analysis. For rare diseases in small areas the alleged cluster may only be one or two cases and may disappear once case histories and diagnoses are verified, and recent migrants and other anomalies detected as each case is reviewed. Clusters may also disappear or reappear by changing the time, space, or time and space boundaries, by over- or under enumeration of the population at risk, or by choosing different sets of standard rates. Decisions are often implicit rather than explicit, as they depend on existing data. Results should be treated cautiously until more about the sensitivity and specificity of the methods used is known.

Brief descriptions and critiques of some of the available statistical techniques are given in the CDC's Guidelines for Investigating Clusters of Health Events (CDC, 1990). Many of these techniques are included in the computer software package STAT! produced by Biomedware.

Step 5: Make a decision: stop and report or investigate further
The decision to stop and report on the investigation or continue to the next stage depends on a number of factors. Further investigation is usually not required if:

- Tthere is no excess disease, and no exposure, and therefore no biological plausibility
- There is no excess disease, a possible exposure, but no biological plausibility that the exposure could result in an excess
- There is excess disease, no identified exposure, and no biological plausibility that the excess rate results from an environmental exposure.

If there is an excess of cases:

- ✓ Is it of concern?
- ✓ Does it warrant further study?
- ✓ Is the exposure biologically plausible?
- ✓ Is there a sudden increase in cases in a recent period or have the cases been increasing over time?
- ✓ Are cases more concentrated around suspected environmental hazards or in suspected occupational groups?

In general, a "yes" answer to these questions increases the need for further follow up to Stage 4. If the decision is made to end the investigation then write a report with a summary and conclusion, obtain appropriate peer review and communicate results to the public.

Stage 4 – Surveillance or Epidemiological Study

There are two options if the cluster warrants further investigation.

1 Surveillance

Surveillance is a more appropriate approach than an epidemiological study where an excess number of cases is found in the cluster but where the excess is of low statistical significance or the exposure has weak biological plausibility. A surveillance programme run over several years determines whether cases are increasing over time and what their geographical distribution is. For example, monitoring of childhood rhabdomyosarcoma incidence in a North Carolina county was proposed for a five-year period after a cluster was confirmed and preliminary investigation had revealed no plausible environmental exposures. If there are no registry or vital statistics data available, a reporting system may have to be established to receive reports about the disease from the public or health professionals.

2 An epidemiological study

If there is an excess of cases and there is a biologically plausible connection between the cases and some environmental exposure, further investigation of the cases and their environment is warranted. Further investigation may involve a case-control, cohort or cross-sectional study and can range from a few days of work to years and hundreds to thousands of dollars. Consultation with appropriate specialists and agencies is recommended. These include the Occupational and Environmental Health Research Centre, University departments of public health, the Institute of Environmental Science and Research, the Ministry of Health and the Department of Veterinary Services, if animals or animal studies are involved.

6.4 SUMMARY

Disease cluster, especially such diseases which are as a result of exposure to environmental hazards require investigation by environmental epidemiologists. We

have defined disease cluster and discussed in details the four stages involved in investigation of disease cluster. In each stage we have also discussed the various steps needed to reach a justifiable conclusion on causal relationship of a disease cluster with environmental events.

6.5 TUTOR-MARKED ASSIGNMENT

1. What is disease cluster?
2. Name the four stages in investigating disease cluster and describe stage 1
3. Describe the three categories of a disease cluster
4. What are the important information that will guide your decision to continue to stage 4 after stage three?

6.6 REFERENCES/FURTHER READING

CDC, 1990. CDC's Guidelines for Investigating Clusters of Health Events

Reid D. and Borman B. 1997. *Investigating Clusters of Non-Communicable Disease. Guidelines for Public Health Services.*

MODULE 3: RECENT ADVANCES

Unit 7: Recent advances in environmental epidemiology

CONTENTS

7.1 INTRODUCTION

In the near future, transformative changes, in particular the rapid pace of technological development and data availability, will require environmental epidemiologists to prioritize what should (rather than could) be done to most effectively improve population health. In this unit, we have discussed the recent advances in environmental epidemiology and how the changes in demographies, technology and man's interaction with their environment will shape the activities of the profession in future.

7.2 OBJECTIVES

In this essay, we map out key driving forces that will shape environmental epidemiology in the next 25 years. We also identify how the field should adapt to best take advantage of coming opportunities and prepare for challenges.

7.3 RECENT ADVANCES IN ENVIRONMENTAL EPIDEMIOLOGY

Future environmental epidemiologists will face a world shaped by longer lifespans but also larger burdens of chronic health conditions; shifting populations by region and into urban areas; and global environmental change. Rapidly evolving technologies, particularly in sensors and OMICs, will present opportunities for the field. The field will best adapt to a changing world by focusing on healthy aging; evidence gaps,

especially in susceptible populations and low-income countries; and by developing approaches to better handle complexity and more formalized analysis

The main challenges in environmental epidemiology will include complex mixtures of a large number of correlated exposures, small effect sizes which can lead to inconclusive studies in the context of residual confounding, and the need for new methods and interdisciplinarity to study links between global environmental changes and health. New technologies, rather than public health importance, might drive research questions. Although notable advances have since been made in statistical tools to derive useful information on mixtures of correlated exposures, these, together with the precise measurement of exposures in space and time, remain some of the key challenges in the field today. The rapid pace of technological development and availability of data have made the need more acute to prioritize what should be done for maximum public health benefit over what could be done.

7.3.1 Demographics and urbanization

Within the broader context of the epidemiologic transition and economic development, the changing age and geographic distribution of the global population will continue transforming environmental health research priorities. Lifespans have lengthened across the globe, including important gains in low-income countries where life expectancy has improved from 53 years in 1990 to 62 years in 2012. According to UN Department of Economic and Social Affairs, adults aged 60 and older, comprised 8% of the global population in 1940, which grew to 12% by 2013 and is projected to be 21% in 2050. This monumental shift in the global age distribution is due in part to public health interventions, but also presents new health challenges.

There will also be no table shifts in the geographic distribution of the global population. In 2015, they stated that most of the population growth between now and 2050 is projected to occur in just nine countries with high fertility or already large populations; more than half of the expected growth will be in Africa alone. The proportion of the population living in Africa will increase from 16% to 25% between now and 2050, while the proportion in Europe will shrink from 10% to 7%. Population growth is projected to remain especially high in the 48 least developed countries, adding to challenges in meeting sustainable development goals. There is currently very little data on environmental exposures and their health effects in many countries with the largest population growth. Effects of environmental exposures are likely to differ from those observed in high-income countries, where most environmental health research has been conducted, due to differences in infectious disease burden, access to health services, and material deprivation. Large-scale migration will add further complexity for environmental epidemiology, presenting challenges for follow-up of study participants and environmental exposure assessment. Individuals living in areas with similar levels of environmental exposures may have highly variable cumulative exposure based on their migration history. For migrants from poorly to better regulated societies, adult health may be influenced by high levels of environmental exposures in early life, exposures which may be particularly difficult to reconstruct. Migration may also present opportunities for using natural experiments to understand how environment shapes health. The global population continues to shift from rural to urban areas. In 2014, 54% of the population resided in urban areas; this is projected to be 66% by 2050. Nearly 90% of the projected increase in the world's urban population will be concentrated in Asia and Africa, with India, China, and Nigeria accounting for a large share of this growth. Urbanization profoundly shapes (both positively and negatively) environmental exposures (e.g. air pollution, noise, green space) and behaviours (e.g. physical activity, food consumption) and thereby disease risks.

7.3.2 Global environmental change

Climate change and emerging environmental risks will define much of the future context for environmental epidemiology. Climate change has been identified as the biggest global health threat of the 21st century. According to Intergovernmental Panel on Climate Change, mean surface temperature is expected to increase by 0.3 to 4.8 °C by 2100, leading to direct impacts on health from heat stress and flooding, as well as indirect health impacts mediated through infectious diseases, air quality, and food security. Recent reports have elaborated the multiple potential health impacts of climate change. There is strong evidence that heat-related mortality is rising as a result of

climate change; the Intergovernmental Panel on Climate Change anticipates an increase in both the frequency and intensity of heat waves under all climate scenarios. The combined effect of global warming and demographic change will expose an increasing number of vulnerable older adults to heat stress. Health impacts of extreme weather events such as storms and floods are likely to increase this century if no adaptation measures are taken. It is also anticipated that climate change increases the risk of intense droughts in some regions, affecting agricultural output and, subsequently, increasing food insecurity and malnutrition. As stated in 2012 report by High Level Panel of Experts on Food Security and Nutrition, climate change has been identified as one of the greatest challenges for food security. Droughts also elevate risks of water-related disease (e.g. *E. coli*, cholera), vector borne disease (e.g. dengue, West Nile Virus), airborne and dust related disease (e.g. coccidioidomycosis) and mental illness. Climate (change) may be an important factor in the dynamics of vector borne disease transmission, including malaria, dengue, and Lyme's disease. Alongside shifts in land use, climate change appears to be altering the geographic range of vectors that transmit pathogens (e.g. *Aedes albopictus*, *Ixodes scapularis*) to humans. Chemical exposures will remain an important environmental health concern. In 2013, Un Environmental Programme reported that chemical production in 2000 was 1000 times higher than in 1930. Although chemical production is not a direct measure of population exposure, it is likely that the number of chemicals to which one is exposed will continue to increase in coming decades. Of particular concern are those with short half-lives in the body, now preferred to those with long half-lives for health and environmental reasons, but which contribute to exposure misclassification in traditional studies that rely on spot biomarkers.

7.3.3 Technology

Technology with applications to environmental exposure and health outcome assessment is evolving rapidly. Technology will generate new opportunities, particularly in regards to population datasets, e-health and mobile health, personal and remote sensor technology, and OMICs data. Expanding data availability will allow prediction of diverse population exposures and create new opportunities for exploring novel exposures that have been previously difficult to quantify. Importantly, geo-referenced data are becoming more widely available in low- and middle-income countries, reducing barriers for conducting environmental epidemiology in these countries. Such data include those collected through remote sensing, sensor networks, smartphones, as well as the “internet of things” (i.e., everyday objects with network connectivity). Remote sensing has been used to estimate environmental exposures including air pollution, green space, and temperature. Opportunities for satellite-based exposure assessment will continue to expand with increasing number of satellites and improved resolution of detection. Quantifying neighbourhood attributes will be enhanced by applying developments in image processing to resources such as Google Street View and to ecological momentary assessment based on individuals taking a photograph of their immediate environment from their mobile phone. (Advances in image processing will also improve measurement of other exposures, such as diet or drug or cosmetics use, for which study participants can take pictures of what they eat or use, or scan barcodes). A new exposure pathway − visual exposure − will be easily investigated using miniaturized cameras or virtual reality to understand how people

internalize and interact with their environment. For example, such technology will allow advances beyond simple proximity to green space to determine whether individuals are visually exposed to green space and which activities they engage in using that green space. Social media data will increasingly play a role in assessing behaviours, exposures and outcomes. Such approaches have already been used to identify symptoms, behavioural risk factors, and population mobility patterns.

7.3 4 Data availability

Data creation is already exceeding worldwide storage capacity; this may become a problem in epidemiologic studies. Genomics is a familiar example where data size is already an issue. The addition of other OMICs escalates the problem (e.g. the human microbiome would contain the genomic information of 100 trillion cells). New technologies (e.g. sensors, medical image and video) are also able to provide huge amounts of data for a single participant. This movement towards Big Data studies will make parallel processing on computer clusters or a cloud, and the use of Big Data platforms more common. In many instances, raw data will be discarded owing to storage problems and only relevant summaries will be stored. Big data created for purposes other than research are likely to present challenges in terms of data quality and representativeness of the wider population.

7.3 5 Study design, models of research

We will increasingly move towards studies with very large sample sizes with individual exposure information, even including the entire population (N = all) as is currently possible with census cohorts. One may think that statistics are no longer needed if the entire population is observed, but this is probably the case only when computing simple summary statistics (e.g. a mean). Environmental epidemiology often deals with complex causal questions, which require the observation of a set of confounders. Empirical estimations of those effects would require calculating averages over all possible combinations of confounders. With just 10 confounders, this becomes unfeasible with huge datasets, because of empty cells, so statistical models will continue to be needed. In addition, if the entire population is observed, the traditional statistical paradigm based on the sampling of independent observations no longer holds. Informative dependencies exist in the population, and some authors suggest that the population's network structure should be taken into account when analysing whole population data. More importantly, considering the expected explosion in OMICs and sensor data, future studies will tend to have a much larger number of variables than participants (so-called high-dimension data). Most of the statistical methods commonly used today such as maximum likelihood estimation do not provide consistent estimates in such settings. Large dimensionality brings spurious correlations, among other problems. Techniques for dimension reduction, variable selection, and sparse models that can work effectively in that setting will become crucial. Other models of research production will come online. Citizen science, to date most widely used in fields of biology and ecology, is likely to play a greater role in environmental epidemiological research production and may offer benefits in terms of better knowledge, empowered communities, and improved health outcomes. However, these benefits have yet to be fully evaluated and several practical challenges remain. The current model of research production encourages publication of single analyses, often performed by a single

research group, which can be dominated by subjective decisions during the analysis and favour extreme results. Moving towards a researcher-based crowdsourced analysis model potentially offers many advantages, including greater transparency, opportunity to vet analytical approaches with peers before publication, and more nuanced, balanced results. The Many Lab, launched by the Centre for Open Science, is a current example of a web-platform for crowdsourced research production where researchers can join projects. The advantages of research involving large groups should be weighed against bureaucratic inefficiencies that hamper individual creativity and curiosity-driven fundamental research.

7.4 SUMMARY

Environmental epidemiology with focus on disease prevention will continue to be valuable. However, the field must adapt to modern trends to remain relevant. In particular, the field must ensure that public health importance drives research questions, while seizing the opportunities presented by new technologies. Environmental epidemiologists of the future will require different, refined skills to work effectively across disciplines, ask the right questions, and implement appropriate study designs in a data-rich world.

7.5 TUTOR-MARKED ASSIGNMENT

1. Describe the place of technology in environmental epidemiology of the future
2. What is the impact of climate change in environmental health
3. How does demography and urbanization affect environmental health
4. what is the effect of large data expected in the future on the environmental research design

7.6 REFERENCES/FURTHER READING

Cathryn Tonnea, Xavier Basagañaa, Basile Chaix, Maud Huynen, Perry Hystad Tim S. Nawrot, Remy Slama, Roel Vermeulen, Jennifer Weuve, Mark Nieuwenhuijsen. 2017. *New frontiers for environmental epidemiology in a changing world; Environment International*, 104: 155–162

UNIT 8: INTERPRETATION OF SCIENTIFIC EVIDENCE RELATING TO POTENTIAL ENVIRONMENTAL HAZARDS TO HEALTH

CONTENTS

8.1 INTRODUCTION

The World Health Organization requires a reliable, transparent and broadly acceptable approach to the identification of potential environmental hazards and to the assembling, evaluation and interpretation of available evidence concerning the causality of associations between a potential hazard and health. This process is called Health Hazard Characterization.

8.2 OBJECTIVES

The purpose of this section is to justify and describe an approach to the evaluation of epidemiological evidence. We recommend that expert groups convened by WHO and regulatory bodies to inform policies concerning environment and health follow this approach.

8.3 EVALUATION OF SCIENTIFIC EVIDENCE RELATING TO POTENTIAL ENVIRONMENTAL HAZARDS

Systematic review of epidemiological evidence for Health Hazard should include a systematic review of all of the relevant evidence, and the process and methods of that review should be clearly documented. Adoption of this approach would help to ensure that the conclusions of the review are transparent, unbiased, replicable, and valid. Such a systematic approach would also provide a foundation for the continued monitoring of additional evidence as it emerges.

Transparency

This means that what is done is clear to the expert group, other scientists, policymakers and the public.

Avoidance of bias.

A systematic approach will help to ensure that each step of the Health Hazard Characterization has been carefully considered to prevent the introduction of bias into the process of review.

Validity

Validity refers to the degree to which the conclusions of the review are likely to be the correct ones. Validity will be increased if the Health Hazard Characterization is systematically conducted so that inferences can be drawn from its findings, especially generalizations extending beyond the studies used in the Health Hazard Characterization.

Replicability.
A systematic and clearly described method of Health Hazard Characterization will allow replication and a basis for comparison with reviews of future evidence as it becomes available.

Cover all relevant issues
A systematically conducted Health Hazard Characterization will help ensure that all relevant issues are considered.

Improve efficiency in updating evidence.
A systematically conducted Health Hazard Characterization will provide an efficient way of updating the evidence base as new studies emerge.

The epidemiological evidence on the association between a risk factor and cancer can be categorized into discrete categories (sufficient, limited, inadequate, no evidence). The distinctions among categories are chiefly based on
(a) Reproducibility of the evidence;
(b) Validity (absence of bias and confounding);
(c) Role of chance.

8.3.1 Protocol for Health Hazard Characterization
The first step in ensuring a systematic approach in conducting a Health Hazard Characterization is to adopt the general protocol for Health Hazard Characterization. The protocol will help ensure that a researcher has a common understanding of its task and will adhere to the systematic approach recommended by WHO. A protocol approach requires the following decisions:
1. Agreement on the question(s) to be dealt with in the Health Hazard Characterization.
2. Justification of the expertise available for on the Health Hazard Characterization
3. Specification of the methods to be used in the Health Hazard Characterization (identification of relevant studies (including reviews), assessment of quality of the studies and interpretation of the evidence). Although these elements should be agreed upon before the Health Hazard Characterization proceeds, it is accepted that mid-Health Hazard Characterization revisions of the protocol may be necessary as more information not appreciated at the outset of the Health Hazard Characterization emerges. The success of the Health Hazard Characterization process will depend on various factors including the adequate and timely preparation of material, the composition of the research group, and the availability of input from scientists (or the general public) outside the research group. The whole process has to be efficient and benefit the conclusions of the Health Hazard Characterization. The composition of the

research group is critical. The criteria for selection should be based on having the appropriate mix of scientific expertise and experience.

8.3.2 Components of reviews of the epidemiological evidence in a Health Hazard Characterization

There are three fundamental steps in the systematic review of the epidemiological evidence in a Health Hazard Characterization.

1. Comprehensive identification of all relevant studies
2. Systematic assessment of the quality of the available studies
3. Interpretation and conclusions from the body of epidemiological and other evidence.

The assessment of studies quality can be divided to the review of each of the individual studies and to the joint analysis of all relevant observations identified in the studies. The recommended approach at each of these steps is described below.

8.3.3 Comprehensive identification of all relevant studies

A comprehensive bibliographic search would include the following:

Involvement of qualified searchers (e.g. librarians, trained investigators);
Definition of an explicit search strategy including identification of key words;
An effort to include all available studies;
Searching of bibliographic databases;
Inclusion of non-English reports.

Optional methods to be specified by the review protocol, would include hand searching of journals, and inclusion of abstracts and unpublished data (including writing to authors of published data). After identifying an initial list of members of the research group, the preparation for the first meeting, should include the results of the initial identification of all relevant studies together with a summary of the quality of the studies. The group will need to be consulted about the search strategy and criteria for quality. All potentially relevant studies should be identified at the first stage of the group's work. However, depending on the types of exposure evaluated, whole categories of studies may be excluded in the second step, on the basis quality criteria. In the evaluation of a specific pesticide, for example, studies of routine statistics on cancer risk in agricultural workers might be excluded because assessment of exposure to a specific pesticide in such studies is problematic. Systematic assessment of the quality of primary studies should consider each of the following questions when assessing a particular study for use in a Health Hazard Characterization:

Is the study question clear?

Was the exposure assessed using valid and reliable measures?

Was the health outcome(s) assessed using valid and reliable measures?

Was the study design appropriate?

Did the analysis of the data take into consideration chance, confounding, and bias (information, selection, and analytic)?

Were the conclusions consistent with the results of the data analysis? As Hill in 1965 emphasized, the fundamental question in assessing epidemiological research for hazard identification (i.e. assessment of causality) is this: "Is there any other way of explaining the set of facts before us, is there any other answer equally, or more, likely than cause and effect?" This concept is appropriate in every assessment of the quality

of epidemiological studies whether individual or collective. Hill offered several attributes (which he pointedly did not call "criteria") to bear in mind while contrasting causality with alternative explanations. Hill's attributes are helpful in the assessment of confounding and bias. One such attribute is the strength of association. If the estimated relative risk is 2.0, for example, a single confounder cannot fully explain the departure of this estimate from the null value of 1.0 unless that confounder at least doubles the risk of the disease and the confounder is at least twice as common among exposed persons as among unexposed persons. Another of Hill's attributes is specificity of cause. Bias from exposure misclassification may be suspected as an explanation for a positive association between a specific exposure of interest and a health effect. However, the same bias may also be suspected with regard to other exposures examined in the same study. If so, then if disease is only associated with the exposure of interest, misclassification would be an implausible explanation. Yet another of Hill's attributes is temporality: hypothetical causes must precede their hypothetical effects. Thus, an important feature of exposure and disease classification is to establish their proper sequence in time, with exposure occurring before disease. Failure to establish this temporal sequence makes the study difficult (if not impossible) to interpret with respect to a causal association. It is important to note that Hill confined his attention to the context of "positive" studies, i.e. studies that appear to suggest the presence of a cause-and-effect relationship. In a comprehensive, weight-of-evidence approach, so-called "negative" studies, i.e. studies that appear not to show an association between exposure and disease, must be considered as well. For these studies, one must consider alternatives to the absence of cause-and-effect. For either purpose, the alternative explanations may be divided into five general categories: chance, confounding, information bias, selection bias (including publication bias) and analytic bias. In a review aiming at the health hazard characterization, these issues should be considered first in the evaluation of individual studies and then in the evaluation of an epidemiological literature as whole.

8.3.4 Chance.

In the context of estimating a measure of effect (for instance, some form of relative risk), the width of a confidence interval should be used to gauge the precision of the estimate. For instance, two studies might each produce relative risk estimates of 1.0, suggesting that exposure has no effect. However, the confidence interval around that estimate might in one case be 0.5 to 2, and in the other be 0.25 to 4.0. The confidence interval conveys clearly the relative imprecision of the latter study, allowing one to infer, for example (by comparison of the upper bounds), that the more precise result is consistent with only a doubling of disease incidence or risk. When exposures are either measured on an ordinal scale, or are measured on a continuous scale and then divided into multiple ordered categories for data analysis, the most important information concerns the change in the effect measure, say the relative risk, over the ordered categories. Therefore, it is the statistical precision of the estimate of the slope or trend in the relative risk that should be assessed, e.g. via the width of a confidence interval, rather than the precision of the category-specific relative risks. Epidemiologists have increasingly eschewed statistical significance testing for the interpretation of study results in favour of interval estimation. However, in a significance testing framework, if the result is strongly statistically significant, chance

does not usually need to be considered. If the result is not statistically significant, the power of the statistical test must be taken into account.

8.3.5 Confounding.

Important confounders are the known, strong risk factors (causative or preventive) for the disease that might be strongly associated with the exposure and that are not consequences of the health effect or the exposure. For example, cigarette smoking would be an important potential confounder for a study of any environmental exposure and lung cancer. Confounding may be upward (i.e. toward spuriously high estimates of effect) or downward (i.e. toward spuriously low estimates), depending on the directions of the associations between the confounder and the exposure and between the confounder and the health effect.

8.3.6 Information bias.

Bias can be produced by poor quality of information on the exposure, the health effect, or potential confounders. The direction of the bias depends on whether the quality of the information differs between groups being compared. If such errors vary approximately at random, and do not differ in frequency between compared groups (i.e. are non-differential), the bias is usually in the direction of underestimating the magnitude of any true association, though there are exceptions to this general rule. Differential information bias may spuriously elevate or reduce observed associations depending on the relative degree of bias between the groups being compared.

8.3.7 Selection bias.

Bias can be introduced by the method of selection of people for studies, by incomplete participation, and by missing information for some study subjects. As with information bias, the direction and magnitude of selection bias depends on particulars of the absolute and relative frequencies with which different kinds of people are included or excluded.

Analytic bias.

Biases can be produced by the manner in which epidemiological data are analysed. Categorization of continuously measured exposures, or the assumption of a linear dose-response relationship when the true relationship is non-linear are important examples. Epidemiological studies of environmental agents will be particularly useful for health hazard characterization if they provide estimates of exposure response-relationships (i.e. which levels of exposure might be expected to affect human health, and the degree of harm expected at various exposure levels). The demonstration of specific patterns of association over ordered categories of exposure, such as monotonic increases in the relative risk, can provide strong support for causal interpretations if they cohere with pathophysiologic models, and because more complex, and hence implausible, patterns of confounding or bias are required as counter-explanations. The information that existing epidemiological studies provide about exposure-response relationships in particular study populations are important components in Health Impact Assessments of other populations. The credibility of a study is enhanced if its results are confirmed in a sensitivity analysis. In such analysis the outcome variable(s) are examined with respect to (1) changes in expression of exposure variables, (2) addition of other plausible explanatory variables, and/or (3) introduction or removal of controlling variables. Inclusion of some form of sensitivity analysis is becoming the norm in published epidemiological studies. As part of the

overall evaluation of epidemiological evidence, sensitivity analysis of primary studies as well as any differences among studies should be explicitly identified. Sometimes information from one study may be used to adjust the results of another study. For example, one study may have measured exposure in two ways, of which one is more accurate than another. Comparisons between the two methods may be used to adjust the results of a study in which only the inferior method was used (Greenland 1987).

8.3.8 Conduct of systematic overviews of evidence from multiple studies: the use of meta-analysis

The following questions should be considered when designing and conducting systematic overviews of epidemiological studies:

What is the question(s) that the review proposed to answer?

Is there a comprehensive strategy for searching the literature?

How will the quality of the individual studies, and their findings, be assessed?

How will the reliability of the reviewers' assessments of the quality of each study be evaluated?

How will the results of individual studies be summarized? · How will heterogeneity among studies be assessed?

Will summary effect estimates be calculated, and by which methods?

Meta-analytic techniques may be profitably used to summarize the available epidemiological studies although meta-analysis is often viewed simply as the statistical combination of results across studies, i.e. as focusing on the last bullet point alone. Meta-analysis has also been described as an approach to the quantitative review of the literature, a "study of studies", which provides a quantitative assessment of the extent to which bias might account for observed results, and of the patterns, and sources of heterogeneity. It is this latter approach, the critical quantitative review, which potentially affords the most insight for hazard characterization. Meta-analyses are usually conducted on the published results of studies, which are often highly summarized. Alternatively, and less often, the data on individual subjects in several studies are included in a pooled analysis. If results from two or more studies are to be aggregated, a decision needs to be made whether to base the aggregation on the published results or whether to obtain the individual subject data from the original investigators. Published results have the disadvantage that they are often already highly summarized, sometimes in ways that make them difficult to combine (e.g. the use of different category boundaries for categorising continuously measured exposures). Individual subject data have the disadvantage of being difficult and time-consuming to obtain; often they are available for only a small and perhaps non-representative subset of all the studies that have been done. When there are important analytic questions about key studies, however, re-analysis of the individual subject data can be highly informative and thus worth the extra time and expense. The following issues should be considered when designing and conducting quantitative reviews (meta-analyses) of epidemiological literatures:

Protocol: Each meta-analysis must have its own protocol, perhaps "nested" within the overall protocol for the health hazard characterization. The protocol should include a clear statement of the objectives of the review, and the methods to be employed.

Inclusion criteria: It is advisable for a meta-analysis to be inclusive rather than exclusive. The criteria that might be used to exclude studies from a meta-analysis that

aggregated effect estimates across studies (an aggregative meta-analysis) can then be used to test hypotheses relating to these criteria in a meta-analysis that focuses on specific study characteristics (a comparative meta-analysis).

Overall quality scores: Reducing the features of a set of epidemiological studies to a single measure of "quality" is not recommended because these features may affect the results of the studies in different directions and to varying degrees. It is preferable to assess the characteristics of the primary studies individually.

Chance: In meta-analysis, the results are usually weighted by the statistical precision (in general, by the amount of information) in each primary study. Technically, in its simplest form, the weights are inversely proportional to a statistical measure known as the "variance" of the study's estimate of effect. Studies with more information (e.g. studies that are "larger") produce estimates with narrower confidence intervals and lower variances. Thus, inverse-variance weighting assigns more weight to the studies based on more information.

Publication bias: The results of certain kinds of primary studies are more likely to be published than of the others. Publication bias can be: minimized – by doing a comprehensive literature search (e.g. including, if possible, unpublished results); detected – by funnel graphs, tests; corrected – by statistical models in which missing data are imputed; assessed by sensitivity analysis – by determining how many studies of what characteristics and with what results would have to be missing to give the literature a substantially different appearance from the one it currently has.

Assessment of overall heterogeneity: The three characteristics of primary studies, which are examined in heterogeneity analyses are: definition of populations, exposure characteristics and exposure contrasts, and, research methods.

Definition of populations: Similar populations are needed if results obtained in one population are to be used to predict effects in another. However, when studies of dissimilar populations yield similar measures of effect, then causal interpretation is strengthened. Heterogeneity of the association may, however, indicate an existence of population(s) with different sensitivity to the exposure and this possibility must be a subject of careful analysis.

Exposure characteristics and exposure contrasts: Did the studies measure the same exposures in the same way using the same metrics and did they compare risk between or among similar levels of exposure? The less similar the studies are in these regards, the less advisable it is to combine their results.

8.3.9 Research methods

Confounding control, selection bias (e.g. characteristic for cohort vs. case control studies), information bias (e.g. blinded vs. not-blinded interviews) and data analysis methods (e.g. cut-point choices for exposure categories) in each primary study must be assessed before deciding to combine the studies in a summary analysis. In general, standard statistical tests of heterogeneity, which do not account for specific study characteristics (such as those listed above) that could produce heterogeneous results, are insensitive, and have low statistical power to detect heterogeneity. For this reason, stratified analysis and visual, including graphical, inspection of stratum-specific results are also valuable tools. Some recommend that heterogeneity tests be performed at less stringent alpha-levels (e.g. 0.1 or 0.2), as well.

8.3.10 Meta-analytic methods that may be used to compare studies

Stratified analysis: This examines one characteristic at a time. It is less formal and more useful with a small number of studies. q Meta-regression: here, the dependent variable is the estimate of effect, and the independent variables are study characteristics (see above). This technique is more formal, can examine more than one characteristic at a time if there are a sufficient number of studies.

Sensitivity analysis of meta-analysis: The results of meta-analytic summaries should be subjected to sensitivity analyses to test their robustness to alternative data specifications and analytic approaches, in the same way that one would apply sensitivity analysis in the evaluation of the results of a single study. In the meta-analytic context, such analyses might, for example, examine the sensitivity of the results to reasonable alternatives with regard to the inclusion and exclusion of particular studies. One can also evaluate the sensitivity to alternative approaches to the extraction of results from published reports; the latter task often requires the exercise of professional judgement on the part of the analyst.

Summary estimates from different studies (aggregative meta-analysis): If health effect, exposure, and methods (for example, the choice of exposure metric) are similar and there is no appreciable evidence of publication bias, overall heterogeneity, or specific study characteristics associated with results, then results from more than one study may be combined to form summary estimates. Conversely, the existence of any one of these considerations may be a contraindication to aggregation.

Conclusions from the body of epidemiological and other evidence

After the epidemiological evidence has been evaluated and appropriately summarized, as discussed above, expert judgement as to whether the observed associations are most consistent with a causal explanation or some alternative is required. A process of scientific reasoning must be followed to arrive at this judgement: a process that draws on all the available epidemiological evidence, as well as evidence from toxicology, clinical medicine, and other disciplines, as appropriate. The method of choice is critical thinking: there are no formulas or checklists that will suffice, although, as noted above, Hill's attributes can provide useful guidance and focus. It is critical, however, that expert review groups make explicit the process of scientific reasoning that led to a judgement concerning causality. This explanation should include explanations of:

How expert reviewers weighted particular features of the epidemiological studies (e.g. assessments of bias, confounding, exposure-response) in reaching their judgement;

How expert reviewers used guidelines such as Hill's attributes;

How non-epidemiological sources of evidence figured in their interpretation of the epidemiological evidence, and how that evidence contributed to their overall judgement.

Expert judgements concerning the causal nature of the observed association will need to be accompanied by statements regarding the degree of uncertainty that the expert reviewers attach to it. When the product of a Health Hazard Characterization is presented as a conclusion about the existence (or not) of a hazard, the degree of uncertainty could be expressed on a qualitative ("weak, moderate, strong evidence for hazard") or on a quantitative scale. If a quantitative scale is devised it should be calculable, and capable of being reproduced by other experts. In either case, the use of a particular scale, and the meaning of each level of it, should be clearly explained.

There may be a need to standardize such scales in order to avoid problems of non-comparability among the reviews produced by different expert review groups.

8.3.11 Role of the Precautionary Principle

We must act on facts, and on the most accurate interpretation of them, using the best scientific information. That does not mean that we must sit back until we have 100% evidence about everything. Where the state of the health of the people is at stake, the risks can be so high and the costs of corrective action so great, that prevention is better than cure. We must analyse the possible benefits and costs of action and inaction. Where there are significant risks of damage to the public health, we should be prepared to take action to diminish those risks, even when the scientific knowledge is not conclusive, if the balance of likely costs and benefits justifies it. The Precautionary Principle, provides a guide to action under (perhaps considerable) uncertainty: the condition under which most, if not all, public health decision-making on environmental issues takes place. It assumes that the available scientific evidence, the "facts", has been objectively assessed, and that the uncertainty of that assessment has been made explicit. Minimum level of acceptable epidemiological evidence, which would act as a point of reference should be defined. The extent to which external or extra scientific factors affected conclusions and decision-making should be stated. A clear demarcation between reviews results and public health decision-making from the evidences should be maintain. It is important to make clear any remaining uncertainties and their implications. Recommendations on the additional research needed to resolve the uncertainties should be made clearly.

8.4 SUMMARY

Evaluation of scientific evidence is necessary to encourage unbiased reporting. To link a disease condition with an exposure to environmental hazard requires serious scrutinization to enable unwarranted inferences to be drawn which might excite panic in the public. Laid down procedures which should be followed to ensure reliability, replicability, validity, transparency; to remove all forms of bias, chance, confounding and to make sure that the right analytical tools were outlined and discussed.

8.5 TUTOR-MARKED ASSIGNMENT

1 What is health hazard characterization and what are the protocol for health hazard characterization.
2 Define transparency, validity and replicability as it applies to health hazard characterization
3 What are the components of review of an epidemiolocal evidence in a health hazard characterization
4 Describe chance and confounding in relation to health hazard characterization

8.6 REFERENCES/FURTHER READING

1 *IARC 1999: http://www.iarc.fr/*
2 *Cochrane 1999. http://www.update-software.com /ccweb/cochrane/hbook.htm*

UNIT 9: STATISTICAL PACKAGES (SPSS, EPI-INFO, EPI DATA AND VITAL STATISTICS)

CONTENTS

9.1 INTRODUCTION

Environmental epidemiological research usually yield large volume of data which must be analysed for inferences and conclusions to be drawn on exposure related health conditions. Analysis then becomes very much time consuming and very difficult to handle; and results could then become error prone due to miscalculations and biases. Several statistical packages have been developed to enable researchers perform analysis easily and at much lower error levels and almost completely devoid of miscalculations. Some of these packages include SPSS, EPI-INFO, STATCALC, OPEN EPI AND VITAL STATISTICS

9.2 OBJECTIVES

In this unit we will discuss different statistical packages available for use to analyse data generated in a environmental epidemiologic research.

9.3 STATISTICAL PACKAGE FOR THE SOCIAL SCIENCES (SPSS)

SPSS was initially produced in 1968 by SPSS Inc. and for a long time became a reliable software for analysis of both simple and complex data for researchers. It was later acquired by IBM corporation in 2009 and renamed IBM SPSS but the current versions starting from 2015 are named IBM SPSS Statistics.

IBM SPSS® Statistics is a powerful statistical software platform. It delivers a robust set of features that lets you extract actionable insights from your data. With SPSS Statistics you can analyse and better understand your data, and solve complex environmental and research problems through a user-friendly interface. You will more quickly understand large and complex data sets with advanced statistical procedures that help ensure high accuracy and quality decision-making. There are a handful of statistical methods that can be leveraged in SPSS, including:

- ✓ Descriptive statistics, including methodologies such as frequencies, cross tabulation, and descriptive ratio statistics. Descriptive, Explore, Descriptive Ratio Statistics
- ✓ Bivariate statistics, including methodologies such as analysis of variance (ANOVA), means, , t-test, correlation (bivariate, partial, distances), Bayesian and nonparametric tests.
- ✓ Numeral outcome prediction such as linear regression. https://www.spss-tutorials.com/spss-what-is-it/
- ✓ Prediction for identifying groups, including methodologies such as cluster analysis (two-step, K-means, hierarchical), Discriminant and factor analysis.
- ✓ Geo spatial analysis, simulation.
- ✓ R extension (GUI), Python

9.3.1The Benefits of Using SPSS for Survey Data Analysis

Thanks to its emphasis on analysing statistical data, SPSS is an extremely powerful tool for manipulating and deciphering survey data. The data from any survey collected using survey tools like SurveyGizmo can be exported to SPSS for detailed analysis there by making the process of pooling, manipulating, and analysing data clean and easy. By doing so, SPSS will automatically set up and import designated variable names, variable types, titles, and value labels, meaning that minimal legwork is required from researchers. Once survey data is exported to SPSS, the opportunities for statistical analysis are practically endless. SPSS is particularly very useful when you need a flexible, customizable way to get super granular on even the most complex data sets. This gives you, the researcher, more time for your research and identify trends, develop predictive models, and draw informed conclusions.

**More information about SPSS can be found in the following websites.*
www.ibm.com/SPSS-Statistics/Free-Trial;
https://www.ibm.com › my-en › products › spss-statistics
https://www.spss-tutorials.com/spss-what-is-it/

9.4 EPI-INFO

Epi Info is statistical software for epidemiology developed by Centers for Disease Control and Prevention (CDC) in Atlanta, Georgia (US) and freely downloadable from the CDC website www.cdc.gov/epiinfo/ .Epi Info has been in existence for over 20 years and is currently available for Microsoft Windows, Android and iOS, along with a web and cloud version. The software is an open-source project with limited support. An analysis conducted in 2003 documented over 1,000,000 downloads of Epi Info from 180 countries.

Epi Info allows anyone with modest computer skills to develop a questionnaire or screen form that automatically creates a database and allows entry of as many records as desired. and analysis of complex survey data. Analysis proceeds through simple commands such as LIST, FREQuency, TABLES, MEANS, MAP and GRAPH. Results include statistics appropriate to the output. For example, the TABLES command with two yes/no variables representing Disease and Exposure, automatically calculates odds ratios and risk ratios with exact confidence limits, various types of chi-squares, and Fisher exact and mid-p tests of association with graphics of the table contents. The MEANS command offers Student t-tests, ANOVA, and Kruskal-Wallis results. More advanced statistics include linear and logistic regression, analysis of complex sample data, Kaplan-Meier and Cox proportional hazards analysis with graphs. A variety of graphs, including graphs automatically stratified by (for example) county, can be produced with the GRAPH command. The MAP command and the EpiMap program offer elementary, but rather extensive possibilities for Geographic Information Systems. Commands used interactively are automatically available for saving as a program that can be run again later. A programmable menu is provided that can be used to develop complete applications that are entirely menu driven. The first version of Epi Info for DOS was developed in 1985 and the Windows version in 2000. A brief history is available in the "Museum" in the Epi Info website http://www.cdc.gov/epiinfo/background.htm . Because Epi Info was originally designed for epidemic investigation, epidemiologists and other public health and medical professionals used it on a laptop computer to rapidly develop a questionnaire and enter and analyse data, often in a motel room near the outbreak site. Over the years, thousands of users have helped to shape Epi Info's features, and it has gradually been adapted for use in more permanent applications, such as surveillance systems or vital statistics at a district or small country level, research studies, record reviews, and even modest Electronic Medical Record systems. In recent years the manual for Epi Info has given way to the electronic help file, which is less convenient for some purposes. The CDC Epi Info Development Team plans to release a printable manual in PDF (Adobe Reader) format. When available, this will be a valuable resource. Features of Epi Info™ for Windows:

9.4.1 Who Uses Epi Info and What For?

Since 1998, there have been approximately 2,000,000 successful downloads of Epi Info from the CDC website in 180 of Earth's 193 countries. A Google search for EpiInfo produces more than a million references. There has not been a proper survey of Epi Info use internationally, but it is used as the core of surveillance systems for immunizable disease in 27 African countries and 8 provinces in Kenya. An Epi Info system for Acute Flaccid Paralysis (possible poliomyelitis) surveillance in India functions in 300 district sites covering 25% of India's population. It is safe to conclude that Epi Info is widely used in public health and clinical medicine. You can perform your own searches to find web pages from or about a particular location and situation. In Lima, Peru, data for a CDC and Partners in Health research project on Multidrug-Resistant Tuberculosis (MDRTB) was entered into an Epi Info questionnaire View with 16 related views. The paper data abstraction form comprises 45 pages, and many patients have scores or hundreds of x-rays, cultures, sputum smears, and drug-months of treatment. Customized menus prepare data tables entered in duplicate by different

operators for comparison in the Data Compare module, disclosing and correcting hundreds of errors that otherwise would have entered the final database.
A menu for Analysis allows graphing of cultures or smears over time for each patient and performs calculations like, "Duration from first MDRTB treatment regimen to first of at least two consecutive negative cultures, provided that a positive culture was obtained within 30 days before or xx days after the start of treatment." The latter makes extensive use of the new SUMMARIZE command in Analysis, which, when combined with RELATE, allows access to each patient's first (min date) or last (max date) record of the type that is selected. The CDC Global AIDS Program (GAP) uses Epi Info for the collection and analysis of data on HIV and AIDS in 27 African countries. GAP and the Global Immunization Division of CDC have collaborated to develop a structured application development framework called SAFE (Structured Application Framework for Epi Info) SAFE uses a standard folder structure, modular programming, dynamic program creation from resource files, an application user interface, variable naming conventions, and a standard analysis and reporting format. It has been used for a data management system for prevention of mother-to child transmission of HIV in Tanzania and Botswana, and Nigeria. It was used to build a Voluntary Counselling and Testing (VCT) application in Mozambique. The HIV/AIDS applications share similar user interfaces and resource files, such as GIS shape files, code tables, and analytic programs. The structured framework will allow more rapid application development, easier support, and faster updates. Because Epi Info may be freely distributed without licensing restrictions or cost, it is a useful resource for applications in developing countries. Since it incorporates many common Windows file formats, it can be combined with commercial programs such as Excel or Microsoft Access where these are available. Maps developed in ArcView at a central site can be used at all sites that have Epi Info and its Epi Map program. The Epi Info menu is programmable and can be used to unite elements of several programs into a single convenient application.

9.5 OPENEPI

OpenEpi is a series of Internet programs providing online or offline calculation for epidemiologic summary data. It provides an alternative to the DOS program Statcalc that is provided with Epi Info. OpenEpi includes statistics for counts and person-time rates in descriptive and analytic studies, stratified analysis with exact confidence limits, matched pair analysis, sample size and power calculations, random numbers, chi-square for dose-response trend, sensitivity, specificity and other evaluation statistics, R x C tables, and links to other useful sites. OpenEpi is free and open source software for epidemiologic statistics. It can be run from the web server at www.openepi.com or downloaded and run without a web connection. A server is not required. The programs are written in JavaScript and HTML, and should be compatible with recent Linux, Mac, and PC browsers, regardless of operating system. A new tabbed interface avoids popup windows except for help files. The open source license allows the programs to be downloaded, distributed, or translated. OpenEpi development and testing was supported in part by a grant from the Bill and Melinda Gates Foundation. Test results are provided for each module so that you can judge reliability, although it is always a good idea to check important results with software from more than one source. Links to hundreds of other Internet calculators are

provided. A toolkit for creating new modules and for translation is included in the downloadable version. The website registers over a million “hits” per year, from 155 countries, about two thirds being outside the US. There are currently (October 2009) 87,000 citations to “OpenEpi” in Google search. The OpenEpi Menu and Framework of Statistical Calculators Chapter 1: Epi Info™ and OpenEpi References www.cdc.gov/epiinfo/ The main Epi Info site, from which you can download Epi Info and find other resources www.openepi.com The site for OpenEpi www.epiinformatics.com A site for Epi Info and OpenEpi resources, including this book

9.6 STATCALC

StatCalc is a statistical calculator that produces summary epidemiologic information. It is a PC calculator that computes table values of many commonly used statistical distributions. It also computes moments, and many other statistics Six types of calculations are available in StatCalc:

- Sample Size and Power calculations include Population Survey, Cohort or Cross-Sectional, and Unmatched Case-Control.
- Chi-square for trend tests for the presence of a trend in studies where a series of increasing or decreasing exposures is being examined.
- Tables (e.g. 2 x 2, 2 x n) – Both single and stratified 2 x 2 tables can be analyzed to produce odds ratios and risk ratios (relative risks) with confidence limits, several types of chi square tests, Fisher exact tests, Mantel-Haenszel summary odds ratios and chi squares, and associated p-values. These calculations are similar to those produced in Classic Analysis and Visual Dashboard.
- Poisson (rare event vs. std.) – A Poisson distribution predicts the degree of spread around a known average rate of occurrence.
- Binomial (proportion vs. std.) – A binomial distribution states the probability of positive outcomes in a two-outcome study (yes/no) based on the number of observations and the expected percent of positive outcomes.
- Matched Pair Case Control Study – calculates the statistical relationship between exposures and the likelihood of becoming ill in a given patient population.

9.7 VITAL STATISTICS

Vital statistics are derived from information obtained at the time when the occurrences of vital events and their characteristics are inscribed in a civil register. Vital acts and events are the births, deaths, fetal deaths, marriages, and all such events that have something to do with an individual's entrance and departure from life together with the changes in civil status that may occur to a person during his lifetime. Recording of these events in the civil register is known as vital or civil registration and the resulting documents are called vital records.

9.7.1 Sources of vital statistics

The PSA maintains an archive of Civil Registration documents. Several basic forms are needed to record vital events from which vital statistics were generated. These are:

- Marriage Certificate
- Certificate of Live Birth
- Certificate of Death
- Certificate of Foetal Death

9.7.2 Uses of Vital statistics

Vital Statistics are useful for local and national authorities specifically for planning of human, social and economic development. They use the data results in the following:

- as input for population estimation/projection for future planning
- as basis for forecasting requirements for food, housing, medical facilities, education and other needs of the population
- to carry out policy making at local levels for planning health, education services, housing, etc.
- to address health inequities from communicable disease, chronic disease and injuries • generate “life tables” and life expectancies for many health-planning purposes
- measure progress on the sustainable development goals and other international health goals • prepare polling lists for eligible voters for election purposes
- calculate the number of members of parliament for each state or province
- allocate budgets for development and for human resources
- calculate the number of citizens each year for administrative areas by age and sex
- provide denominator data for calculating health-related indicators
- help to guide efficient resource allocation
- other analytical studies which are important and useful to planners and policy-makers

9.7.3 Using vital statistics in epidemiological studies

Descriptive studies exploring patterns of disease distribution in populations often make use of routinely available health data. The results can be used for a variety of purposes, including generating hypotheses about the possible determinants of disease and for service planning.

Data derived from vital statistics are usually analysed with respect to three main categories:

- Time – when?
- Place – where?
- Person – who?

a) Time

There are three broad patterns of variation in disease incidence with time:

- Secular (long-term) trends – changes in disease incidence over a number of years that do not conform to an identifiable cyclical pattern. For example, the secular trend in mortality from TB in England shows a steady decline over many years. However, this does not give any indication of the cause of the decline.

- Periodic changes including seasonality – regular or cyclical changes in incidence, for example in infectious diseases. Cases of influenza typically reach a peak in the winter months.

- Epidemics – strictly speaking, an epidemic is a temporary increase in the incidence of a disease in a population

b) Place

- Variations in disease incidence by place also fall under three main headings:

- Broad geographical differences – sometimes related to factors such as climate, or social and cultural habits. Some cancers show marked geographical differences in incidence.

- Local differences – distribution of a disease may be limited by the localisation of the cases, for example a contaminated water supply.

- Variations within a single institution – variations in attack rates by hospital ward, for example, may help identify possible sources or routes of spread of a gastrointestinal infection.

c) Person

The chances of an individual developing a disease may be affected by their personal characteristics, so exploring this area may provide useful clues about possible causes. Personal characteristics can be classified in several ways, but important features include:

- Intrinsic factors such as age, gender and ethnic group– these are not amenable to change
- Occupation, marital status, behavioural habits and lifestyle

9.8 SUMMARY

Analysis of epidemiological data usually require a platform which is capable to analyse large data. We have discussed some packages which are appropriate for analysis of data generated from environmental epidemiology research.

9.9 TUTOR-MARKED ASSIGNMENTS

1. What are the different statistical methods that computed with SPSS?

2. Describe EPI INFO and state what it's use for in epidemiological studies.
3. Describe StatCalc and the type of calculation it can be applied.
4. Describe how vital statistics can be used in epidemiological studies.

9.10 References/ Further Reading

Leadbeter D, *Harnessing Official Statistics*, Radcliffe, 2000.

Ben-Shlomo Y, Brookes S, Hickman M. 2013. Lecture Notes: *Epidemiology, Evidence-based Medicine and Public Health* (6th ed.), Wiley-Blackwell, Oxford.